Public Private Partnerships in the Development of Food Safety Regulations

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GMA
The Association of Food, Beverage and Consumer Products Companies

JOHNS HOPKINS
UNIVERSITY

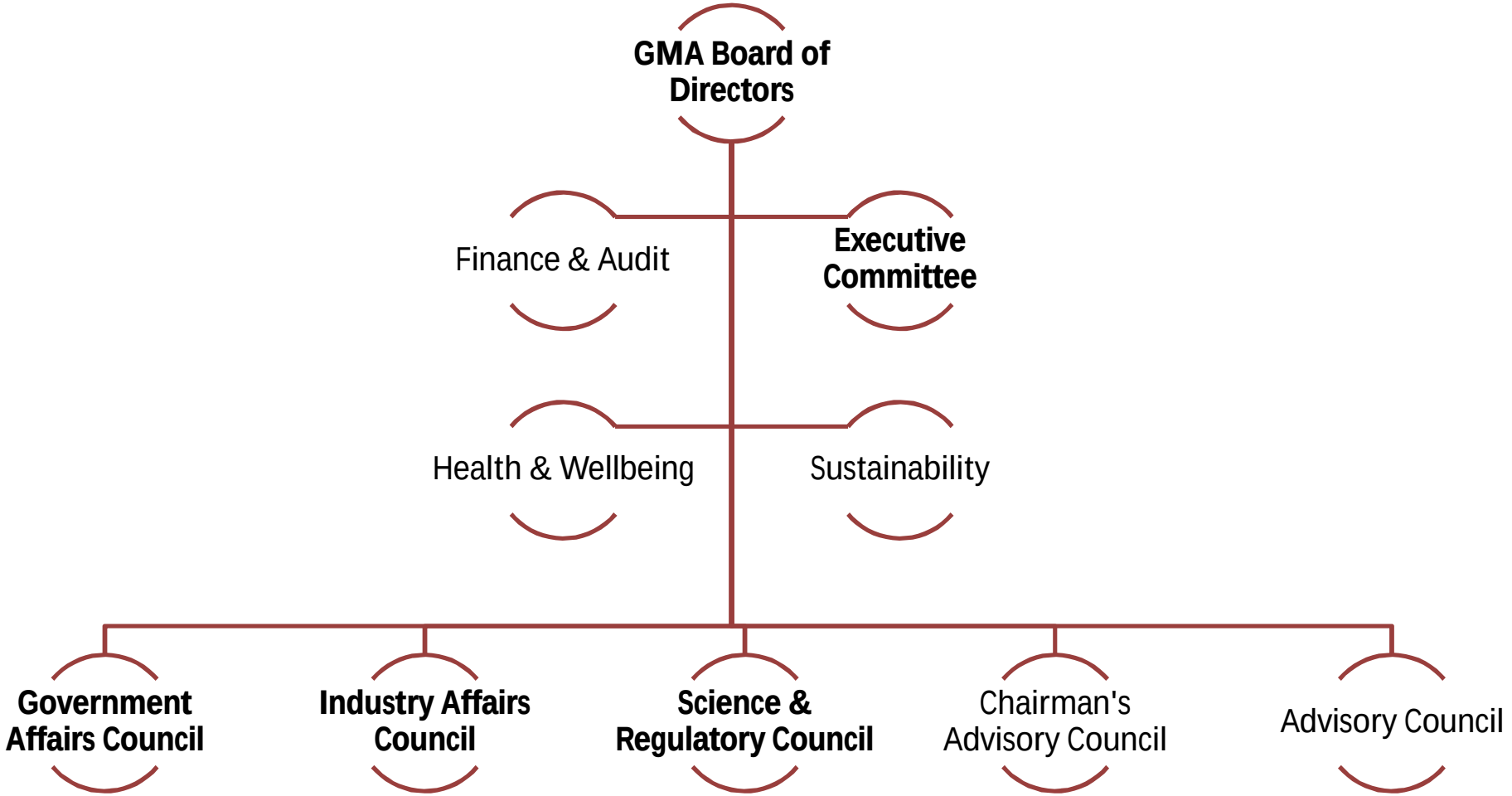
Agenda

- 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



