FSMA Preventive Controls: Implications for Suppliers to the USA

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John Donaghy
Corporate Quality Management,
Vevey, Switzerland
The FSMA Rules

Some Implications for Food Industry

FSMA & GFSI-Recognized Schemes

How to Familiarize & FSMAtize
The FSMA Rules of Food Safety Modernization Act

- Preventative Controls for Human Food
- Sanitary Transport of Food
- Preventative Controls for Produce Safety
- Foreign Supplier Verification Program
- Preventative Controls for Animal Food
- Accreditation of Third-Party Auditors
- Food Defense/Intentional Adulteration

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Industry Impact: The Time Lines

FSMA into Law

PC Human food

PC Animal food

Sanitary Transport

FSVP

3rd party Accred

Produce Safety

Food Defense

2011

Sept' 2015

Nov' 2015

April 2016

May' 2016

Sept' 2016

April 2017

May' 2017

Dec' 2017

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Industry Impact: Extent of Impact: Nestlé Example

- > 45 Factories
- > 8 Business categories
- Multiple US & non-US Suppliers
Industry Impact: Extent of Impact: Nestlé Example

> 20 Nestlé Markets Supplying Products
> 30 Factories Supplying
> 300 SKUs supplied
> 900 SKUs via 3rd party distributors
Industry Impact: The Internal stakeholders

- Factory Management
- Factory Food Safety Leader/Team
- Factory Hygienist
- Factory Human Resources
- Factory/Corporate Supply Chain
- Contract Manufacturers
- Procurement/Regulatory/legal - Local & International
Industry Impact: Some Implications

- Plant and other key supply chain employees will need to be trained on the new requirements
- Customers, contract manufacturers and suppliers will also need to be in compliance with the new requirements
- Supply Chain Program -(a PC): Conduct appropriate verification activities - onsite audits; sampling/testing; Records review
- Foreign supplier subject to same requirements -potential need for annual auditing
- Increased focus on management of allergens, economic adulteration and environmental monitoring
- Focus on validated control measures necessary for safety
Industry implications ... ’No evidence... it wasn’t done’

More emphasis on record keeping and documentation e.g. preventative controls, supplier records, training

Education and Training are now binding v’s previous Non-binding requirement

All employees must be ‘Qualified Individuals’ (must receive training in principles of food hygiene and food safety/employee health and personal hygiene) - Mandated under current GMPs).
Industry Implications...The PCQI

The final Human Food rule requires appointment of a preventive control qualified individual (PCQI).

The qualified individual must do or oversee the following:

- Preparation and reanalysis of the food safety plan
- Validation of preventive controls
- Records review (for monitoring, corrective actions, calibration, product testing, environmental monitoring, and supplier verification activities)
FSPC Alliance:

FSPCA Steering Committee

FSPCA International Subcommittee

Core Outreach Team

Training Content WG
- Develop educational materials
- Lead efforts to translate materials
- Maintain consistency of materials

Trainer Network WG
- Develop and execute a plan to employ FSPC educational materials in capacity-strengthening efforts internationally
- Ensure materials availability to the international community

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KEEP CALM SOMETHING NEW COMING SOON

Just because
What Exists Already in Food Safety Management Schemes?

- GFSI
- BRC
- SQF
- Global GAP
- FSSC 22000

Benchmarking Schemes Certification

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'Robust food safety management systems and practices to ensure confidence in the delivery of safe, wholesome food to consumers worldwide'.
Some Comparisons: FSMA v’s GFSI - Recognized Schemes

**FSMA**

Food Safety Plan requirement:

- Hazard analysis
- Implementation and monitoring of preventative controls
- Corrective Action
- Verification
- Supply chain management
- Recall programme
- Records

**GFSI - recognised schemes**

Mandates that Processors have a documented food safety management system (FSMS)

Includes a food safety team or HACCP team lead by a trained individual

Elements of FSMA FSP should be covered as part of the FSMS
Some Comparisons: FSMA v’s GFSI - Approved schemes

**FSMA**

**Hazard Analysis:**

- Requires that processors conduct a hazard analysis to identify/evaluate known/foreseeable biological, chemical, physical hazards AND potential risk associated with potential adulteration of products for economic gain

- **SAHCODHA** (Significant Adverse Health Consequences Or Death to Humans or Animals)

