

Martin Bauer Group

Update on Regulations: US & Canada

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USA: Regulatory update regarding The Food Safety and Modernization Act

FSMA: What Does It Mean For Tea?

Background to FSMA

US Food Industry Sponsored Survey Results:

- 50% of Americans have confidence in the safety of the US Food Supply
- 61% of Americans think imported food is less safe due to inadequate government oversight
- Current Scope of FDA oversight:
- There are over 130,000 registered importers using over 300 Ports of Entry into the USA
- There are over 300,000 registered food facilities in more than 150 countries

FSMA: What Does It Mean For Tea?

Background to FSMA

- 48 million people get sick, 128,000 are hospitalized, and 3,000 die each year in the US from foodborne diseases
- FDA believes foodborne illness is preventable providing the global food chain is held responsible and accountable for controlling hazards that can cause illness
- More product recalls in 2010 than ever before – nearly all concern pathogens Ecoli and Salmonella, or undeclared allergens
- Shift from cure to prevention to try and avoid such products entering into US commerce

FSMA: What Does It Mean For Tea?

Change in Focus...

Post- FSMA



Producer / Exporter

Importer



Pre- FSMA



Packer / Consumer



The Food Safety and Modernization Act (FSMA)

FSMA: What Does It Mean For Tea?

Background to FSMA – FDA Indicated Priorities

- Dairy/Cheese
- Fresh Produce
- Low-acid canned foods
- Seafood/Fishery Products
- Infant Formula
- Dietary Supplements
- Previously recalled Foods
- Geographic

FSMA: What Does It Mean For Tea?

Key Provisions of FSMA

a.) Preventive Controls

FSMA requires all food facilities to implement “preventive controls”

- Evaluating hazards that could affect food safety
- Specifying controls to minimize or prevent these hazards
- Specifying how the facility will monitor these controls
- Maintain records of monitoring
- Specify actions the facility will take to correct problems that arise
- Verifying the program is effective

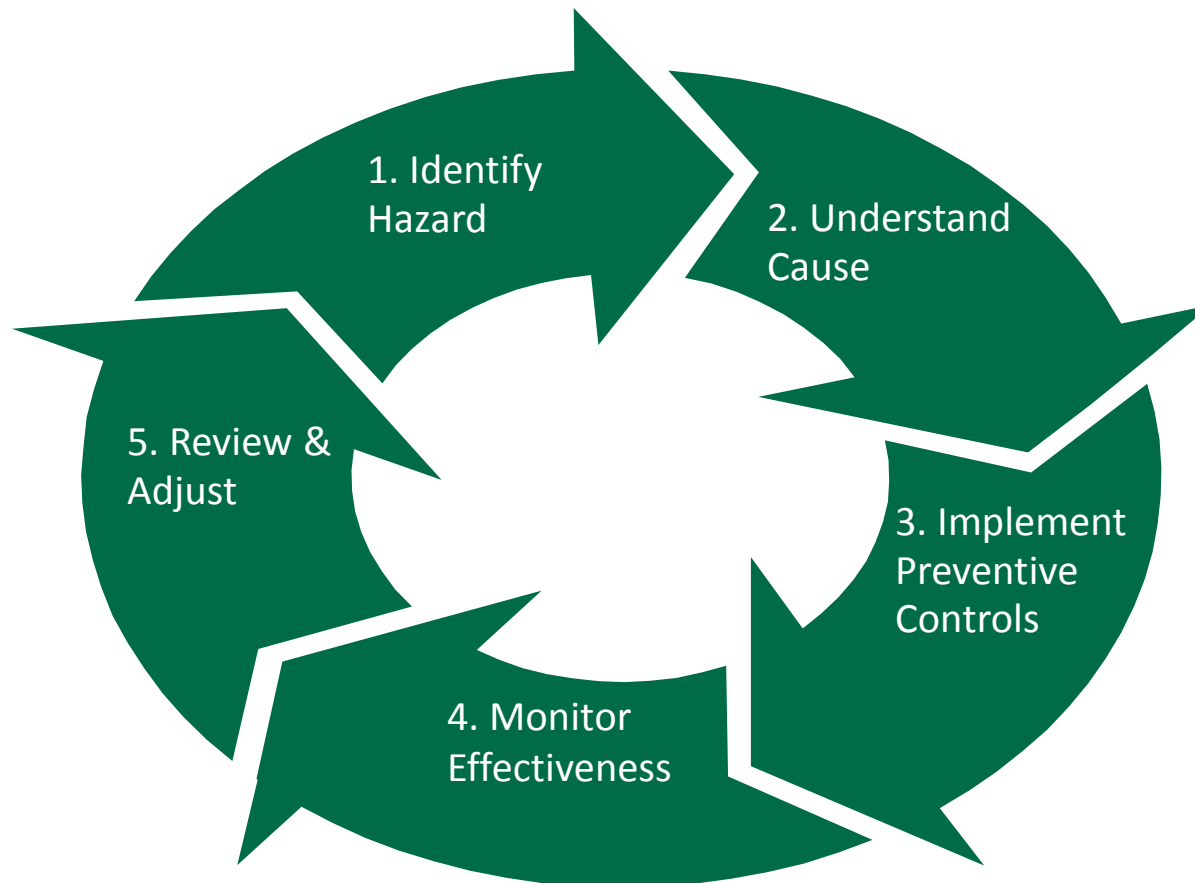
Although the exact scope of these requirements has not yet been determined, food facilities that have implemented thorough HACCP programs will be well on their way to compliance. For more information:

