GMA

Representing the Makers of the World's Favorite Food, Beverage and Consumer Products

Food Product Standards to Support Exports

March 14, 2018
Lusaka, Zambia

Presentation Overview

- GMA Background
- Core Regulatory Principles to Support Food/Ag Exports
- Science-Based Standards
- Regulatory Coherence and Codex
- Predictable/Transparent Rulemaking
- Cultivating a Positive Culture
- Case Studies

Who We Are:
More Than 100 Years of Industry Advocacy

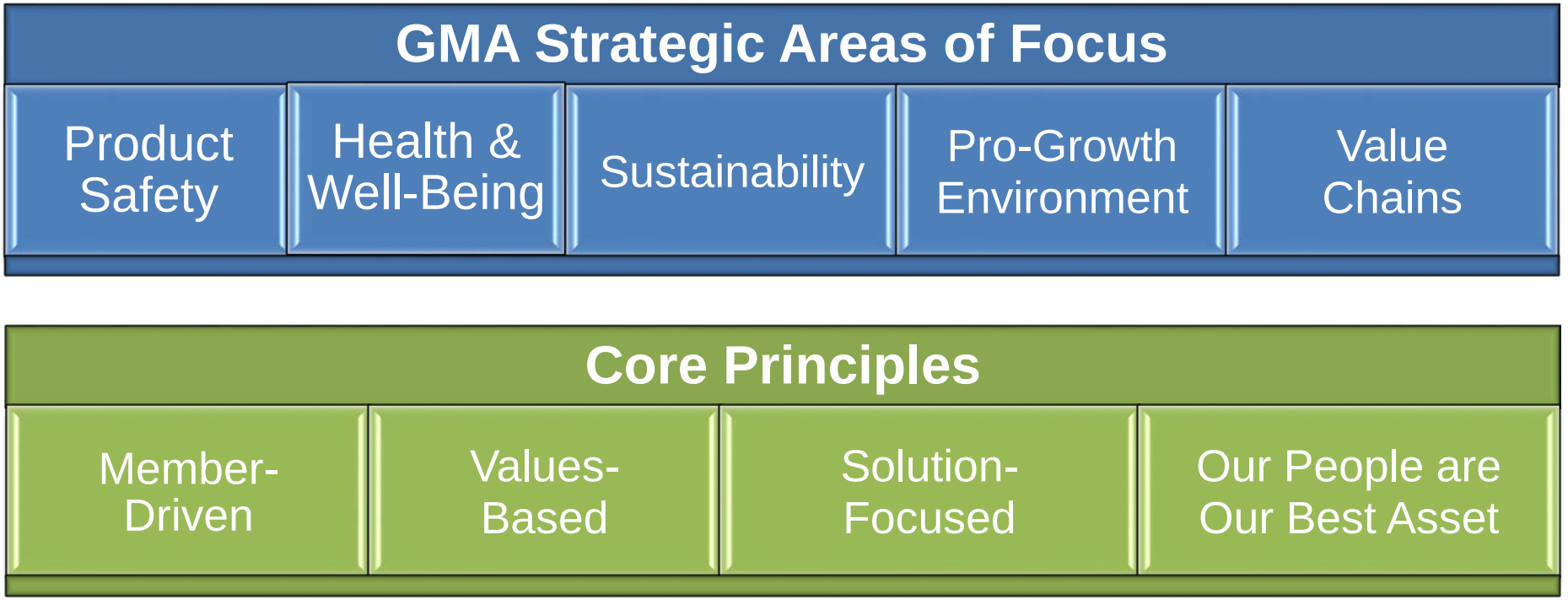
GMA

Founded in 1908 and based in Washington, DC, GMA is an active, vocal advocate for its member companies and a trusted source of information about the industry and the products consumers rely on and enjoy every day.

The association and its member companies are committed to meeting the needs of consumers through product innovation, responsible business practices, and effective public policy solutions developed through a genuine partnership with policymakers and other stakeholders.

GMA Objectives and Core Principles

Objective: Support a regulatory and commercial environment that enables our members to succeed.



