



GRAS Proposed Rule: MAHA's Push for Transparency Through Mandatory Notifications

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Step toe LLP

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Step toe's FDA and Global Regulatory Team

What we do

- Food Additive Petitions, Color Additive Petitions, and Food Contact Notifications
- Generally Recognized as Safe (GRAS) "Self-Determinations" and GRAS Notifications
- Regulatory Compliance Opinion Letters
- Good Manufacturing Practice (GMP) Assistance and Audits
- Labeling and Claims Assistance
- Food Safety and Risk Assessments
- Food Industry-Related Legislation and Policy Developments
- Import Issues
- Recall Issues



Our areas of practice extend beyond food and food packaging:

- Drugs and Drug Packaging Materials | Dietary Supplements | Medical Devices | Cosmetics

We are a global practice – our clients need global solutions

- North America, EU, China, Japan, MERCOSUR (South America)



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About the Presenters – Danny Rubenstein, Partner

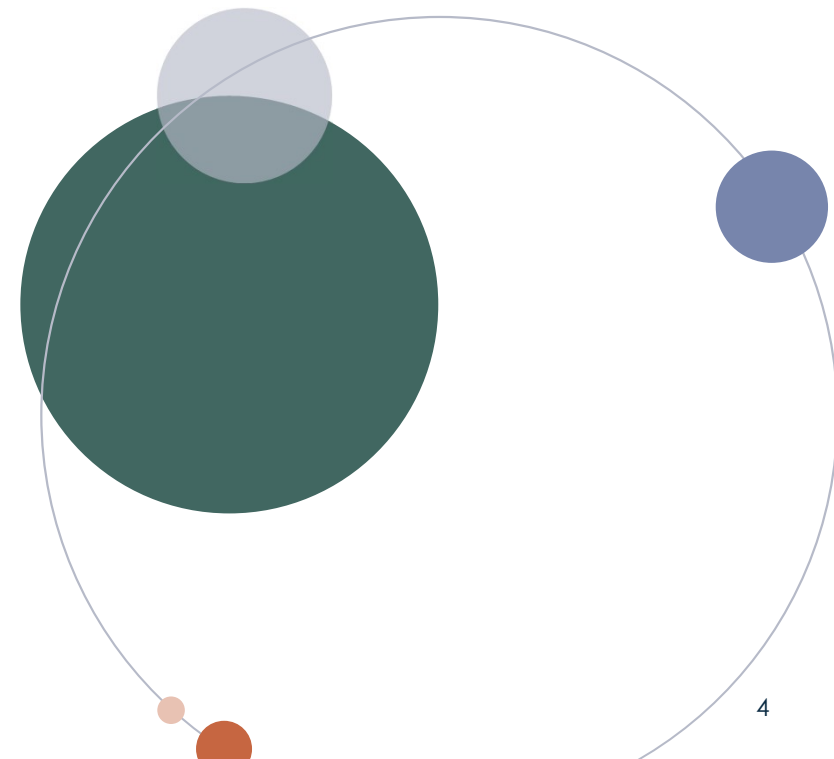
- **Bachelor of Science – Industrial Engineering**
University of Pittsburgh Swanson School of Engineering
- **Juris Doctor (J.D.)**
University of Maryland Carey School of Law
- 17 years of experience advising clients on the regulation of food-contact materials and articles in the European Union, United States, China, Asia-Pacific, and MERCOSUR (South America)
- Former manufacturing and supply chain analyst for medical device company based in Pittsburgh, Pennsylvania



Today's Presentation

GRAS Proposed Rule – MAHA's Push for Transparency Through Mandatory Notifications

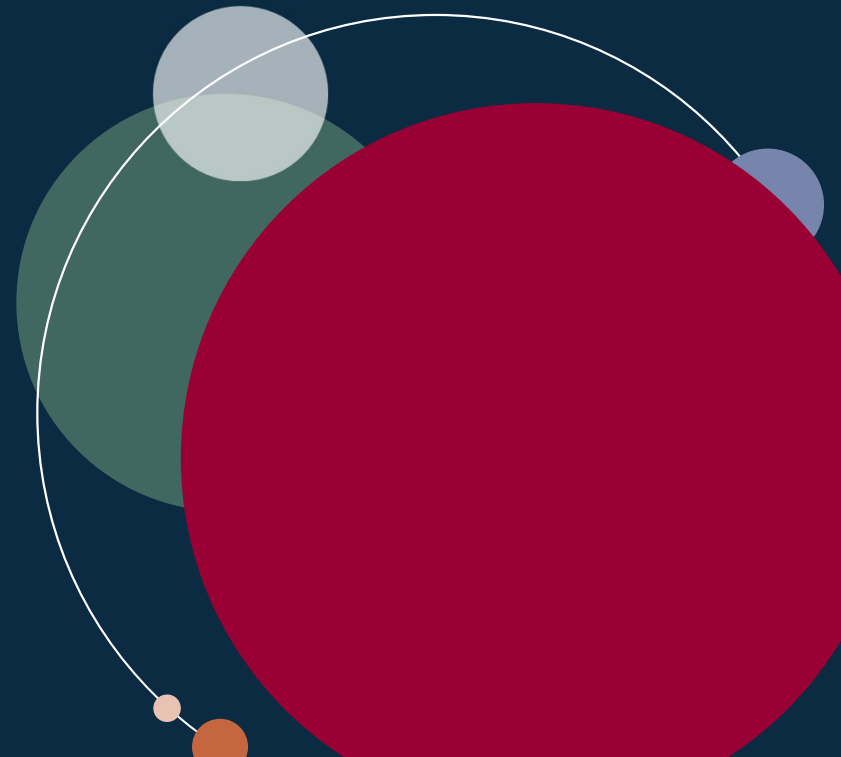
- Background: The GRAS Exemption and the MAHA Agenda
- **GRAS Reform — The Proposed Mandatory Notification Rule**
- Food-Contact Considerations
- The Broader Food-Chemical Safety Agenda
- Legal & Legislative Landscape
- Key Dates & Action Plan
- How to Prepare



