

Wales Food and Drink Export to the USA:

Food Safety requirements,
how can we comply?



Contents

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Background

- Foodborne illness is a significant burden
 - About 48 million (1 in 6 Americans) get sick each year
 - 128,000 are hospitalized
 - 3,000 die
- Immune-compromised individuals more susceptible
- Foodborne illness is not just a stomach ache—it can cause life-long chronic disease



Why is Regulation needed :

- **Globalization** - 15% US Food supply is imported
- **Food supply more high-tech** and complex – more foods, new hazards
- **Shifting demographics** – growing population **30% 'at risk'**



USA Agencies involved in Food Safety

FEDERAL:

- U.S. Food and Drug Administration (FDA)
- USDA/Food Safety and Inspection Service (FSIS)
- Environmental Protection Agency (EPA)
- National Oceanic and Atmospheric Agency (NOAA)
- Center for Disease Control and Prevention (CDC)

STATES:

- State food safety agencies
- “Cooperative Programs” with FDA (e.g. Interstate Shellfish Sanitation Program)



USA Agencies involved in Food Safety

- Two Main Federal Food Safety Regulatory Agencies
 - **USDA/FSIS**
 - Cattle, Sheep, Goats, Horses, Mules, Egg products, catfish
 - **FDA**
 - All foods **NOT** covered by USDA
 - Dairy, Produce, Bakery, Dietary Supplements, Seafood, Ingredients, Game Meats

(Environmental Protection Agency –sanitizers)



Two Main Federal Food Safety Regulatory Agencies

FDA

- Periodic inspection
- 2000 Inspectors 130,000+ Facilities
- On farm authority
- Diverse product matrices

USDA

- Continuous inspection
- 7800 inspectors for 6800 facilities
- Similar food matrices



Food Groups Under FDA Authority

- **Dairy Products**

- Milk
- Cheese
- Butter

- **Plant products**

- Vegetables
- Fruits
- Nuts
- Juices

- **Spices**

- **Dietary Supplements**

- **Seafood**

- Finfish
- Shellfish
- Crustaceans
- Surimi based

- **Grain-based**

- Bread
- Cereals
- Flour

- **Bottled water**

- ***Cosmetics***



Statutory Authority

- The Federal Food and Drugs Act of 1906
- The Federal Meat Inspection Act of 1906
- The Federal Import Milk Act (1927)
- The Federal Food, Drug, and Cosmetic Act of 1938, as amended
- The Public Health Service Act (1944)
- The Poultry Products Inspection Act of 1957
- The Fair Packaging and Labeling Act (1966)



FSMA

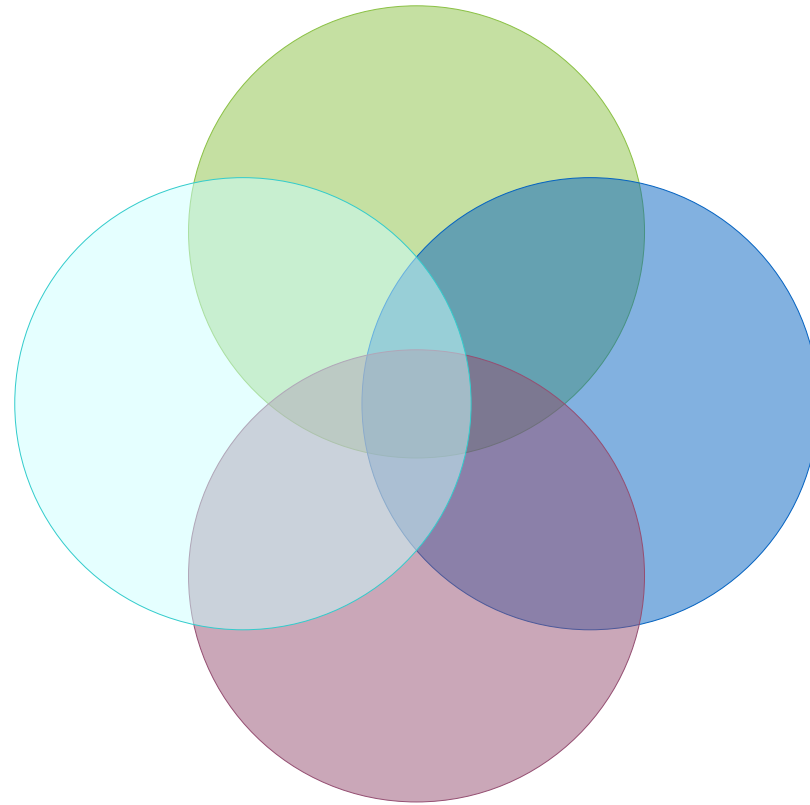
- The FDA Food Safety Modernization Act (FSMA)
- Signed into law by President Obama on January 4, 2011.
- It aims to ensure the U.S. food supply is safe by shifting the focus of federal regulators from responding to contamination to preventing it.