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

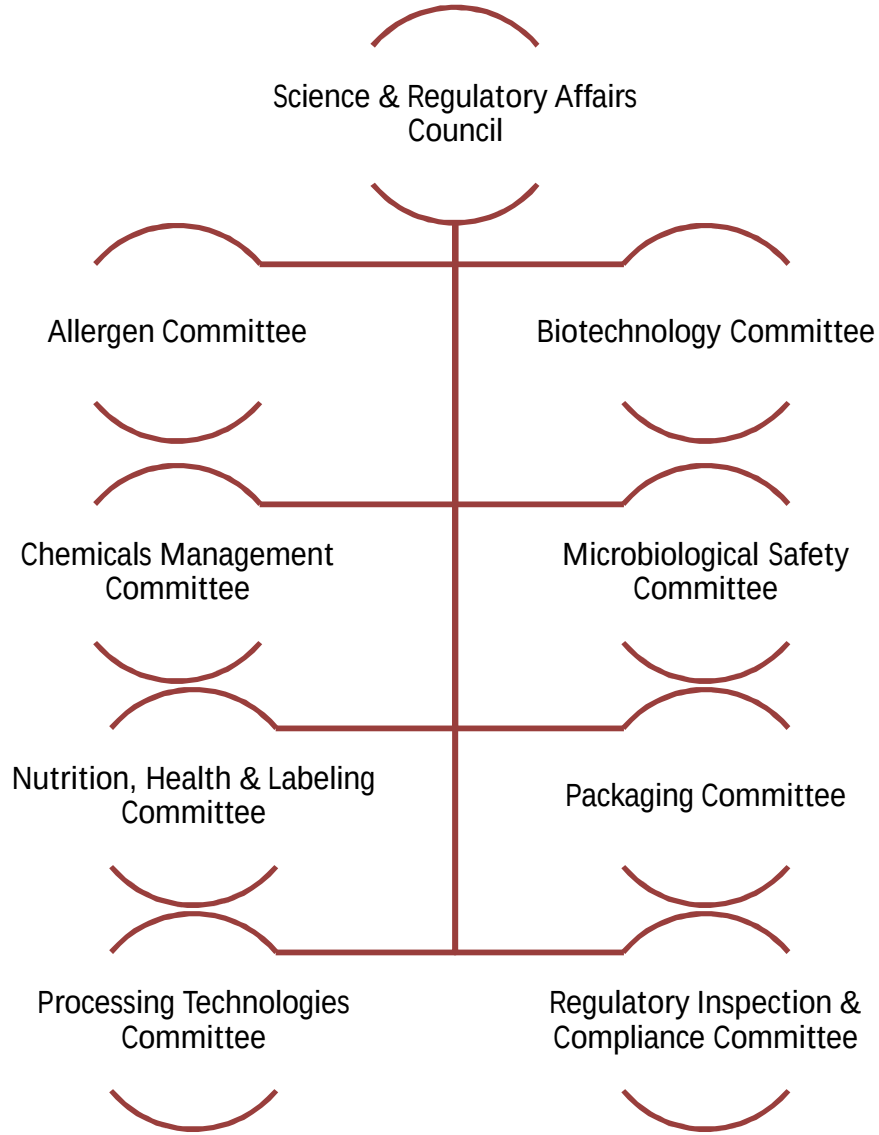
Product Safety & Regulatory Compliance

- **Policy engagement**
- **Member collaboration**
- **Technical service**

Consumer Product Information & Transparency

Nutrition, Health & Wellbeing

