

What is the FDA Food Safety Modernization Act (FSMA)?

- The FDA Food Safety Modernization Act (FSMA), was signed into law by president Obama on Jan. 4 2011 and enables the FDA
 - to better protect public health by strengthening the food safety system
 - to focus more on **preventing** rather than reacting to food safety problems after they occur.

How does prevention work?

The FDA now has a legislative mandate to require comprehensive, science-based preventative controls across the food supply chain. The following areas are now mandatory:

Preventative controls for food facilities

- Food facilities are required to implement a written preventative controls plan specifying preventative steps, or controls put in place to significantly minimize or prevent the hazards
- the facility should also monitor these controls to ensure they are working maintaining routine records.

Produce safety standards

- The FDA has established science-based, minimum standards for the safe production and harvesting of fruits and vegetables
- Standards must consider naturally occurring hazards, those introduced either unintentionally or intentionally, and must address soil amendments (materials added to the soil such as compost), hygiene, packaging, temperature controls, animals in the growing area and water.

Authority to prevent intentional contamination

- The FDA has issued regulations to protect against the intentional adulteration of food, including the establishment of science-based mitigation strategies to prepare and protect the food supply chain at specific vulnerable points

Preventative Control Qualified Individuals

Why is a PCQI necessary?

- The individual is qualified to create and manage a FSMA-compliant food safety plan
- They ensure that plan is implemented by deadline date

Is my HACCP appointed individual a PCQI?

- Not necessarily since there are differences between HACCP and FSMA.
- The FSMA-compliant plan must be prepared and applied by a properly trained PCQI

Where are PCQI's trained?

- There is an official course developed by the Food Safety Preventative Controls Alliance (FSPCA) which is the 'standardized curriculum' recognised by the FDA
- exporTT offers this course which is facilitated by trainers trained by the FSPCA.

What does the USFDA do to ensure compliance?

Mandated inspection

- The mandated inspection frequency is determined based on risk
- All high risk domestic facilities must be inspected within 5 years of enactment and every 3 years after.
- Within one year of enactment, the law directed the FDA to inspect at least 600 foreign facilities and double those inspections every year for the next 5 years.

Records Access

- The FDA has access to records including industry food safety plans
- Records pertaining to the implementation of those plans should also be made accessible.

Details of Inspection

FDA's 10 Components of an Inspection

1. Prepare for inspection
2. Conduct initial interview
3. Determine processing steps via walk through
4. Evaluate sanitary conditions
5. Conduct and compare hazard analysis
6. Evaluate food safety plan components
7. Evaluate implementation of the plan
8. Conduct record review
9. Evaluate inspection findings
10. Document inspection findings

Details of Inspection

Essential Records Under FSMA

Food Safety Plan	Corrective Actions
- Hazard Analysis (and re-analysis)	Verification Activities
- GMPs	- Environmental and Product Testing
- Sanitation Controls	Supplier Verification Plan and Implementation Activities
- Allergen Controls	Food Defense Plan and Implementation Activities
- Process Controls	Sanitary Transportation Procedures
Validation Data for Process Controls	Recall Plan and Related Records
Monitoring	

Consequences of Non-Compliance

Mandatory recall

Expanded
administrative
detention

Leveraging of local
agencies to
conduct
inspections

Require
certification for
high risk food

Authority to deny
entry

exporTT's Assistance in FSMA Compliance

FSMA Workshops

exporTT in collaboration with International Food Safety Consultants and Lead Instructors for US FDA Approved Food Safety will host.

Lead Instructor coordinates the Training Curriculum: Food Safety Preventative Controls Alliance (FSPCA) Preventive Controls for Human Food programme.

Successful participants of these training session will become certified Preventive Controls Qualified Individuals (PCQI)

The Preventive Controls Qualified Individual is charged with overseeing the validation that preventive controls are capable of controlling identified hazards as well as the records review.

At the end of this training program, participants will be able to:

- Discuss Good Manufacturing Practices and Prerequisite Programs
- Conduct hazard analysis and determine preventive controls
- Define process, food allergen, sanitation and supply-chain preventive controls
- Discuss verification, validation, recall and recordkeeping requirements

exporTT's Assistance in FSMA Compliance Food Safety Plan Training

At the end of the workshop, participants will have a completed Food Safety Plan for one product from which learnings can be used to apply to other products within their portfolio

Phase 1: Site Visit to Participating Companies

Prior to the three day workshop, each selected participating company facility will be visited by the Facilitator and exporTT representatives, to familiarise the team with the product flow at the facility so that greater value can be added to the food safety plan development process.

Phase 2: Workshop

This phase encompasses the classroom sessions, which will take place for three days over a three week period. These sessions will assist participants building out the components of the Food Safety Plan using the FDA Food Safety Plan Builder (FSPB). See outline as follows:

Day 1:

1. A Review of Good Manufacturing Practice (GMP) findings
2. Discussion on how their current GMP's compared to the requirements.
3. Completion of the first 5 sections of the FSPB (Facility Information, Preliminary Steps, Good Manufacturing Practices (GMP) & Prerequisite Programs, Hazard Analysis & Preventive Controls Determination, Process Preventive Controls

exporTT's Assistance in FSMA Compliance

Day 2:

- Discussion on findings of walkthrough with group and review compliance with standards
- Restart FSPB:
 - Food Allergen Preventive Controls
 - Sanitation Preventive Controls
 - Supply-Chain Preventive Controls
 - Recall Plan
 - Reanalysis of Food Safety Plan

exporTT's Assistance in FSMA Compliance

Day 3:

- Review all elements of the FSPB completed
 - Food Safety Plan Report
 - Signatures
 - Recordkeeping Procedures
 - Important Contacts
 - Supporting Documents
 - Address all outstanding challenges experienced while developing the Food Safety Plan

exporTT's Assistance in FSMA Compliance

Standards Implementation

- A company shall receive financial support from exporTT Limited on the condition that the company will be reimbursed for a portion of the pre-approved expenses under this grant facility. This service is meant to treat with the business constraints related to accessing exports markets.
- The project must be financed fully by the applicant via their own resources and the grant will reimburse funds upon completion of the project. The grant allows companies to be reimbursed *up to* 50% of the total cost of the project value to a maximum of TTD 50,000.00 **per company per 2 years**.

Contact Details

Manager- Capacity Building and
Programme Financing

cmaharaj@export.co.tt

Tel.: (868) 623-5507 ext 7904

Mobile: (868) 796-4276