

Food Labeling and Advertising FDA's Generally Recognized as Safe List

AGSC 5540: Food Policies and Regulations

11-11-2021

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Today and Rest of the Class



- **So far:** Public Health Necessity for Food Regulations; USDA Dietary Guidelines; CIFOR; HACCP; PC Human Food; FDA and TN Food Code; FSMA Produce Rule.
- **Today:**
 - ☐ Brief Summary of FSMA Preventive Control for Animal Foods
 - ☐ Food Labeling, Health Claims, and Food Advertising
 - ☐ FDA's Generally Recognized as Safe (GRAS) list
- **Last class** (11-18-2021)- Climate Change and Food Safety
 - ☐ Review of the class material of the semester
 - ☐ Release of take-home final exam in the class
 - ☐ Option (A) a HACCP or FSMA Plan
 - ☐ Option (B) take-home exam, short answers
 - ☐ **11/18/2021: Final Paper Due**
 - ☐ **11/24/2021: Final Exam Due (by email or in person)**
 - ☐ 11/20/2021: Commencement (revised date)
 - ☐ 12/16/2021: Annual Competition (revised date, via Zoom)
 - ☐ **Cannot accept late submission please as I will have a deadline to submit grades to university.**

Food Labeling and Advertising

- **Food Labeling:**
- **Valuable source of information** for consumers
- Could be **false, misleading, or true-but-trivial** marketing claims

e.g. Cholesterols-free potato chips; No Added sugar (added juice); Made with real fruit; N&A flavors; WONF vanilla extract

- **Challenge for consumers:**
- Distinguish the signal from noise
- **Challenge for policy makers:**
- Strengthening the signal to noise ration





Food Labeling and Advertising

Regulation for food producers:

- Mandatory information
- Voluntary information: weakly regulated
- Voluntary information: strongly regulated
- Prohibited Claims

Consumers can get information:

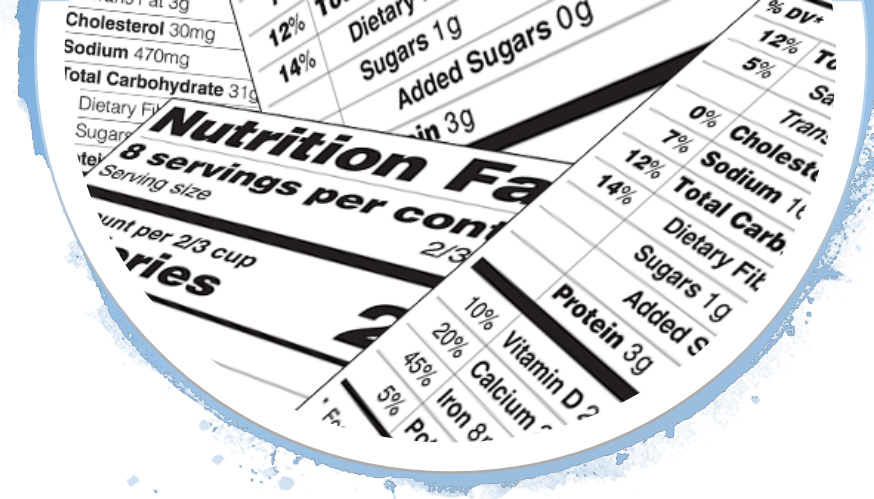
- **Search** properties: comparing products in market
- **Experience** properties: relying on personal experience
- **Credence properties**: consumers cannot confirm product quality

e.g.: **organic** production; **country of origin**; **nutrition and health claims**; **humane treatment** of workers or animals (fair trade)