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

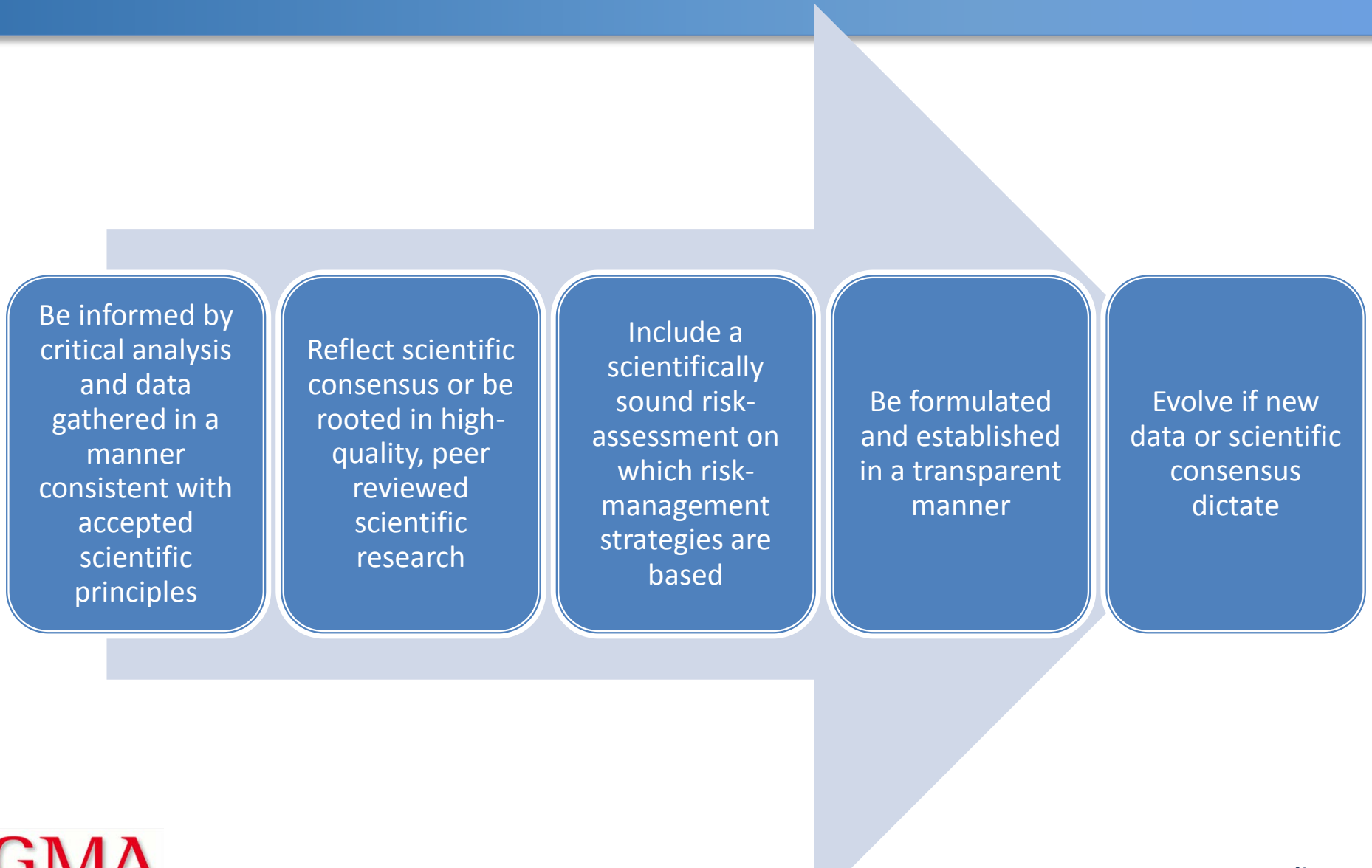
Core Principles to Support Food/Ag Exports

- **Science- and risk-based standards**
- **Harmonization with international standards**
- **Predictable, transparent, inclusive rulemaking process**
- **Importance of updating/modernizing regulations**
- **Cultivating a positive culture of responsibility**
- **Support for capacity building and organizational engagement**
- Equal/national treatment of producers
- Competitive marketplace that rewards innovation and technological advancement

