



Quality

FSMA Preventive Controls: Implications for Suppliers to the USA

**IAFP's 12th European Symposium on
Food Safety
Athens, Greece
May 2016**

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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



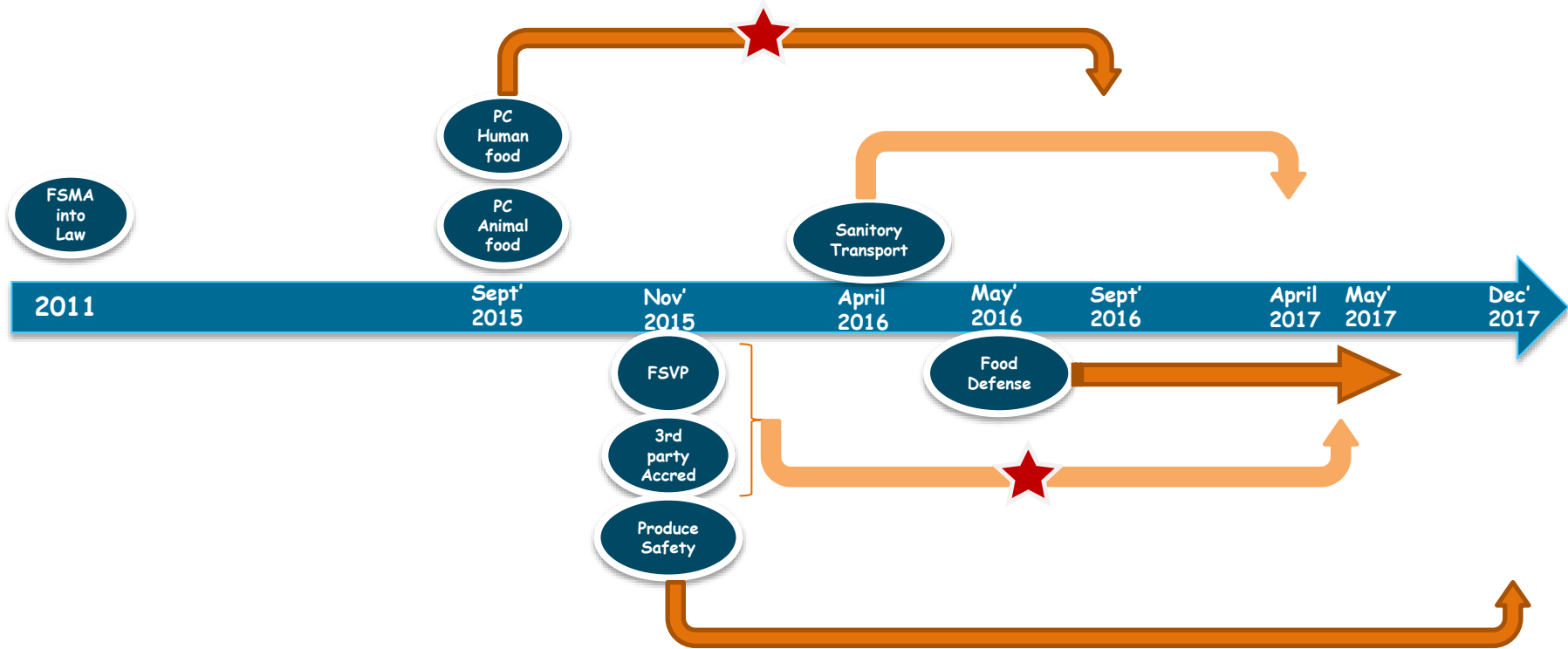
Accreditation
of
Third-Party
Auditors



Food
Defense/
Intentional
Adulteration



Industry Impact: The Time Lines



Industry Impact: Extent of Impact: Nestlé Example

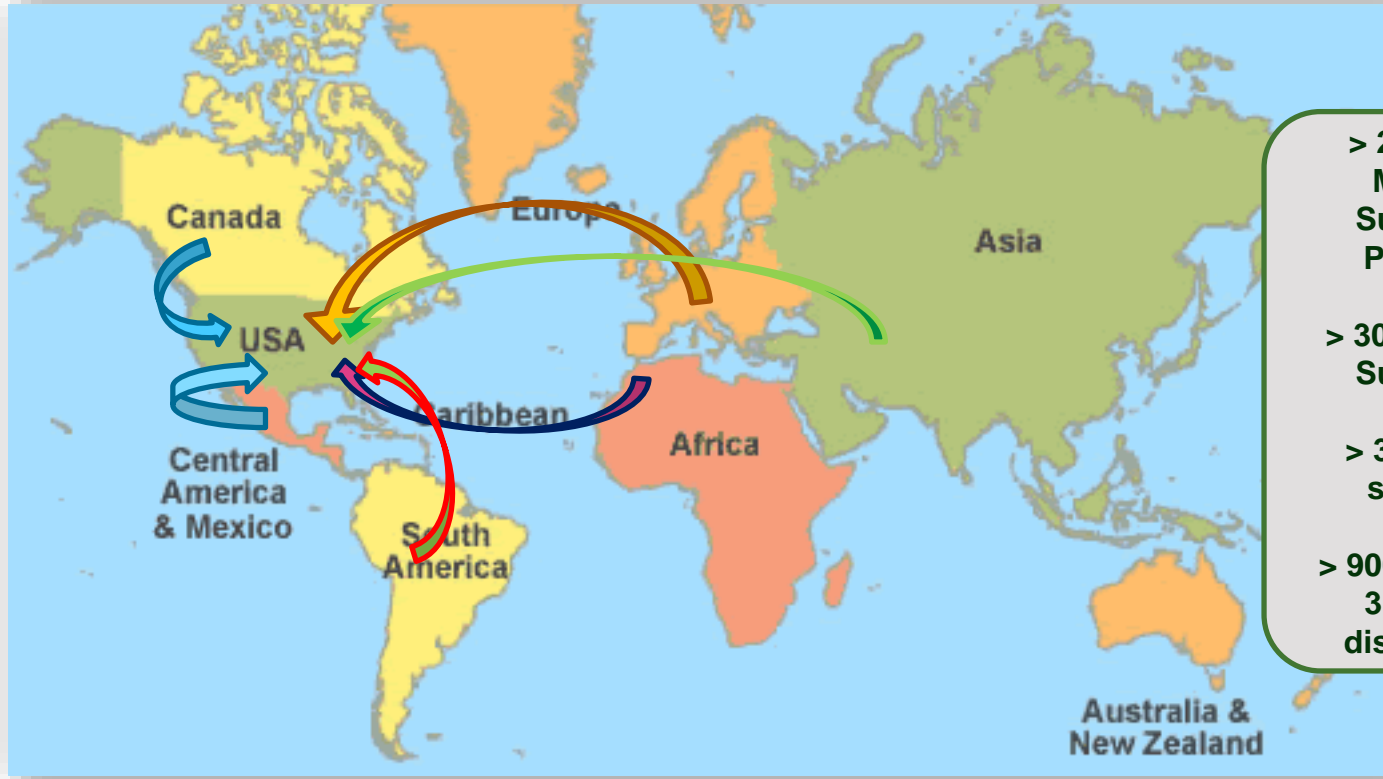


**> 45
Factories**

**> 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

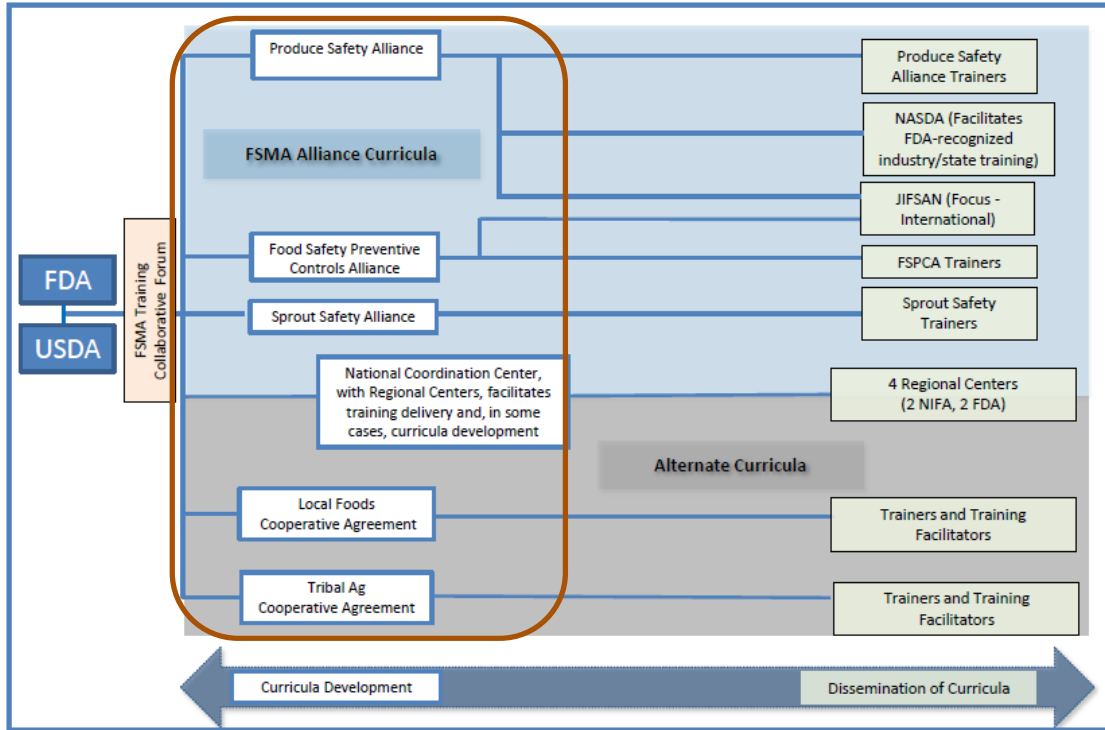
The final Human Food rule requires appointment of a **preventive control qualified individual (PCQI)**.



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 FSPCA educational materials in capacity, strengthening efforts internationally
- Ensure materials availability to the international community

John Donaghy



What Exists Already in Food Safety Management Schemes?

What is GFSI

The Global Food Safety Initiative is an industry-driven global collaborative platform to advance food safety.



Benchmarking

Schemes

Certification

FSMSs & FSMA-The 'What' and the 'How'...Not so Different