Food Labeling and Advertising

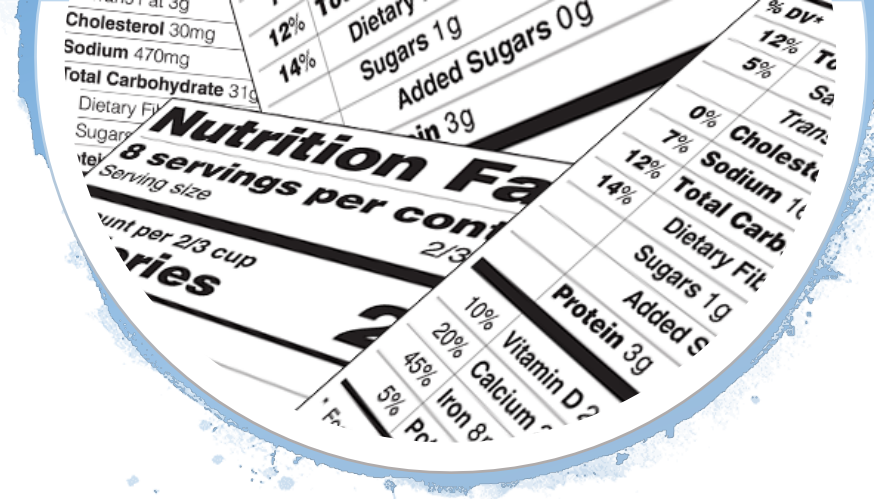
- The food industry is one of the United States' **largest manufacturing sector**
- **10 percent of all shipments** in the United States are associated food industry
- More than a **third of the world's top 50 food and beverage processing firms** are headquartered in the United States (CASE, 2021)
- **Efficiency and public health?**
- **FDA's Four Flavor Categories**
- **Natural Flavors**
- **Natural With Other Natural Flavors (WONF)**
- **Artificial Flavors**
- **Natural and Artificial (N&A) Flavors**



Food Labeling and Advertising

- A USDA Survey (*Golan et al.*):
- **Widespread deception** in food market
- Leading to **consumer insecurity**
- *i.e.* Consumers less **responsive to messages**, even truthful information
- Consumers get information from **less reliable sources**

- **One recent trend:**
- Respected non-for-profit organization: offer **third party certifications**
- *i.e.* American Heart Association: AHA heart-check symbol



Legal Principle

Agencies Regulating Food Labeling:

- Food and Drug Administration
- USDA Food Safety Inspection Service (FSIS)

(2% or more raw meat or 3% or more cooked meat)

Agencies Regulating Food Advertisement:

- Federal Trade Commission (FTC)- Main regulatory body
- Federal Communication Commission (FCC)- for Broadcast media (TV, radio, online)
- National Advertising Division (NAD) of Council of **Better Business Bureaus (BBB)***

**BBB is industry's self-regulatory initiative*



A Challenge for Regulatory Agencies

Commercial Speech Limitation

Constitutional Limitation First amendment in the constitution (Freedom of Speech):

- In most 20th century applied only to “**Political speech**” [Academic freedom]
- Since 1970’s applied to “**Commercial Speech**” [Protection by commercial speech]
- Thus **limiting federal authority to fully regulate food advertisement.**

*e.g. in mid-2000s FTC was unsuccessful for mandate policies for “**Food Advertising to Children**”*

Despite this constitutional limitation:

- “Speech” of **illegal products** could be prohibited by federal agencies

e.g. Advertisement of alcohol to children could be restricted

- **Misleading and false** advertising is also **not protected** by “**Commercial Speech**”

e.g. Untrue health claims



Legal Principle

Ban of a Commercial Speech:

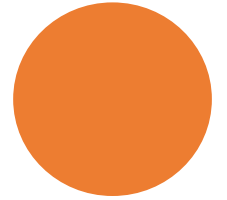
Easier: **inherently misleading** *i.e. therapeutic claims*
[weigh loss, hair growth]

More difficult: **potentially misleading** *i.e. Nutella as*
a wholesome food

[DGA sugar and saturated fats]

Recent years, **several cases that had strengthen**
“Commercial Speech,”

In contrast to **“activist government”** many support
“free market” (laissez-faire) for the food industry



Mandatory Labeling

- **Early in 20th century:** Food Labeling unregulated and voluntary
- **Pure Food and Drug Act of 1906:**
 - Food Name
 - Standard of identity
 - Net weight
 - List of ingredients
 - Manufacturers name and address
- **1970s:** Voluntary nutrition panel introduced
- **The Nutrition Labeling and Education Act of 1990:** **Mandatory Nutrition Fact Panel**
- **2016** Labeling was revised by FDA:
 - Made the panel **easier to read**
 - Put greater emphases on information for **maintaining healthy weight**
 - New Information about **added sugars**
- **Since 2017:** implementation of 2016 has **postponed:**
- Over concern about **added sugars** (**subsidized ingredient**) [*Corn and HFCS*]

