

The role of public private partnerships (PPP) in the development and enforcement of regulations: a food safety example

*Akhila Vasan, Ph.D.
Senior Program Manager, Food Safety & Education
GMA Science and Education Foundation
Washington D.C.
E-mail: avasana@gmaonline.org*

AGENDA

- Who we are: GMA and GMA SEF
- Global Food System: Challenges and Landscape -> Global to Local
- US Food regulations, process and industry impact
- Building consensus and PPP in emerging markets
- Proven model for food safety capacity building

GMA Members | General Members



GMA Members

Associate Members



THE BOSTON CONSULTING GROUP



LABELINSIGHT



McKinsey & Company



IRI

Growth delivered.

ORACLE



ECOLAB

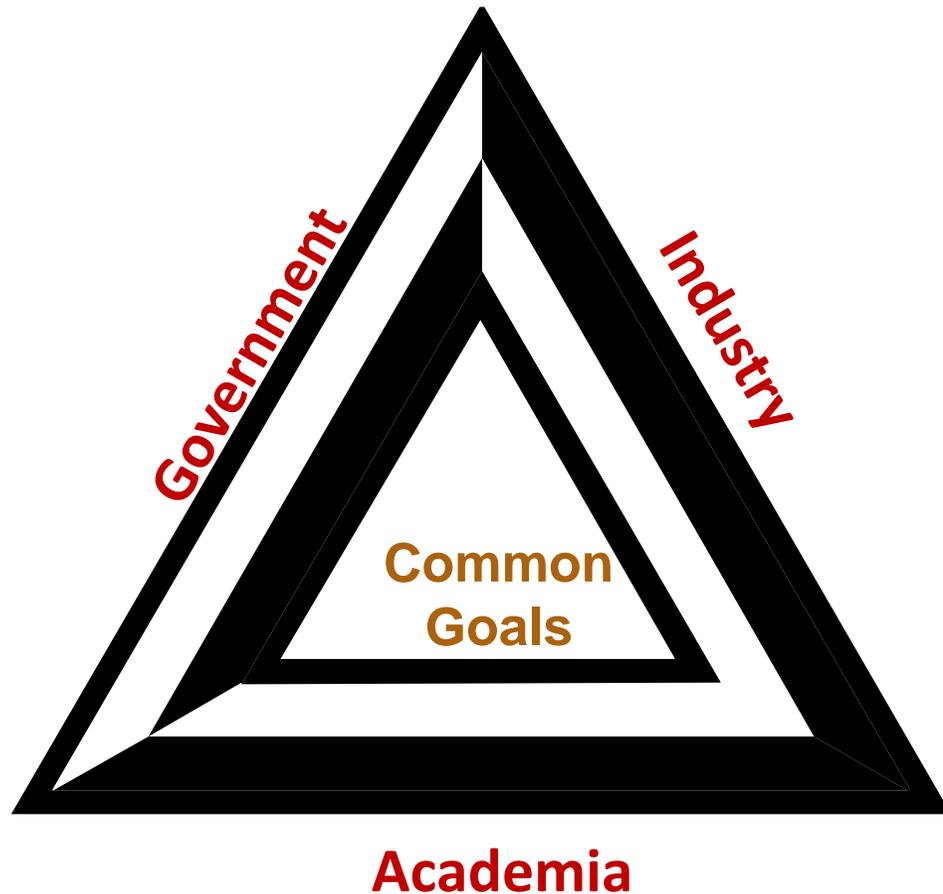
nielsen



pwc



SHARED RESPONSIBILITY, COMMON GOALS



- 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.

GLOBAL REACH

Caribbean HACCP Project
Jamaica Food Safety Capacity Building
China: Supplier Food Safety Training

- ✓ Global Food Safety Initiative
- ✓ Global Food Safety Partnership
- ✓ Inter-American Institute for Cooperation of Agriculture
- ✓ United Nations Industrial Development Organization
- ✓ International Food Protection Training Institute
- ✓ USDA Foreign Agriculture Service
- ✓ US Food & Drug Administration
- ✓ World Bank

Better Process Control Schools
Certified in Comprehensive Food Safety
Food Safety Preventative Controls Alliance
Hazard Analysis and Critical Control Points
Publications

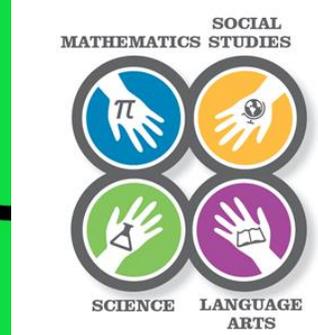
Hands-On Classrooms (middle schools)
www.handsonclassrooms.org
Partnership for Food Safety Education
www.fightbac.org
Apprenticeships
Scholarships
Fellowships
Internships

Development of Methods for Food Authenticity Analysis
Survival of Thermal Resistance of *Listeria monocytogenes* in Powdered Foods

