SAFETY ASSESSMENT OF FOOD ADDITIVES

How FDA Regulates Food Additives

Department of Health and Human Services
U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Acronyms to Know

- Center for Food Safety and Applied Nutrition (CFSAN)
  - One of six product-oriented centers that carry out the mission of the Food and Drug Administration (FDA).
  - [Link](#)

- Office of Food Additives and Safety (OFSA)
CFSAN’s Mission

- To promote and protect the public health by ensuring that:
  
  - The food supply is safe and wholesome and cosmetics are safe
  
  - Food and cosmetic products are honestly and accurately labeled

OFAS --- Food Ingredients
What Is a Food Additive?

- **Ingredients** are component parts of food products that are generally recognized as safe
  - An ingredient list indicates what has been combined to make a food product
- A **food additive** is a substance added to food to cause a desired positive change in the product’s characteristics

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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 (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food;....

if such substance is not Generally Recognized As Safe,
What Is a Food Additive?

- Food additives
  - may or may not have nutritional value
  - can be added at any point from the farm to the kitchen table
  - are regulated by the USDA and FDA
  - undergo extensive testing and research to confirm their safety

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What Is a Food Additive?

- Additives get into foods in 2 main ways
  - **Intentional food additives** are added on purpose to give food specific characteristics
  - **Incidental food additives** get into foods unintentionally
- Both intentional and incidental food additives are regulated to protect the consumer from health hazards
What is a Food Additive?

Sec. 201(s) FFDCA: Definition

IN SHORT

- Any substance, that is reasonably expected to become a component of food as a result of its intended use,

- If such use in not Generally Recognized As Safe (GRAS)
OFAS’s “Food Ingredients” Universe

- **Direct Food Ingredients**
  - Sweeteners; Preservatives; Fat;
  - Nutrients; Texturizers (thickeners, Emulsifiers, etc.); Flavors

- **Color Additives**
  - In food, animal feed, drugs, cosmetics, medical devices (i.e. sutures and contact lenses)

- **GRAS Ingredients**
  - Enzymes; Fiber; Proteins;
  - Lipids; Sugars; MSG; Antimicrobials;
  - Phytosterols/stanols; Flavors;
  - Infant formula ingredients

- **Foods/Ingredients produced using modern biotechnology**
  - Plants w/herbicide resistance or insect resistance, delayed ripening, etc.;
  - often use GRAS concept

- **Processing Aids**
  - Antimicrobials (meat and poultry Processing); Defoamers; Ion exchange resins

- **Food Irradiation Equipment**
  - To process food
  - To inspect food

**Food Packaging/Food Contact Substances**

- Coatings (paper, metal, etc);
- New/recycled plastics including both polymers and monomers;
- Paper;
- Adhesives; Ingredients in Pkgs. (i.e. colorants, antimicrobials, antioxodants, etc.);
- Packaging material for use during food irradiation.; Food packaging “formulations”
Food and Drug Law

- **Sec. 409 Unsafe Food Additives**: the use of a food additive is unsafe, unless that use conforms to a regulation, notification, or exemption issued by FDA under Sec. 409.

- **Sec. 402 Adulterated Food**: a food is adulterated...if it is, or if it contains any food additive that is unsafe.

- **Sec. 301 Prohibited Acts**: the introduction or delivery into interstate commerce of any food that is *adulterated or misbranded*. 
The concept of safety used in this legislation involves the question of whether a substance is hazardous to the health of man or animal. Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive.

It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance.

H.R. Report, No. 2284, 85th Congress (1958)
Balancing Benefits and Risks

- Benefits of food additives include
  - an expanded and varied low-cost food supply available throughout the year
  - a reduced risk of foodborne illness
  - less time required for food preparation tasks
  - greater variety of convenience foods
  - more job opportunities
Balancing Benefits and Risks

- Concerns of food additives include:
  - unknown health hazards that may be revealed in future research
  - allergic reactions in certain people

- The FDA operates an Adverse Reaction Monitoring System (ARMS) to monitor the safety of additives

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Balancing Benefits and Risks

- Steps to reduce possible risks linked to food additives include
  - wash all produce before eating
  - choose fresh produce over processed snack foods
  - learn to prepare foods from scratch
  - read food product labels
  - read reports from FDA on additives