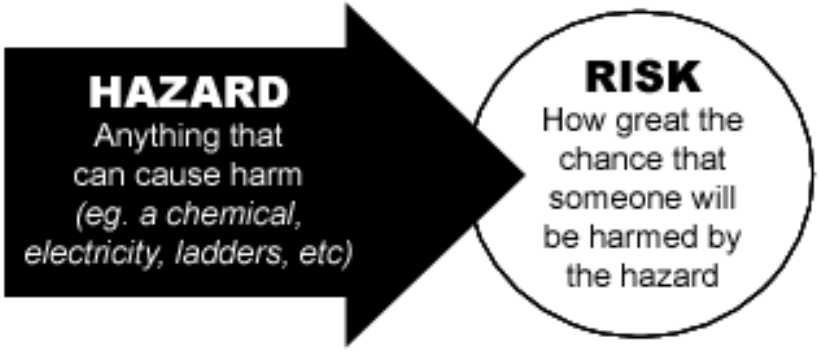
Science-Based Food Standards

Science-based standards form the roots from which global food and agriculture commerce will grow

Science-Based Food Standards



Risk vs. Hazard-Based Approach



To set risk-based standards, one MUST conduct a scientifically sound risk assessment. Without risk assessment, there is no way to responsibly manage risk—nearly anything could cause harm at

Risk vs. Hazard-Based Approach

RISK = HAZARD x EXPOSURE

A chemical may present a major hazard, but the risk to human health is minimal if exposure is very low.

A chemical may present a very low hazard, but the risk to human health is significant if exposure is very high.

Advantages of Science- and Risk-Based Standards

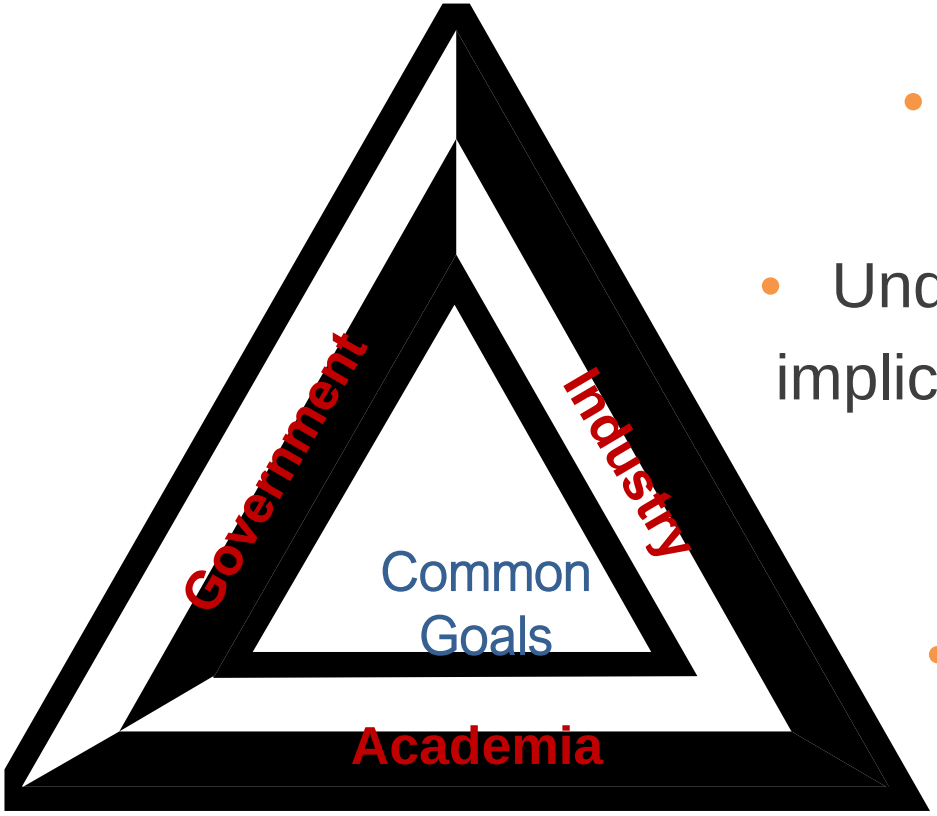
- Protect consumers
- Reduce uncertainty/assumptions
- Reflect current scientific consensus
- Foster collaboration
- Enhance transparency
- Facilitate international trade

Advantages realized through collaboration

Science-Based Standards: U.S. System

- Regulators and the U.S. food industry share a **common goal - ensure safe food**; science-based standards are essential to our common goal
- U.S. food industry has a long-standing commitment to providing safe, high quality food
- Federal law requires U.S. agencies to use science-based risk assessments
- Government and industry work together to conduct risk assessment and develop standards