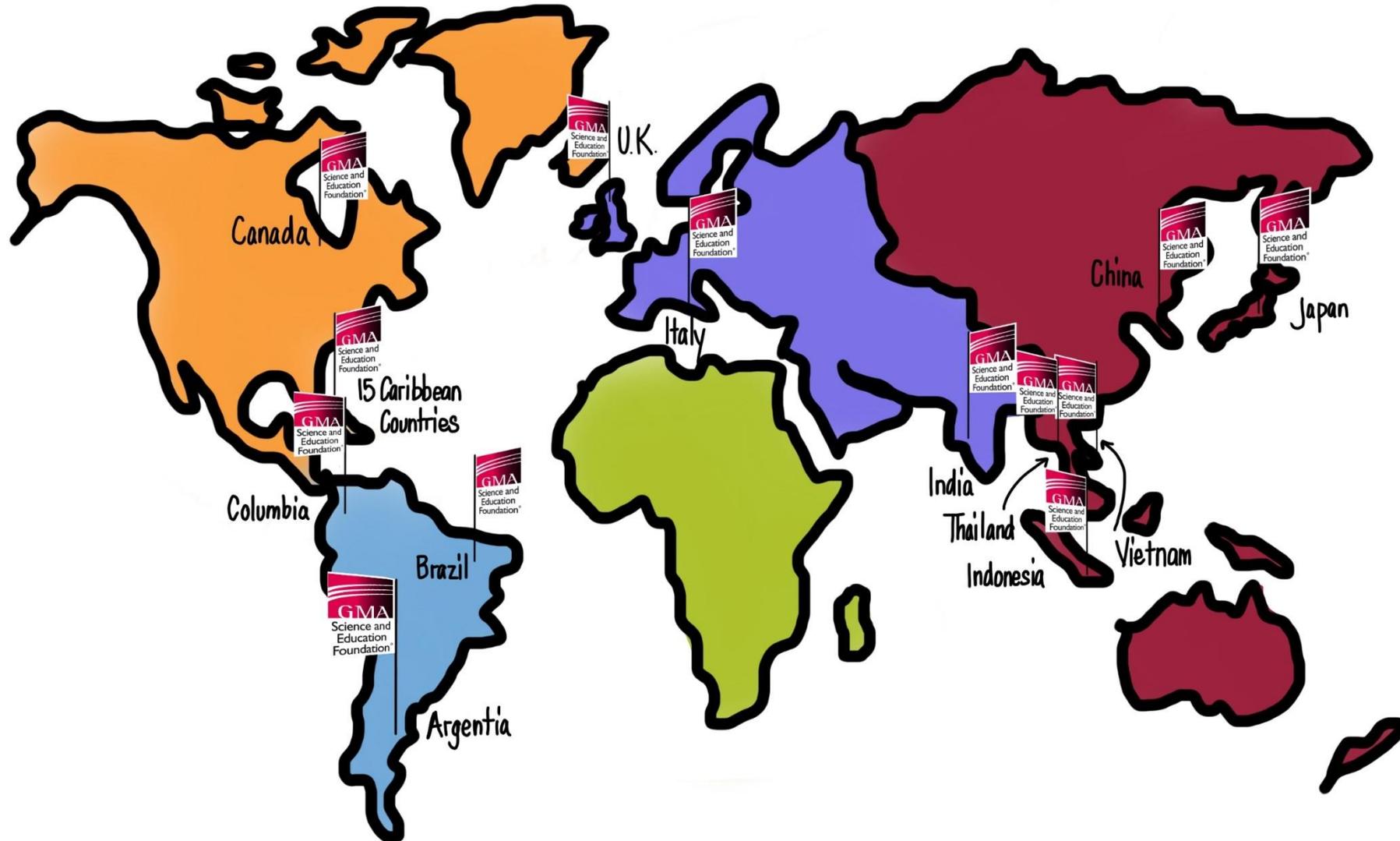
research

training

education

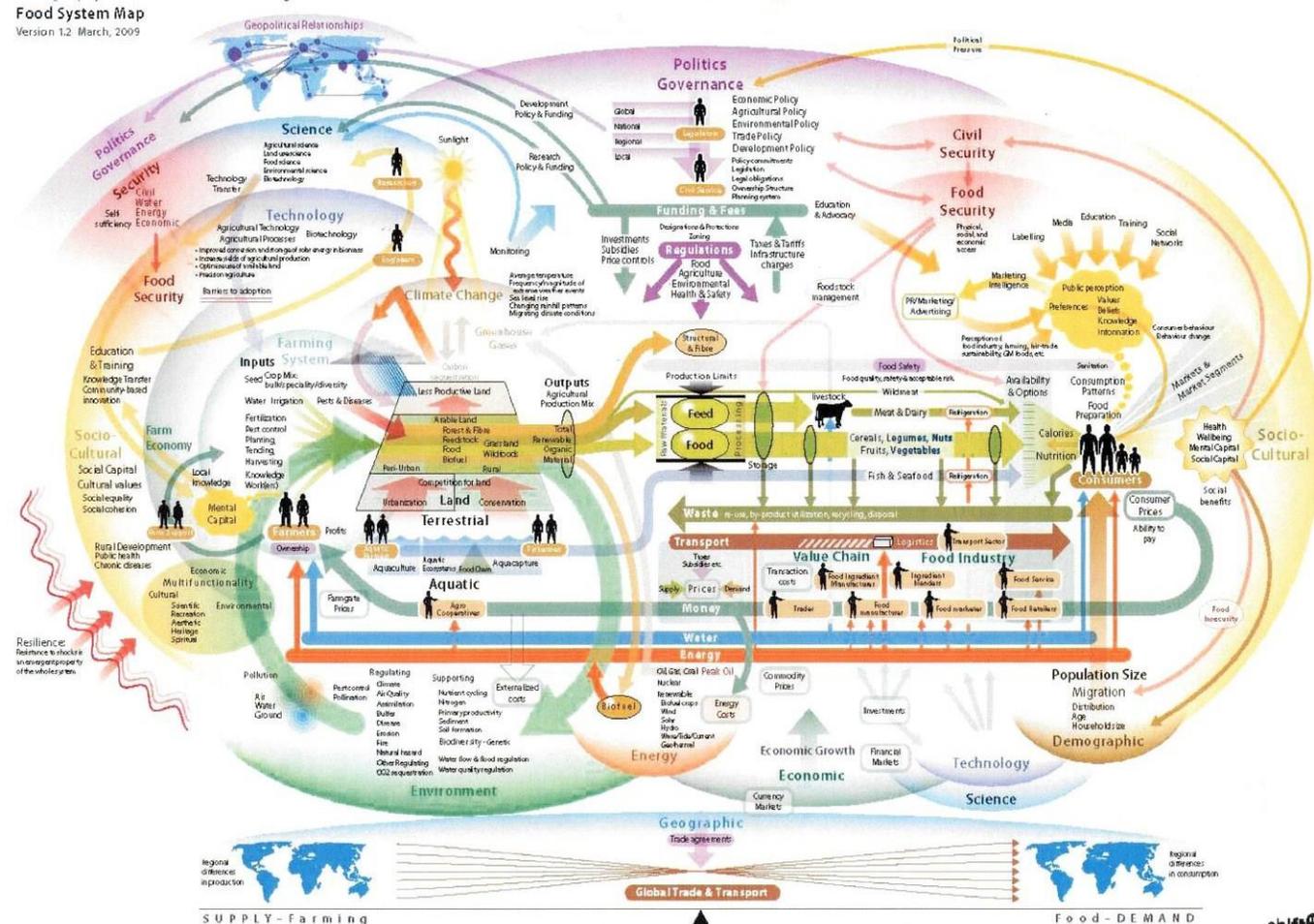


training, mentoring & programming global impact



The Global Food System

- Need for harmonization
- Local, national and global requirements
- Role of regulations



TRUST

TRANSPARENCY



IMPORTANT DIFFERENCES

FSMA/ GOVERNMENT REGULATIONS

PRIVATE FOOD SAFETY SYSTEMS

Required by law

Optional, eg. GFSI

Minimum, baseline requirements

Typically perceived as higher standard

Food safety

May be food safety and/or quality

FSMA: FOOD SAFETY MODERNIZATION ACT



EXAMPLE: FSMA REGULATORY PROCESS

At appropriate stages
combine knowledge from:

- Industry
- Government Agencies
- Many other interested groups

To produce more effective
regulations.