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Background

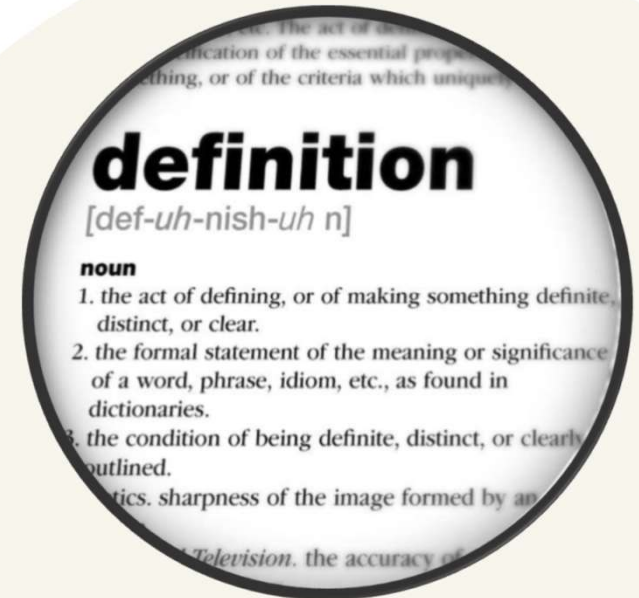


Background: Definition of a Food Additive

Food additives are subject to premarket approval by FDA

- What is a **food additive**?
 - Any **substance**
 - The **intended use** of which
 - **Results**, or may reasonably be expected to result
 - In its **becoming a component** of or **otherwise affecting** the characteristics of **food**

Unless it is the subject of an exemption or exception...



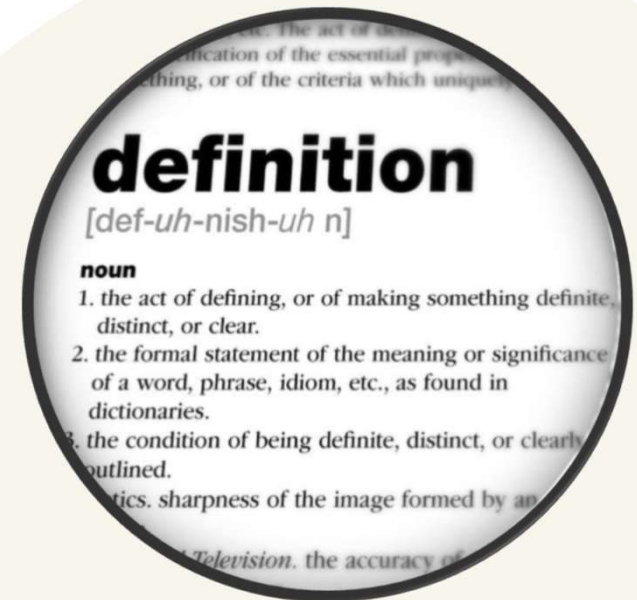
Background: Definition of a Food Additive

An exception applies here!

Definition of a Food Additive, continued:

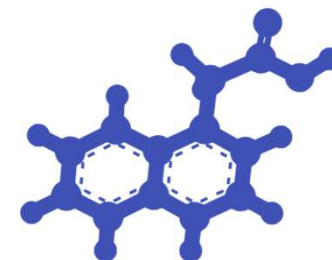
...[except for substances that are] generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use

- GRAS concept is unique to the U.S. food regulatory system



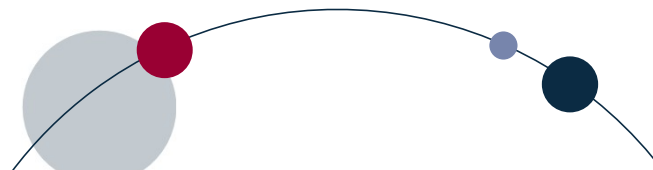
Generally Recognized as Safe

Prior to 1958	After 1958
A substance that is <i>generally recognized as safe</i> – by experts qualified by scientific training to evaluate a substance’s safety – based on:	
Common use in food; or	–
Scientific procedures	Scientific procedures (only!)