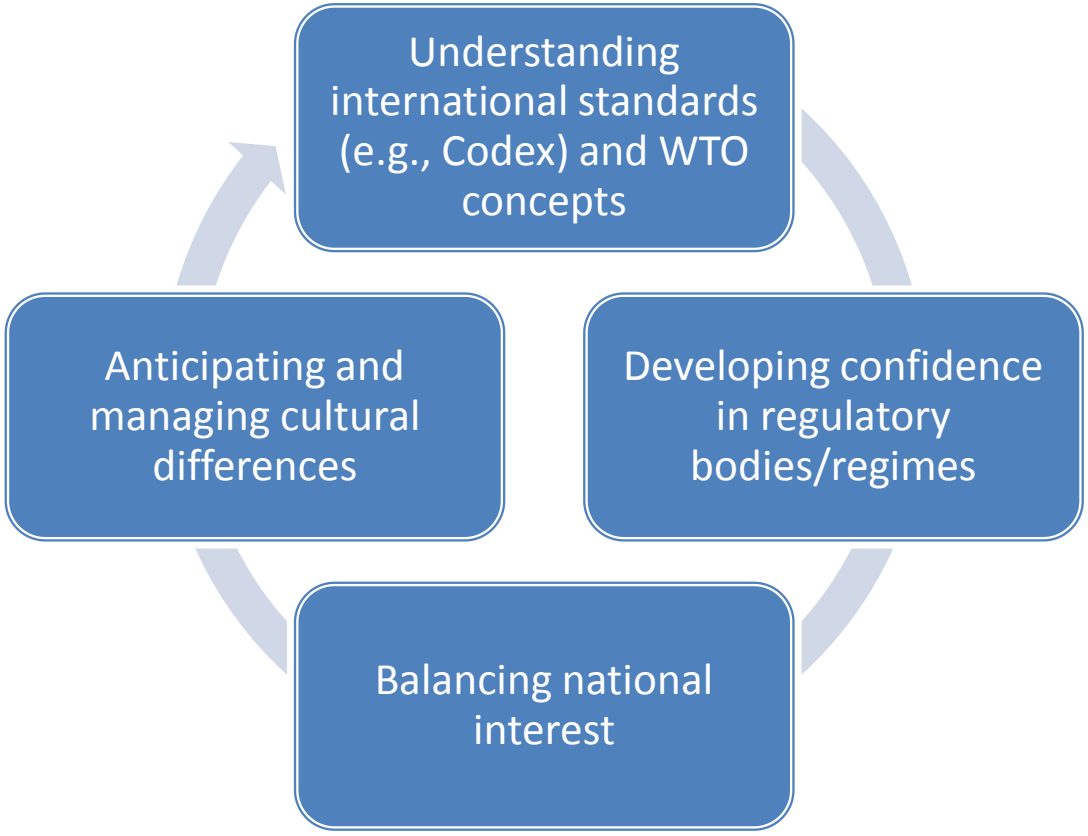
Science-Based Food Standards-The Role of the Private Sector



- Scientific data and expertise
- Understanding practical business implications and costs of legislation and regulation
- Cross-cutting awareness of potential impact on trade and value chains

Regulatory Coherence

Regulatory requirements that are inconsistent regionally or with trading partners hinder commerce, increase costs and may deter investment