MILESTONES

FSMA Signed: January 4, 2011

Proposed Rule: January 16, 2013

Supplemental Proposed Rule: September 29, 2014

Final Rule: September 17, 2015

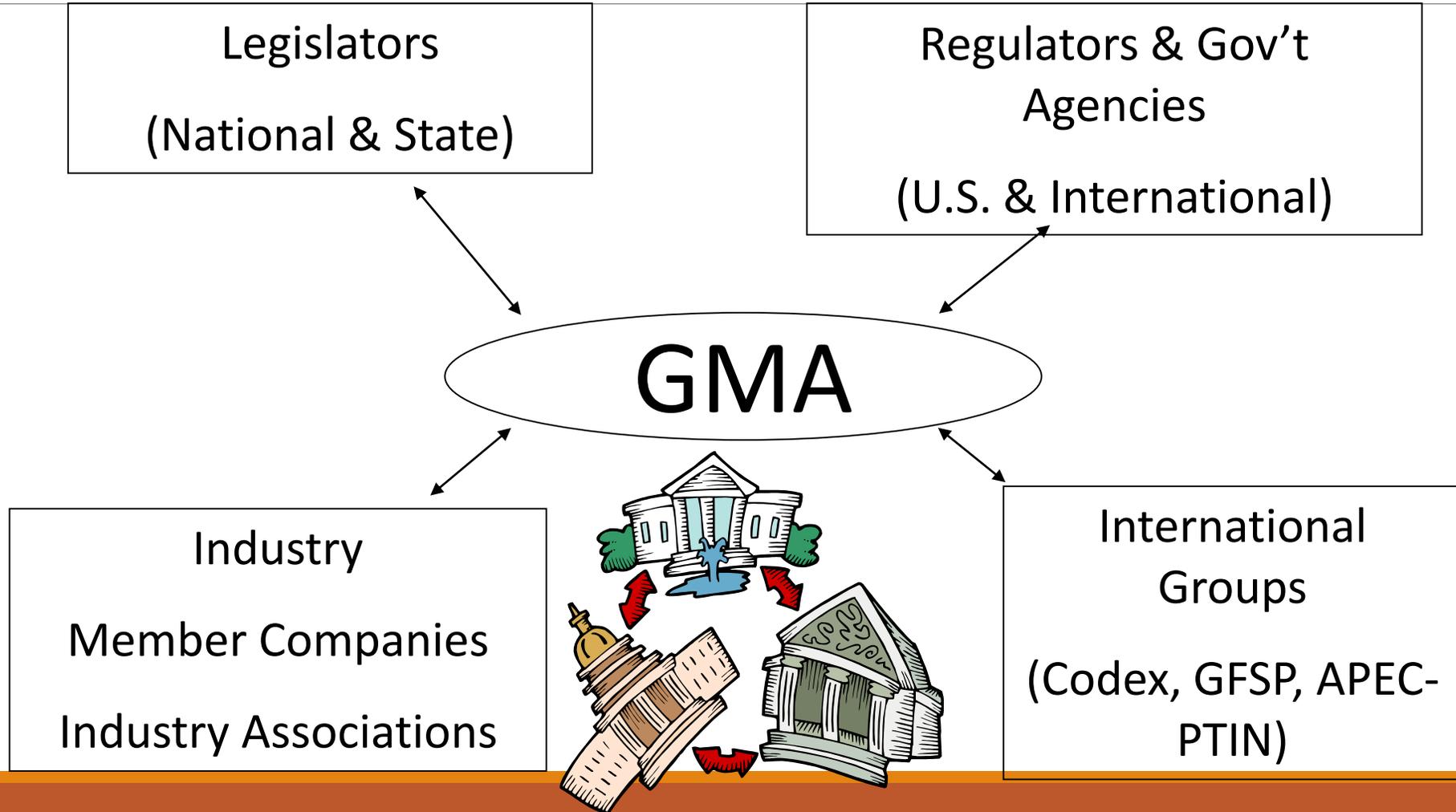


A LAW VS. A RULE

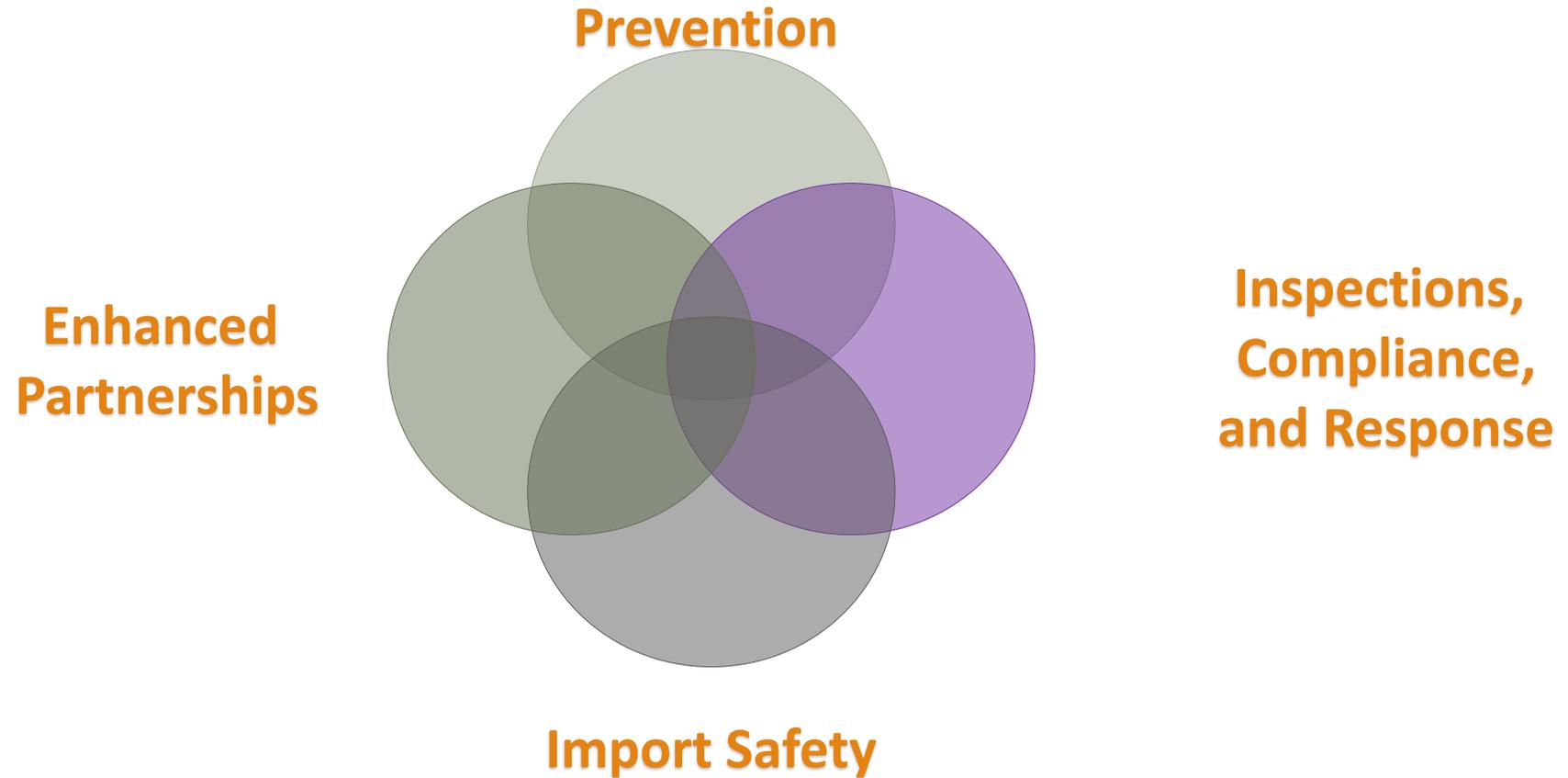
- ❖ FSMA is a law passed by the US Congress and signed by the president.
- ❖ FSMA, the law, told FDA to promulgate seven new food safety rules:
 - Preventive controls for human food (PCHF)
 - Foreign supplier verification program (FSVP)
 - Preventive controls for animal food
 - Produce safety
 - Intentional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

