Public Private Partnerships in the Development of Food Safety Regulations

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Agenda

- Overview
- Suitability of Food Additives
- Case Studies
  - Titanium Dioxide (work in progress)
  - FDA Guidance on Fruit and Vegetable Juice Colors
- Q & A
The GMA Purpose

Provide a voice for the CPG industry as we seek to improve the health and wellbeing of consumers and society.
Executive Leadership

GMA Board of Directors

- Finance & Audit
- Executive Committee
- Health & Wellbeing
- Sustainability

- Government Affairs Council
- Industry Affairs Council
- Science & Regulatory Council
- Chairman's Advisory Council
- Advisory Council
Science & Regulatory Affairs

Mission

Develop and promote science-based solutions that enhance the safety, quality and compliance of GMA member’s products in order to build the trust and confidence of consumers.
What We Do

Provide science-based solutions that help members improve integrity of consumer products to build consumer confidence and trust.

- Policy engagement
- Member collaboration
- Technical service
Science & Regulatory Affairs

Science & Regulatory Affairs Council

Allergen Committee

Biotechnology Committee

Chemicals Management Committee

Microbiological Safety Committee

Nutrition, Health & Labeling Committee

Packaging Committee

Processing Technologies Committee

Regulatory Inspection & Compliance Committee
Ingredient Safety

- Consumer Packaged Good
  - Ingredients
  - Contaminants
GMA Participation in Codex

ICGMA Mission:

Advance science-based international policy in Codex Alimentarius

• Promoting harmonization within Codex standards and policies, and
• Facilitating international trade

ICGMA is accredited as an observer organization in Codex
Shared Responsibility, Common Goals

Industry, government & academia must work together to enhance food safety
Facilitating Collaborations

GMA

- Research
- Industry
- Legislators
- Intl. Groups
- Regulators & Govt. Agencies
At appropriate stages combine knowledge from:

- Industry
- Government Agencies
- Many other interested groups

To produce effective regulations
Policy: Stakeholder Engagement

- Participation at Public Consultations – Not Restricted to U.S. Citizens
  - Congressional hearings
  - Public Meetings
  - Federal Register Notices – Requests for Comments
  - WTO Notifications – https://tsapps.nist.gov/notifyus

- Participation in Trade Advisory Committees
  - USDA
  - Department of Commerce
  - White House

- Meetings with U.S. Officials Upon Request – Open and Transparent
“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 ... if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown ... to be safe under the conditions of its intended use (GRAS)…"
Safety of Food Additives

Food additives are thoroughly studied, including extensive toxicological testing, before they are approved for use in food.

Testing includes short-term and long-term toxicity studies, including carcinogenicity studies with a built in safety factor to account for uncertainties.

U.S. FDA “Guidance for Industry and Other Stakeholders: Toxicological Principles for the Safety Assessment of Food Ingredients” (Redbook)

Food additive identity, purity and quality is provided through adherence to specifications, which are developed prior to use in food.

Food additives have been used safely for decades.
Suitability of Food Additives

Food additives afford consumers added convenience and enjoyment of a wide variety of appetizing and nutritious foods and beverages.

Food additives are critical to the safety and nutritional composition of many foods and beverages.

Food additives used for technical purposes in finished foods and beverages fall into four main categories:

- Support nutrition delivery
- Maintenance of food quality and freshness
- Processing and preparation aids
- Enhanced appeal
Codex International Numbering System (INS) lists 23 functional classes for food additives. These functional classes include acidity regulator, anticaking agent, coloring, emulsifier, flavor enhancer, gelling agent, stabilizer, and thickener. The INS is hierarchical in that each of the 23 functional classes has sub-classes with additional functions. For example, sub-classes under “anticaking agent” include anti-stick agent, drying agent, dusting powder, and release agent.
Inherent properties of food additives like taste or technological functions limit the amount that can be added to foods—Too much of an additive can result in undesirable effects or off-taste. E.g. using a high level of a particular food gum in salad dressing production causes the product to become viscous, thick and undesirable.

