

US Regulations: An Overview

Market Requirements

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GMA Member Companies

General Members



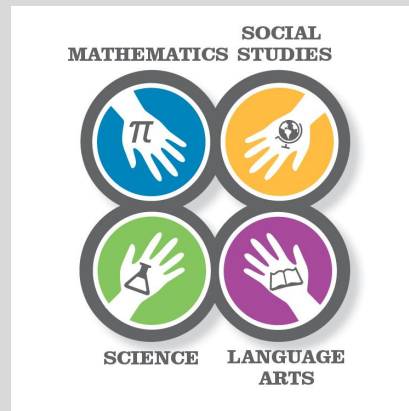
Associate Members



*Represents a sample of GMA members

GMA Science and Education Foundation

- ◉ Non-profit focusing on food safety
- ◉ Education – Hands On
- ◉ Research Funding – need based
- ◉ State of the Art Training
- ◉ International Food Safety Capacity Building



Food Safety Training

Training

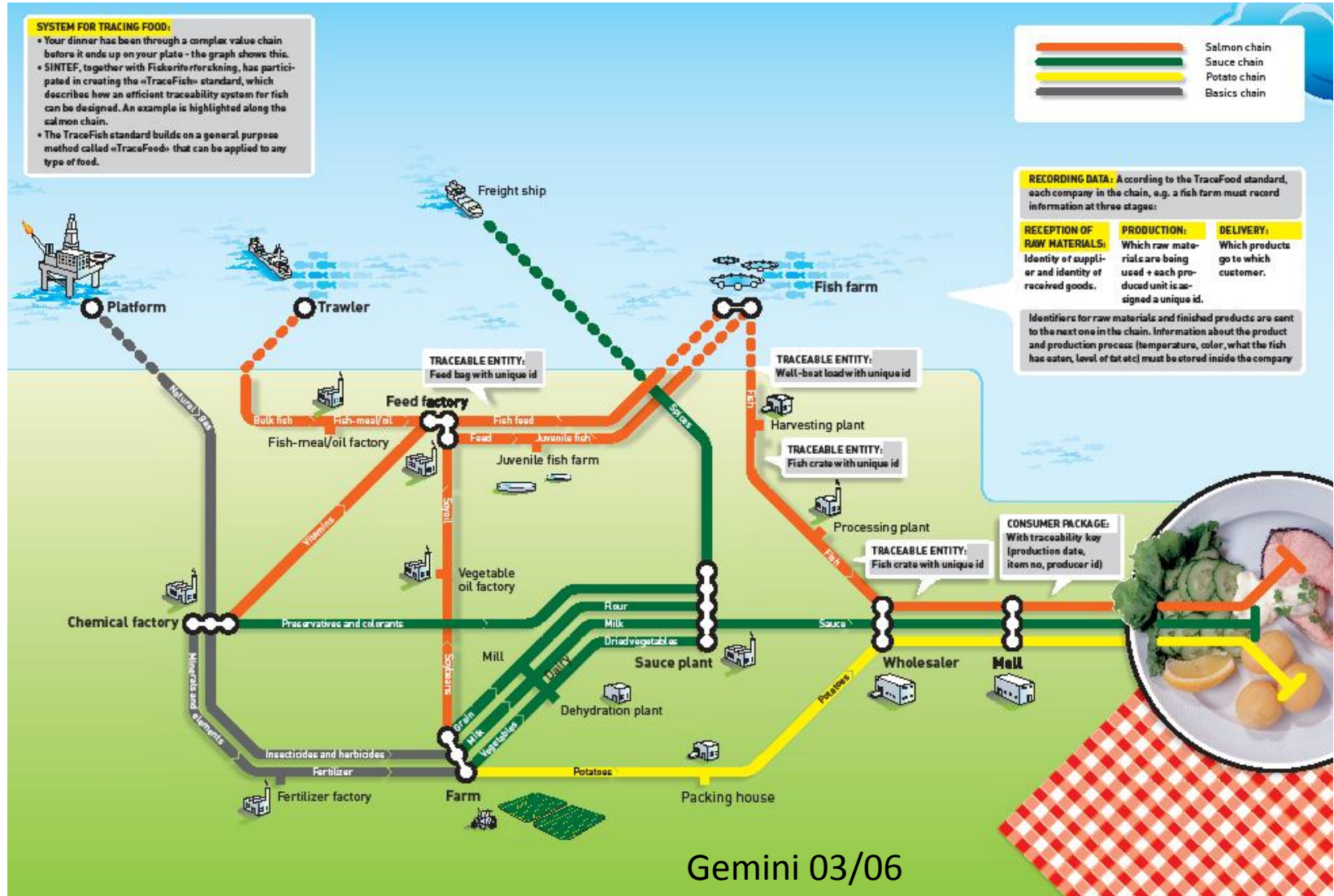
- Technical based on GMA members needs:
 - Plant operators → Managers
- HACCP Training of Trainers (IHA certified)
- Better Process Control Schools
- Food Safety Modernization Act (FSMA) → PCQI, LI
- Certified in Comprehensive Food Safety (NEHA)
- Supplier Training Programs