Typical values	100ml contains	250ml contains	%GDA*	typical adult
Energy	199kJ 47kcal	500kJ 120kcal	6%	2000kcal
Protein	0.5g	1.3g		
Carbohydrate	10.5g	26.3g	29%	90g
of which sugars	10.5g	26.3g		70g
Fat	trace	trace		
of which saturates	trace	trace		
Fibre	trace	trace		

Criticism to current Nutrition Labeling Fact

1. Unrealistic serving size *[0 calorie in oil spray....service size one puff]*

i.e. not based on RACC: Reference Amount Customarily Consumed

2. Misleading food energy information

Could be difficult to follow specially since it depends on serving size

2016 had made the calorie information more user-friendly

3. Total Fat, Saturated Fat, and *Trans* fats could be misleading

All three listed, *Dietary guidelines for Americans* recommend:

- **Increase** in unsaturated fats
- **Decrease** in Saturated and *trans* fats
- **Could be misleading for increasing unsaturated fats** (with essential fatty acids)

Nutrition Facts	
8 servings per container	
Serving size	2/3 cup (55g)
Amount per serving	
Calories	230
% Daily Value*	
Total Fat 8g	10%
Saturated Fat 1g	5%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 160mg	7%
Total Carbohydrate 37g	13%
Dietary Fiber 4g	14%
Total Sugars 12g	
Includes 10g Added Sugars	20%
Protein 3g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 235mg	6%
* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.	

Criticism to current Nutrition Labeling Fact

4. Sections encouraging increase in Vitamin D, Calcium, **Iron**, and Potassium

Not based on Dietary guideline for Americans

5. Recommended levels is not inclusive, could be misleading

Adult male: 2,500 calories per day

Adult female: 2,000 calories per day

5. Daily Value (DV) could be misleading

Reported based on 2,000 calorie that inflates micro and macronutrients

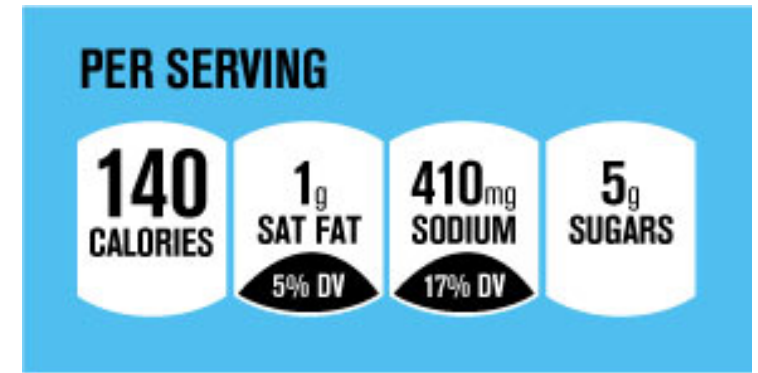
6. Before 2016 **added sugars** were not included

Added sugars section helps meeting the Federal Dietary Guidelines

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Additional Mandatory Labeling?

- Surveys indicate (Todd et al., 2008):
- Around **65% of consumers sometimes or always** check the labels
- New and voluntary guidelines for:
- **Front-of-pack** labeling approaches (small amount of key information)
- **Benefit:** Information for all consumers (not just 65%)
- **Concern:** Misuse in marketing
- Could be required for **high-risk commodities** [100% of recommended daily intake of sodium]
- IOM 2011 recommendation about Front-of-pack labeling:
- **Ignoring** less important nutrition facts in front
- **Including:** Saturated fats, *trans* fats, sodium, and sugar



FOOD TYPE	CALORIES APROX.	WALK OFF KCAL (medium walk 3-5mph)	RUN OFF KCAL (slow running 5mph)
 Sugary soft drink (330ml can)	138	26 min	13 min
 Standard chocolate bar	229	42 min	22 min
 Sandwich (chicken & bacon)	445	1 hr 22 min	42 min
 Large Pizza (1/4 pizza)	449	1 hr 23 min	43 min
 Medium mocha coffee	290	53 min	28 min

Exercise 1

- Please name four examples of false, misleading, or true-but-trivial marketing claims related to packaged foods.
- Please name and explain one challenge for consumers and one for policy makers related to food labeling.
- Please name four credence properties of food products. Why are they important in food regulatory affairs?
- What federal agencies oversee food labeling and food advertisement?
- What is the agency responsible for self-regulation created by the food industry?
- Please name to categories of products that are not protected “freedom of commercial speech”?
- Which one do you think is more important to assure the public health safety for consuming food products: “activist government” or “free market”
- What information become mandatory on food products due to *Pure Food and Drug Act of 1906*?
- What was the purpose of revising the existing food labeling by FDA in 2016? And why was it posted postponed in 2017?
- What are the six criticism to the current nutrition labeling fact?
- What is IOM? What is the main 2011 recommendation of IOM about front of pack labeling?

