



## Food Chemical Safety at FDA

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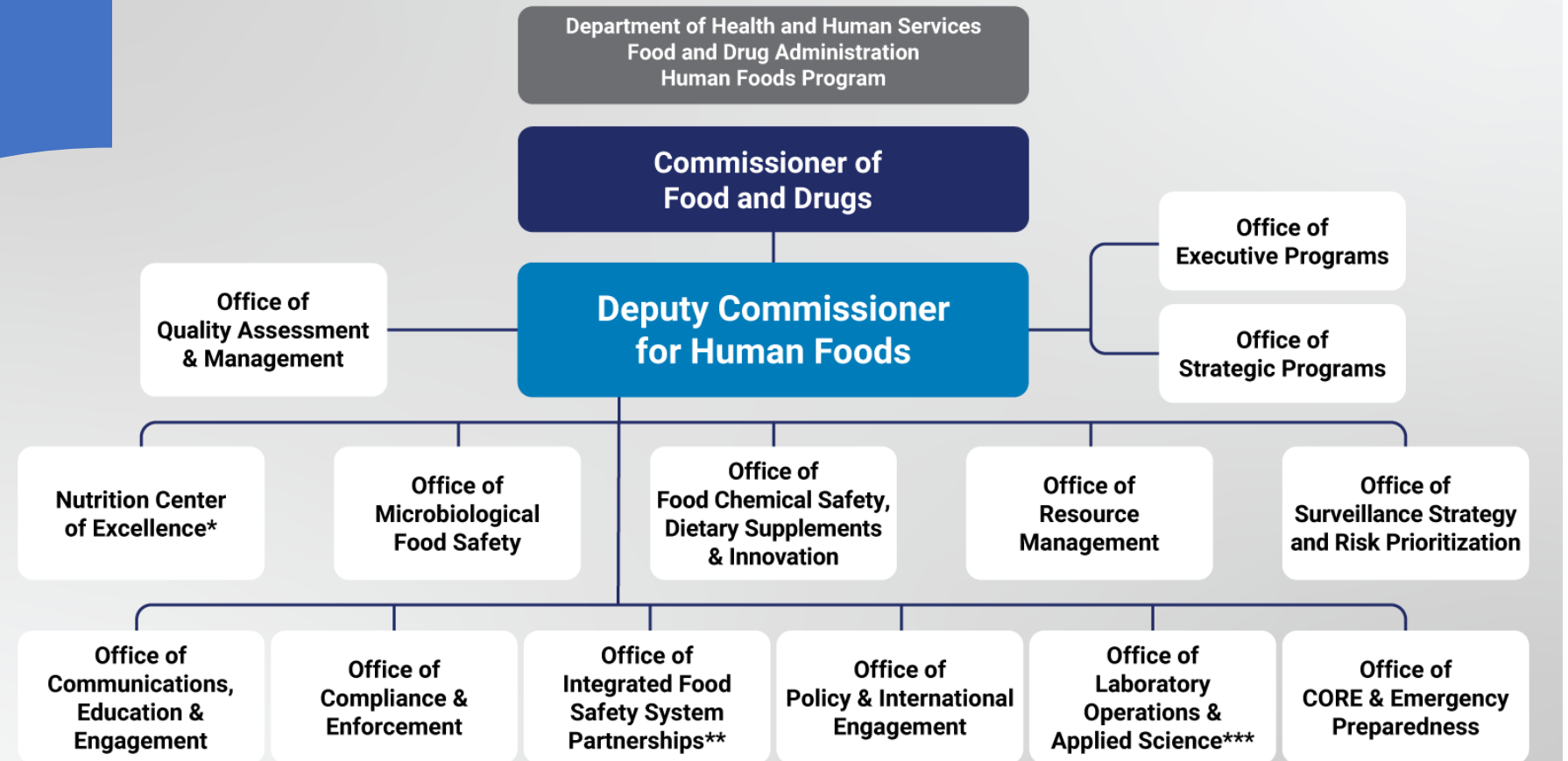
Office of Food Additive Safety, Director

Center for Food Safety and Applied Nutrition (CFSAN), FDA

# Food Chemical Safety at FDA

- Food Chemical Safety is one of the pillars of the proposed unified FDA Human Foods Program.
- FDA supports innovation while maintaining as its first priority the safety of the foods available to U.S. consumers, including our most vulnerable populations, such as children.
- Includes both pre-market and post-market programs.

