

# STATUTORY AND REGULATORY FRAMEWORK FOR THE SAFETY OF FOOD INGREDIENTS

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PUBLIC HEARING: CONVENTIONAL FOODS BEING  
MARKETED AS “FUNCTIONAL FOODS”

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# Today I'll Discuss...

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- Regulation of ingredients intentionally added to conventional foods
  - Food additives
  - Generally recognized as safe (GRAS) substances



# Regulatory Considerations

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- There are no statutory or regulatory definitions for **novel foods** or **functional foods**
- If the intended use is in food, an ingredient must be an approved food additive unless it is GRAS (or is otherwise exempt from the definition of food additive).



# Federal Food, Drug, and Cosmetic Act (1938)

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----- 1958 Amendments -----

Defined “food additive”

Required premarket approval of new uses of food additives

Established the standard of safety

# Statutory Definition of “Food Additive”

FD&C Act Section 201(s)

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“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...”



# Scope of FDA's Premarket Approval Authority

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**Certain classes of substances are explicitly excluded from requirement for FDA premarket approval under Section 409:**

- Use of substances authorized by other laws: e.g., pesticides; animal drugs; dietary ingredients in dietary supplements; color additives
- Prior-sanctioned substances
- Substances “generally recognized as safe” (GRAS)



# The “GRAS EXEMPTION”

FD&C Act Section 201(s)

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“The term ‘food additive’ means any substance...

...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 Status

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- May be based only on the views of experts qualified by scientific training and experience to evaluate the safety of substances added to food
- Determination of GRAS status is not limited to FDA scientists



# Basis for GRAS Status

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- Scientific procedures
- Experience based on common use in food prior to January 1, 1958

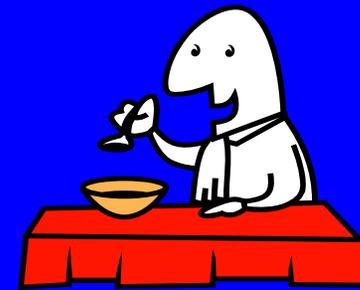


# Safety Standard

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...reasonable certainty of no harm...



# The Same Safety Standard Applies to:

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- Premarket safety evaluation of new uses of food or color additives
- GRAS food ingredients



# Food Additive/GRAS Evaluations

## Some Characteristics

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- Safety-based only:
  - No explicit balancing of risks/benefits
- Standard of safety:
  - “Reasonable certainty of no harm”
- Regulations/GRAS determinations are “generic” and are not “licenses”



# Food Additive Petition: Petition Content

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Identity and composition  
Amount to be added and proposed use  
Data establishing its intended effect  
Analytical methodology  
Full reports of safety studies  
Proposed tolerances, if needed  
Environmental information



# Food Additive vs. GRAS

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## ■ Food Additive:

- At least some data and information are not generally available
- FDA reviews the data and “owns” the safety decision

## GRAS:

- Data and Information are generally available
- Reviewed by experts qualified by training and experience to evaluate the safety of the substance
- Determination reflects the consensus of experts
- Although manufacturers can self-determine that the use of a substance is GRAS, that determination is not binding on FDA