Claims About Nutrition and Health

- Four Types of Claims are Possible for Food Products:
 - (1) Nutrient Content Claim
 - (2) Health Claim
 - (3) Qualified Health Claims
 - (4) Structure/Function Claims
-
- **All must be in close harmony with Dietary Guidelines for Americans**
 - **Must be evaluated by regulatory agencies**



Claims About Nutrition and Health

(1) Nutrient Content Claim:

Describes level of nutrient or food component

e.g. “Low sodium,” “Low fat,” “High in oat bran.”

Must follow **specific requirements** of **NLEA**

The Nutrition Labeling and Education Act of 1990 (NLEA)

Sodium as an example:

< 5 mg per reference amount*: **“Sodium Free”**

Reduced by at least 25% from reference amount **“Reduced Sodium”**

Reduced by at least 50% from reference amount **“Light in Sodium”**

140 mg or less per reference amount **“Low Sodium”**

Reference amount should be obtained from: **Reference Amount Customarily Consumed (RACC)**



Claims about Nutrition and Health

(1) Nutrient Content Claim:

- **True-but-misleading claims** must be prohibited e.g. “*low-fat broccoli*”
- **Half-truth** and misleading claims must be prohibited e.g. if the product: **Both high in saturated fat and high in fiber**, the claim:

Claim could not just mention “High in fiber”

Reason: Against the Dietary guideline: Food high in Saturated fat could not be promoted



Claims about Nutrition and Health

(2) Health Claim (aka *Real* or *Authorized* Health Claim)

- Connects a food product to **disease** or health condition

e.g. “ may reduce the risk of heart diseases”

Another example: Adequate calcium and vitamin D as part of a healthful diet, along with physical activity, **may reduce the risk of osteoporosis later in life.**

- This requires approval from **Food and Drug Administration**
- Only approved if there is “**significant scientific agreement**”
- **Has to be derived from a statement from Dietary Guideline** or highly respected authorities/institutions (**IOM**)
- Usually a **lengthy process and rare in food industry** [*Oat and Cholesterol*]
- [*Cost for clinical trials >\$40K per patient, >\$19m for a new drug*]



Claims about Nutrition and Health

(3) Qualified Health Claim

- Is a claim that **lack significant scientific agreement**
- **FDA allows such claim when some health benefit studies are available.**
- **Label should indicate:**
- “*FDA has determined that this evidence is limited and not conclusive*”
- They should also indicate “*This statement is not approved by FDA.*”
- “Scientific evidence suggests, but does not prove, that whole grains (three servings or 48 grams per day), as part of a low saturated fat, low cholesterol diet, **may reduce the risk of diabetes mellitus type 2.**”
- Could lead to **legal complication** for companies if not stated correctly.



Claims about Nutrition and Health

(4) Structure and Function Claim

- Connects food to structure or function of human body
- Most common in the food industry
- Allows food industry to “**hint**” at health benefits
- Does not requires FDA approval
- But companies would **need to have strong scientific evidence [DGA or IOM]**



“*Prevents Osteoporosis*” is a **health claim** requires lengthily **FDA approval**

“*Builds strong bones*” is a **structure/function claim** that does **not require FDA approval**

Claims in Food Advertising

Claims of **nutrient content** and **food labeling** are typically **highly regulated**.