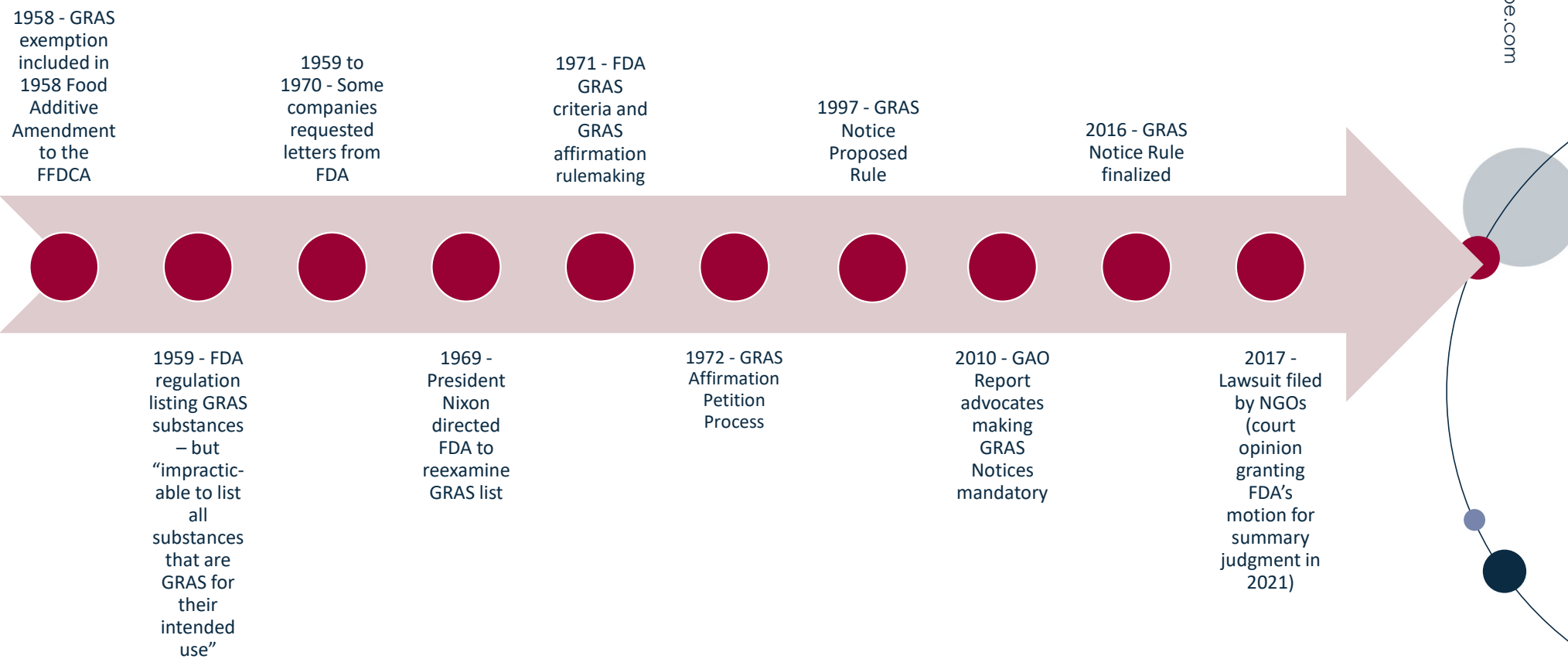


Scientific Procedures

- **The same quality and quantity of information that you would need for a Food Additive Petition**
- Requires published studies (to allow opportunity for peer review and debate)
- Supported by unpublished studies, information, and evidence



GRAS Under Scrutiny – History



Make America Healthy Again (MAHA)

- MAHA agenda driving food-ingredient transparency
- HHS Secretary Kennedy directed FDA (March 2025) to explore closing the “GRAS loophole”
 - Secretary Kennedy has attributed chronic illnesses to the presence of self-determined GRAS substances in foods
- Consumer-transparency message with bipartisan appeal
- “The proposal would modernize the GRAS framework, increase transparency, and give the FDA greater visibility into substances entering the food supply.”

We Are Winning



The MAHA agenda has been making strides in combating chronic disease in America. The data is clear. We are improving the lives of our communities and children, and on our way to Make America Healthy Again.

42 States
Forty-two states have implemented legislation advancing the MAHA agenda.

23 Waivers
Twenty-three SNAP food waivers signed, limiting purchase of unhealthy food items.

40%
Forty percent of the U.S. food and beverage industry has committed to removing artificial dyes from their food.