# The Essence of GRAS

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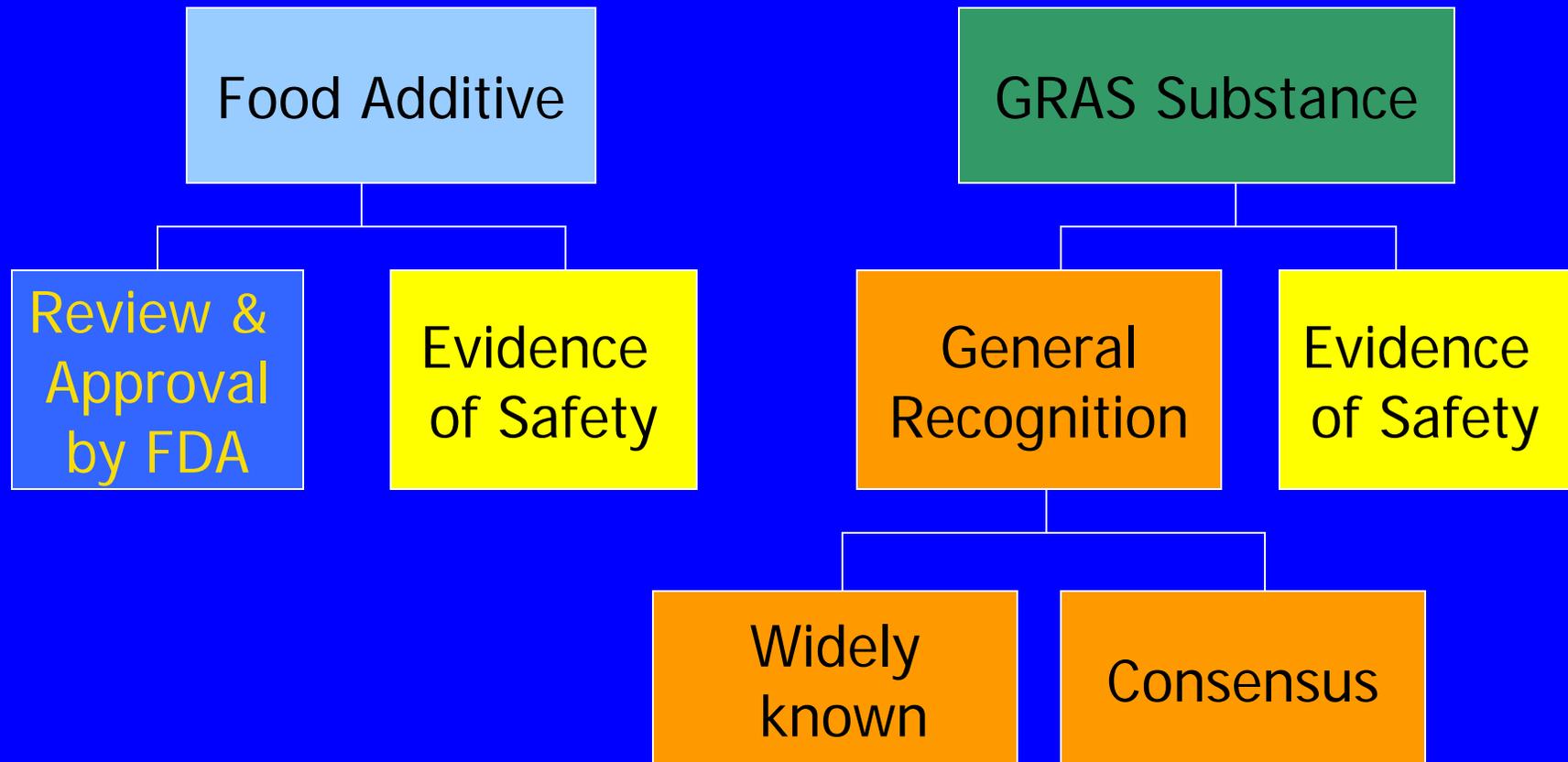
- **Information:** This is what distinguishes a GRAS substance from a food additive
  - The information relevant to the safe use of a GRAS substance is widely known (generally available)
  - There is consensus among qualified experts that the available information establishes that the intended use of a GRAS substance is safe (generally accepted)



# GRAS Criteria: What distinguishes a GRAS substance from a food additive?

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# Basis for GRAS Status

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- Common Use in Food
  - Substantial history of consumption for food use by a significant number of consumers
  - Should ordinarily be based upon generally available data and information
  - The fact that a substance was added to food before 1958 does not, in itself, demonstrate that such use is safe.



# Basis for GRAS Status

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- Scientific Procedures
  - Same quantity and quality of evidence as is needed to approve the use of a food additive
  - Generally available
  - Consensus



# GRAS Process

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- Self-Determination  
or
- Petition to affirm GRAS status  
or
- Notification



# GRAS Notification Procedure

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- Proposed rule, published April 17, 1997
- Voluntary
- Notifier informs FDA of notifier's view that a use of a substance is GRAS
- FDA responds by letter
- Inventory of GRAS notices, and FDA responses are listed on CFSAN's website



# GRAS Notification

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- What it is:
  - The notifier's determination
  - A time-dependent determination, based on the information available at the time
- What it is not:
  - It is not an FDA approval
  - It is not a license or company-based determination
- Other uses of a GRAS substance may also be GRAS, but are not necessarily so



# Examples of GRAS Notices

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- GRN 28: Seaweed-derived calcium
- GRN 48: Vegetable oil phytosterol esters
- GRN 110: lutein esters
- GRN 116: carrot fiber
- GRN 146: salmon oil
- GRN 173: lycopene from *Blakeslea trispora*



# Food Ingredient: Safety Assessment

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- What is it and how much is there in food?
  - Identity and composition
  - Method of manufacture
  - Specifications
  - Use level and exposure
- Is it safe for its intended use?
  - ADME data and information
  - Preclinical or clinical studies as appropriate
- Is other case-specific information needed?



# Conclusions

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- Foods and substances added to food must be in compliance with the Federal Food, Drug, and Cosmetic Act
- The legal and regulatory framework allows FDA to meet its public health responsibilities and to deal with recent innovations.



# For more information

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- CFSAN Homepage:

<http://www.cfsan.fda.gov/list.html>

- Food Ingredients and Packaging (OFAS Homepage):

<http://www.cfsan.fda.gov/~lrd/foodadd.html>

- Available CFR Titles on *GPO Access*:

<http://www.access.gpo.gov/nara/cfr/cfr-table-search.html#page1>

- Inventory of GRAS Notices:

<http://www.cfsan.fda.gov/~rdb/opa-gras.html>

- Guidance and Reference Documents:

<http://www.cfsan.fda.gov/~dms/opa-guid.html>