Science & Regulatory Affairs



Ingredient Safety

- **Consumer Packaged Good**
  - Ingredients
  - Contaminants

GMA Participation in Codex

ICGMA International Council of Grocery Manufacturer Associations ***Mission:***

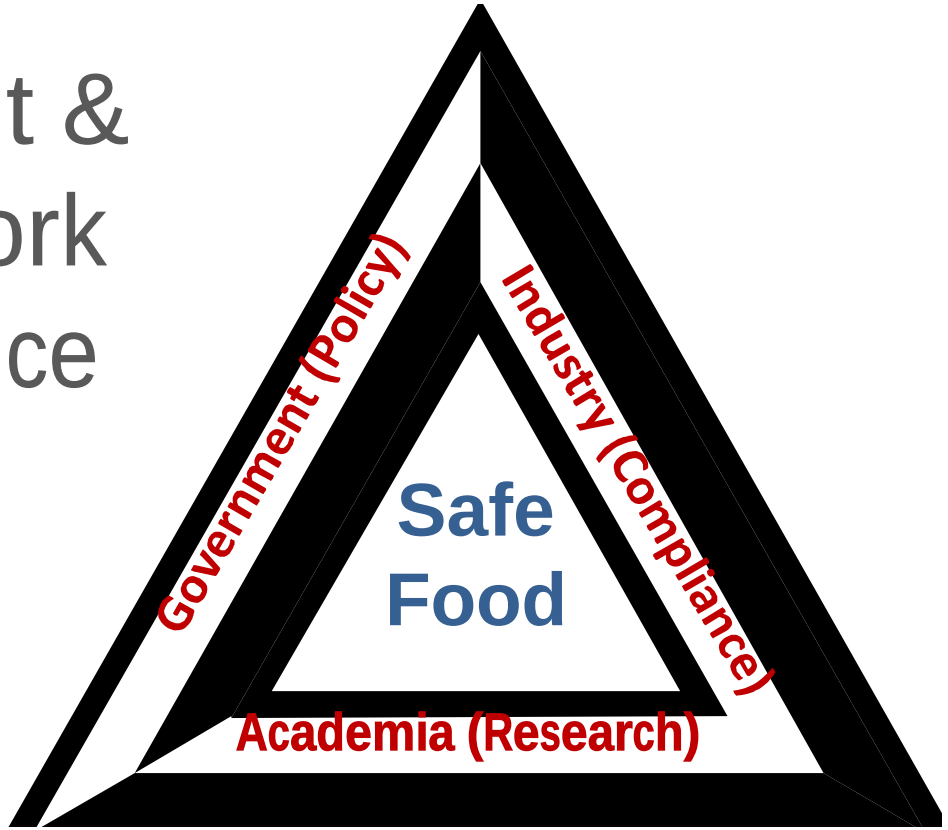
Advance science-based international policy in Codex Alimentarius

