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: avasan@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
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

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, Fellowships, Scholarships, Internships

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

Development of Methods for Food Authenticity Analysis
Survival of Listeria monocytogenes in Powdered Foods
• Need for harmonization
• Local, national and global requirements
• Role of regulations
Global Food System Integrity

- Food Safety • safe from hazards? Micro/Chem/Phy
- Food Security • Is there enough?
- Food Fraud • Is it what it claims to be?
- Food Defense • Will this food cause intentional harm?
- Food Authenticity • Scientifically Genuine?
- Food Nutrition • Is it healthy?
- Food Quality • Appearance Texture Flavour

TRUST

TRANSPARENCY
# IMPORTANT DIFFERENCES

<table>
<thead>
<tr>
<th>FSMA/ GOVERNMENT REGULATIONS</th>
<th>PRIVATE FOOD SAFETY SYSTEMS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Required by law</td>
<td>Optional, eg. GFSI</td>
</tr>
<tr>
<td>Minimum, baseline requirements</td>
<td>Typically perceived as higher standard</td>
</tr>
<tr>
<td>Food safety</td>
<td>May be food safety and/or quality</td>
</tr>
</tbody>
</table>

**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

- Legislators
  (National & State)

- Regulators & Gov’t Agencies
  (U.S. & International)

- Industry
  Member Companies
  Industry Associations

- International Groups
  (Codex, GFSP, APEC-PTIN)
Food Safety Modernization Act

Enhanced Partnerships

Prevention

Import Safety

Inspections, Compliance, and Response
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

Food Safety Modernization Act Implementation

- Policy Development (Rules & Regulations)
- Domestic Regulatory Compliance
- International Regulatory Compliance
- Domestic In-Plant Member Assistance
- Food Safety Preventive Controls Alliance (Education & Training)
# GMA GOALS FOR FINAL RULES

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Requirements/standards</strong></td>
<td><strong>should be risk based and promote food safety</strong></td>
</tr>
<tr>
<td><strong>2. Rulemaking</strong></td>
<td><strong>should stay within FSMA’s framework that protects public health</strong></td>
</tr>
<tr>
<td><strong>3. Consistent and appropriate enforcement of FSMA</strong></td>
<td><strong>is required to promote food safety</strong></td>
</tr>
</tbody>
</table>
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
Major Functionaries in the State

- Food Safety Commissioner
  - Referral Lab
  - Accredited Lab
  - Designated Officer
    - Food Safety Officer
    - Food Analyst
    - Adjudicating Officer
  - Food Safety Appellate Tribunal
  - Special Courts (wherever required)
Standard Development Procedure

1. Perceived need and justification for setting a standard
2. Study, discussion and development of Draft standard by Scientific Panel
3. Forwarding the draft standard to Scientific Committee
4. Review by Scientific Committee and recommendation to Food Authority
5. Approval by Food Authority and Ministry of Health & Family Welfare
6. Legal Vetting by Ministry of Law & Justice and draft notification for inviting public comments
7. Consideration of public comments and Final Notification after approval

Courtesy: Mr. Anil Kumar, Standards Advisor, FSSAI
SEVERAL NEW REGULATIONS AND AMENDMENTS

- 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)
- Food Safety and Standards (Import) Regulation, 2017 (20 Mar 2017)
TRENDS AND CHALLENGES: INDIA

Industry - Regulator Relationship

- 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.
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.

Source: MSU and Global Food Safety Initiative (GFSI)
The Requirements: Complete Overview

Global Markets:
- Basic Level
- Intermediate Level

Matching Level
- 100%
- 70%
- 30%

GFSI Recognized Manufacturing Schemes:
- BRC
- Dutch HACCP
- FSSC 22000
- Global Red Meat Standard
- IFS
- PrimusGFS
- SQF 2000
- Level 2
- Synergy 22000

Source: GFSI
Key parties to facilitate food safety training collaboration:
- Stakeholders
- Government
- Service Providers
- Industry Partners
- MSU and GMA SEF

Basic Level
- Awareness
- Blended Learning

Intermediate Level
- HACCP, TtT
- FSSAI regulations
- GFSI competency framework

Mentoring
- Train SME food suppliers, Lead Trainers
- At Center of excellence

Each Lead trainer carries out mentored training to supplier SMEs – building scale

Sustainable Food Safety Development Program

GMA SEF-MSU Team Experiences

USAID: India, Malawi, Rwanda

IICA: Caribbean capacity building

IFC: Jamaica Food Safety

WTO-STDF: Vietnam, Thailand

World Bank: China STP Vietnam

SSAFE: India, Brazil

Demand from manufacturers and retailers

Sustained continuous improvement, cost recovery basis

SMEs compliant with Food Safety Assessments

Deliver safe ingredients and products

Train regulators

Experiences
- WTO- STDF: Vietnam, Thailand
- SSAFE: India, Brazil
- USAID: India, Malawi, Rwanda
- IICA: Caribbean capacity building
- IFC: Jamaica Food Safety
- WTO-STDF: Vietnam, Thailand
- World Bank: China STP Vietnam

Experiences
- WTO- STDF: Vietnam, Thailand
- SSAFE: India, Brazil
- USAID: India, Malawi, Rwanda
- IICA: Caribbean capacity building
- IFC: Jamaica Food Safety
- WTO-STDF: Vietnam, Thailand
- World Bank: China STP Vietnam
Mentored training of supplier SMEs

BUILD SCALE: NOT PILOTS
FOOD SAFETY PROBLEM TREE: ZAMBIA

Effects:
- Foodborne illnesses, mortality and morbidity
- Constrained access to markets, especially export
- Unrealized opportunities to improve public health

Causes:
- Lack of public awareness
- Bad infrastructure/near absence of cold chain
- Weak or near absent demand for safe food
- Poverty and inequality
- Lack of data on foodborne illnesses
- Weak regulations and poor government finances

Source: World Bank
### KEY FOOD SAFETY ISSUES IDENTIFIED

<table>
<thead>
<tr>
<th>Issue</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small and medium businesses maintain limited or no food safety practices (e.g. fruit and veg. processing, peanut butter)</td>
<td>Retail chains are not interested in enforcing food safety requirements, because the majority of processed food in supermarkets is imported and is private label</td>
</tr>
<tr>
<td>Water contamination</td>
<td>Chronic risk of aflatoxin is recognized amid push of donor programs, but no structured initiative to address it</td>
</tr>
<tr>
<td>Lack of technical capacity and lack of demand by the SME processing sector (e.g. food scientists)</td>
<td>Government contention that enforcing food safety may result in SME closures, increased unemployment</td>
</tr>
</tbody>
</table>

**Similar problems in other emerging economies:** Use solutions that have worked, customize to local value chains

*Source: World Bank*
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; avasan@gmaonline.org

http://www.gmaonline.org/sep/

Skype: akhila840