'Robust food safety management systems and practices to ensure confidence in the delivery of safe, wholesome food to consumers worldwide.'



**FSMA
Is about
Preventative Controls**

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 (**S**ignificant **A**dverse **H**ealth **C**onsequences **O**r **D**eath to **H**umans or **A**nimals)

Preventative Controls, including CCPs -Must be Documented and Recorded

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

Some Comparisons: FSMA v's GFSI - Approved schemes

FSMA

Re-analysis:

Requires that a FSP be 're-analysed 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.

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'

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?

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...))

Getting prepared for FSMA. What is needed?

- Wider awareness among Producers, Processors & Suppliers

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

FSMA versus FSSC 22000 Gap Analysis

In order to help FSSC 22000 certified facilities meet the requirements of the Food Safety and Inspection Service's Food Safety Modernization Act (FSMA), the Foundation FSSC 22000 has commissioned a gap analysis comparing FSSC 22000 against the FSMA final rules for Preventive Controls for Human Food. The first results of this analysis are encouraging and suggest that FSSC 22000 is well aligned with the requirements of the "Preventive Controls Rule" as it was compared.

An extract of the report states of FSSC 22000:

"It's required elements exceed the rule in several areas. Where it is not, it is in very large measure comparable to the Final Rule requirements."

	SQF – Level 2	FDA Preventive Controls Food Safety Plan	FDA GMPs (117 subpart B)
Overarching policy statement	Yes	No	No
Written Plan	Yes	Yes	No
Experienced individual in charge	Yes	Yes	No
Trained Staff	Yes	Yes*	Yes
Prerequisite programs	Yes	No	Yes
Raw material/incoming product safety assurance	Yes	No	No
Supplier Verification	Yes	Yes, in specific cases**	No
Allergen Management	Yes	Yes	Yes

"BRC in the Age of FSMA" – October 30 Webcast Features

- Dedicated Training requirements



Welcome to FSPCA Online

The Food Safety Preventive Controls Alliance (FSPCA) is a broad-based public private alliance consisting of key industry, academic and government stakeholders whose mission is to support safe food production by developing a nationwide core curriculum, training and outreach



What We (Nestlé) have done or are doing.

