State of the Food Additives Program

Dennis Keefe, PhD
Director, Office of Food Additive Safety
U.S. Food and Drug Administration

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Office of Food Additive Safety (OFAS)

• Our Mission
• Our Vision
• Who We Are
• What We Regulate
• What We Have Accomplished
• Where We Are Going: Challenges
Our Mission

To protect and enhance consumer health by ensuring the safety of substances added to food and food packaging materials.
Our Vision

Our vision is to be recognized globally for impactful food safety decisions that are developed with integrity and based on sound science.
Who We Were:
The People
Who We Are:
The People
What We Regulate:  
The Food “Ingredient” Universe

Added Directly to Food for an Intended Effect

- **Direct Additives:** Sweeteners; preservatives; nutrients; fat substitutes; texturizers (e.g., thickeners, emulsifiers); flavoring agents
- **Color Additives:** In food (also includes animal feed, drugs, cosmetics, and medical devices (e.g., sutures, contact lenses))
The Food “Ingredient” Universe (continued)

Indirect Additives

- **Food Contact Substances:** Coatings (paper, metal, etc.); new/recycled plastics including polymers and monomers; paper; adhesives; colorants, antimicrobials, and antioxidants in packaging; packaging materials used during food irradiation; packaging “formulations”

- **Processing Aids:** Antimicrobials; enzymes; de-foaming agents; ion exchange resins
The Food “Ingredient” Universe (continued)

Other “Ingredients”:

– **Food Irradiation Equipment:** To process food or to inspect food
– **GRAS Substances:** Enzymes; fibers; proteins; lipids; carbohydrates
– **Foods/Ingredients Derived from Plants Produced via Biotechnology:** Plants with enhanced agronomic properties (herbicide or pest resistance) or enhanced production properties (delayed ripening, delayed browning, etc.)
Accomplishments Since 1958

- Food Additive Petitions >4800
- Color Additive Petitions >300
- GRAS Affirmation Petitions >400
- Food Contact Notifications >1660 (since 2000)
- GRAS Notifications >655 (since 1998)
- Biotechnology Consultations >150 (since 1995)

Total: ~8000 petitions/notifications/consultations
What We’ve Accomplished:

**Code of Federal Regulation Listings**

**Regulations/Effective Notifications**

- Food Additive > 700
- Affirmed GRAS ~ 350
- GRNs > 650
- Color Additive > 200
- FCNs > 1200
- **Total: ~3100**

**Substances**

- Direct Food Additives > 800
- Indirect Food Additives ~ 3500
- GRAS Substances > 1000
- Color Additives ~ 300
- **Total: > 5600**
Our Numbers:

OFAS Human Capital: FTEs 1998-2016
Accomplishments by Fiscal Year
All Submissions Completed

FY 2009-2015 Submissions Completed

- PNC
- FAP/CAP
- GRN
- FOI
- FCN
- CORR
- BNF
Accomplishments by Fiscal Year

Petitions/Notifications/Consultations

![Graph showing data for Accomplishments by Fiscal Year: Petitions/Notifications/Consultations]
Submissions Completed by Fiscal Year
Significant Accomplishments

2015-2016

• Completed EPA-FDA MOU on information sharing
• Updated USDA/FSIS-FDA information sharing MOU
• Final determination on the GRAS status of partially hydrogenated oils (PHOs) published in the Federal Register (80 FR 34650; 6/17/15).
• Draft Guidance on Sodium (81 FR 35363; 6/2/16)
• Strategic and organizational support to the Codex Committee on Food Additives as the US Delegate and Alternate Delegate
• Strategic and technical experts in support of JECFA and the EFSA/WHO Expert meeting to review the science underlying the Threshold of Toxicological Concern (TTC) Concept
Recent Food Additive/Color Additive Petitions
2015-2016

• **Synthetic iron oxide** to color candy, chewing gum, and mints (80 FR 14839; 3/20/15).
• Mica-based **pearlescent pigments** in food (80 FR 32303; 6/8/15).
• Amended the specifications for **TBHQ** (80 FR 34274; 6/16/15).
• **Spirulina extract** as a color additive in coating formulations for drug and dietary supplement tablets and capsules (80 FR 50762; 8/21/15).
• Mica-based pearlescent pigments in distilled spirits (80FR5860; 9/30/15).
• Revocation of provisions for **perfluoroalkyl ethyl compounds** (81FR 5; 1/4/16)
• **Folic acid** in corn masa flour (81 FR 22176; 4/15/16)
• **Vitamin D₂** in edible plant-based beverages (milk) and yogurt alternatives (81 FR 46582, 7/18/16)
Biotechnology Consultations
2015-2016