In contrast: food advertising claims are more permissive

The Nutrition Labeling and Education Act of 1990 (NLEA) gives authority to FDA:

- (a) Ensuring food labels are **truthful and not misleading**
- (b) Food labels are **educating public about nutrition and health**

In contrast, **Federal Food Commission Act** gives authority to **Federal Trade Commission** (FTC):

Only **assure advertising claims are truthful and not misleading**
i.e. Advertisements are not required to educate the public



Claims in Food Advertising

Federal Trade Commission (FTC) usually only stops:

“Outrageously misleading claims”

Example: a 2010 FTC court order against an acai berry producer claiming:

“Acai berry juice lead to weight loss in short period of time”

Advertisement reviews usually start by **petition from competitors**

Unlike **labeling**, no need for **“Significant Scientific merit.”**

- It is generally accepted that advertisement are subjected to **“Puffery”** [Legal term for exaggeration]
- Typically companies are **not require** to provide health benefits for reasonable **“Puffery”**



*Claims in Food Advertising for **Children***

- Is **more regulated** since children do not have **critical thinking skills** thus more **vulnerable**
- **American Psychological Association:**
- Kids **under the age of 8** can **not understand** persuasive intent of advertisement
- Suggest **no advertisement** to kids of that age

Food Industry and BBB

- Kids have to be protected by **parents**
- Advocate for **unrestricted advertisement**



Claims in Food Advertising for Children

- Currently, guidelines some restriction for advertising:
- **Children's television shows** (Nickelodeon or Disney cartoon)
- **Family shows are excluded** (*American idol*) that may expose children to harmful advertisement
- **Legal argument** is ongoing since **1978** to limit advertising of “**high-sugar foods**” to kids
- 2007 publication of IOM indicates:
 - Advertisement to children out of balance
 - Putting their health at risk
- **Since 2011 new legislation:**
 - Avoid advertisement of **foods high in sugar, salt, and fat**
 - Kids under the age of 17



Checkoff Programs and “Government Speech”

- Commodity Checkoffs:
- **Advertisement programs by government**
- To provide **evidence-based** information to consumers
- **Largest checkoff programs: meat and dairy checkoffs**
- Example of successful Commodity Checkoffs Programs:
 - “Got Milk?”
 - “Milk Mustache”
 - “Beef. It’s What’s for Dinner”
 - “Pork. The other White Meat”
 - “Ahh, the Power of Cheese”
 - “The Incredible Egg”



Checkoff Programs and “Government Speech”

- Commodity Checkoffs:
- **Stablished** by the Congress
- **Funded** by producers boards (i.e. \$1/per cattle sale)
- **USDA manages and approves** marketing and advertisements
- **Major concern:**
- **Contradiction of Checkoff programs with *Dietary Guidelines***
- Consuming **diary and beef** increases **saturated fat intake**
- There is **no checkoff program for poultry, fish, or whole grain foods**
- A **very small checkoff** for supporting **fruit and vegetable** consumption
- Checkoff programs are **economically justified** not necessarily promoting the **public health**



Exercise 2

- Please define in your own words the below terminologies and provide one example:
 - Commercial Speech
 - Commodity Checkoff
 - Credence Attributes
 - Front-of-pack
 - Government Speech
 - Health Claim
 - Puffery
 - Qualified Health Claims
 - Structure/function claim
 - Third-party certification in food labeling
- Please name the four type of Nutrition and Health Claims in Food Industry?
- Please briefly describe Nutrient Content Claim in food labeling and provide one example.
- Please briefly describe “Real Health Claim” in food labeling and provide one example.
- Please briefly describe Qualified Health Claim in food labeling and provide one example.
- Please briefly describe Structure/function claims in food labeling and provide one example.
- In your own words, please compare and contrast the regulatory climate for health claims in food label and those in food advertisement.
- In your own words, please explain what checkoff programs are and do you think they should be maintain or not in future.

