Generally Recognized as Safe (GRAS): FDA's Final Rule and Industry GRAS

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GMA
The Association of Food, Beverage and Consumer Products Companies

Agenda

- GMA overview
- Food Additives - GRAS
- FDA: GRAS Final Rule
- GMA's GRAS Modernization Initiative
- Q & A

GMA
The Association of Food, Beverage and Consumer Products Companies

GMA - Overview

Founded in 1908
We represent the world's leading food, beverage and consumer products companies.

$415 billion
in economic added value

$1 trillion
in sales annually

30,000
communities served

CPG is the single largest U.S. manufacturing industry with

1.7 million
manufacturing workers.

GMA – What we do

GMA has a primary focus on: product safety, science-based public policies and industry initiatives that seek to empower people with the tools and information they need to make informed choices and lead healthier lives

GMA Members | General Members

GMA Members | Associate Members

GMA – Global Focus

Area of Focus	Platforms for Engagement
Product Safety	APEC (FSCF, PTIN) GFSP Science Training Codex (ICGMA, FICC), ISO
Health and Wellness	APEC (advertising) LAWG WHO, FAO, Codex
Trade Liberalization and Regulatory Coherence	U.S. Trade Advisory Committees APEC (GRP, Export Certificates, etc.) WTO, Codex, ISO Trade Negotiations

U.S. government, bilateral, and multilateral advocacy

GMA Participation in Codex

ICGMA International Council of Grocery Manufacturer Associations ***Mission:***

Advance science-based international policy in Codex Alimentarius

- •Promoting harmonization within Codex standards and policies, and
- •Facilitating international trade

ICGMA is accredited as an observer organization in Codex

FDA - Food Additives

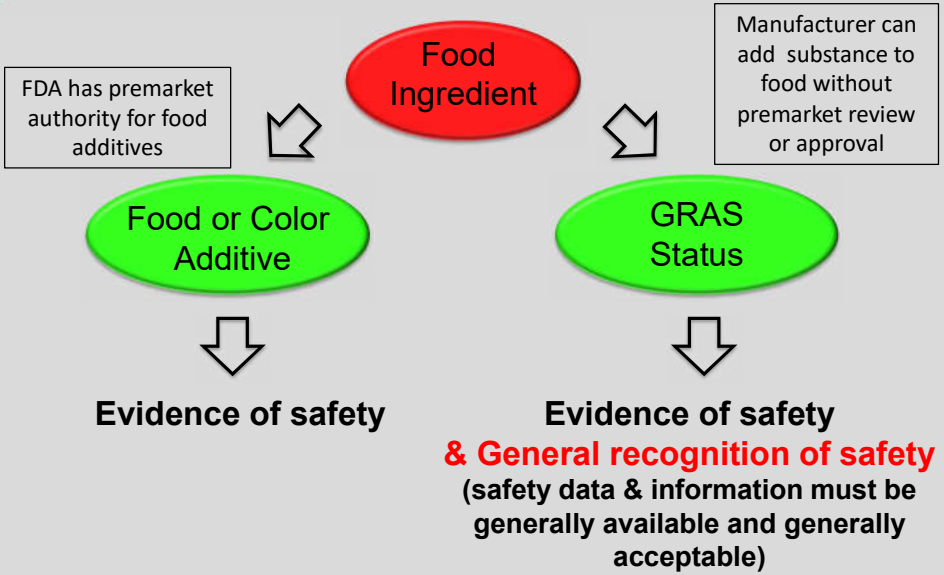
"The term ''food additive'' means **any substance** the intended use of which results or may reasonably be expected to result, **directly or indirectly**, in its becoming a component or otherwise **affecting the characteristics of any food** …if such substance is not generally recognized, among experts 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 (GRAS)…"