All 7 FSMA FINAL Rules Are Published

FACILITATING COLLABORATIONS



Food Safety Modernization Act



MAIN ELEMENTS OF FSMA

- **Placed New Responsibilities on Companies**
- **New Controls over Imported Food**
- **Enhanced Enforcement Powers**
- **Created New Fees on Companies and Importers**



Understanding FSMA



GMA GOALS FOR 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

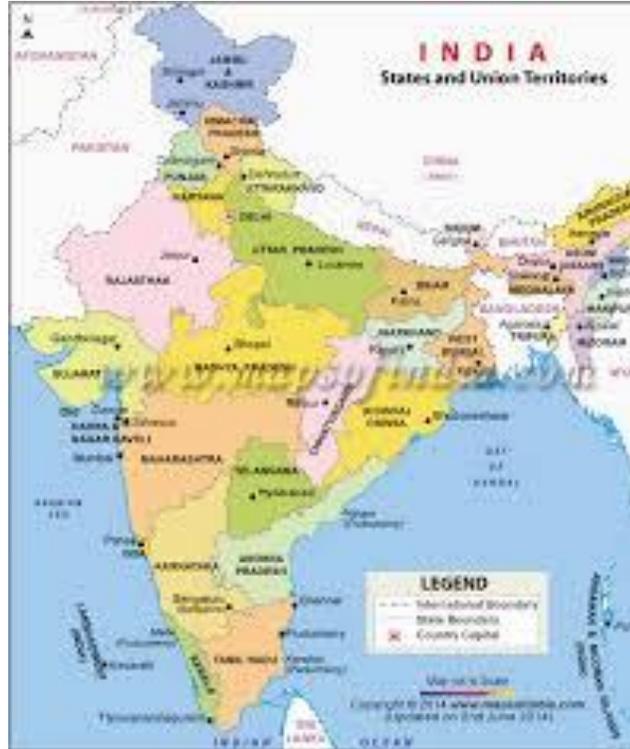
KEY OUTCOMES

- Conducted >100 meetings with FDA SMEs and Leadership
- Submitted >1000 pages of written technical, economic and legal recommendations
- Saved the industry >\$20 billion in first year implementation costs
- Final rules are more general, flexible and risk based
- Coalition consists of >175 stakeholders, trade associations and embassy personnel
- FSMA Task Force consists of >750 GMA members

FSMA 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, February 2011



THE EVOLUTION OF FSSAI: HOW THE INDIAN REGULATOR IS UPGRADING REGULATIONS

CHALLENGES AND BACKGROUND

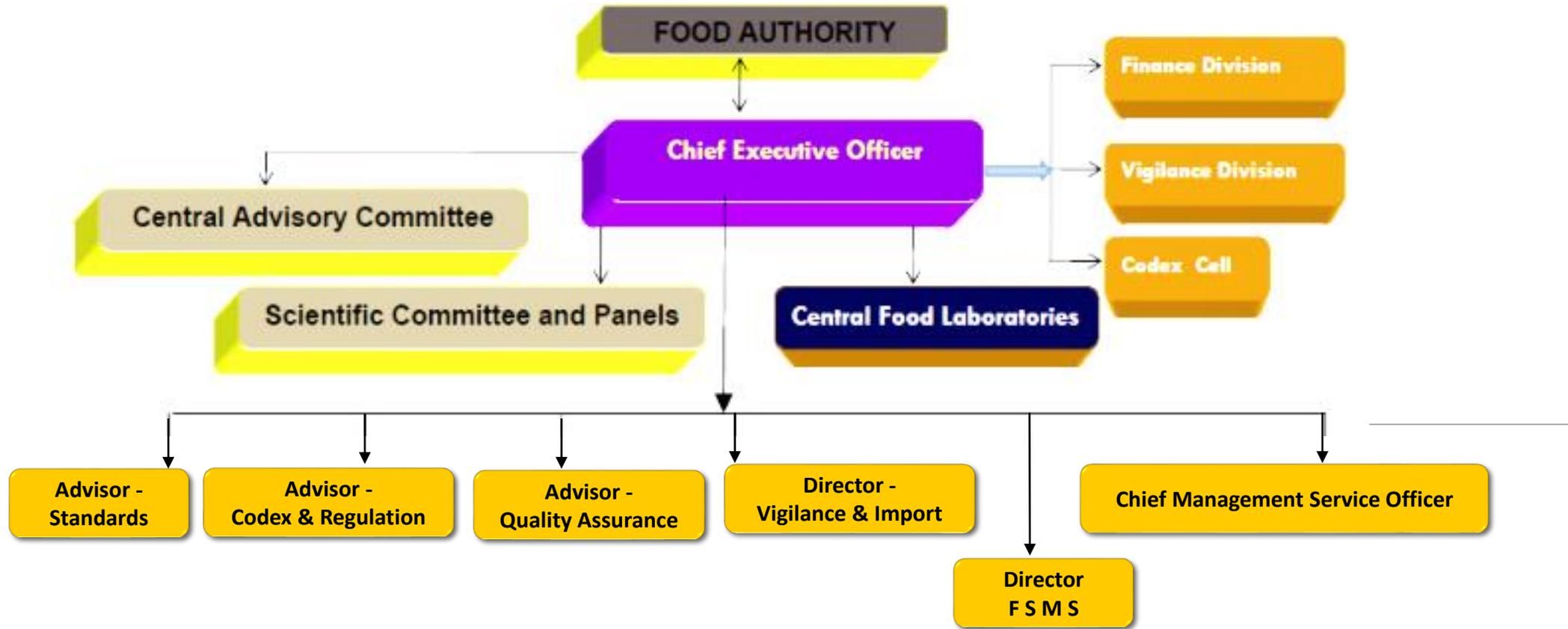
- 29 states, 7 union territories; National and state level regulations
- Informal wet markets, door-to-door vendors, unique challenges of street food versus manufacturing, scale in manufacturing (micro, small, medium and large)
- Lack of data on food borne illness outbreaks and implicated food products (no centralized system)
- Cold chain challenges, regulatory personnel problems (low numbers)

