Public Private Partnerships in the Development of Food Safety Regulations

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Agenda

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

• Q & A



GMA - OverviewSolutionFounded in 1908We represent the world's leading
food, beverage and consumer
products companies.\$415
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30,000 communities served



manufacturing industry with

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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 – 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

GMA Participation in Codex

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

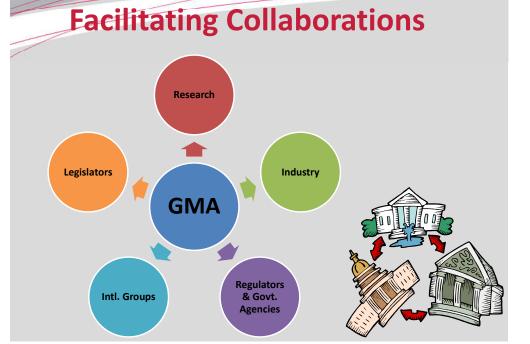
Industry, government & academia must work together to enhance food safety



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









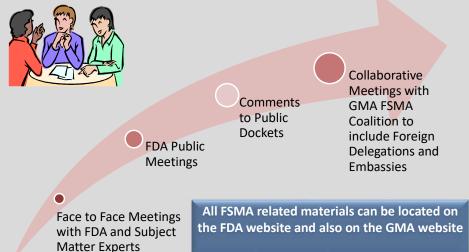
Goals for FSMA Final Rules

1. Requirements/standards should be <u>risk based</u> and promote <u>food safety</u>

2. Rulemaking should <u>stay within FSMA's</u> <u>framework</u> that protects public health

3. <u>Consistent and appropriate enforcement of</u> FSMA is required to promote food safety

Public Dialog Fundamental in the Development of FSMA Final Rules



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

	and a second second
Economic Analysis (CF	SAN)
	+
Review by Office of Ch	ief Counsel
	+
Review by Commissior	ner's Office (Mike Taylor)
Review by HHS Office (Sebelius's staff)	of the Secretary (Secretary
	+
Review by Office of Ma	anagement and Budget
	*
May go to the White H	ouse staff for Review
Notice of Proposed Ru	le in Federal Register
	.
Public Comments (writ	ten) and Public Meetings
For Final Regulation, re	epeats steps 1-7
	Ļ
Final Regulation Publis Implementation	hed and Industry

Policy: Stakeholder Engagement

- Participation at Public Consultations <u>Not Restricted to U.S.</u> <u>Citizens</u>
 - Congressional hearings
 - Public Meetings
 - <u>Federal Register</u> 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

Key Messages

- Throughout the FSMA rule-making process FDA was directly responsive to many requests from the food industry
- The revised FSMA rules are more flexible, more risk-based and preventive in nature
- All but one major issue in the FSMA rule-making process has been resolved and GMA, and industry, requested that FDA devise a solution to this major issue, which they are currently working on

Key Messages

- Through GMA the industry is significantly engaged in the development of FSMA regulations
 - GMA Members
 - Industry Coalition
- GMA has established a robust program to assist industry with practical implementation of FSMA requirements, including delivery of FSPCA training
- GMA is working with members and stakeholders to anticipate issues associated with the final rules and inspections and is prepared to respond as needed

Case Study: 2. 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) (3)), 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 unitum ensurements on the draft encloses by Teherman 20 corre

DOCUMENT DETAILS

Printed version

Publication Date 12/14/2016

Agencies:

Food and Drug Administratic

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: 00057 00070 (4 pages)

Need of a Guidance

- FDA does not regard food ingredients, such as cherries, green or red peppers, and orange juice, which contribute their own natural color when mixed with other foods to be color additives
- When a food substance, such as beet juice, is deliberately used as a color, as in pink lemonade, it is a color additive
- In 1966, FDA amended the color additive regulations by listing fruit and vegetable juice as a color additive for use in food, provided that the liquid is expressed from mature varieties of fresh, edible fruits / vegetables
- FDA received inquiries from industry regarding whether certain color additives made from various plant materials meet the specifications in the fruit juice or vegetable juice color additive regulations.

Features in the Guidance

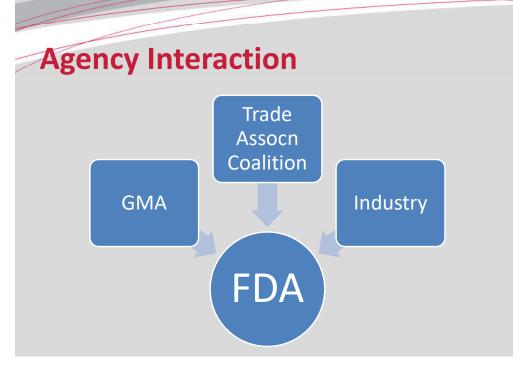
Definition of "Edible":

- **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



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?

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