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

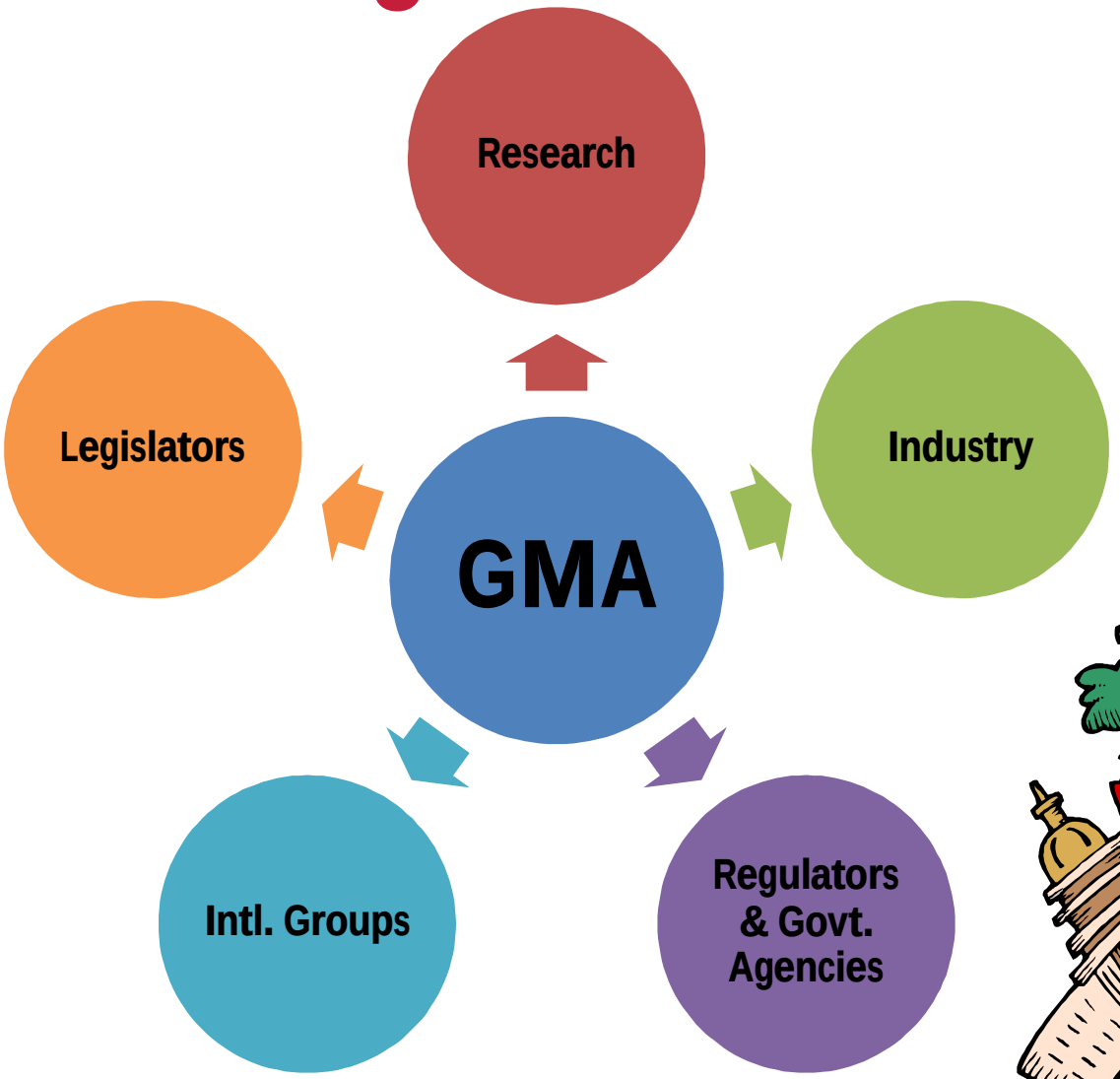
ICGMA is accredited as an observer organization in Codex

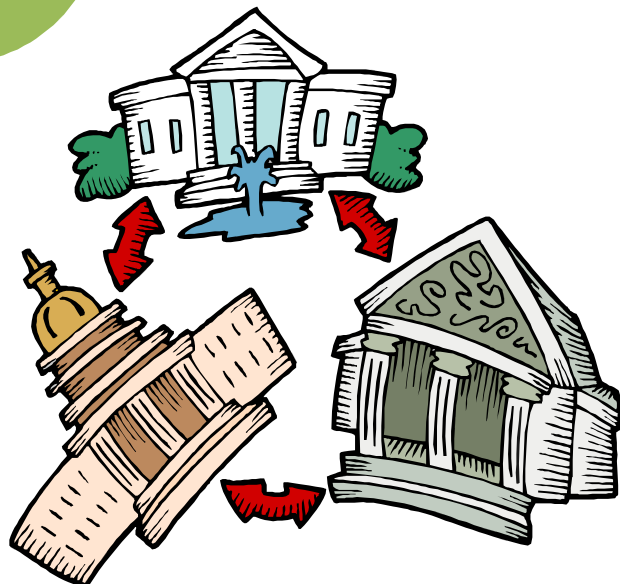
Shared Responsibility, Common Goals

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



Facilitating Collaborations





Policy: Industry Input in U.S. Regulatory Process

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

FDA - Food Additives

"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)..."

Sec. 201(s) FFDCA: Definition

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

Technological Function

Codex International Numbering System (INS) lists 23 functional classes for food additives

- Ex.: functional classes include acidity regulator, anticaking agent, coloring, emulsifier, flavor enhancer, gelling agent, stabilizer and thickener