Codex: International Standards and Risk Assessment Bodies

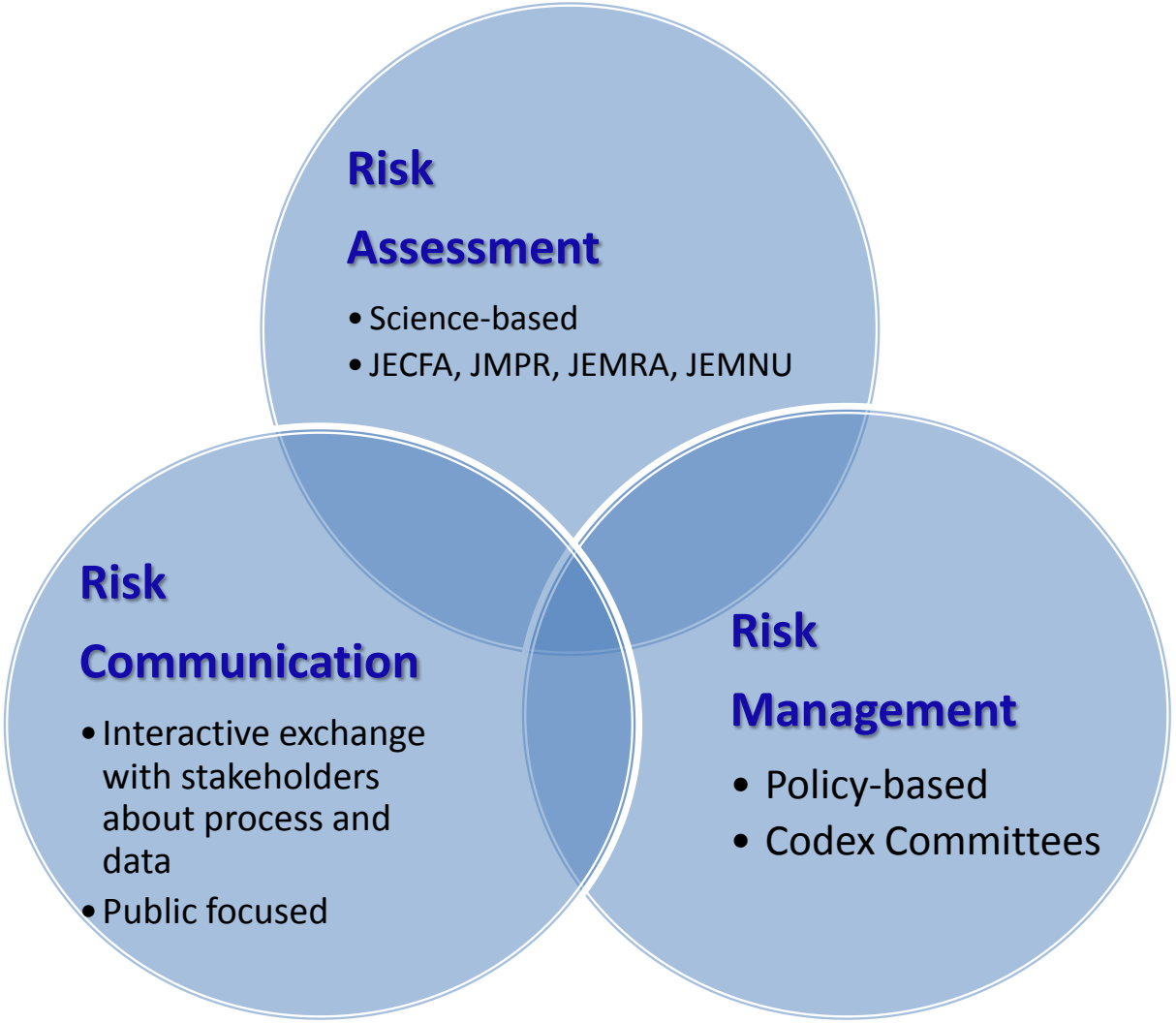
- Joint intergovernmental body of the Food and Agriculture Organization of the United Nations (FAO) and World Health Organization (WHO)
- **Mission:** to create harmonized international food standards that protect the health of consumers and ensure fair trade practices
  - Assisted by independent international risk assessment bodies or ad-hoc consultations
- Codex standards are voluntary and science-based
- Codex generally operates by consensus

CODEX
International Food Standards
ALIMENTARIUS

World Health Organization

Food and Agriculture Organization of the United Nations

WHO Risk Analysis Framework (1997)



Predictable, Transparent and Inclusive Rulemaking Process

- Regulated industry (foreign and domestic) benefits from such a rulemaking process
  - Predictability invites investment, innovation and domestic growth
  - Transparency promotes fairness, improves the policymaking process and invites collaboration
  - Inclusiveness accomplishes the public/private partnership described in the Codex slides

Predictable, Transparent and Inclusive Rulemaking Process

- Regulatory/rulemaking systems established in this manner will feature common characteristics:
  - Clear, consistent process with well understood deliverables and deadlines
  - Public consultation and publication process consistent with WTO obligations
  - Meaningful consideration of public comment