<http://www.regulations.gov/#!documentdetail;D=FDA-2011-N-0238-0001>

UPDATE: Regulations have been drafted and are under review by OMB

FSMA: What Does It Mean For Tea?

General Approach to Preventive Controls



FSMA: What Does It Mean For Tea?

Key Provisions of FSMA

b.) Produce Safety

FDA is required to propose standards for produce safety by January 2012

Standards relate to production and harvesting of those types of fruits and vegetables that are raw agricultural commodities for which FDA has determined such standards minimize risk of serious adverse health consequences or death

Updates:

- Regulations drafted and under review by OMB
- Creation of the Food Safety Prevention and Controls Alliance (FSPCA)
- Contracted with IFT to improve traceability on “high risk” foods

FSMA: What Does It Mean For Tea?

Primary Preventive and Product Safety Issues for Tea

- Pesticide Residues
- Microbiological Contamination
- Foreign Material
- Heavy Metals
- Other Contaminants?

FSMA: What Does It Mean For Tea?

Key Provisions of FSMA

c.) Import Controls

- The law requires importers to verify that their foreign suppliers have adequate preventive controls in place to ensure the food produced is safe (“Foreign Supplier Verification Program”)
- Verification must be adequate to ensure foreign supplier produces imported food in accordance with US law governing preventive controls and produce standards (as already mentioned) as well as US law governing allergen labeling and other adulteration standards.
- FDA is required to publish a regulation and guidance by January 2012 and the program takes effect one year later in January 2013
- The law directs FDA to inspect foreign facilities
- As part of prior notice importers must inform FDA if any country has refused entry of the same product
- “Voluntary Qualified Importer Program” (Implementation – July 2012)

UPDATE: Regulations drafted and under review by OMB

FSMA: What Does It Mean For Tea?

Key Provisions of FSMA

a.) FDA Enforcement Authority

- FDA has the authority to suspend registration of a food facility
- FDA has the authority to detain food up to 30 days if it believes the food may be misbranded or adulterated
- FDA for the first time will have mandatory recall authority for all food products

UPDATE: FDA has used its' new powers of administrative detention already 3 times

FSMA: What Does It Mean For Tea?

Key Provisions of FSMA

b.) FDA Inspection Authority

- FSMA gives FDA authority to inspect food establishment's records
- FDA may inspect all records relating to a food if FDA believes there is “reasonable probability that use or exposure to” a food will cause serious adverse health consequences or death
- Not only this product but any other article of food FDA believes could be affected in a similar manner.
- The new preventive controls and import safety programs include authority for FDA to inspect all plants and records required to be maintained relating to these programs.
- Food companies need to anticipate a wide range of records will become available to FDA inspectors

FSMA: What Does It Mean For Tea?