FDA GRAS LIST

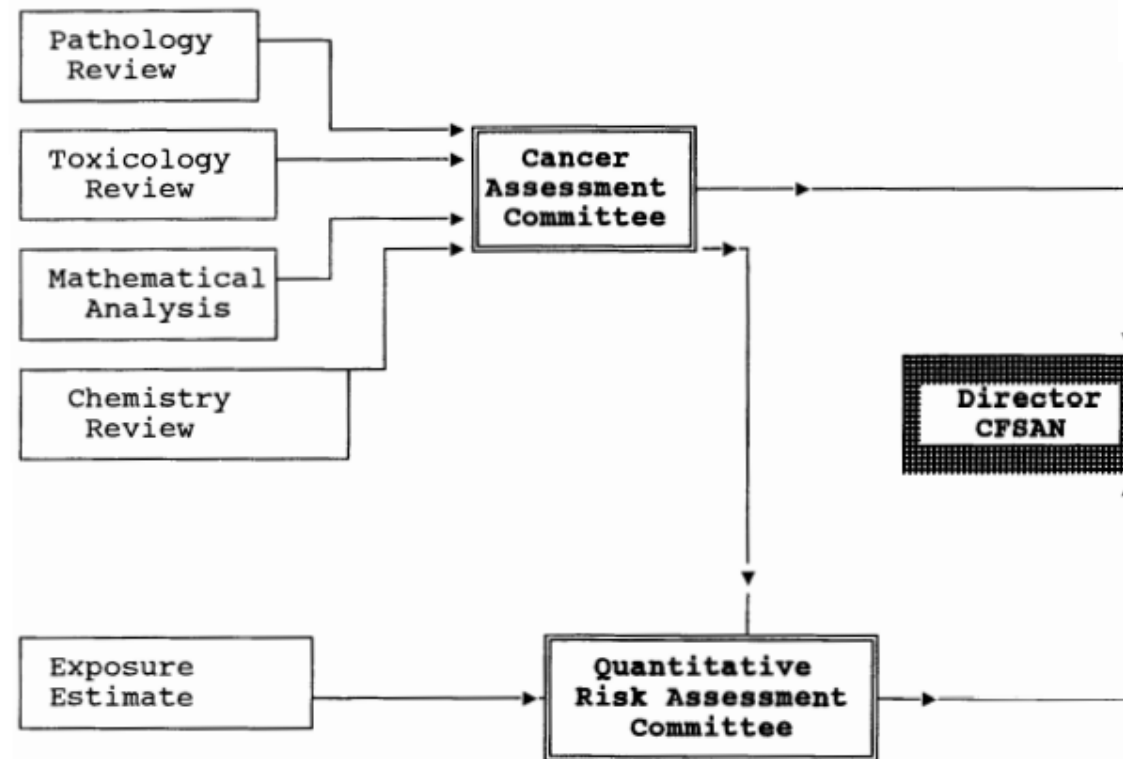
- Any substance that is **intentionally added to food** is a **food additive**
- **All additives** are: subject to **premarket review and approval by FDA**, **unless those with GRAS status**
- Food Industry is **extremely dynamic** with many ingredients (**natural and artificial**)
- **Practically impossible** for companies to test all ingredients for safety
- There is a similar list (**Animal Food GRAS**) for **feed industry**
- **When an ingredient is not listed** in GRAS list:
- Manufacturer may obtain GRAS status by **applying to the FDA**
- This is much **less conservative than pharmaceutical industry**. [LD50 in animals/100]
- Takes over **10 years** to receive approval for new drugs [typically >\$19 B]



Pre-market safety evaluation process

- **1958:** Congress enacted the **Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act**
- **1960:** Color Additive Amendments to the **Federal Food, Drug, and Cosmetic Act**

Flow Chart Depicting the Various Groups Involved in the Assessment of Cancer Risk at the Center for Food Safety and Applied Nutrition (CFSAN) of the Food and Drug Administration



Chapter II

Agency Review of Toxicology Information
in Petitions for Direct Food Additives
and Color Additives Used in Food

A. Introduction

The food additive petition review process came into existence in 1958 when Congress enacted the Food Additives Amendment¹ to the Federal Food, Drug, and Cosmetic Act (the Act).² This Amendment provides a pre-market safety evaluation process for new substances added to food, "food additives." A similar statute, the Color Additive Amendments of 1960,^{3,4} created analogous requirements for color additives used in foods, drugs, cosmetics, or medical devices. "Color additive" used in food is defined in section 201(t) of the Act; "food additive" is defined in section 201(s) of the Act.

