

FDA assessment approaches for innovative foods and food ingredients

Kristi L. Muldoon Jacobs, Ph.D.

Director, Office of Food Additive Safety

Center for Food Safety and Applied Nutrition, US FDA

FDA Office of Food Additive Safety

- **Responsibility:** ensuring substances added to food are safe and lawful
- **Primary Programs:**
 - petition programs for food and color additives,
 - notification programs for GRAS ingredient uses and food contact substances,
 - consultation programs for plant-derived products of modern biotechnology
 - plus other duties as assigned
- **Expertise:** chemists, toxicologists, biologists, regulatory scientists, microbiologists, pathologists environmental scientists, informatics specialists



Federal Food, Drug & Cosmetic Act



- Defines prohibited acts
- Defines adulterated foods
- Defines “food additive”, with an exemption for “GRAS”
- Defines “color additive”
- Requires pre-market approval of new uses of food additives and color additives
- Establishes the standard of review
- Establishes the standard of safety
- Establishes formal rulemaking procedures

FD&C Act: Adulterated Food

Section 402



Any food that is, or bears or contains, an unapproved food or color additive is deemed **unsafe** (per Sections 409 and 721) and is therefore **adulterated** under the FD&C Act.

Section 402



Any food that is, or bears or contains, an added poisonous or deleterious substance which may render it injurious to health is **adulterated** under the FD&C Act.

Section 402



Any food that has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health is **adulterated** under the FD&C Act.

What Is A Food Additive?

Section 409

Any substance the intended use of which

results or may reasonably be expected to result

in its becoming a component

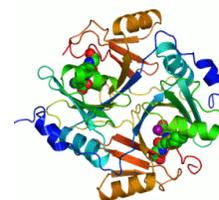
or otherwise affecting the characteristic of any food

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

Generally Recognized as Safe: Provision within the “Food Additive” Definition

...if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use

- **Safety by general consensus vs. FDA’s safety decision**
- **Data supporting safety must be:**
 - **Generally available (public!)**
 - **Generally accepted (consensus by experts)**



Safe or Safety: Definition

“reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of its use” (21 CFR 170.3(i))

–Complete certainty of absolute harmlessness not possible

Safety determination specific to the condition of use.



Our Programs

- **Food and color additive petitions**

- FDA approval, resulting in a regulation
- Irradiation

- **GRAS Notifications**

- FDA evaluation of notifiers conclusions that uses of substances are safe
- Public inventory of completed notifications, generally applicable

- **Food Contact Notifications**

- FDA authorization of company-specific uses of food contact substances
- Public inventory of effective FCNs.

- **Biotechnology Consultations**

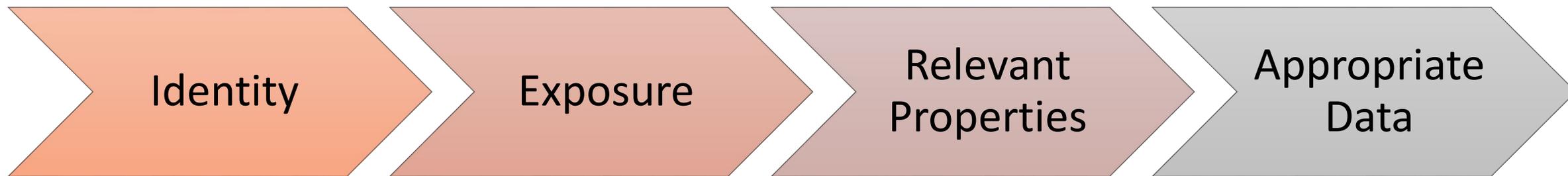
- FDA evaluation of information showing that food from genetically engineered plants is safe

- **Cell Culture Consultations**

- Two consultations recently completed by FDA (CCCCO02, CCCOO!