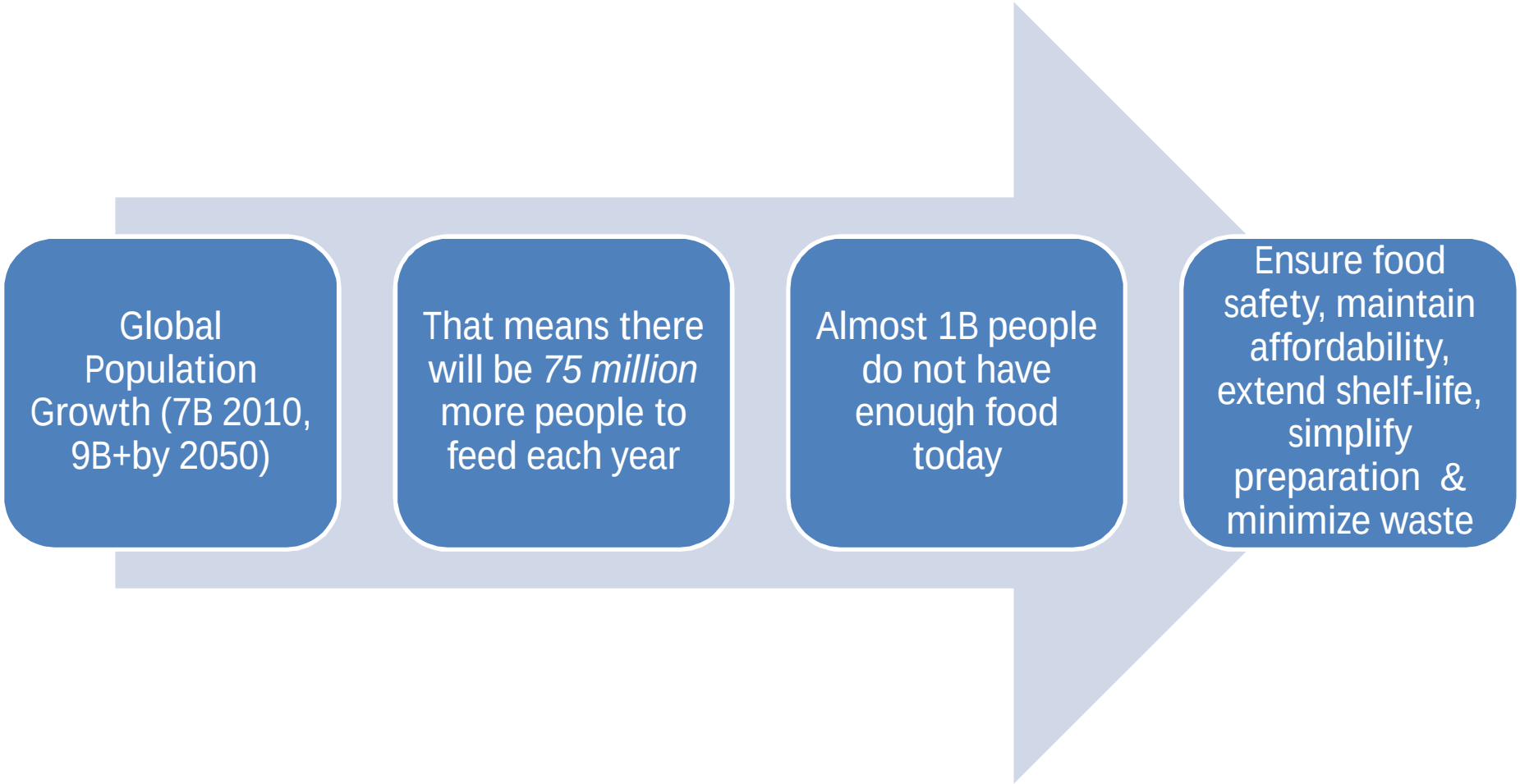
The INS is hierarchical in that each of the 23 functional classes has sub-classes with additional functions

- Ex.: sub-classes under "anticaking agent" include anti-stick agent, drying agent, dusting powder and release agent

Food Additives: Self Limiting

- 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



Case Study: Titanium Dioxide

SCIENTIFIC REPORTS

Article | OPEN | Published: 20 January 2017

Food-grade TiO_2 impairs intestinal and systemic immune homeostasis, initiates preneoplastic lesions and promotes aberrant crypt development in the rat colon