Sec. 201(s) FFDCA: Definition

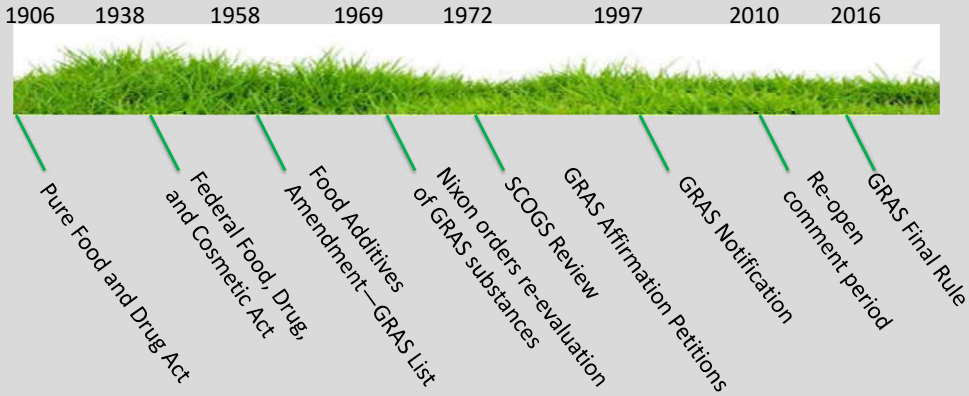
1958 Food Additive Amendment

- Defined "food additive" with a provision for generally recognized as safe (GRAS)
- Required premarket approval of new uses of food additives
- Established the standard of safety, the standard of review, and formal rulemaking procedures for food additives

Food Additive vs. GRAS



GRAS Timeline



GRAS Final Rule

54960 Federal Register/Vol.81, No. 159/Wednesday, August 17, 2016/Rules and Regulations

Depart of Health and Human Services

Food and Drug Administration
21 CFR Parts 20, 25, 170, 184, 186, and 570

[Docket No. FDA-1997-N-0020 (formerly 97N-0103)]

Substances Generally Recognized as Safe

AGENCY: Food and Drug Administration
ACTION: Final rule.

GRAS Final Vs Proposed Rule

- What is the same?
- What has changed?

The Scope of GRAS Final Rule

The final rule is consistent with the original, key objectives:

1. To amend and clarify the criteria to qualify as GRAS; and,
2. To establish the GRAS notification procedures for submitting a GRAS notice (GRN) as a replacement for the GRAS affirmation petition process.

Final Rule Specifies….

- Definitions for certain terms.
- Who can submit: any person.
- How: information on format and where to submit .
- What: data/information that may be incorporated into a GRN and information that you must submit.
- Procedures for a notifier to submit a supplement or an amendment.
- That a notifier can request that FDA cease to evaluate their submission.

FDA Actions….

- Evaluate the submission
  - Consider any timely amendment to a filed GRN if feasible within established timeframes.
- Send a letter informing the notifier of FDA's decision
  - Responds within 180 days of filing, or extends the timeframe to respond by 90 days.
- Make a list of filed GRNs and FDA letters readily accessible to the public.

FDA's Response….

* Includes a subcategory: FDA has no questions; some uses may require a color additive listing.

GRAS Notice Inventory

Inventory of GRAS notices, and FDA responses are listed on CFSAN's website: http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=grasListing.

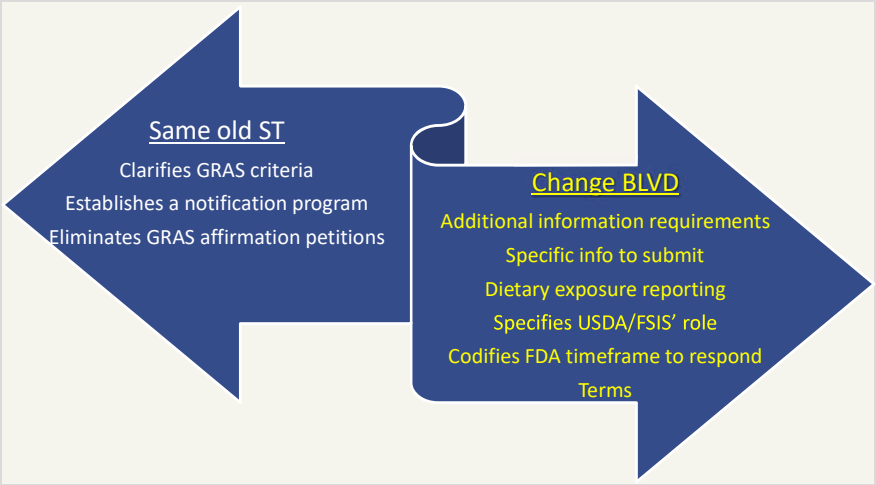
Notifier Actions….