Awareness

Nestlé US Food Safety Specialists

FSMA
Overview
@ Zone level



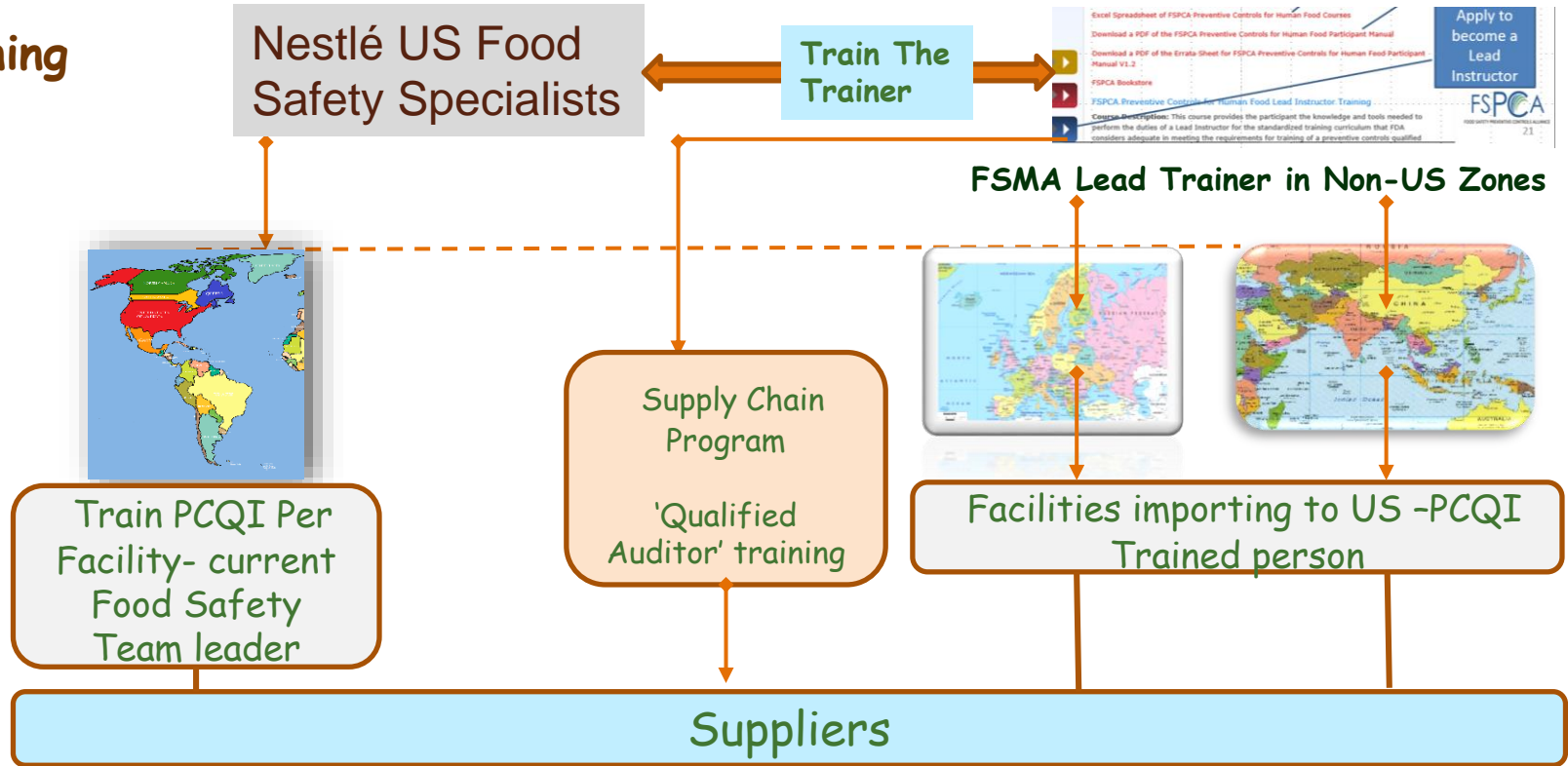
FSMA
Detail/Rules/
Implications
@ impacted
Markets

Market and Factory quality managers importing to US

Suppliers

What We (Nestlé) have done or are doing.

Training



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

US Importers need to verify:



Documentation

- 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 - Accessibility
 - Do we need training hubs outwith US?
- How do they FSMAize 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’