BUT

- Research (Subitha L. and others, 2015. *J. Nat Sci Biol. Med.*) 13% of all deaths per year is due to diarrhea in children < 5 years =>> 300,000 deaths/ year!!
- Stunted growth, malnutrition and access to nutritionally dense food

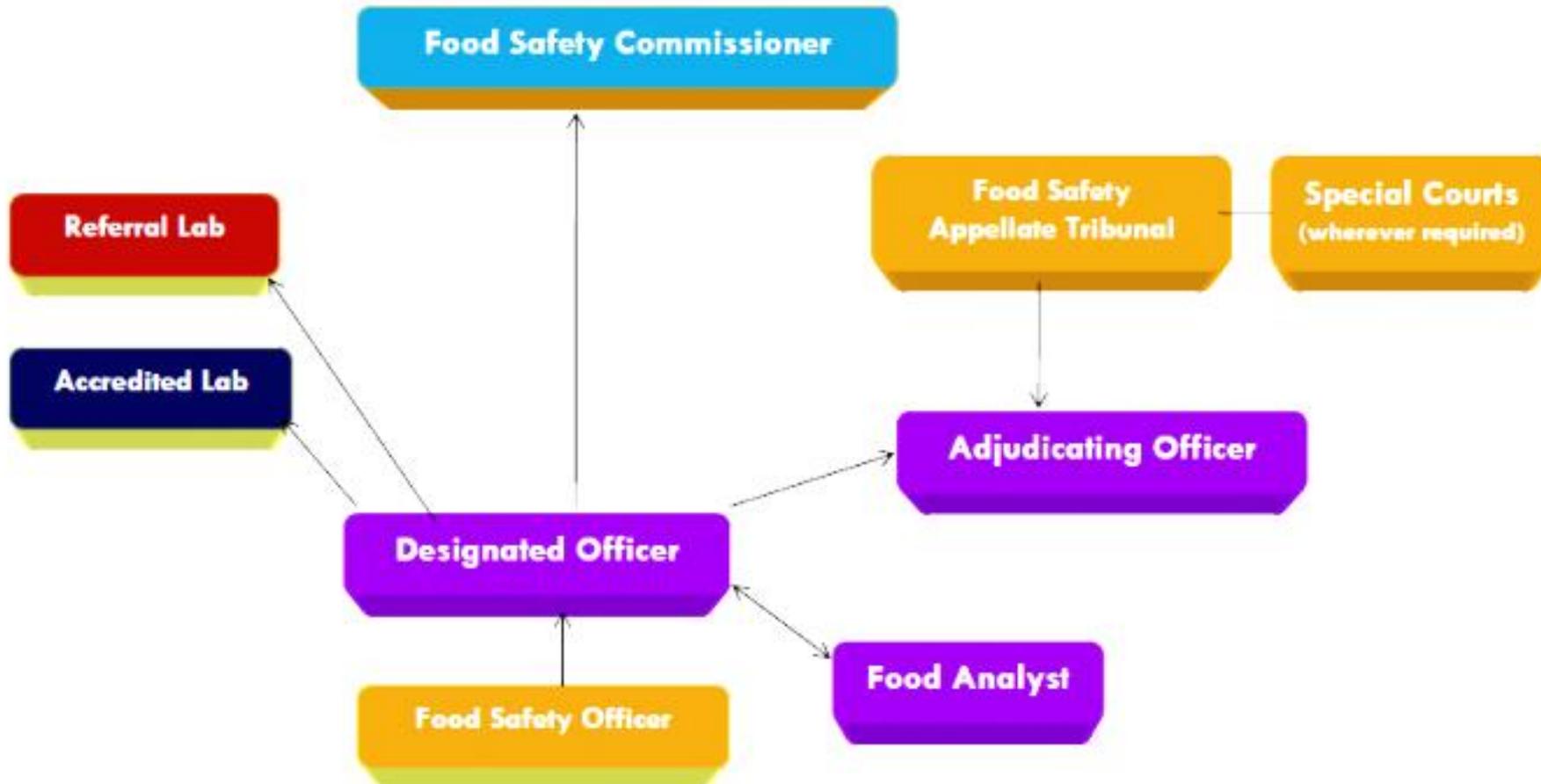
PREVENTABLE!

FSSAI - Structure - Central



FSSAI - Structure - States

Major Functionaries in the State



Standard Development Procedure



SEVERAL NEW REGULATIONS AND AMMENDMENTS

- FSSA ACT (fully in force 5 Aug 2011)
- Food Safety and Standards Regulations, 2011 (Amdt 14 Sep 2017)
- FSS (Licensing and Registration of Food Businesses) Rules, 2011 (Amdt 3 Nov 2017)
- FSS (Packaging and Labelling) regulation, 2011 (Amdt 31 Aug 2016)
- FSS (Food Product Standards and Food Additives) regulation, 2011 (Amdt 3 Nov 2017)
- FSS (Prohibition and Restriction on Sales) regulation, 2011 (Amdt 31 Aug 2016)