Sarah Bettini, Elisa Boutet-Robinet, Christel Cartier, Christine Coméra, Eric Gaultier, Jacques Dupuy, Nathalie Naud, Sylviane Taché, Patrick Grysan, Solenn Reguer, Nathalie Thieriet, Matthieu Réfrégiers, Dominique Thiaudière, Jean-Pierre Cravedi, Marie Carrière, Jean-Nicolas Audinot, Fabrice H. Pierre, Laurence Guzylack-Piriou & Eric Houdeau

Scientific Reports **7**, Article number: 40373 (2017) | Download Citation

ELSEVIER

NanoImpact

Volume 5, January 2017, Pages 70-82

Research paper

Titanium dioxide nanoparticle ingestion alters nutrient absorption in an *in vitro* model of the small intestine

Zhongyuan Guo [a], Nicole J. Martucci [a], Fabiola Moreno-Olivas [a], Elad Tako [b], Gretchen J. Mahler [a]

Show more

https://doi.org/10.1016/j.impact.2017.01.002 Get rights and content

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

Héloïse Proquin, Carolina Rodríguez-Ibarra, Carolyn G. J. Moonen, Ismael M. Urrutia Ortega, Jacob J. Briedé, Theo M. de Kok, Henk van Loveren, Yolanda I. Chirino

Mutagenesis, Volume 32, Issue 1, 1 January 2017, Pages 139–149,

Journal Nanotoxicology

Volume 10, 2016 - Issue 10

Enter keywords, authors, DOI etc.

3061 Views

25 CrossRef citations

21 Altmetric

Original Article

Risk assessment of titanium dioxide nanoparticles via oral exposure, including toxicokinetic considerations

Minne B. Heringa, Liesbeth Geraets, Jan C. H. van Eijkeren, Rob J. Vandebriel, Wim H. de Jong & Agnes G. Oomen

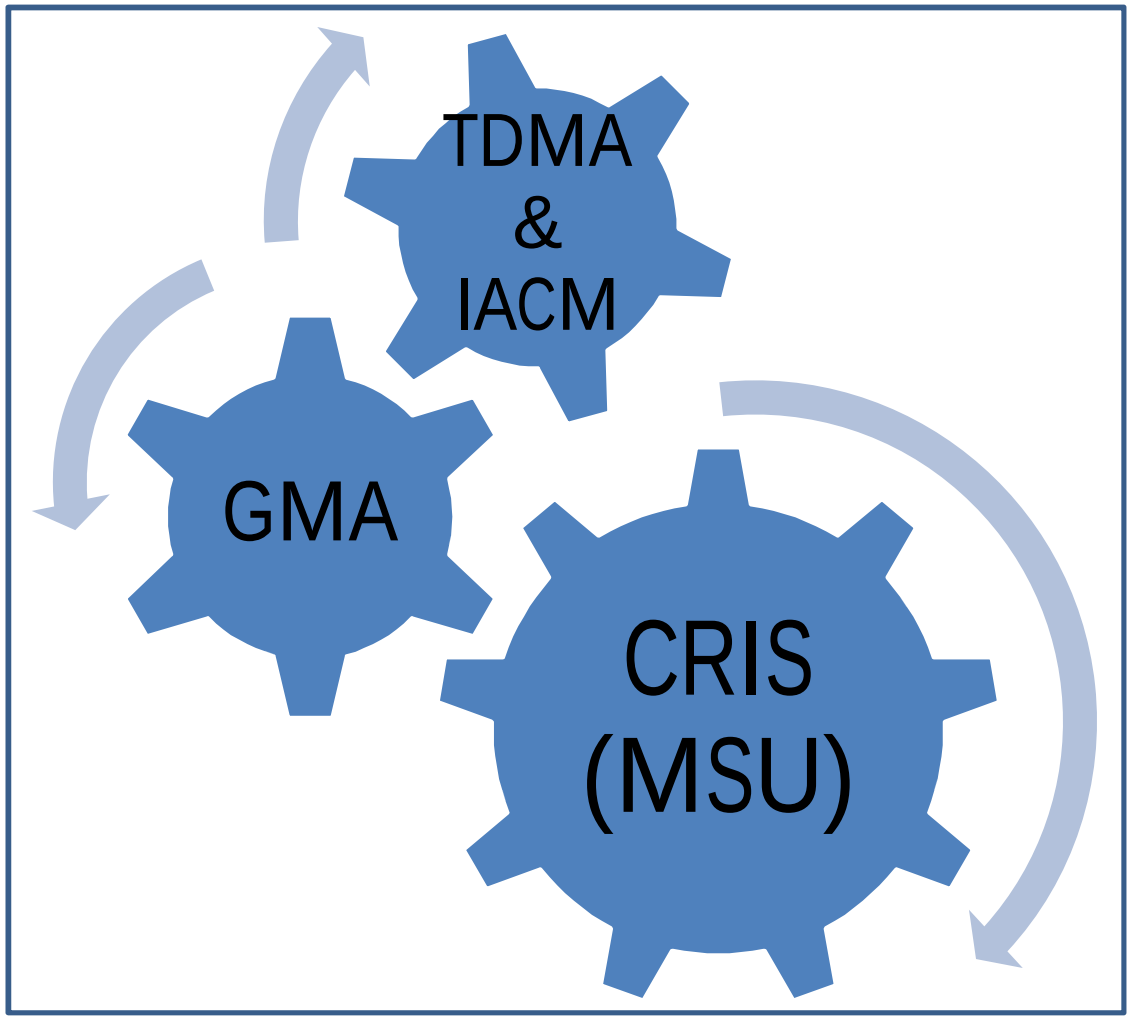
Pages 1515-1525 | Received 15 Feb 2016, Accepted 14 Sep 2016, Accepted author version posted online: 29 Sep 2016, Published online: 11 Oct 2016