For these reasons, manufacturers use no more of any food additive than absolutely necessary to achieve a desired technical effect.
Food Additives are Essential

Global Population Growth (7B 2010, 9B+by 2050)

That means there will be 75 million more people to feed each year

Almost 1B people do not have enough food today

Ensure food safety, maintain affordability, extend shelf-life, simplify preparation & minimize waste
Case Study: Titanium Dioxide

Food-grade TiO₂ impairs intestinal and systemic immune homeostasis, initiates preneoplastic lesions and promotes aberrant crypt development in the rat colon.

Titanium dioxide food additive (E171) induces ROS formation and genotoxicity: contribution of micro and nano-sized fractions.

Risk assessment of titanium dioxide nanoparticles via oral exposure, including toxicokinetic considerations.
The INRA Study

- Food Grade TiO2 (Nano)
- Ultrasonicated
- Doses: 200 mcg & 10mg/kg bw
- Exposure: 1mg/ kg bw
- Controls used for the study
- Lack of data
Agency Interaction

Addressing data gaps and commented on the current studies.
Addressing the Data Gap

- Two Studies
- Food Grade TiO2 (E171)
- Feeding study
- Multiple Doses
- Dietary Analysis
- Proper controls
Use of the Study Outcome

- EFSA submission
- Publication
- Industry Next Steps
- EC Action
Bettini study did not provide enough justification for a new carcinogenicity study

Proquin study did not modify the conclusion on the genotoxicity of TiO2 (EFSA opinion of 2016)

Guo study were of uncertain biological significance and therefore of limited relevance for the risk assessment

Heringa study made numerous assumptions, which resulted in large uncertainty in their conclusion

Recent Studies do not support re-evaluation of EFSA’s 2016 decision. **Should additional useful mechanistic information become available, this could be reconsidered in future**
Case Study: Fruit & Vegetable Juice Color Guidance

AGENCY:
Food and Drug Administration, HHS.

ACTION:
Notification of availability.

SUMMARY:
The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled “Fruit Juice and Vegetable Juice as Color Additives in Food.” The draft guidance, when finalized, will help manufacturers determine whether a color additive derived from a plant material meets the specifications under certain FDA color additive regulations.

DATES:
Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that we consider your comment on the draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 13, 2017.
Features of the Guidance

Definition of “Edible”:

• **Consumption as food**: Is the mature fruit or vegetable consumed for its taste, aroma, or nutrient properties in its “fresh” state? Plants used for medicinal or food decoration purposes cannot be considered as evidence of consumption as food.

• **Consumption amount and frequency**: Is the amount customarily consumed per eating occasion, and frequency of consumption, similar to that of other commonly eaten fruits and vegetables?

• **History of safe consumption**: Has the mature and fresh fruit or the mature and fresh vegetable been consumed by a large, geographically diverse human population over a significant period of time (i.e., generally for 20 years or more) without known detrimental health effects? If relying primarily on consumption outside of the United States, are there well-publicized studies?
Features of the Guidance

Processing

• Only minimal processing methods
• Minimal processing steps include washing with a potable water rinse; fresh cutting; and drying either naturally, by sun drying, or through the use of specialized dryers or dehydrators
• Minimal processing does not include aging, freezing, canning, pasteurizing, cooking or milling
• Extracts produced using solvent extraction, acid hydrolysis, and enzymatic processes are not permitted
Agency Interaction

GMA

Trade Assocn Coalition

FDA

Industry
Feedback to the Agency

Unintended consequences of the proposed guidance:

- Defines Edible
- Minimal processing is in conflict to the Hazard analysis and critical control points or (HACCP) principles for fruit juices
- Increases Regulatory Burden
- Impediment to using natural colors
Outcome

• The Food and Drug Administration withdrew the 2016 draft guidance on the use of fruit juice and vegetable juice as color additives based on public comments that raised substantive technical concerns.

• The agency announced that it will be seeking stakeholder inputs for developing a new guidance document.
Thank You

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