• BNF 132 Non-Browning Apples;
• BNF 141 Low Asparagine, Low Black Spot Bruise Potatoes;
• BNF 142 Herbicide Tolerant Cotton;
• BNF 144 Insect Resistant Soybean;
• BNF 145 Insect Resistant Corn;
• BNF 146 Altered Composition & Blight Resistant Potato;
• BNF 147 Corn with Altered Growth Properties;
• BNF 148 Herbicide Tolerant Corn;
• BNF 150 Herbicide Tolerant Corn;
• BNF 151 Insect Resistant & Herbicide Tolerant Corn; and
• BNF 152 Low Asparagine, Low Black Spot Bruise Potatoes
New Guidance for Industry

2015-2016

Level I

• Food Allergen Labeling Exemption Petitions and Notifications (80 FR 35372; 6/19/15)
• Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants (80 FR 73194; 11/24/15)
New Guidance for Industry
2015-2016

Level II

– Colored Sea Salt (September 2015)
(http://www.fda.gov/forindustry/coloradditives/guidancecompliance/legislativeinformation/ucm464600.htm)
Significant Accomplishments:
GRAS Notification Program Final Rule (81 FR 54960, 8/17/16)

• Clarifies the criteria for GRAS
  – Scientific evidence of safety
  – Role of publications and public information
  – Limitations on the use of confidential information
  – Same safety standard for food additives and GRAS
  – Criteria applies whether or not FDA receives a GRN
• Encourages industry to submit GRAS Notifications
• Increases transparency and information on the safety of food ingredients
• Establishes 180 day + optional 90 day timeframe
Challenges

Law

• **Safety Standard**
  – Reasonable Certainty of No Harm

• **Burden of Proof**

• **Statutory Timeframes** for Premarket Review
  – Food Additive and Color Additive Petitions
  – Food Contact Notifications

• Implementation of the **GRAS Provision**

• Implementation of the **Delaney Clause**
Challenges

Science

• Validating *in silico*, *in vitro*, and high throughput screening assays for hazard identification (e.g., ToxCAST, Tox 21).
• Applying emerging methodologies for risk assessments (e.g., read across, AOPs, threshold approaches, decision trees).
• Role of epidemiology studies in risk assessments?
• Utilization of risk factors for chronic disease vs frank organ/tissue lesions as endpoints?
• Updating risk assessments based on new data and information (e.g., cyclic review)
• Collecting, organizing, and interpreting new and different data sets within the context of safety assessments
• Updating Redbook Guidance
Science Challenges

SOT-FDA Colloquia on Emerging Toxicological Science

- Complexities in Evaluating Human Clinical and Observational Data for Ingredient Safety Assessments: PHOs as a Case-Study (December 2014)
- Application of ADME/PK Studies to Improve Safety Assessments for Foods and Cosmetics (February 2015)
- Immunotoxicology in Food and Ingredient Safety Assessment: Approaches and Case Studies (April 2015)
- Contemporary Issues in Risk Assessment (June 2015)
- A Path Forward for Using Computational and *in vitro* Methods for Food Ingredient Assessments (October 2015)
- Secondary Mechanisms, Mode of Action, and Thresholds for Carcinogens (December 2015)
- State of the Art in the Cramer Classification Scheme and Threshold of Toxicological Concern (March 2016)
- Safety Assessment Approaches to Sensitive Subpopulations (May 2016)
- Developmental Neurotoxicology (October 12, 2016)
Challenges

Policy

• Public Health Protection Priorities
  – Reduction of foodborne illnesses
  – Chronic disease and food ingredients (e.g., PHOs, sugar, sodium, saturated fats)

• Science-Based Cyclic Review of Approved Uses
  – Priority ranking
  – Access to supporting information
  – Creation of administrative record to support action

• Resources/Priorities
Challenges

Recent Events of Note

• **GAO:** “Food Safety: FDA Should Strengthen Its Oversight of Food Ingredients Determined to Be Generally Recognized as Safe” (GAO-10-246) (2010)

• **Citizen Petitions** to initiate FDA rulemaking to amend existing food additive or color additive regulations (e.g., BPA, BHA, certified color additives) or to prohibit the use of a food ingredient (e.g., PHOs).

• **Litigation to compel FDA** to: respond to Citizen Petitions (e.g., BPA, PHOs, salt & sodium); finalize proposed rules (e.g., FSMA, GRAS Notification Program) or finalize food additive petitions (perchlorate).

• **Food Additive Petitions (5)** to revoke food additive regulations based on abandonment (e.g., BPA (2), 2 perfluoroalkyl compounds, perchlorate, styrene).

• **Food Additive Petitions (5)** to revoke food additive regulations based on safety (e.g., perfluoroalkyl ethyl compounds, perchlorate, 7 synthetic flavoring agents and 30 ortho-phthalates).

• **Color Additives:** Increased interest in biological vs. coal tar starting materials

• **Food Additive Petition (1)** for the use of partially hydrogenated oils (PHOs)
Questions?