Process to Update and Modernize Regulations

- Designing regulatory frameworks that respond to changing data, trends, scientific consensus and technology is essential
  - Enhances safety in domestic market
  - Increases global competitiveness of domestic producers
  - Harmonizes with developments in other markets
  - Reduces uncertainty
- Consider the power of Codex
- Provide opportunities for stakeholder feedback outside of the rulemaking process
- Consider regional and international developments

Cultivation of positive industry culture and sense of responsibility

- Food safety culture can be a major differentiating factor to enhance or decrease exports of food and agriculture products
  - Focus limited resources on education and training programs that train trainers
  - Prioritize enforcement resources on intentional violators
  - Incentivize improvement
  - Include cultural goals in rulemaking and regulatory policy
  - Embrace collaboration with regulated industry, including established companies with significant experience/expertise and capacity
- Culture change is HARD and SLOW; Keep working

Support for capacity building and organizational engagement

- Support and collaborate with industry associations, non-governmental organizations, educational institutions and philanthropic initiatives
  - Partnerships benefit exporter and importer
  - Consider contributions of private sector organizations
- Facilitate food safety educational programs to enhance food safety awareness throughout the food chain
- Make regulators accessible to learn and to teach-promote dialogue
- Incentivize improvement and educational efforts

Case Studies

- Codex and the Private Sector
- APA Rulemaking
- General Standard for Food Additives
- US Food Safety Modernization Act

Case Study 1: Codex and the Private Sector

Goal: Develop science-based standards and guidelines that promote a safe food supply and to facilitate trade

Strategy: Include national governments, private sector and civil society in transparent setting process

Value: Safe food supply and improved trade environment based on inclusive, consensus based process that is globally applicable

Observer Participation in Codex

- Accredited Observer organizations participate in Codex meetings, working groups and submit written comments
- Organizations apply for accreditation and must contribute to Codex process
- Observers provide data, technical expertise, practical knowledge, etc.
- Representation is broad, including civil society, industry, scientific and standard setting bodies
- 219 Codex Observers, 147 NGOs

GMA Participation in Codex

- GMA participates in Codex via the International Council of Grocery Manufacturer Associations (ICGMA)
- Members include GMA Counter Parts in Argentina, Australia, Brazil, Chile, Mexico, New Zealand, South Africa, United Kingdom

ICGMA
International Council of Grocery Manufacturer Associations

U.S. Codex Process-Inclusive Model

USDA maintains U.S Codex Office-oversees U.S. Codex strategy and formulates U.S. positions for Codex Meetings