\$1.8 Billion
HHS has redirected \$1.8 billion per year to combat the childhood chronic disease epidemic.

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Policy Reforms

Dietary Guidelines for Americans (DGAs): USDA and HHS will update the 2025 - 2030 DGAs which will align with science, data, and health recommendations in a concise, user-friendly format. USDA and HHS will further reform future DGA development processes, including structure and members of the advisory committee and scientific review of future DGAs.

Food Dyes: FDA will continue to advance and implement policies to limit or prohibit the use of petroleum-based food dyes (FD&C certified colors) in all food products approved in the U.S. The USDA will apply the framework to food served through Federal nutrition programs, especially the school lunch program. USDA and HHS will work to develop research and policies to support domestic agriculture production of plants used as natural color sources. FDA will continue to expedite its review and approval of color additive petitions for colors from natural sources and explore ways to provide greater flexibility in connection with the use of “no artificial color” and other labeling claims.

Post Market Review of Chemical Additives in Food: FDA will continue to develop and implement an enhanced evidence-based systematic process for the post-market assessment of chemicals in food, including food additives, color additives, “Generally Recognized as Safe” (GRAS) substances, substances used in contact with food, and chemicals present as unintentional (for example, environmental) contaminants.

Ultra-Processed Foods: USDA, HHS, and FDA will continue efforts to develop a clear definition for “Ultra-processed Food” to support potential future research and policy.

Nutrition Labeling: FDA will consider revisions to its proposed Front-of-Pack Nutrition Information rulemaking based on input received during the comment period and the forthcoming rulemaking and will work toward development of a potential Front-of-Pack Nutrition Information rule.

GRAS Reform: FDA will update regulations to reform the GRAS designation authority, by closing the “GRAS loophole,” implementing a mandatory GRAS notification process, and increasing consumer transparency with respect to substances found in our food.

Food Allergies: FDA will develop guidance on diagnostics and treatments for food allergies and make recommendations about requiring transparency in disclosures of ingredient conditions, such as gluten for those with Celiac disease, and other established allergens.



Overhauling the GRAS Standard

MAKE AMERICA HEALTHY AGAIN **MAHA** PRESIDENT

Sources: <https://www.hhs.gov/maha/index.html> and <https://www.whitehouse.gov/wp-content/uploads/2025/09/The-MAHA-Strategy-WH.pdf>

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Proposed Rule on GRAS Reform



GRAS Under Scrutiny – *Center for Food Safety et al. v. Becerra* (2021)

NGO lawsuit contended:

- 2016 GRAS Final Rule unlawfully subdelegates FDA's duty to regulate the food supply
- 2016 GRAS Final Rule is arbitrary and capricious and FDA exceeded its own authority by issuing it
- 2016 GRAS Final Rule conflicts with the FFDCA:
 - Does not adequately address potential conflicts of interest in GRAS determinations
 - Discusses relying on unpublished data in a GRAS determination
 - Fails to clarify that a GRAS substance can never be a carcinogen

and FDA Responded:

- **FFDCA does not require FDA premarket approval of GRAS substances – FDA still has authority to take enforcement action against substances that inaccurately claim to be GRAS**
- **FDA's interpretation of the FFDCA is reasonable**
- **FDA has issued guidance on GRAS Panels and insists that GRAS Notices be balanced**
- **FDA made clear that pivotal data must be publicly available**
- **GRAS criteria must be met**

Seven-Part GRAS Notice under 7 CFR Part 170/570, Subpart E

- Signed statements & certification
- Identity, method of manufacture, specifications, physical/technical effect
- Dietary exposure data
- Narrative basis for the GRAS conclusion
- Use-in-Food prior to 1958 discussion
- Self-Limiting Use discussion
- List of supporting data & information

Content of Notice NOT changing

Voluntary Notices Become Mandatory

Proposed § 170.205(a):

“Any person introducing a substance into interstate commerce under the GRAS provision of section 201(s) of the Act **must notify** FDA of the basis for their conclusion that the substance is GRAS under the conditions of its intended use, except as provided under paragraph (b) of this section. For the conditions of use that meet the definition of a food-contact substance in accordance with § 170.3(e)(3), a manufacturer or supplier may alternatively submit a food-contact notification as specified under § 170.100.”