**Preventative Controls, including CCPs - Must be Documented and Recorded**

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**GFSI - recognised schemes**

**Hazard Analysis, Controls (oPRPs), including CCPs are part of majority of the Schemes and Food Safety Management System (FSMS)**

**Adulteration?**

FSSC 22000 Food Fraud Community of Practice

Food fraud is of growing concern within the food industry and a much debated topic among the food safety community. This development is reflected in the GFSI Guidance Document, Version 7, which requires all certified organizations to specifically target food fraud.
Some Comparisons: FSMA v’s GFSI - Approved schemes

**FSMA**

Recall Plan:

- Protocols to notify consignees
- Protocols to notify public
- Conduct mock recalls
- Procedures to dispose of recalled food (documented)

**GFSI - recognised schemes**

Recall Plans are a Key part of GFSI- recognized schemes

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Some Comparisons: FSMA v’s GFSI - Approved schemes

FSMA

Re-analysis:
Requires that a FSP be ‘re-ana lysed every 3 years or as and when under other circumstances. Must be conducted by PCQI

GFSI - recognised schemes

Already an integral part of other schemes - perhaps more frequent.
It is part of Management of Change for many companies
The availability of the PCQI may be the issue.

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Some Comparisons: FSMA v's GFSI - Approved schemes

**FSMA**

**Monitoring:**
The What, When, How & Who

**Corrective Actions / Corrections**
- Ensure Documented Corrective Actions

**Validation, Verification** – verification of implementation and effectiveness
- ’The validation must be developed by a competent individual’

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**GFSI - recognised schemes**

Essential part of any FSMS
Principle 4 of the HACCP 7 Principles

Essential element of all FSMS

Basic requirements of GFSI-recognized schemes.

?? Validation?? - Will some additional work be required for some processes?

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Some Comparisons: FSMA v’s GFSI - Approved schemes

**FSMA**

**Implementation of Records**

Processors required to develop, document and implement programs for recordkeeping and to maintain same to demonstrate compliance to FSP

**GFSI - recognised schemes**

Record Keeping is an important part of any FSMS (written FSP, control monitoring, verification records, training records, calibration (EM, equipment, validation, etc...)

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Getting prepared for FSMA. What is needed?

- Wider awareness among Producers, Processors & Suppliers

- Initial Technical compatibility assessment - gaps with current system/scheme

- Dedicated Training requirements
What We (Nestlé) have done or are doing.

**Awareness**

- Nestlé US Food Safety Specialists
- FSMA Overview @ Zone level
- FSMA Detail/Rules/Implications @ impacted Markets
- Market and Factory quality managers importing to US
- Suppliers

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What We (Nestlé) have done or are doing.

Training

- Nestlé US Food Safety Specialists
- Train The Trainer
- FSMA Lead Trainer in Non-US Zones

Suppliers

- Train PCQI Per Facility - current Food Safety Team leader
- Supply Chain Program
  - 'Qualified Auditor' training
- Facilities importing to US - PCQI Trained person

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Foreign Supplier Verification Program (FSVP) … Requirements similar to US domestic Supply Chain Program

US Importers need to verify:

- Hazard Analysis is being performed
- Which entity is minimizing or preventing the hazards (could be the foreign exporter or their materials supplier)
- The foreign supplier’s procedures, processes and practices related to the safety of food
- Applicable FDA food safety regulations, and information regarding the foreign supplier’s compliance
- The foreign supplier’s food safety history, including the responsiveness of the foreign supplier in correcting past problems
- Other factors as necessary, including storage and transportation practices
Foreign suppliers: Are they ready...Getting Ready quickly?

- What is their level of awareness of FSMA
- Relatively small and larger Suppliers -
  Direct/Indirect – different Impact
  - Cascading from FSPCA not always possible
- Global Capability – Sustainability – Accessability
  Do we need training hubs outwith US?
- How do they FSMAtize current schemes they belong to?
Conclusions

# The FSMA Rules (most of them) will Influence how Foreign Suppliers operate

# Good News!
- GFSI-Recognized Schemes (e.g. FSSC 22000) go a long way to satisfying FSMA

# Suppliers & Producers will have to learn the language and adjust to comply

# Education, Awareness & training are key in the Preventative Rules

# The PCQI will have a key role & requires ‘official training’