SEVERAL NEW REGULATIONS AND AMMENDMENTS

- FSS (contaminants, toxins and residues) regulation, 2011 (Amdt 1 Aug 2017)
- FSS (Laboratory and sampling analysis) regulation, 2011 (Amdt 8 Feb 2013)
- Legal Metrology Packaged Commodity Rules 2011 (Amdt 23 Jun 2017)
(Department of Consumer Affairs not FSSAI)
- FSS (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016 (23 Dec 2016) – 132 pp.
- FSS (Food Recall Procedure) Regulation, 2017 (25 Jan 2017).
- Food Safety and Standards (Import) Regulation, 2017 (20 Mar 2017)



Industry - Regulator Relationship

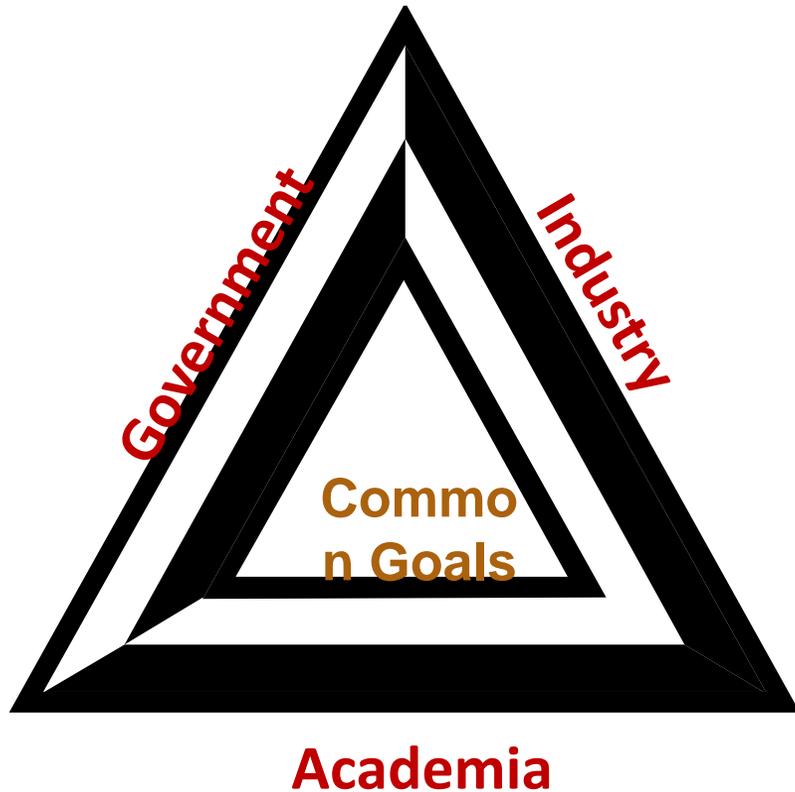
TRENDS AND CHALLENGES: INDIA



- **Indian Food Regulatory climate has improved dramatically in the past 18 months!**
- Industry representation in committees and bodies making regulation and standards improving
- Still too much **bureaucracy**
- Still **not** much **risk-based** standard setting
- Major improvements in lab situation in 2017
- However, **Capacity building** continues to be big challenge: FSSAI/Customs/Labs not entirely equipped to meet the challenges of food safety and food standards

Foundational Food Safety for Indian Regulators and Suppliers

A food safety capacity building program



- Engagement with FSSAI, Ministry of Food Processing Industries, NIFTEM (academia) and Industry
- Align FSSAI requirements with globally recognized GFSI requirements
- Add Indian regulations and needs to 'Indianize' standard curricula
- Build Institutional capacity with resources for SMEs in India



The key to producing safe food for consumers is ensuring appropriate knowledge and skills of the individuals who are responsible for food safety

REGULATORS + INDUSTRY SMEs/ SUPPLIERS + ACADEMIA





The Global Markets Programme

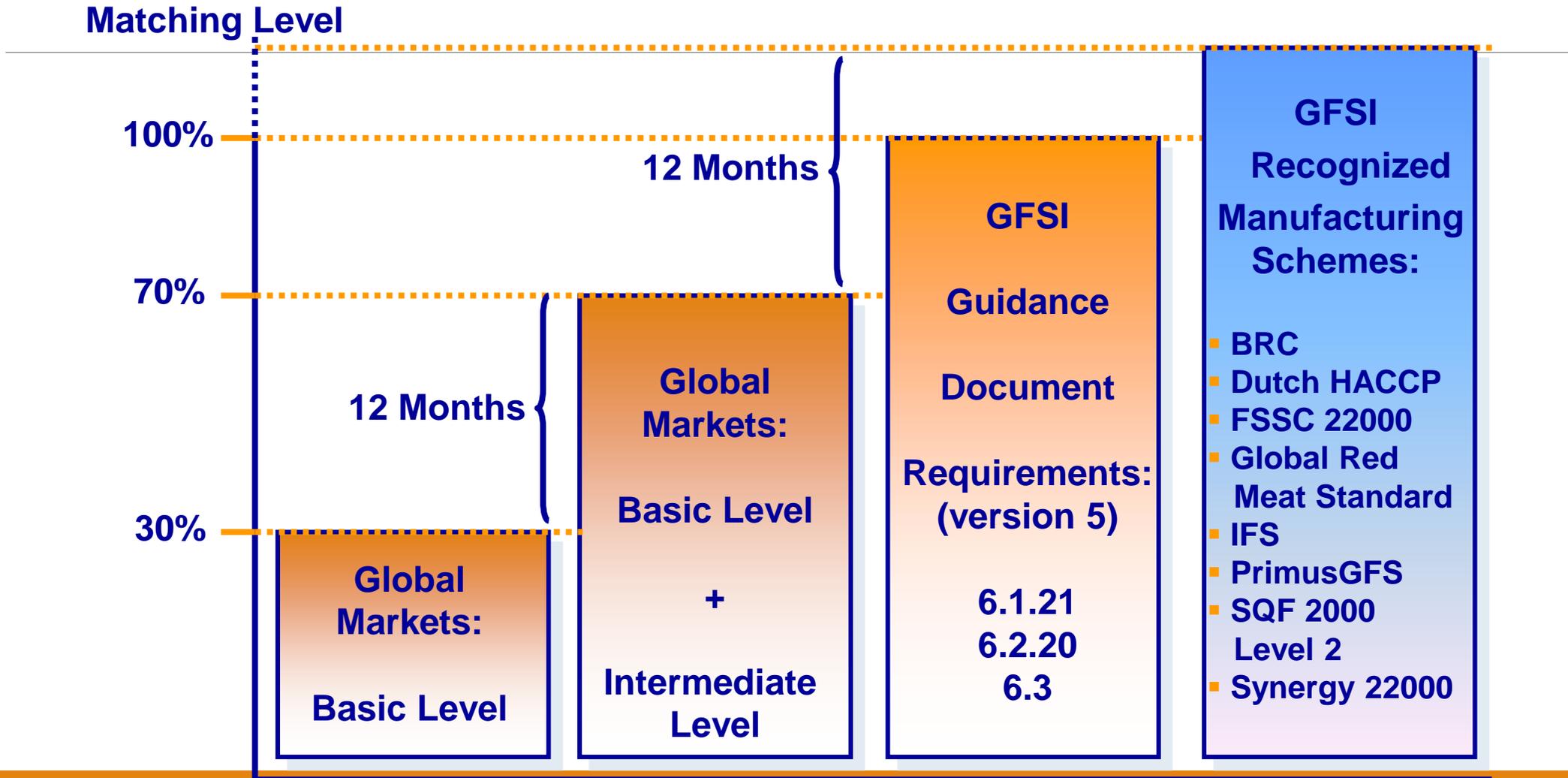
A response to business needs: a local sourcing strategy