Joint FAO/WHO Expert Committee on
Food Additives (JECFA)

Guidance document for
WHO monographers and reviewers
evaluating food additives
(excluding enzyme preparations and
flavouring agents)

FDA GRAS LIST

- GRAS (Generally Recognized as Safe) list of FDA:
- **Help producers avoid unnecessary testing**
- Provide a list of all **approved ingredients** and **approval concentrations** [*e.g. nisin 900 IU/gram*]
- **Created in 1958** as amendment to Food and Drug Cosmetic Act
- Ingredients already in use **before 1958** received GRAS status **without testing (Old Additives)**
- **This created some problem:**
- Example: **1985 cinnamyl anthranilate** (artificial cinnamon flavor) linked to liver cancer.
- **Was part of GRAS list from 1958 to 1985, banned in 1985.**



FDA GRAS LIST

- A large online data inventory: **GRAS Notice Inventory**
- **Some decision controversial:**
- **Lysozyme**: an natural enzyme in human breastmilk
- In 2006, Artificially produced Lysozyme did not receive GRAS status for **infant formula**
- Other examples:
- **Caffeine** did not receive GRAS status for **caffeinated alcoholic beverages**
- **Trans fats** were part of GRAS list until 2015
- **Sodium chloride** is still on GRAS list, **IOM recommends removal**



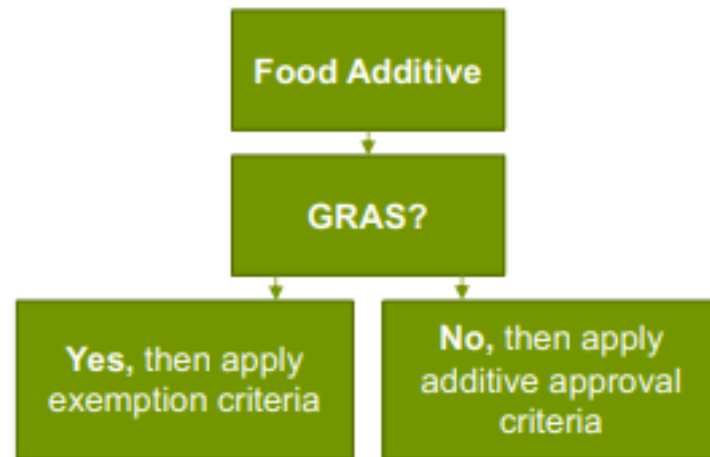
FDA GRAS LIST

- **Major problems with GRAS list:**
- **Old additives** were not all reviewed
- Studies are not from **human clinical trials** (in vivo or animal studies) *[LD50 in animals divided by 100]*
- Do not consider the **additives synergism** *[Benzoic acid, sulfate, phosphoric acid, citric acid]*
- **Does not address color additives** (covered by FD&C act)
- **Does not address pesticides**
- **Does not address GMO**

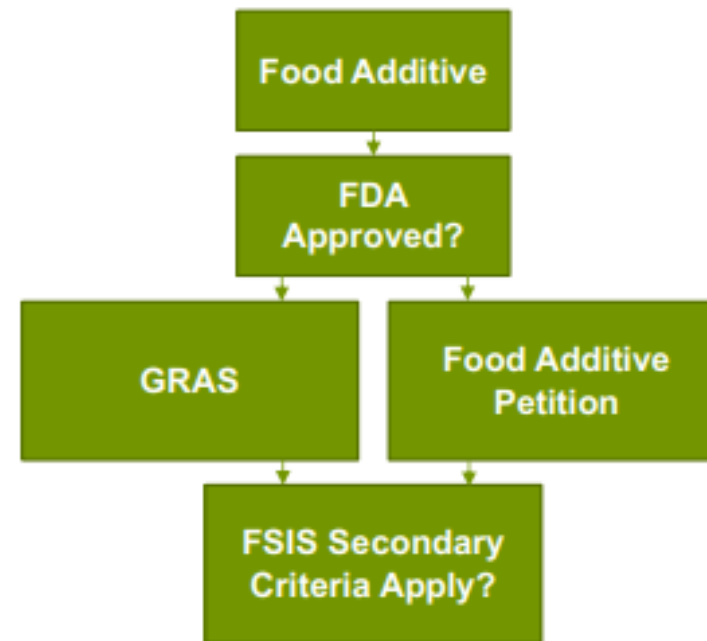
- **Other agencies** have additional requirements:
- **USDA FSIS:** additives for meat products
- **Animal Food GRAS List**



FDA GRAS LIST



**Food Additive Decision
Tree for FDA Products**



**Food Additive Decision
Tree for FSIS Products**

Exercise 3

- What is GRAS List and what year it was created?
- Please name three recent controversial decision about GRAS status.
- Please name five limitations of GRAS list?
- In your opinion how the GRAS list could be improved to further protect the public health?



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