- No more self-determined GRAS positions that are kept private
- Would amend human AND animal food regulations (Parts 170 & 570)
- Covers substances already on the market AND new ones
- Electronic submission via Centralized Online Submission Module (COSM); waiver needed to submit paper notice



Not a *Premarket-Approval* Regime

Company may market a GRAS substance prior to receiving FDA's response

Companies (not FDA) still make the GRAS determination

Notification is a transparency/information-gathering step, not an approval

When has “notice” been provided? Proposed Revisions to § 170.265

- Within 45 days of receipt, FDA will decide whether to file.
- If GRAS notice filed, FDA will send letter within two days. Mandatory notification requirement under Section 170.205 when notice is *filed*.
- *If FDA issues a “cease to evaluate” response, FDA will consider Section 170.205 to not be met.*

Ramifications for non-compliance: *Potential Post-Market Review*

Justifications in Preamble

- **Three identified issues**
 - Inadequate analyses behind some GRAS conclusions
 - Substances marketed after a “cease to evaluate” letter
 - Insufficient information hindering FDA administration
- **Specific Examples**
 - 2024 warning letters to firms selling human foods represented as containing **Delta-8 THC**
 - 400 illnesses caused by use of **tara flour** in a meal delivery product
 - FDA deems **ashwagandha extract** to be unsafe in 2023 and places foods containing it on Import Alert
 - 2023 FDA action on **Areca catechu (palm leaf)** dinnerware due to safety concerns
- >1,300 voluntary human GRAS notices filed since 1998; 100 animal notices

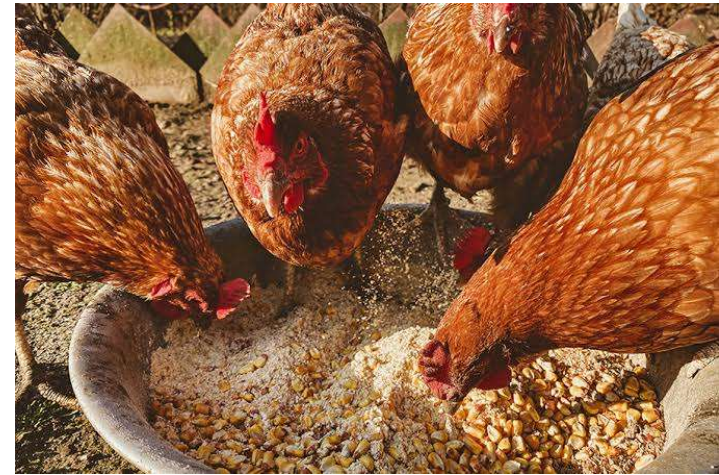
FDA's Proposed Review Timelines & Process

- Initial adequacy check within 45 days (goal, not hard requirement)
- FDA notifies within 2 business days
 - Note that current experience indicates a 5-6 month wait to receive receipt notification
- Substantive review within 180 days, extendable by 90 days up to twice (up to ~360 days)
 - Current reviews have been known to last 18-24 months



Scope: What Is Covered?

- Direct food ingredients
- Secondary direct additives and processing aids (e.g., solvents, enzymes)
- Flavors, including those assessed by the Flavor and Extract Manufacturers Association (FEMA)
- Food-contact substances migrating to food



Not covered/Not eligible for GRAS exemption: pesticide residues, color additives, dietary ingredients (in supplements), contaminants

Exceptions from Notification

- Existing “no questions” letter covers the use
 - *Consider manufacturing process and impurities*
- Substance listed/affirmed GRAS in 21 CFR Parts 182, 184, or 186
- GRAS under § 170.30(d) or (i)(1)
 - Natural *biological* origin, widely consumed for its *nutrient* properties in the US before January 1, 1958, without known detrimental effects, subject only to conventional processing and for which no known safety hazard exists
 - GRAS under Parts 184 or 186 with no limitation other than GMP if use is not “significantly different” (no examples provided)
- Cleared via an established FDA process: Cell Culture Consultation, Petition, TOR exemption, FCN (*Proprietary*: manufacturer/supplier-specific)
- Legacy streamlined submission on FDA’s public list

Streamlined Submission for Legacy Substances

- New Subpart F (21 CFR §§ 170.303, 170.305):
 - Time-limited (one year), abbreviated pathway for substances already in interstate commerce under a self-GRAS conclusion before the final rule's effective date
- ***NO underlying safety data required***, but ***evidence of presence in interstate commerce is required*** (*examples of evidence not provided*)
- File electronically via COSM within one year of the effective date
- FDA posts the info on a public list but may later require a full GRAS notice or food additive petition
- Listing is NOT an FDA GRAS finding
- Not available where an insufficient-basis letter or a not-GRAS determination already exists

Contents of a Streamlined Submission

- Name and address of the submitter
- Name of the substance (appropriately descriptive term)
- Intended conditions of use (foods contacted, use levels, purposes)
- Evidence of presence in interstate commerce before the effective date
- If applicable, the GRN No. of a prior “cease to evaluate” GRAS notice
- May optionally state the statutory basis (scientific procedures or pre-1958 common use)

Proposed Amendment of Threshold of Regulation (TOR) Regulation

TOR Expansion

- Proposed § 170.39 retitled and EXPANDED beyond food-contact articles to cover substances used in food and food-contact substances generally (direct and indirect uses)
- A granted TOR exemption is an exception to the GRAS-notice requirement (§ 170.205(b)(5))
- TOR submissions require less data and based primarily on low exposure
- Electronic submission via COSM; three-copy requirement removed