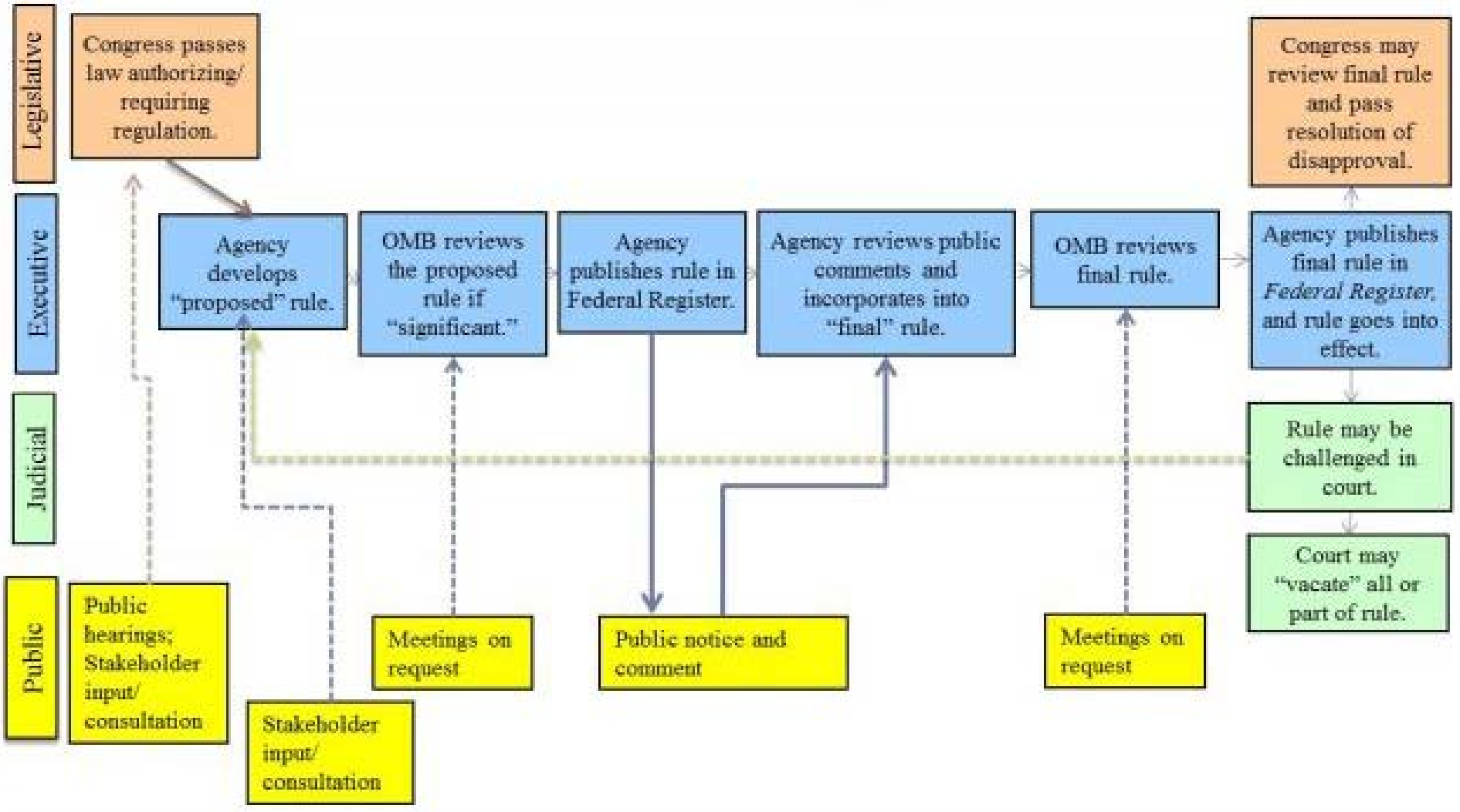
- Public meetings
- Draft U.S. positions

U.S. Codex Office prioritizes input and expertise from private sector

Case Study2: APA Rulemaking

- Administrative Procedures Act (APA) requires all U.S. regulatory agencies to consult with public when implementing most laws
- Consistent and transparent process for soliciting and responding to stakeholder input
- International stakeholders are encouraged to participate

Basic APA Rulemaking Process



Case Study 3: GSFA

- The General Standard for Food Additives (GSFA) establishes conditions under which permitted food additives may be used in foods (Codex Stan 192-1995)
  - Maximum use levels in specific food categories based on JECFA evaluations and CCFA recommendations
  - Specifies general principles for the use of additives and food safety
  - Explains justifications for use
- Extremely valuable tool for regulating the use of food additives
- GSFA is updated each year by the CCFA and the CAC:
  - New additives added
  - Usage levels adjusted
  - Older additives removed

GSFA

- Like the GSFA, national regulations should reflect trends in use as well as changes in scientific understanding of hazards
  - Deferring to the current version of the GSFA is one option
  - Provide a clear mechanism to petition for change
  - Consider ways to harmonize when changes occur with major trading partners
- Embracing technology can help to reduce food costs, enhance availability and foster export

Case Study 4: U.S. Food Safety Modernization Act (FSMA)

Signed in 2011. Most significant U.S. food safety reform in 70 years

FSMA:

- Places new responsibilities on companies – will significantly impact daily operations and supply chain management.
- Creates new controls for imported food
- Enhances FDA's enforcement abilities

FSMA industry-regulator dialogue

Face to Face Meetings with FDA and Subject Matter Experts from industry

FDA Public Meetings

Comments to Public Dockets

Collaborative Meetings with GMA FSMA Coalition (including other trade associations), Foreign Delegations and Embassies

FSMA: The Value of Dialogue

- Built task force of more than 750 company experts and external coalition of more than 175 other stakeholders to effectively communicate with regulators.
- Participated in more than 100 meetings with FDA subject matter experts and other stakeholders
- Submitted more than 1000 pages of written comments, including technical, economic, and legal analysis
- Final rules are more flexible and risk based, and we estimate first year implementation will be $18 billion less burdensome

FSMA: The Value of Dialogue (contd.)

GMA

Representing the Makers of the World's Favorite Food, Beverage and Consumer Products

Thank you

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