Download citation https://doi.org/10.1080/17435390.2016.1238113

The INRA Study

Food Grade TiO_2 (Nano)	Ultrasonicated	Doses: 200 mcg & **10mg/kg bw**
Exposure: 1mg/ kg bw	Controls used for the study	Lack of data

Agency Interaction



efsa
European Food Safety Authority

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

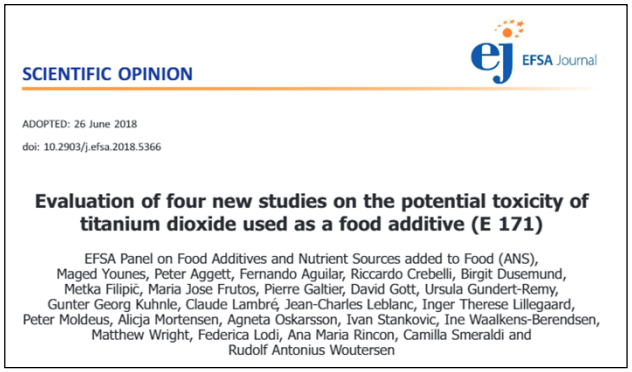
EFSA submission

Publication

Industry Next Steps

EC Action

Current Status



SCIENTIFIC OPINION

EFSA Journal

ADOPTED: 26 June 2018

doi: 10.2903/j.efsa.2018.5366

Evaluation of four new studies on the potential toxicity of titanium dioxide used as a food additive (E 171)

EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS), Maged Younes, Peter Aggett, Fernando Aguilar, Riccardo Crebelli, Birgit Dusemund, Metka Filipič, Maria Jose Frutos, Pierre Galtier, David Gott, Ursula Gundert-Remy, Gunter Georg Kuhnle, Claude Lambré, Jean-Charles Leblanc, Inger Therese Lillegaard, Peter Moldeus, Alicja Mortensen, Agneta Oskarsson, Ivan Stankovic, Ine Waalkens-Berendsen, Matthew Wright, Federica Lodi, Ana Maria Rincon, Camilla Smeraldi and Rudolf Antonius Woutersen

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

PUBLISHED DOCUMENT

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

DOCUMENT DETAILS

Printed version:
PDF

Publication Date:
12/14/2016

Agencies:
Food and Drug Administration

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.