International programming

- Training
- Technical assistance projects and consulting
- International network of partner institutions

Transparency will not be an option

The Food Chain is global...and complex !

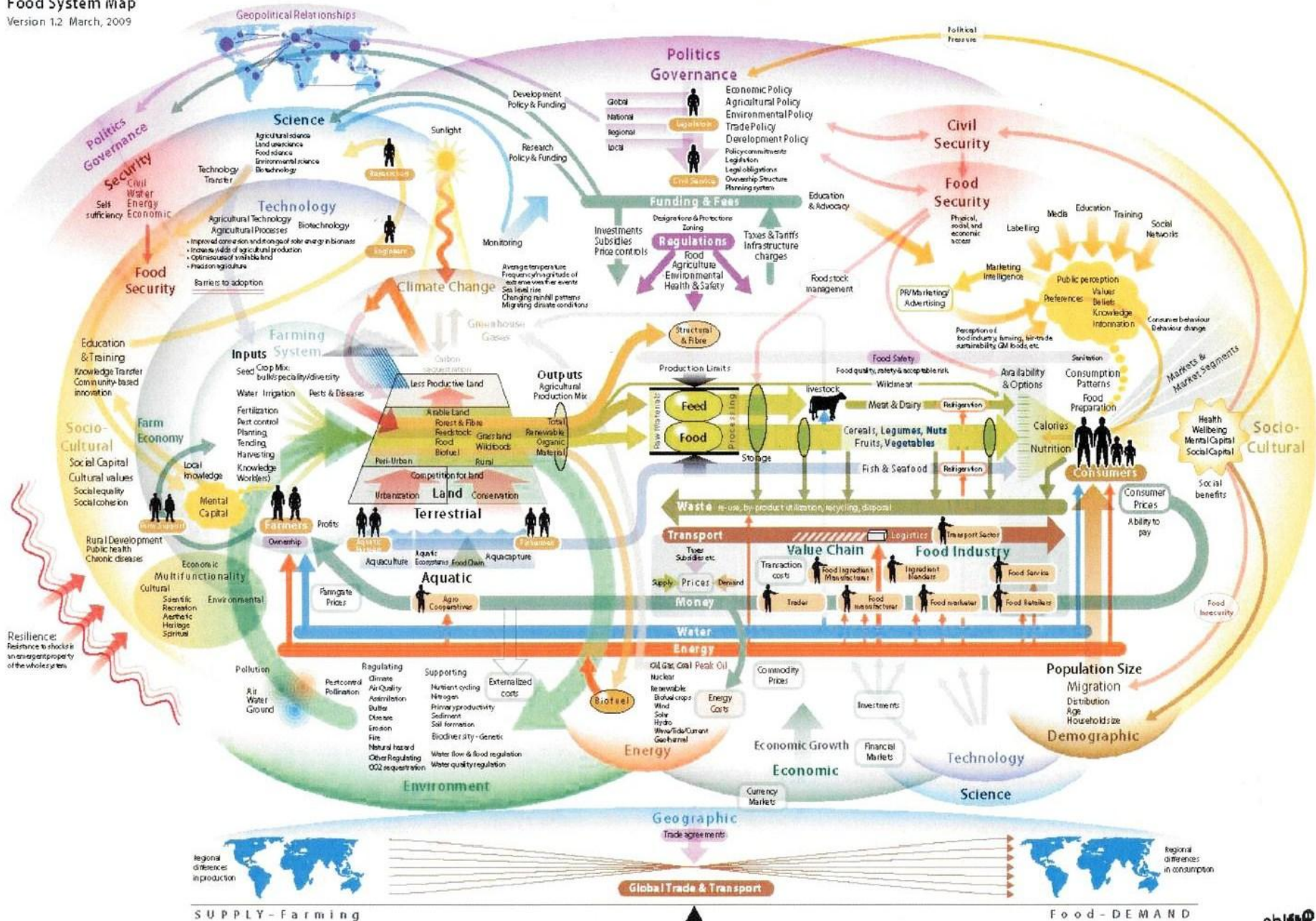


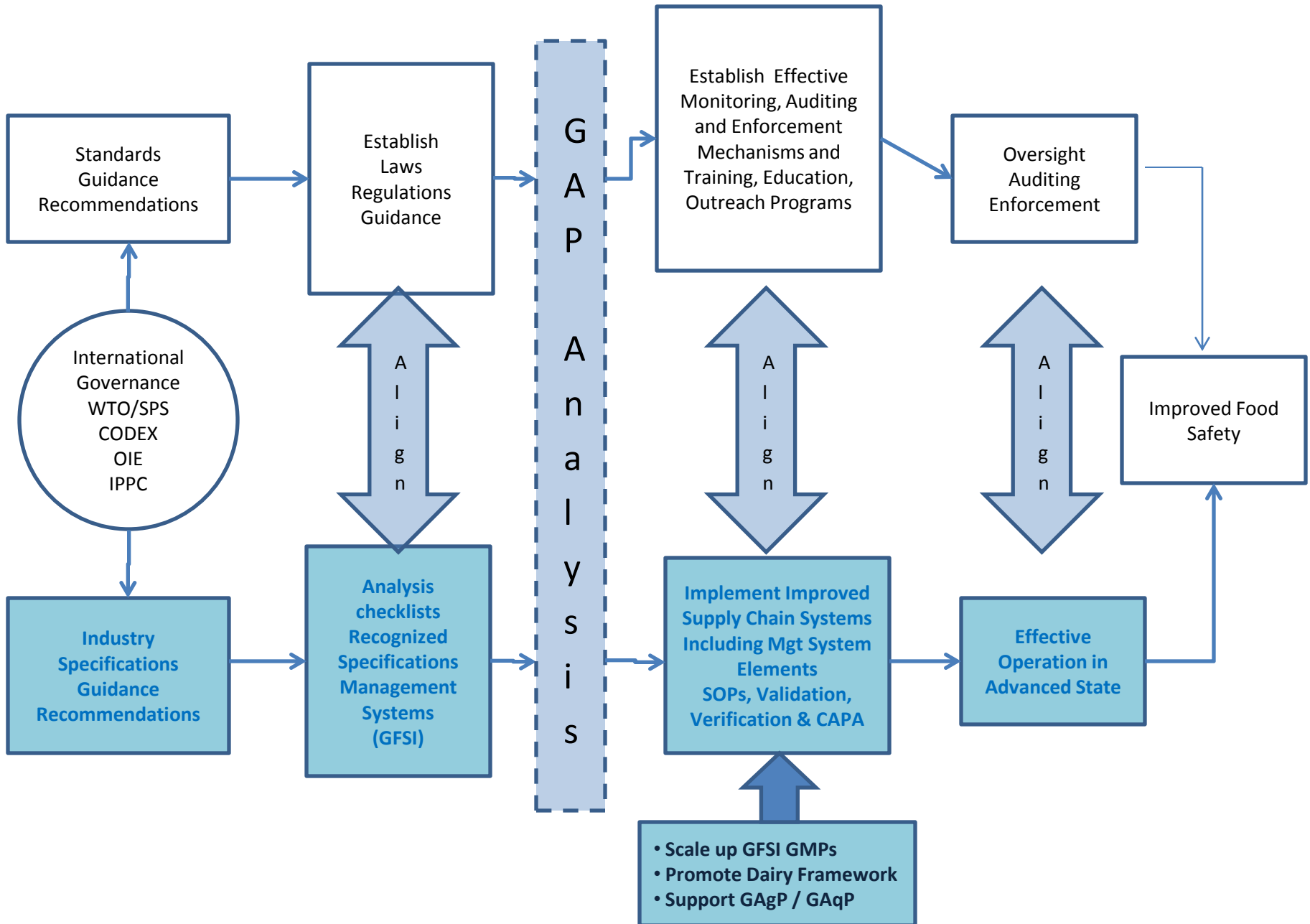
Gemini 03/06

The Global Food System

Food System Map

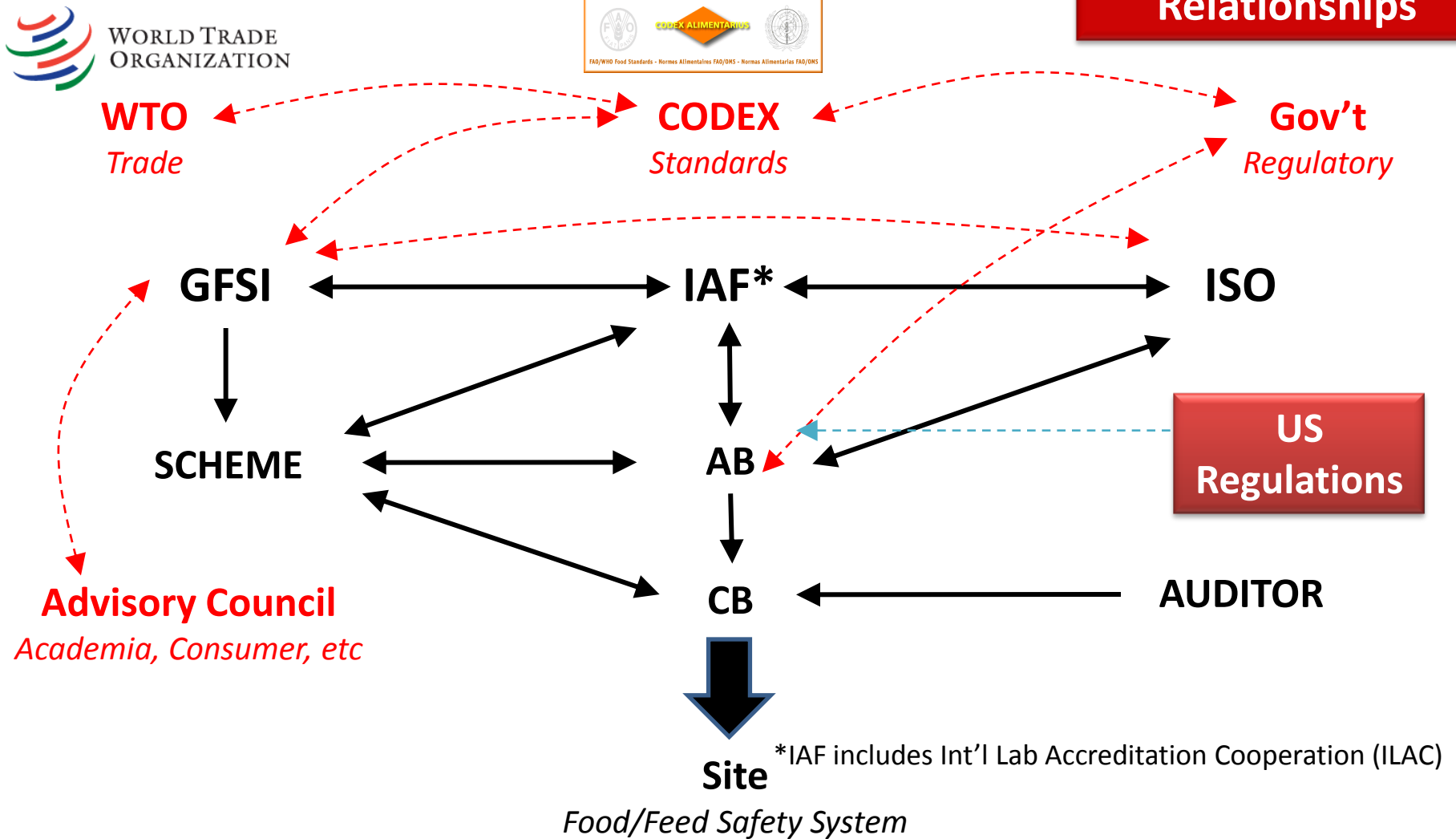
Version 1.2 March, 2009





Global Food Safety Certifications

Extended Relationships



US Regulations: Various agencies

Federal Agencies

