

# Public Private Partnerships in the Development of Food Safety Regulations

Manojit Basu, PhD  
Senior Director, Product Safety and Regulatory Affairs, GMA &  
Adjunct Professor, Johns Hopkins University



## Agenda

- GMA overview
- Case Studies
  - FSMA
  - FDA Guidance on Fruit and Vegetable Juice Colors
- GMA: Science Education Foundation
- Q & A



## GMA - Overview



**Founded in 1908**

We represent the world's leading food, beverage and consumer products companies.



**30,000**

communities served

**\$415 billion**

in economic added value



CPG is the single largest U.S. manufacturing industry with

**1.7 million**

manufacturing workers.

**\$1 trillion**  
in sales annually



## GMA – What we do

GMA has a primary focus on: product safety, science-based public policies and industry initiatives that seek to empower people with the tools and information they need to make informed choices and lead healthier lives



## GMA Members

### General Members

5

## GMA Members

### Associate Members

6

## GMA – Global Focus

Area of Focus	Platforms for Engagement
Product Safety	APEC (FSCF, PTIN) GFSP Science Training Codex (ICGMA, FICC), ISO
Health and Wellness	APEC (advertising) LAWG WHO, FAO, Codex
Trade Liberalization and Regulatory Coherence	U.S. Trade Advisory Committees APEC (GRP, Export Certificates, etc.) WTO, Codex, ISO Trade Negotiations

U.S. government, bilateral, and multilateral advocacy

## GMA Participation in Codex

**Mission:**

Advance science-based international policy in Codex Alimentarius

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

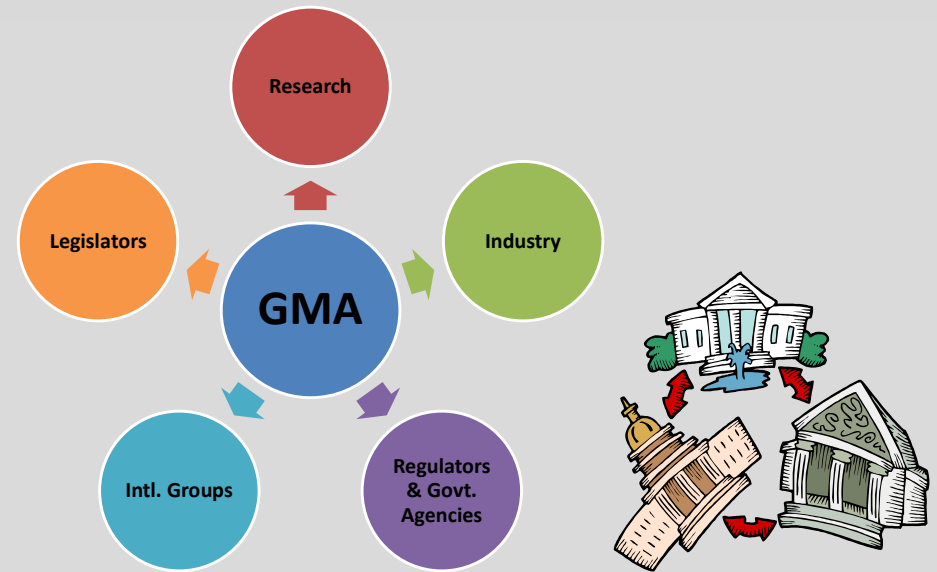
ICGMA is accredited as an observer organization in Codex

## Shared Responsibility, Common Goals

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



## Facilitating Collaborations



## Case Study – 1. FSMA

Food Safety Modernization Act (FSMA)

- Signed into law by President January 4, 2011
- Amends the Food Drug and Cosmetic Act
- Will Require over 50 new FDA Regulations
- Seven Major Rules Have Been Finalized
- Has Significant Implications for Trade

## FSMA

Most significant food safety reform in 70 years

- Made possible through partnerships with allied Non-Governmental Groups (NGOs) groups
- GMA took the lead on implementation of private sector AND regulatory aspects of FSMA



## Goals for FSMA Final Rules

1. Requirements/standards should be risk based and promote food safety
2. Rulemaking should stay within FSMA's framework that protects public health
3. Consistent and appropriate enforcement of FSMA is required to promote food safety

## Public Dialog Fundamental in the Development of FSMA Final Rules



- Face to Face Meetings with FDA and Subject Matter Experts
- FDA Public Meetings
- Comments to Public Dockets
- Collaborative Meetings with GMA FSMA Coalition to include Foreign Delegations and Embassies

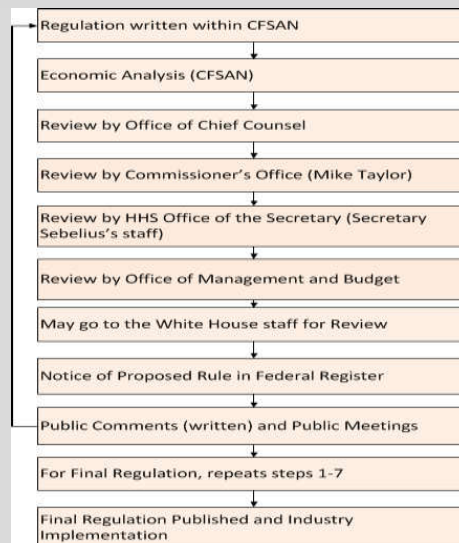
All FSMA related materials can be located on the FDA website and also on the GMA website

## 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





## Features in the Guidance

### Definition of “Edible”:

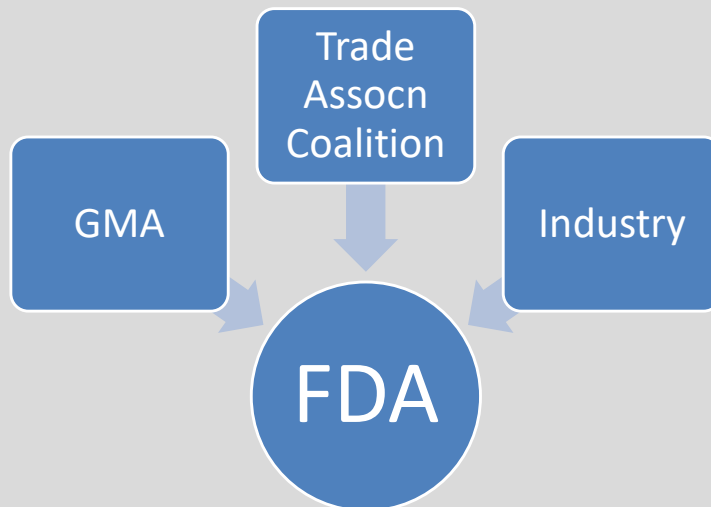
- **Consumption as food:** Is the mature fruit or vegetable consumed for its taste, aroma, or nutrient properties in its “fresh” state? Plants used for medicinal or food decoration purposes cannot be considered as evidence of consumption as food
- **Consumption amount and frequency:** Is the amount customarily 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 in 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 is withdrawing a 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 concerns include that the guidance promoted practices that may be inconsistent with current industry practices intended to enhance food safety.

## Thank You: Questions?

### Contact:

**Manojit Basu, PhD**

Senior Director, Product Safety and Regulatory Affairs, GMA  
1350 I Street NW. Washington DC - 20005

Email: [mbasu@gmaonline.org](mailto:mbasu@gmaonline.org)

Phone: 1-202-639-5983