TOR Exemption Criteria

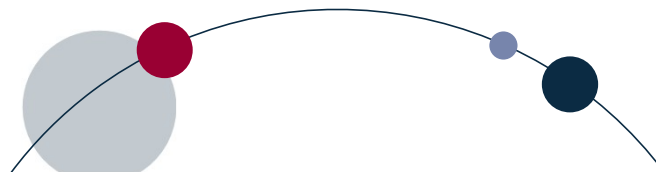
- Not a carcinogen (and no carcinogenic impurity above a one-in-one-million lifetime cancer risk, e.g., $TD50 \geq 6.25 \text{ mg/kg bw/day}$)
- Dietary exposure $\leq 0.025 \text{ } \mu\text{g/kg body weight/day}$ (or $\leq 1\%$ of the ADI for a substance already regulated for direct addition to food)
- No significant adverse environmental impact
- The $0.025 \text{ } \mu\text{g/kg bw/day}$ intake metric replaces the prior 0.5 ppb dietary-concentration standard to normalize across subpopulations

Food-Contact Focus: Don't Forget about 'No Migration' and FCNs

For a substance to be considered a “food additive,” it must migrate to food at “**more than insignificant**” levels
Monsanto v. Kennedy (613 F.2d 947 (D.C. 1979))

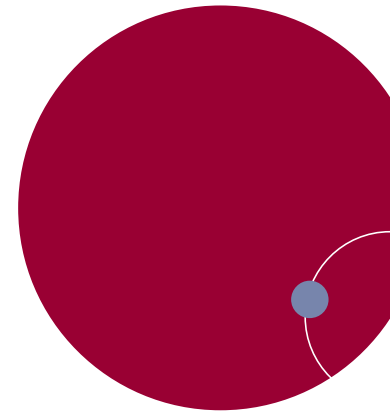
Comes from the definition of a **food additive**...

- Any **substance**
 - The **intended use** of which
 - **Results**, or may **reasonably be expected to result**
 - In its **becoming a component** of or **otherwise affecting** the characteristics of **food**
-
- If a substance is **not** reasonably expected to become a component of food, then:
 - The substance is **not** a food additive; and therefore,
 - The substance does **not** require premarket clearance



Food-Contact Focus: Don't Forget about 'No Migration' and FCNs

- Food Contact Notification (FCN) submissions instead of Food Additive Petitions
- FCNs become “effective” 120-days after receipt by FDA unless FDA objects (Petitions can take years)
- **FCNs are proprietary** – only the manufacturer/supplier listed in the FCN (and its customers) can rely on the FCN clearance
- FDA's **existing indirect additive regulations are still in effect**, but new food-contact materials are typically cleared via FCN (if not exempt)
- **Common application:** Expand limited clearances with Condition of Use or Food Type limitations



Food-Contact Focus: Don't Forget about 'No Migration' and FCNs

U.S. Department of Health & Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

Inventory of Effective Food Contact Substance (FCS) Notifications

[FDA Home](#)
[Packaging & Food Contact Substances](#)
[Food Ingredient & Packaging Inventories](#)
[Inventory of Effective Food Contact Substance \(FCS\) Notifications](#)

The database lists effective premarket notifications for food contact substances that have been demonstrated to be safe for their intended use. The list includes the food contact substance (FCS), the notifier, the manufacturer of the FCS, the intended use, the limitations on the conditions of use for the FCS and its specifications, the effective date, and its environmental decision. Under section 409(h)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348 (h)(2)(C)) a food contact substance notification (FCN) is only effective for the manufacturer or supplier identified in the notification. Persons who market a FCS based on an effective notification must be able to demonstrate that the notification is effective for their food contact substance. All persons who purchase a food contact substance manufactured or supplied by a manufacturer or supplier identified in an effective notification may rely on that notification to legally market or use the food contact substance for the use that is the subject of the notification, consistent with any limitations in that notification. Additional information about Food Contact Substances and the definitions of [Food Types](#) and [Conditions of Use](#) are available on the [FCS Program page](#).

Search and display hints:

- Select the FCN number below to view the record details, including its intended use, limitations, specifications, and the Final Environmental Impact Decisions.
- To sort by a specific field, click on the column header for that field.
- To browse the records, use the Show All, First/Previous/Next/Last, and Jump To options at the bottom of the data table.
- To search for a specific substance/term, enter the term in the Search box and select Show Items to display only those records that contain the selected term. (The search results also includes terms not shown on this page, but included in the full record on the detail page.)
- The search results will return hits of records containing words that include the search term. For example, a search for the color **red** will return results that include terms such as **reduce**, **ingredient**, and **manufactured**. To limit results to only the searched term, place a space before and after the word in the basic search or in the advanced search "this exact phrase" field.