THEMES

Prevention

Enhanced Partnerships



Inspections, Compliance, and Response

Import Safety



Groundbreaking Shift

- Importers now responsible for ensuring that their foreign suppliers have adequate **preventive controls** in place
- FDA can rely on **third parties to certify that foreign food facilities** meet U.S. requirements
- Can require **mandatory certification** for high-risk foods
- Voluntary qualified importer program
- Can deny entry if FDA access for inspection is denied



Prevention: The Cornerstone

- Comprehensive preventive controls for human and animal food facilities
- Prevention is not new, but Congress has given FDA explicit authority to use the tool more broadly
- Produce safety standards
- Intentional adulteration standards



FSMA -Part 117 (17.09.2015)

Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food

- USA and foreign facilities **MUST** adopt controls .Facilities covered by the preventive controls requirements in 21 CFR 117 are those that **manufacture, process, pack or hold human food.**
- This applies to **both domestic and foreign food processors** exporting food covered by 21 CFR 117 to the U.S.
- Farms and retail food establishments are not covered.... other exemptions



FSMA -Part 117 (17.09.2015)

The regulation requires:

- **“preventive controls qualified individual (PCQI) ”**
- **“successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and apply a food safety system”**



PCQI is responsible for:

1. Food safety plan
2. Perform a hazard analysis
3. Institute preventive controls for the mitigation of those hazards
4. Recall plan



1. Food Safety Plan

- Registered facility with the FDA
- PCQI - FDA will assess the adequacy of a facility's food safety plan rather than an individual's documented qualifications
- Per facility
- Every 3 years



2. Perform a Hazard Analysis

- Biological , chemical (Radiological) and physical Hazards
- HACCP & PRP's



3. Institute Preventive controls

- Those risk based, reasonably appropriate procedures, practices and processes that a person knowledgeable about safe manufacturing, process , packing , or holding of food would employ to significantly minimise or prevent hazards identified under the HA that are consistent with the current scientific understanding of safe food manufacturing , processing , packaging or holding at the time of the analysis

21 CFR 117.3 Definitions

- Verification and validation



3. Institute Preventive controls

- **PROCESS SPECIFIC** – control measures, critical limits and CCP's, monitoring , corrective action and corrections
- **ALLERGEN** – Cross contact prevention & label controls
- **SANITATION** –Major food safety hazards controlled by sanitation practices. e.g. pathogens and allergens.
- **SUPPLY CHAIN** –ingredient /raw material hazards controlled by supplier



Supply chain preventive control *not required*:

- HA concludes that there are no hazards requiring a supply-chain-applied control
- You control the hazards requiring a preventive control within your facility
- You rely on your customer to control the hazard, you identify for your customer that the food has not been processed to control the hazard, and you have annual written assurance from your customer that they are following procedures to do so.
- Food supplied for research or evaluation not required and exceptions FDA
- For very small businesses, farms and shell egg producers (as defined by FDA)



4. Recall Plan

- Recall Plan must be written and in place before an adverse event takes place to ensure that actions taken to recall a food are conducted efficiently and as soon as possible.
- A rapid response is especially important for Class I and Class II recalls for which public health is at risk.
- The written Recall Plan must include procedures that describe the steps to take and assign responsibility for taking those steps.
- Document & test



FSPCA

- Established in 2011



- Support the safe food production by developing a standardised curriculum and technical educational materials on food safety risk – reduction controls compliant with the Preventive Controls regulations, and providing technical assistance outreach to the food industry , particularly SME's



FSPCA PROGRAM

- Collaboration
- Standardised curriculum - 3 Days
- Preventive controls qualified individual (PCQI)



FSPCA PROGRAM

PCQI Perform and oversee :

1. Preparation of food safety plan
2. Validation of preventive controls
3. Records and review
4. Reanalysis of food safety plan

(Association Of Food and Drug Officials (AFDO) and the International Food Protection Training Institute (IFPTI) Administer certificates for all delegates)



Certification....



FSPCA Course:

Meet the requirements for training under Title 21 Code of Federal Regulations PART 117.180©(1) for the Preventive controls qualified individual who conducts certain Food Safety Plan Activities





FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE



Menu ▾

<https://www.ifsh.iit.edu/fspca/fspca-technical-assistance-network>

FSPCA Technical Assistance Network

CONTACT FSPCA ABOUT FSMA

The FSPCA Technical Assistance Network (TAN) is now operational and providing technical assistance to industry, academia and others regarding training and scientific/technical questions related to FDA's Preventive Controls human food and animal food regulations. For more information, download

- « FSPCA HOME
- + THE ALLIANCE
- + COURSES
- LEAD INSTRUCTOR
- TECHNICAL ASSISTANCE (TAN) DATABASE
- + RESOURCES
- + FAQ





Food

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Food Safety Modernization Act (FSMA)

The Law, Rules & Guidance

Fact Sheets & Presentations

Frequently Asked Questions on FSMA

FDA Actions and Meetings

FSMA Training

FSMA Technical Assistance Network (TAN)

FSMA Technical Assistance Network (TAN) Inquiries Report

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Report Dates: 9/10/2015 through 8/31/2017

The [Technical Assistance Network \(TAN\)](#) provides technical assistance to industry, regulators, academia, consumers and others regarding FSMA implementation. The TAN addresses questions related to the FSMA rules, programs, and implementation strategies after the rules are final.

This report summarizes, both for a recent time period and cumulatively since September 2015 key statistics about who is submitting FSMA inquiries; their topics of interest; and what channels of communication they are using to ask questions.

<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm498163.htm>





BRC GLOBAL STANDARD FOOD SAFETY

PREVENTIVE CONTROLS FOR HUMAN FOOD RULE COMPARISON

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• 116 PAGES

• PCQI –QA MANAGER



Next Steps:

- PCQI course – Food Innovation Wales
- Accredited third party certification programme (pre audit, unannounced 3rd party report to FDA)
- Foreign Supplier Verification Programme for USA importers





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Cronfa Amaethyddol Ewrop ar gyfer Datblygu Gwledig
Ewrop yn Buddsoddi mewn Ardaloedd Gwledig
European Agricultural Fund for Rural Development
Europe Investing in Rural Areas



Llywodraeth Cymru
Welsh Government



Arloesi Bwyd
Cymru
Food Innovation
Wales

HELIX



United Kingdom Association for
Food Protection

Food Industry Centre
Cardiff Metropolitan University

ZERO2FIVE

Canolfan Diwydiant Bwyd
Prifysgol Metropolitan Caerdydd