Document Type:
Proposed Rule

Document Citation:
81 FR 90267

Page:

Features of the Guidance

Definition of “Edible”:

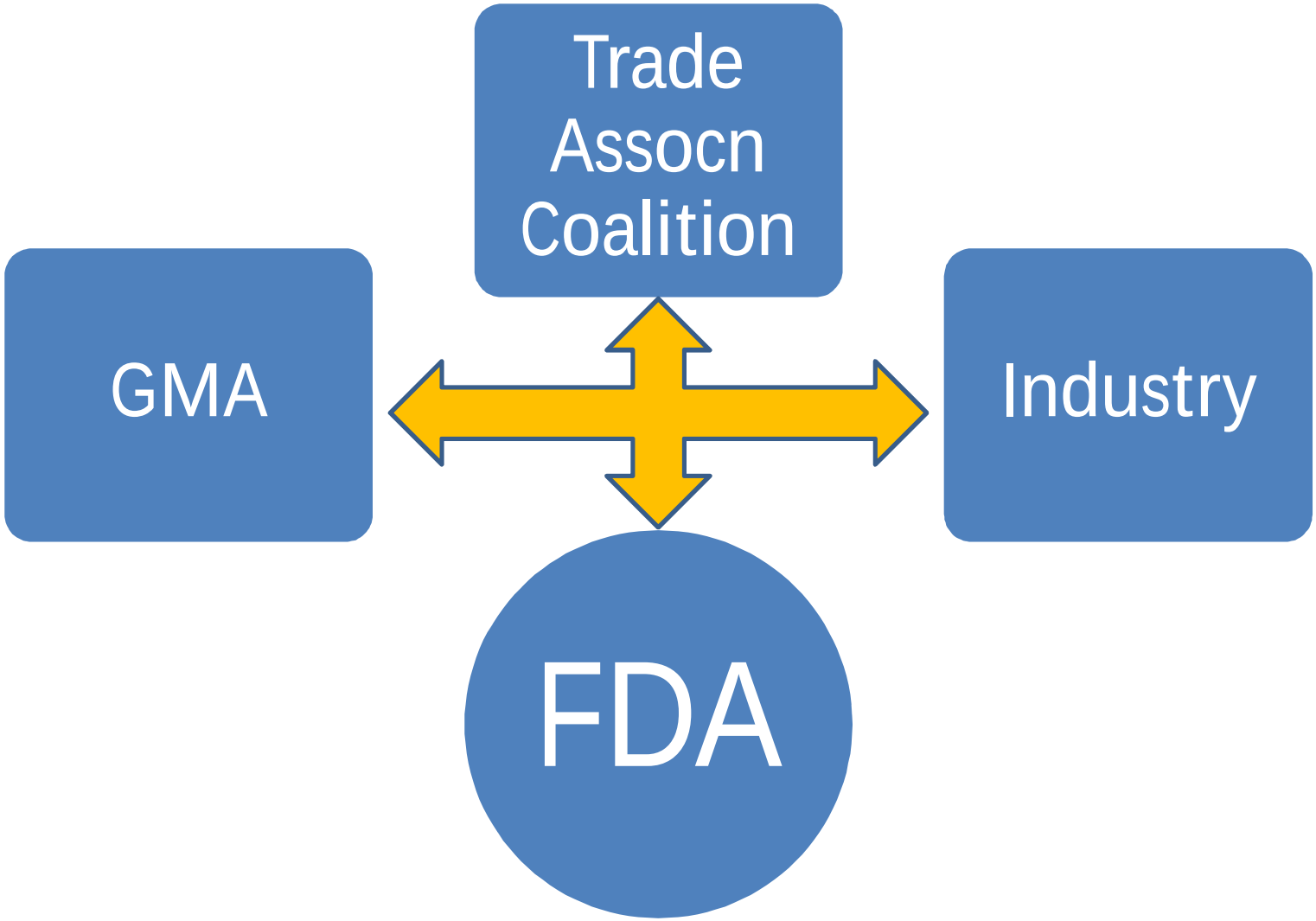
- **Consumption as food**: Is the mature fruit or vegetable consumed for its taste, aroma, or nutrient properties in its “fresh” state? Plants used for medicinal or food decoration purposes cannot be considered as evidence of consumption as food
- **Consumption amount and frequency**: Is the amount customarily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



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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GMA

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