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

Search:

Records Found: 1674 [Show All](#) Page 1 of 34

FCN No. (sorted Z-A)	Food Contact Substance	Manufacturer/Supplier	Effective Date
2321	1,2-Cyclohexanedicarboxylic acid, calcium salt (1:1), (1R, 2S)-rel- (CAS Reg. No. 491589-22-1).	GCH Technology Co. Ltd.	Dec 2, 2023
2316	Hypochlorous Acid (CAS Reg. No. 7790-92-3). REPLACES FCN 2186	Clarentis Technologies, LLC	Nov 23, 2023
2315	Ethylene/1-butene copolymer (CAS Reg. No. 25087-34-7).	Formosa Plastics Corporation, USA	Nov 18, 2023
2313	2,5-Dihydro-3,6-bis(4-methylphenyl)pyrrolo[3,4-c]pyrrole-1,4-dione (CAS Reg. No. 84632-66-6).	Sun Chemical Corporation	Nov 2, 2023
2312	Poly(lactide (Polylactic acid; PLA) optionally containing up to 4 weight percent D-lactic acid polymer units (CAS Reg. No. 9051-89-2).	Pliith Biomaterials Co. Ltd.	Oct 24, 2023
2311	Polypropylene homopolymer (CAS Reg. No. 9003-07-0).	Hunan Liwei New Material Co., Ltd.	Oct 12, 2023

Public Disclosure & Competitive / CBI Considerations

- GRAS-notice data available for public disclosure as of FDA's receipt and is posted to the GRAS Notice Inventory (21 CFR Part 20)
- Data viewed as FOIA-exempt must be identified at submission or confidentiality is waived (§ 170.250(d))
- For non-public safety-related data, the notifier must explain how a GRAS conclusion is possible even though qualified experts lack access (§ 170.250(e))
- Substance identity, method of manufacture (and related impurity profile), food applications, and use levels become visible to competitors/plaintiffs
 - Trade secrets/confidential commercial information are not disclosed
- Justification is required for any confidential markings

GRAS Submission Estimates

- 194 per year for Human Food
- 16 per year for Animal Feed
- 7 Threshold of Regulation Submissions
- 2,418 One-Time Submissions for Existing GRAS Substances in Human Food
- 155 One-Time Submissions for Existing GRAS Substances in Animal Feed
- No estimate of FCN Submissions



Consequences for Non-Compliance & Enforcement

- No new penalties created
- Non-compliance is a FACTOR in FDA's post-market review prioritization
- Existing FFDCA remedies remain (seizure § 304, injunction § 302, criminal § 303)
- An unapproved food additive renders food adulterated (§ 402(a)(2)(C)(i))

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Filter

Chemical Type

Process Contaminant

Food Contact Substance

Food Contact Substance Impurity

Food Ingredient

Food Ingredient Impurity

3-Monochloropropene-1,2-diol (MCPD) esters and Glycidyl Esters (GE)[Process Contaminant](#)

4-Methylimidazole (4-MEI)
CAS Number 822-36-6[Food Ingredient Impurity](#) and [Process Contaminant](#)

Arsenic[Environmental Contaminant](#)

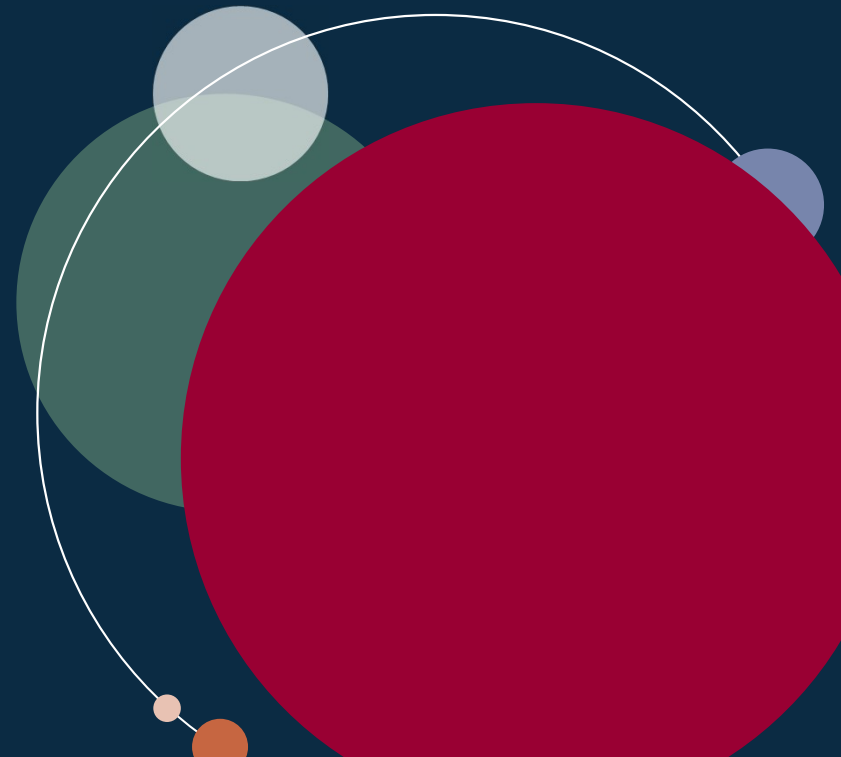
Authorized food contact substances that contain Certain Short-Chain Per-[Food Contact Substance Impurity](#)

A decorative graphic on the right side of the page. It features a vertical line with several colored circles (red, blue, grey, dark blue) and a curved line passing through them.