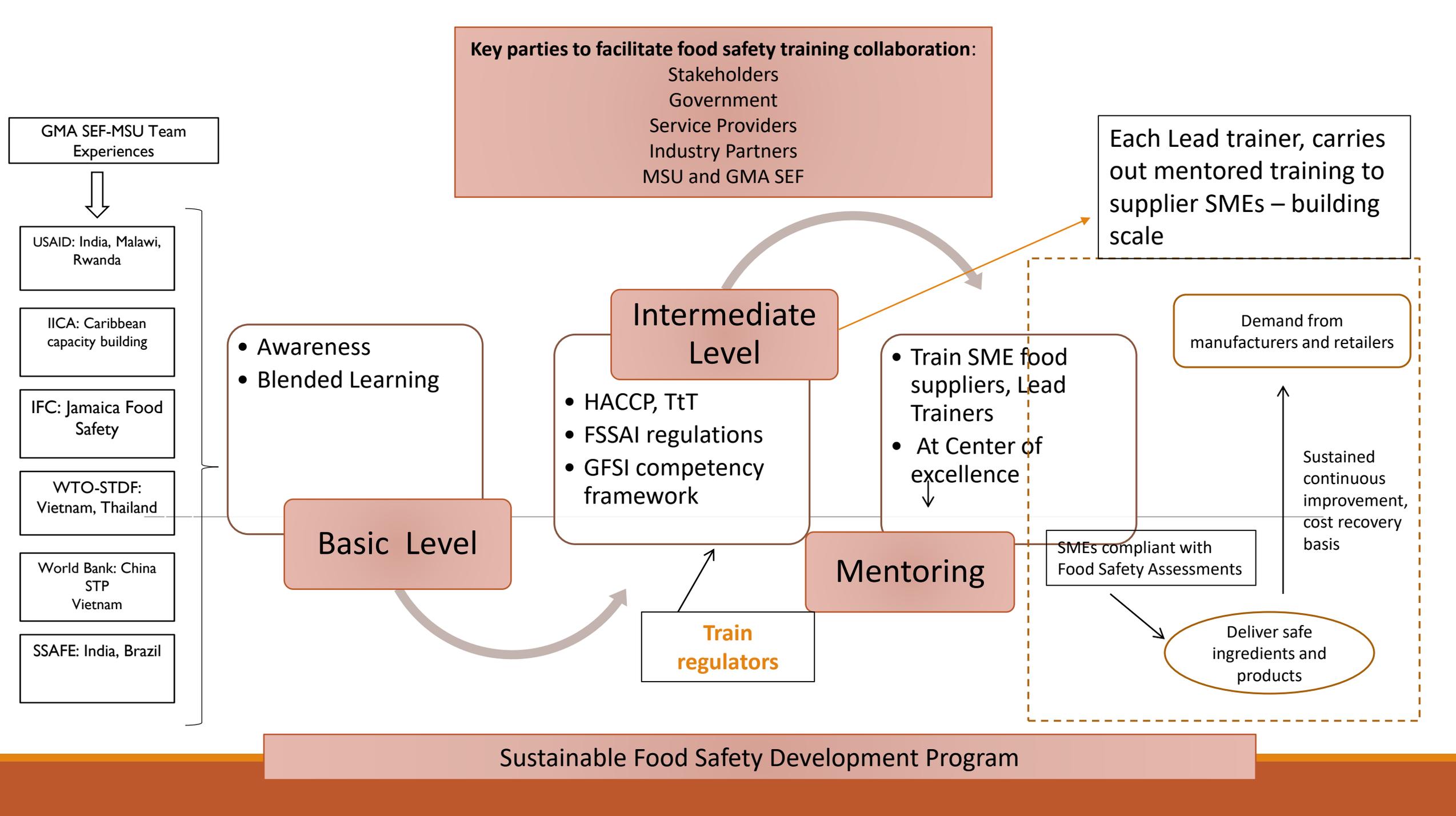
- ✓ A new unaccredited entry point for small or less developed businesses that aspire to achieve certification.
- ✓ It considers both primary production and manufacturing.
- ✓ Capacity building in food safety is achieved and access to local markets is facilitated.
- ✓ It's a system for mutual acceptance at this “entrance level.”
- ✓ It is unaccredited, so **is not a scheme or a standard**.

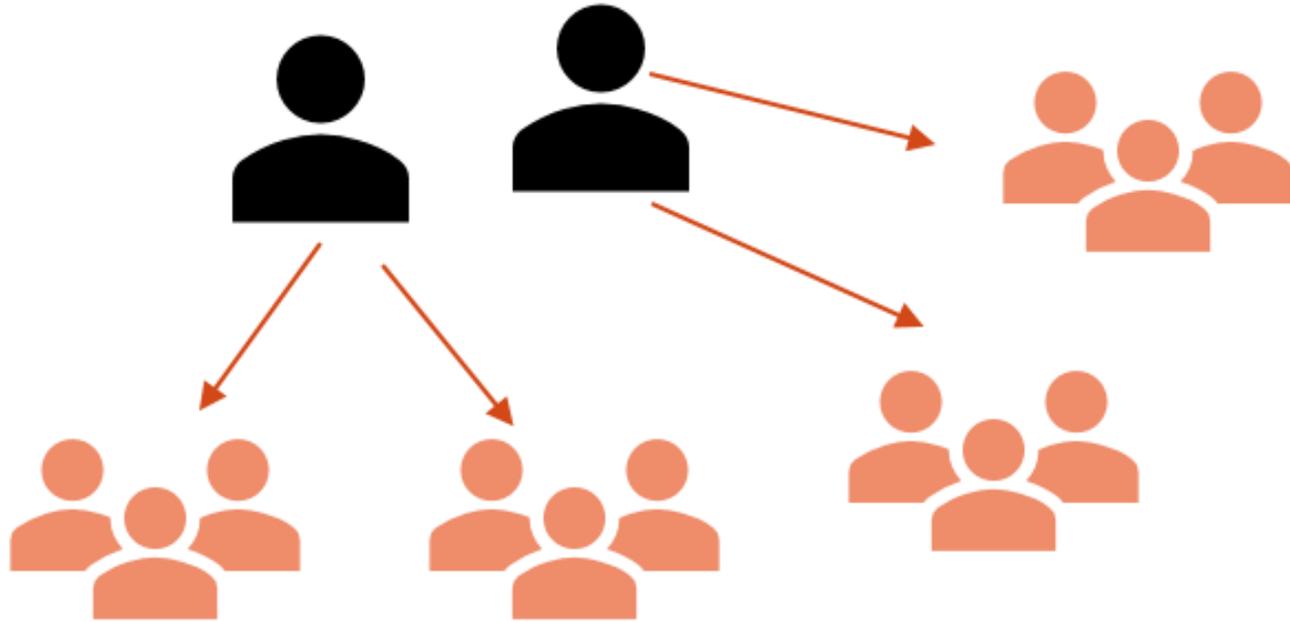
The programme is primarily based upon the Codex General Principles of Food Hygiene Code of Practice.



