

**Food Labeling and Advertising
FDA's Generally Recognized as Safe List
Food Safety and Climate Change**

AGSC 5540: Food Policies and Regulations

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Tennessee State University, Nashville, TN

A. Fouladkhah: Faculty Director, Public Health Microbiology Laboratory

Today and Rest of the Class



- **So far:** Public Health Necessity for Food Regulations; USDA Dietary Guidelines; CIFOE; HACCP; PC Human Food; FDA and TN Food Code; FSMA Produce Rule; Brief Summary of Preventive Control for Animal Foods
- **Today:**
 - ☐ Food Labeling, Food Claims, and Food Advertising
 - ☐ FDA's Generally Recognized as Safe (GRAS) list
 - ☐ Climate Change in picture
 - ☐ Food Safety and Climate Change
- **Last class** (11-19-2020)- Climate Change and Food Safety
 - ☐ Remaining of the Climate Changes Slides
 - ☐ Review of the class material of the semester
 - ☐ Review of Food Safety Plans for final exam (2 complete food safety plan from FSPCA)
 - ☐ Release of take-home final exam (by email and on eLearn)
 - ☐ **The take home final Exam and final paper due 11-25-2020**
 - ☐ **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. Cholesterol-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

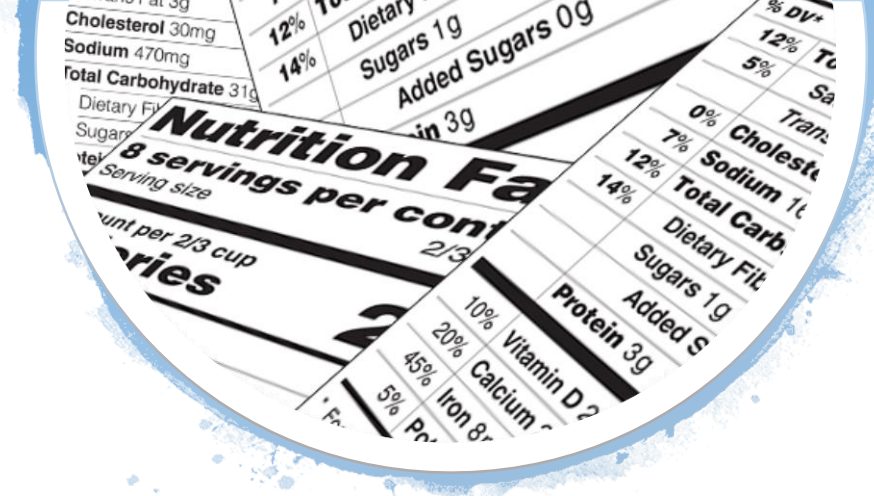
Consumers can get information:

- **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



Food Labeling and Advertising



- A USDA Survey (Golan et al., 2001):
- **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)

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:

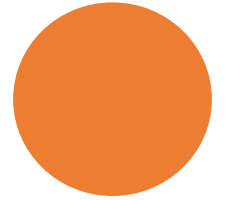
Easier: **inherently misleading** *i.e. therapeutic claims*
[weigh loss, hair growth]

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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Total Sugars 12g	
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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 evdy** *[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]



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**



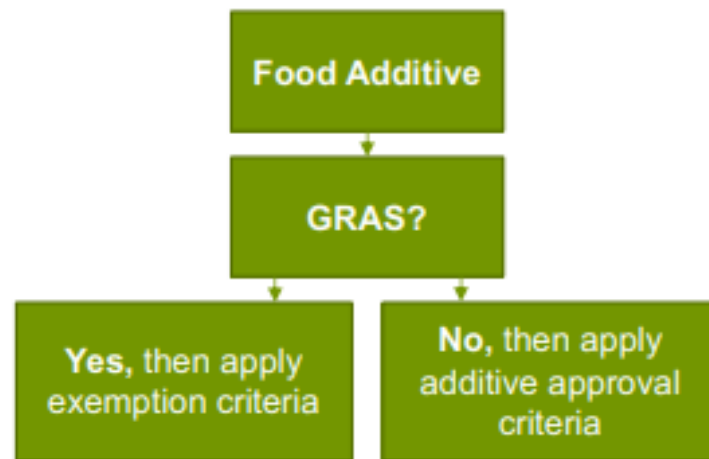
FDA GRAS LIST

- **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**

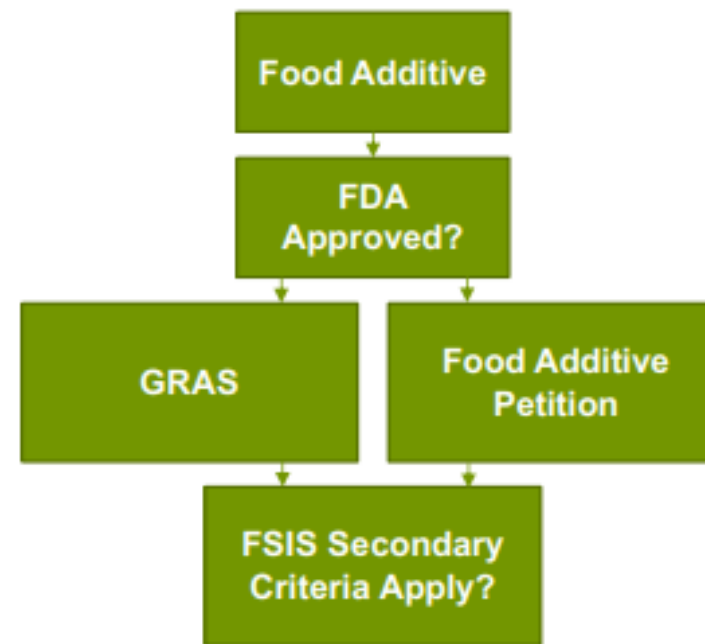
- **Other agencies** have additional requirements:
- **USDA FSIS:** additives for meat products
- **Animal Food GRAS List**



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?

Thank you