- U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS): **meat; poultry; frozen, dried & liquid eggs.**
- Food and Drug Administration's (FDA) Center for Food Safety and Applied Nutrition (CFSAN): **covers everything else.**
- Environmental Protection Agency's (EPA) Office of Prevention, Pesticides and Toxic Substances (OPPTS): **pesticides**
- U.S. Centers for Disease Control and Prevention's (CDC) Food Safety Office: **foodborne infections***

Food Industry

Growers

Processors

Preparers

Internal quality control procedures

State and local governments

On-the-ground inspections - restaurants and food preparation sites

Consumers

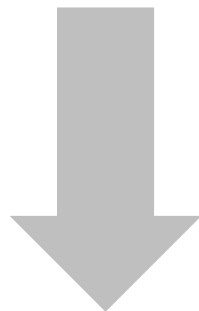
- Informed by social media and education
- Driver of industry

US Food and Drug Administration

- ◉ Food Safety Modernization Act (FSMA)
 - Comprehensive top-to-bottom overhaul
 - A culture of food safety



Proactive
approach



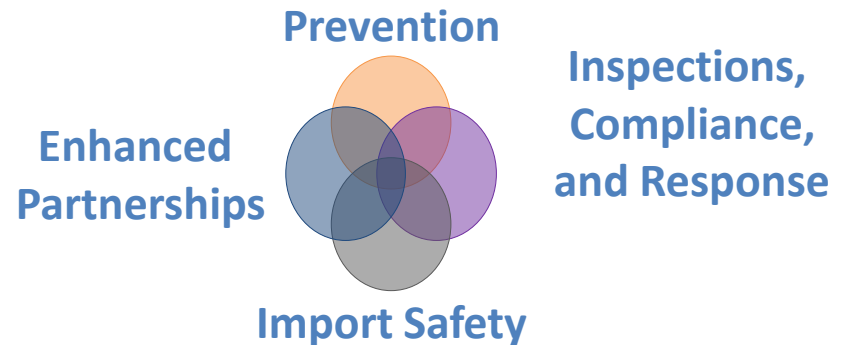
Reactive
approach

Law versus Rule

- ⊙ FSMA Law is passed by Congress and signed by President
- ❖ FSMA law → FDA to promulgate seven new food safety rules:
 - Preventive controls for human food (PCHF)
 - Foreign supplier verification program (FSVP)
 - Preventive controls for animal food
 - Produce safety
 - Intentional adulteration (food defense)
 - Sanitary transportation
 - Third party auditing & accreditation (3PAC)

Main elements of FSMA

- ◉ New responsibilities on companies
- ◉ New controls on imported foods
- ◉ Enhanced enforcement powers
- ◉ New fees on companies and importers
- ◉ Significant impact on trade