FDA inventory lists: [Search Food Ingredient and Packaging Inventories \(fda.gov\)](https://www.fda.gov/food/food-ingredient-and-packaging-inventories)

Approach to Safety Assessment of Substances Added to Food



Food Safety Assessment: Basic Elements

- **What is it?**
 - Identity, properties, and composition
 - Manufacturing process
 - Specifications, limits on impurities/contaminants
- **What are its intended uses?**
 - Purpose or technical effect (why is it added to food?)
 - Food categories
 - Use levels
- **How much will people consume of it?**
 - Exposure estimate based on maximum intended use levels and food consumption data
- **Will amounts consumed be safe?**
 - Data and information supporting safety at estimated exposure levels
 - Appropriate data informed by exposure, biochemical properties, functional properties

Innovative Food Technologies

Examples from Past Experience

Historical Approach to Food Innovation

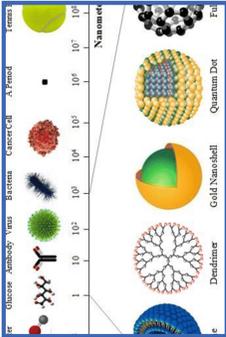
- Innovations in science and technology continue to generate new ways of making food
- FDA combines long-standing authorities with policy and scientific knowledge to regulate food safety
- This approach is flexible and adaptable to a wide variety of new food production technologies
- FDA safety evaluation is targeted to the ingredient and its intended use, method of manufacturing is considered as it pertains to safety

Pre-market programs support food innovation



New innovative food ingredients

- The GRAS Notification Program routinely evaluates new food ingredients produced through novel application of food technologies such as genetic engineering, fermentation, and bioprocessing



Nanoscale substances

- Guidance issued by FDA in 2014 on how to consider significance of changes to manufacturing process for safety assessment, including use of nanotechnology



New plant varieties produced by modern biotechnology

- Plant Biotechnology Consultations are a long-standing process to evaluate potential effects of genetic engineering or gene editing on safety of food from a new plant variety



New food contact and packaging materials

- New substances or changes in manufacturing or uses of existing packaging are reevaluated through the food contact notification program



Innovation in food colors

- New colors, either derived from natural sources or newly synthesized must be evaluated through the Color Additive petition process

Consistent Approach Over Time

Process considered only insofar as it affects properties or safety of food



Important to understand potential impacts on properties relevant for safety



Information needed to establish safety may change if process changes

Cultured Animal Cell Foods

- FDA and the U.S. Department of Agriculture, Food Safety Inspection Service (FSIS) jointly oversee human food products incorporating cultured cells from livestock (including Siluriformes fish) and poultry
 - FDA oversees cell collecting and culturing, and conducts premarket consultations on production processes
 - FDA and USDA/FSIS share oversight of harvesting of live cellular material
 - FSIS oversees processing, packaging, and labeling of harvested cellular material
- FDA oversees both cell culture and food processing, packaging, and labeling for human foods incorporating cultured fish and seafood cells
- FDA oversees both cell culture and food processing, packaging, and labeling for all animal feeds incorporating cultured animal cells and their byproducts
- The division of roles and responsibilities are outlined in the March 2019 Formal Agreement, available at the following webpage:
 - <https://www.fda.gov/food/domestic-interagency-agreements-food/formal-agreement-between-fda-and-usda-regarding-oversight-human-food-produced-using-animal-cell>

FDA's Roles and Responsibilities

- Conduct premarket consultations
- Oversee cell collection, cell banking, cell culture
- Coordinate with FSIS on oversight at harvest of cellular material for livestock (including Siluriformes fish) and poultry
- Enforce applicable FDA requirements
- Conduct inspections and related activities
- Oversee food products incorporating cultured fish and seafood cells
- Share information with FSIS

FDA's Premarket Consultation

- FDA conducts premarket consultations to evaluate:
 - Production materials/processes and manufacturing controls
 - Initial tissue collection
 - Development and maintenance of cell lines and banks
 - Proliferation and differentiation of cells through the time of harvest
 - Components and inputs
- FDA will engage with FSIS on consultations involving livestock (including Siluriformes fish) and poultry cell lines, and share the results of consultations. FDA will help to coordinate the transfer of regulatory oversight to FSIS



Thank - you