Key Provisions of FSMA

c.) FDA Inspection and Enforcement Information

- FDA now publishes on its website data on inspections and enforcement actions that are more extensive than was available in the past. More information is available at:

<http://www.fda.gov/AboutFDA/Transparency/Transparencyinitiative/ucm254426.htm>

Updates

Foreign inspections – FDA has met FSMA mandate in 2011

Domestic inspections – more than 20,000 food facilities in 2011 in line with the 5 year mandate within FSMA

FSMA: What Does It Mean For Tea?

Key Provisions of FSMA

d.) FDA Fees

Beginning October 2011 the FDA will assess the following fees

- Re-inspection to determine whether corrective actions have been implemented and are effective, necessitated as a result of a previous inspection that identified non-compliance materially related to a food safety requirement
- Fees for import re-inspection or re-examination when the initial inspection identified noncompliance materially related to a food safety requirement
- Fees to cover FDA's work when a firm does not comply with an FDA recall order

The fees for the above are assessed on an hourly basis at \$224 per hour (or \$325 if foreign travel required)

Canada – A Regulatory Update

Canada: Regulatory Update

Current situation

- Agricultural commodities (including tea) are monitored by the Canadian Food Inspection Agency (CFIA). They are responsible for enforcing restrictions on the production, sale, composition and content of foods (Food and Drugs Act and Regulations)
- Health Canada's Pest Management and Regulatory Agency (PMRA) is responsible for registration and regulation of pesticides and the establishment of maximum residue limits (MRL's) (Pest Control Products Act)

New Development

- June 7th 2012 – “Safe Food for Canadians” Act introduced by federal Government. The Act represents a consolidation and revamping of :
 - Meat inspection Act
 - Canadian Agricultural Products Act (tea)
 - Fish Inspection Act
 - Consumer Packaging and Labelling Act

Canada: Regulatory Update – key points from the “Safe Food for Canadians” Act

- The Act aims to make the Canadian food supply system safer than it is today by:
 - Modernizing processes and obligations on regulated parties
 - Ensuring the Government has appropriate tools to efficiently manage food safety issues
- Provide penalties up to \$5m for contravening the law and for knowingly or recklessly causing a risk of injury to human health
- Prohibit the sale of foods that have been recalled
- Provide authority to make regulations respecting the traceability of food commodities.
- Provide authority to make regulations to require the licensing of food importers/exporters
- *N.B. A substantial portion of the new system will be in regulations yet to be developed. There are significant portions of the Bill that will require regulatory change, a process that takes years.*

Canada: Regulatory Update – The Food Safety Action Plan (FSAP)

“...ensuring the Government has appropriate tools to efficiently manage food safety issues”

- The Food Safety Action Plan aims to modernize and enhance Canada’s food safety system
- FSAP’s “enhanced surveillance initiative” has led to targeted surveys of various foods to test for specific hazards – including tea...
- The Tea Association of Canada has an active dialogue with both CFIA and Health Canada and with the support of the board (and members) is committed to working with the authorities in developing a road to compliance.

Canada: Requirements for Licensing

Under the new Act a single licence will be issued to individual facilities and importers to carry out operations based upon those facilities/importers providing:

- Money!
- General Information about business
- Summary of business Activities
- Details regarding Products and Processes
- A signed statement indicating management's commitment to meeting regulatory requirements
- Develop, document and maintain a preventative control plan, suitable to their activities and operations, to meet food safety and regulatory requirements (HACCP)

Canada: Regulatory Cooperation Council

- On February 4, 2011, Prime Minister Stephen Harper and United States President Barack Obama announced the creation of the Canada-United States Regulatory Cooperation Council (RCC) to better align the two countries' regulatory approaches, where possible.



Thank you!

FSMA Website – www.fda.gov/food/foodsafety/fsma

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