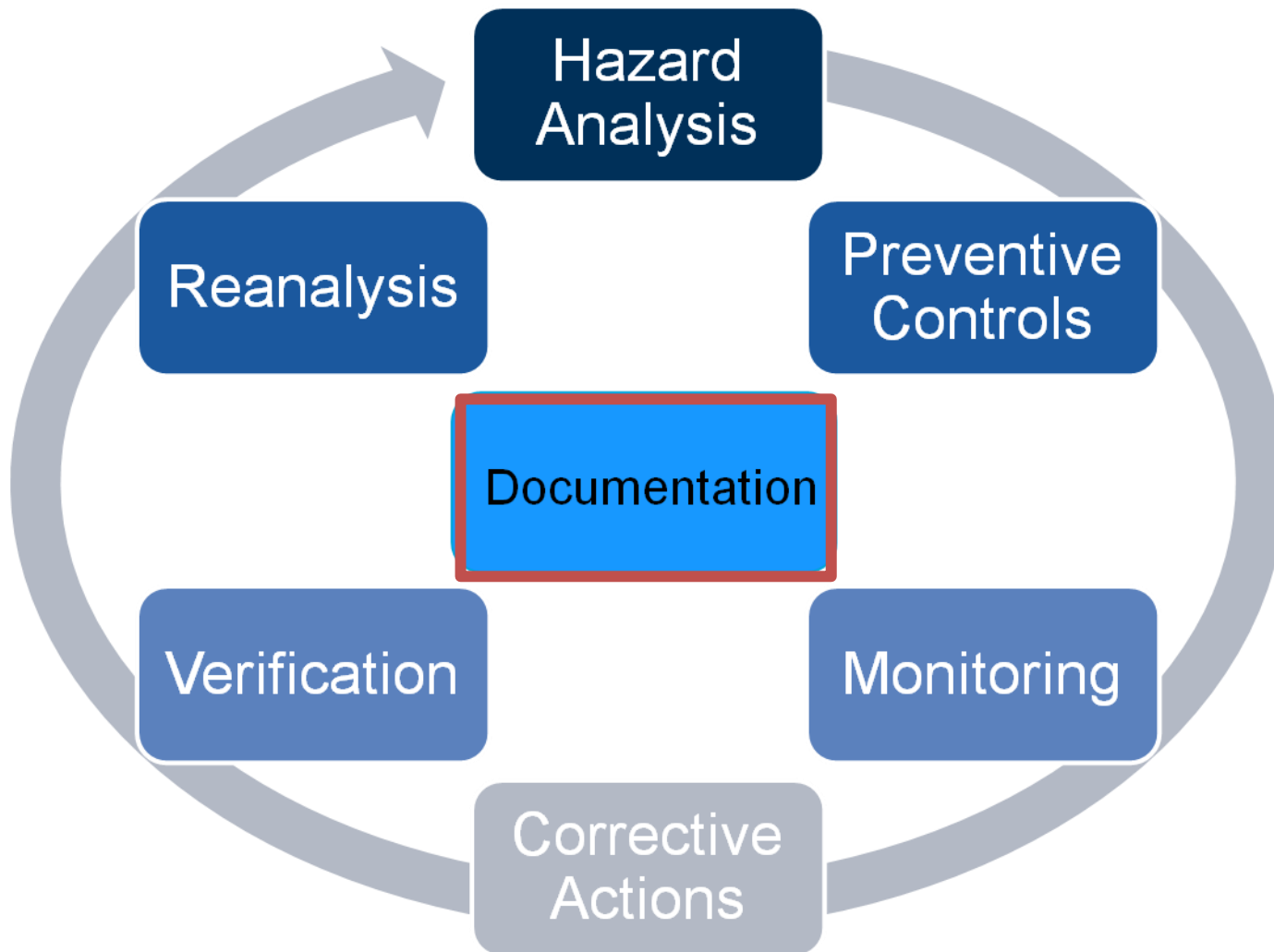
Main Elements of FSMA



Preventive Controls Program

- ◉ A hazard analysis for foreseeable hazards for each type of food manufactured, processed, packed/held at the facility.
- ◉ Preventive controls to significantly minimize or prevent hazards that are reasonably likely to occur.
- ◉ Monitoring procedures → assurance that PCs are consistently performed.
- ◉ Corrective actions if preventive controls are not properly implemented.
- ◉ Verification activities → ensure PCs consistently implemented /effective.
- ◉ Record-keeping systems to keep a written food safety plan regarding all of the above elements.
- ◉ HACCP ++ → environmental monitoring verification or sanitation procedures.