- Once a GRN is submitted, a notifier may:
  - Submit a timely amendment.
  - Request in writing that FDA cease to evaluate their GRN.
  - Submit a supplement to a filed GRN after FDA has completed the evaluation or ceases to evaluate.

Seven Required Parts to a GRN

- 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
- Part 7: List of supporting data and information in your GRAS notice

Proposed to Final GRAS Rule



GMA: GRAS Modernization Initiative

In 2015, GMA announced a five-part initiative to advance the procedures used to assess the safety of ingredients used in food products

GMA launched a modernization initiative to improve the process and increase transparency for making GRAS determinations of ingredients added to food

GRAS Modernization Initiative

- Board Resolution
- Publically Available Specification
- Database
- Education and Training
- Communication

1. Board Resolution

GMA members have committed to drive improvement in the GRAS assessment process by **adopting a Board Resolution**. The Resolution outlines the commitments GMA members have made to **conduct assessments according to the procedures defined in the PAS**, to **maintain the database** with up to date information and to ensure that their **employees are fully trained** on GRAS procedures.

2. Publically Available Specification

- GMA will take the lead in **defining a standard** that will provide clear guidance on how to conduct transparent state of the art ingredient safety assessments.
- These advanced procedures will be **documented in a Publicly Available Standard (PAS)** for GRAS determinations.
- The PAS will be a **science-based framework** that specifies a rigorous and transparent ingredient safety assessment process.
- The procedures included in the PAS will also ensure GRAS assessments **meet the regulatory requirements** of the Food, Drug and Cosmetic Act.
- The PAS will be developed by an **independent body of technical experts** in an open public process that includes interested stakeholders.
- The PAS will be suitable for **accreditation** using an independent official accreditation body.

3. GRAS Database

- Ensure the FDA **has increased visibility** to the ingredients that are assessed as GRAS by members of the food industry.
- The increased visibility will be made possible through the establishment of a **GMA-sponsored database** that will list information on all GRAS assessments conducted by the food industry.
- Information in this database will be made **available to FDA and other stakeholders (public)** to provide increased visibility of ingredients used in the food supply that have been assessed for safety using the procedures defined in the PAS on GRAS assessment procedures.
- In addition to self determination, the database will also **include all GRAS substance (SCOGS and Notification)** – www.grasdatabase.org making it a one stop shop for everything GRAS

4. Education & Training

- GMA will expand its curriculum of GRAS education and training programs in order to further increase the capability of scientists who assess the GRAS status of ingredients used by the consumer packaged goods industry.
  - GMA's broad-based educational programs provide GMA members and other interested stakeholders **a clear understanding** of the scientific procedures that need to be followed in order to complete a robust and transparent safety assessment. They also provide training on requirements defined in GRAS regulations so new ingredients are fully compliant with US food additive law and regulations.
  - GMA has taken the lead in **establishing the Center for Research and Ingredient Safety (CRIS) at Michigan State University** launched in the spring of 2014. CRIS will serve as an independent academic center of expertise on the safety of ingredients used in foods and consumer products. Their expertise on ingredient safety and independent analysis will be available to all interested stakeholders.

5. Communication

GMA will execute a communications outreach program to **inform stakeholders** and consumers of the steps being taken by industry to increase the integrity of procedures used to assess ingredient safety

Thank You: Questions?

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