# FDA Human Foods Program



\*Includes Office of Critical Foods

\*\*OIFSSP will work in close coordination with the Center for Veterinary Medicine

\*\*\*OLOAS will work in close coordination with the Office of the Chief Scientist and Center for Veterinary Medicine

# HFP OFCSDFI

Deputy Commissioner of  
Human Foods

Office of Food Chemical Safety, Dietary  
Supplements, and Innovation  
Director (acting), Kristi Muldoon Jacobs,  
Ph.D.

Operations

Innovative  
Foods Staff

Office of Pre-  
Market Additive  
Safety

Office of Post-  
Market  
Assessment

Office of Dietary  
Supplement  
Programs

# FDA's Pre-market Authorities



# FD&C Act: pre-market food additive and color additive authorities

“...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...”

- Require pre-market approval by FDA
- FDA reviews data and makes a safety determination
- Results in a food additive regulation in 21 CFR
- Exempts authorization requirement for uses generally recognized as safe (GRAS), applies to food additives only.

All substances used in food, whether GRAS, additive, or food contact substance must be safe.



# Color Additives: Legal Definition

## 201(t) of the FD&C Act

“--a dye, pigment, or other substance made by a process of synthesis ... or extracted, isolated, or otherwise derived...from a vegetable, animal, mineral, or other source,”

“when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through the reaction with other substance) of imparting color thereto.”

- Includes black, white, and shades of gray
- **No GRAS exemption**
- **Colorants** are substances used to color food contact materials