The Requirements: Complete Overview



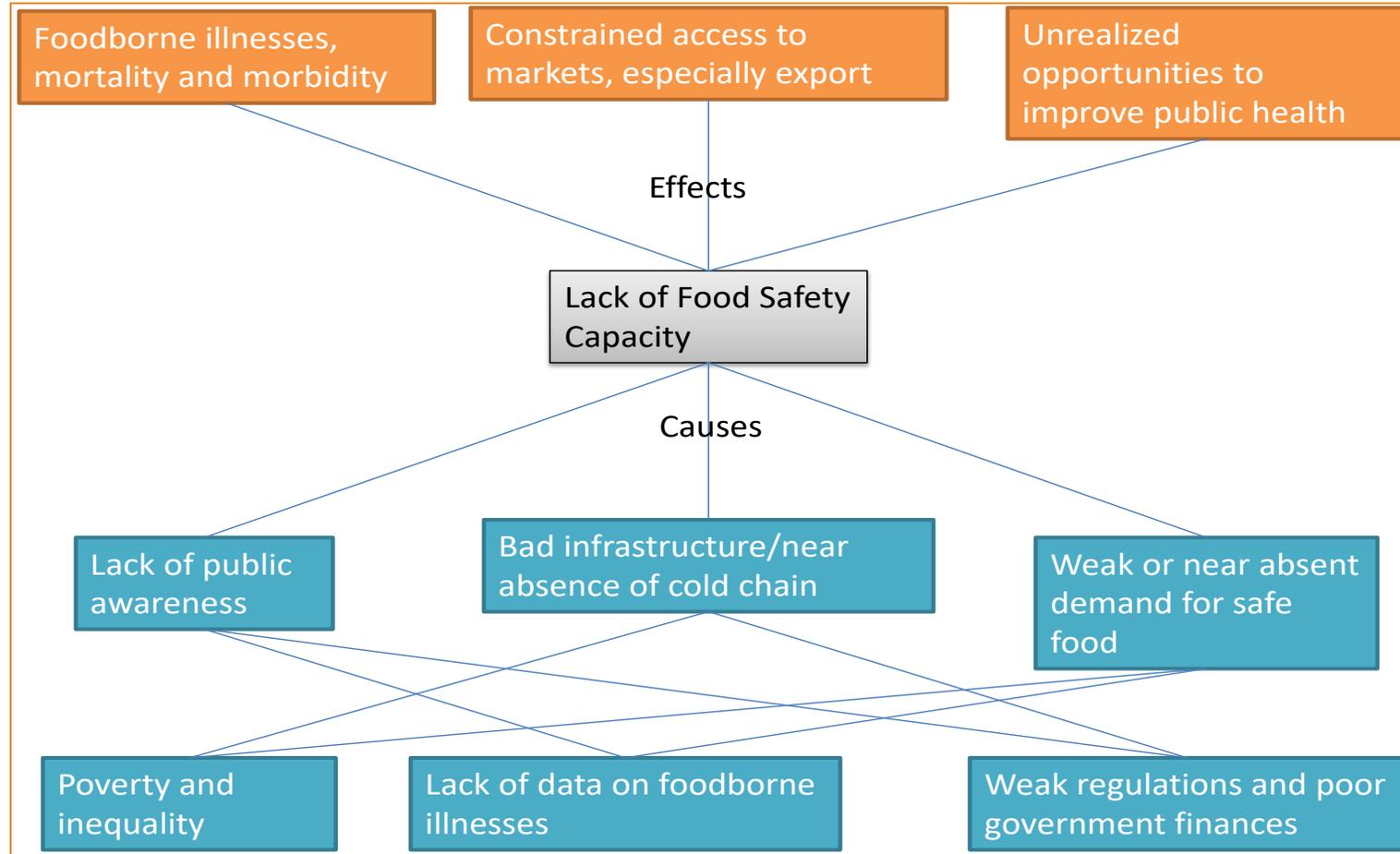




Mentored training of supplier SMEs

BUILD
SCALE:
NOT
PILOTS

FOOD SAFETY PROBLEM TREE: ZAMBIA



Source: World Bank

KEY FOOD SAFETY ISSUES IDENTIFIED

Small and medium businesses maintain limited or no food safety practices (e.g. fruit and veg. processing, peanut butter)

Retail chains are not interested in enforcing food safety requirements, because the majority of processed food in supermarkets is imported and is private label

Chronic risk of aflatoxin is recognized amid push of donor programs, but no structured initiative to address it

Water contamination

Lack of technical capacity and lack of demand by the SME processing sector (e.g. food scientists)

Government contention that enforcing food safety may result in SME closures, increased unemployment

SIMILAR PROBLEMS IN OTHER EMERGING ECONOMIES: USE SOLUTIONS THAT HAVE WORKED, CUSTOMIZE TO LOCAL VALUE CHAINS

THANK YOU FOR YOUR TIME

AKHILA VASAN

SENIOR PROGRAM MANAGER, FOOD SAFETY & EDUCATION

1350 I Street, NW

Suite 300

Washington, DC 20005

(202) 639-5000

sef@gmaonline.org; avasana@gmaonline.org

<http://www.gmaonline.org/sef/>

Skype: akhila840



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