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Logistics and Timing



Regulatory Process & Key Dates

- Proposed rule published Aug. 11, 2026
- Comments due **Dec. 9, 2026** (docket FDA-2025-N-3262)
 - 515 Comments submitted so far
- Final rule effective 60 days after publication
- Section 170.205/570.205 compliance date 18 months after the effective date
- Subpart F streamlined-submission window is one year from the effective date

Third-Party / Group Submissions

- A “submitter” (and a “notifier”) may be an association or other legal entity, and another person (attorney, agent, qualified expert) may prepare/submit — enabling third-party or association submissions
- Any person may rely on a substance’s inclusion on the public Subpart F list for the same conditions of use
- FDA invites comment on abbreviated procedures and on incorporating previously submitted data

TOR: A Key Comment Opportunity

- FDA expressly invites comment on the TOR expansion and the mechanics of TOR requests
- Industry may weigh in on simplifying/streamlining TOR and on how quickly FDA acts on requests
- TOR request contents include chemical composition, conditions of use, basis, dietary exposure data, and a toxicology literature search

State Activity and Preemption

- No discussion in the proposal of pending bills (e.g., in PA, NY, NJ) to regulate GRAS substances at the state level
 - Congress has not delegated FDA the authority to preempt states in this space
- MAHA website applauds that 42 states have passed laws in areas like food safety
 - Possible that mandatory submissions could be required at the state level

Requests for Comment & Alternatives

- FDA seeks comment on alternatives that reduce burden while meeting its goals
- The 45-day pre-filing period and ways to reduce delays
- Scenarios qualifying for abbreviated procedures / coverage by an existing no-questions letter
 - For when existing GRAS notice with no questions letter or when there is a change in manufacturing process related to the uses of a substance discussed in an existing GRAS notice that received a no questions letter
- Procedures for animal-food substances already in the GRAS inventory
- The Paperwork Reduction Act burden estimates

What Should I Do?

- **Be prepared!**
 - Review historical GRAS opinion letters, GRAS notices in your files
 - Consider whether alternative approaches may also be suitable
 - Threshold of Regulation
 - No Migration
 - Food Contact Notifications
 - If so, start planning for those submissions *today*, before FDA becomes “busy”
 - If GRAS remains most appropriate option, consider business impacts:
 - Disclosures in the public domain / CBI
 - Benefit of submitting comments to the docket (individually, through a trade association, or as a “Steptoe client”)

Additional Resources



Food packaging regulation in plain language.

www.steptoe.com/stepladder



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STEPLADDER SERIES Food Contact Notifications (FCNs) Part Nine in our <i>StepLadder</i> Series about Food Packaging Regulation September 27, 2023 By: Daniel C. Rubenstein
STEPLADDER SERIES Food Type Distribution Factors Part Eight in our <i>StepLadder</i> Series about Food Packaging Regulation September 6, 2023 By: Daniel C. Rubenstein
STEPLADDER SERIES Consumption Factors Part Seven in our <i>StepLadder</i> Series about Food Packaging Regulation August 8, 2023 By: Daniel C. Rubenstein
STEPLADDER SERIES The "No Migration" Position Part Six in our <i>StepLadder</i> Series about Food Packaging Regulation July 28, 2023 By: Daniel C. Rubenstein, Caleb Holland
STEPLADDER SERIES FDA's General Safety Clause and Good Manufacturing Practice (GMP) Requirements Part Five of our <i>StepLadder</i> Series about Food Packaging Regulation June 21, 2023 By: Daniel C. Rubenstein
STEPLADDER SERIES Components of the Basic Resin Part Four in our <i>StepLadder</i> Series about Food Packaging Regulation June 12, 2023 By: Daniel C. Rubenstein
STEPLADDER SERIES Functional Barriers Part Three in our <i>StepLadder</i> Series about Food Packaging Regulation June 5, 2023 By: Daniel C. Rubenstein, Caleb Holland
STEPLADDER SERIES FDA's Food Additive Regulations Part Two in our <i>StepLadder</i> Series about Food Packaging Regulation April 20, 2023 By: Daniel C. Rubenstein
STEPLADDER SERIES FDA Food Types and Conditions of Use Part One in our <i>StepLadder</i> Series about Food Packaging Regulation March 20, 2023 By: Daniel C. Rubenstein

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Thank you!

Step toe Food and Food-Contact Materials Team

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