**“Reasonable certainty of no harm”**

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

**Based on safety only**

- No risk/benefit analysis

**Safety is determined by intended use.**

# Standard of Safety



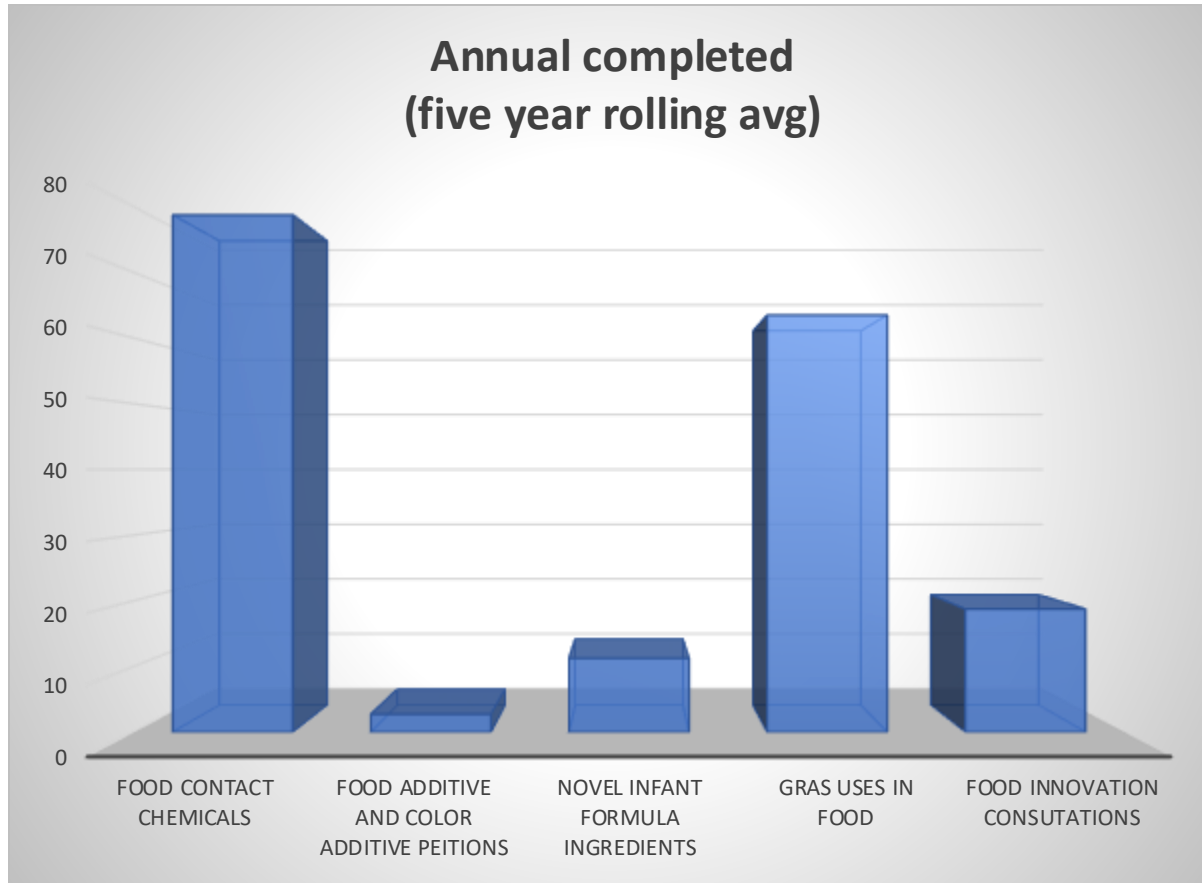


# Food Ingredient Safety Assessment: Basic Elements



- **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, considering sensitive sub-populations such as children and pregnant women.
  - Appropriate data informed by exposure, biochemical properties, functional properties

# FDA Pre-market Programs



- **Food Additive and Color Additive Petitions**
  - FDA approval applicable to all industry
  - Requires regulation posting in Federal Register
- **Food Contact Chemicals (Notifications)**
  - FDA authorization of company-specific uses of food contact substances.
  - Posted on FDA website
- **Novel Infant Formula Ingredients**
  - Typically through GRN, required for IFN
  - FDA issues letter and posts on website
- **GRAS Uses in Food (Notifications)**
  - FDA evaluation of notices that specific use is safe under specific conditions in food.
  - FDA issues letter and posts on website.
- **Food Innovation Consultations**
  - FDA evaluation of safety for innovative food products (GMO and Cell Agriculture).

# FDA's Post-market Assessment Process

# Enhanced Approach

- FDA is enhancing our approach to food chemical safety, with a focus on post-market work
- Includes improved transparency and involvement of stakeholders







**Public  
Meeting:**

# Enhanced Systematic Process for FDA's Post-Market Assessment of Chemicals in Food

**September 25, 2024**

**12:30 – 4:30 pm ET**

**Great Room, White Oak Campus and Virtual**

[Public Meeting website](#)



# Update Processes to Identify, Evaluate, Prioritize, and Communicate New and Evolving Information



Establish a framework to systematically review the post-market safety of chemicals in food



Seek information on the post-market use of approved chemical substances from industry and other stakeholders



Establish prioritization based on science and public health for post-market assessment activities



Establish publicly available list of chemicals we intend to reassess

# Select List of Chemicals in the Food Supply Under FDA Review

- contaminants
- food contact substances
- food ingredients, including food and color additives
- food ingredient impurities

- Thallium
- Per- and Polyfluoroalkyl Substances (PFAS)
- Mycotoxins (T-2 toxin, HT-2 toxin and zearalenone)
- Mercury
- Lead
- Cadmium
- Arsenic
- Phthalates - Other names include: *ortho*-phthalates, plasticizers, and components of adhesives, resins, lubricants, and sealants
- Irgafos 168 (Tris(2,4-di-*tert*-butylphenyl) phosphite)
- Fluorinated High-Density polyethylene (HDPE)
- Bisphenol A (BPA)
- Authorized PFAS: Uses of other PFAS in food contact applications
- Authorized PFAS: Certain Short-Chain PFAS in food contact substances (6:2 FTOH)
- Titanium Dioxide
- FD&C Red No. 3
- Potassium Bromate
- Partially Hydrogenated Oil (PHO)
- Brominated Vegetable Oil (BVO)
- Propylparaben
- 4-Methylimidazole (4-MEI)
- 3-Monochloropropane-1,2-diol (MCPD) esters and Glycidyl Esters (GE)

# Recent Actions and Ongoing Activities

- PFAS - Completion of market phase-out of PFAS grease-proofing substances
- BVO – published final rule to remove authorization
- Phthalates – revoked authorizations of 19 phthalates approved for use in food contact materials as plasticizers.
- Aspartame –participated in WHO and JECFA evaluation of safety, concluded authorized use level in food is safe
- TiO<sub>2</sub> full assessment ongoing expected to complete this year.
- FDA's "Not GRAS" Memos Inventory
- Establish new dedicated team for post-market food chemical assessment as part of the new HFP





**U.S. FOOD & DRUG**  
**ADMINISTRATION**