FSMA Process Flow – Food Safety Plan



Comparison of pre- and post- FSMA

HACCP

- ◉ Worldwide standard
- ◉ Applies to a wide variety of food products
- ◉ Focus on control steps
- ◉ Requires qualified team

HACCP++ (FSMA)

- ◉ US standard
- ◉ Applies to FDA regulated products
- ◉ Preventive programs
- ◉ Needs qualified individual

Comparison of pre- and post- FSMA Compliance

HACCP

- ◉ Voluntary across most food industry
- ◉ Mandatory for certain foods like seafood, juice, meat and poultry

HACCP++ (FSMA)

- ◉ Mandatory for all facilities requiring FDA registration
- ◉ Exemptions for FDA mandatory HACCP programs

General Implications of FSMA

- ❖ Records management & access
- ❖ Training requirements
- ❖ Suspension of registration
- ❖ Mandatory recall
- ❖ Increased inspections
- ❖ Records
- ❖ More records

New responsibilities (food companies) – PC HF

- ❖ Food Safety Plans (FSPs) for **all food processors & some warehouses.**

Preventive Controls (PCs) - HACCP and more

- Process preventive controls
- Allergen preventive controls
- Sanitation preventive controls
- **Supply chain preventive controls**
- Supply chain programs
- Hazard analysis may include
 - Environmental pathogens
 - Economically motivated adulteration

New responsibilities (food companies) – Importers

- ❖ Foreign Supplier Verification Program
 - Importers required to perform risk-based activities to verify food imported into the U.S. meets the same food safety standards as those required of U.S. producers.
 - **Applies to foreign packaging suppliers**
 - Hazard analysis
 - Determine supplier risk
 - Approve suppliers
 - Determine verification activities
 - Identify an importer
- ❖ Other import programs: VQIP, MIC coupled with 3PAC.

General compliance period

Proposed Rule	Final Rule	Requirement	Deadline
Preventive Controls for Human Food	8-30-15	1 year from final rule	9-19-16
Preventive Controls for Animal Feed	8-30-15	1 year from final rule	9-19-16
Produce Safety	10-31-15	2 years + 60 days from final rule*	1-26-18
Foreign Supplier Verification Program	10-31-15	18 months from final rule†	5-27-17
3 rd Party Accreditation and Certification	10-31-15	After Model Accreditation Standards‡	-
Sanitary Transportation	3-31-16	1 year from final rule	4-6-17
Food Defense	5-31-16	1 year + 60 days from final rule	7-31-17tbd

*All farms have an additional 2 years to comply with certain water-related requirements.

†All importers must comply with FSVP requirements 18 months after the final rule OR 6 months after their foreign suppliers' reach their FSMA compliance deadlines, whichever is later.

‡ 3PAC's provisions are effective immediately following the final rule, but can only be implemented after publication of Model Accreditation Standards, which are yet to be released by the FDA.

§ If there is no special compliance period noted, then follow the General Compliance Period rule.

Records Maintenance and Access

- FDA will have legal access to:
 - Food safety plan and related documents
 - Includes environmental and finished product testing
 - Includes corrective actions and related rationale
 - Includes monitoring of supply chain
 - Includes consumer complaint documents related to a food safety event

Good documentation and record-keeping practices will be critical

Intentionally introduced hazards

Food Defense

- Company vulnerability assessments should include *risks that may be introduced by acts of terrorism*
- Implement appropriate mitigation steps in your company's process and document your food defense plan
- Risks associated with Economically Motivated Adulteration (EMA) will also need to be managed

Imported food controls

- **Foreign Supplier Verification Program**
 - Imported products and ingredients = requirements as US-produced food
 - Importer is responsible
- FDA has authority to require third party certification for safety-related reason (Import Alert)
- Expedited entry at border if safety and security guidelines are met
 - Voluntary Qualified Importer Program

Summary

“Things that might have seemed like just a good idea before, are now going to be mandatory, require records to support compliance, and those records are going to be available to FDA*.”

*Warren Stone, 2011

Upcoming Caribbean Training

- ◉ Preventive Controls Qualified Individual, HF
 - May 1-3, 2017
- ◉ Better Process Control School (BPCS)
 - May 4-5, 2017

Location: Jamaica

For more information: sef@gmaonline.org

WE ARE THANKFUL

Hope you enjoyed the presentation

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