



Food Safety Modernization Act – Potential Implications for the Brewing Industry

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Food Safety Modernization Act (FSMA)



What is the Food Safety Modernization Act (FSMA)?

- FSMA was passed into law on 4th January 2011
- It is the first major revision of the U.S. federal food safety laws since the Food, Drug and Cosmetic Act of 1938, over seventy (70) years ago
- It aims to better protect human and animal health by implementing requirements to ensure the safety and security of food and feed supply
- It embraces the need for a global approach to food and feed safety and brings significant changes to the U.S. food safety landscape
- Its Framework consists of **seven** Proposed Rules, of which six **directly** impact the Brewing Industry

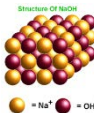
Why is Food Safety Modernization Act (FSMA) important?

- FSMA includes new regulations for safe food handling practices from “field to fork”, or in the case of brewing industry from “grain to glass”
- It has been proven that contaminated foods are preventable if food safety hazards are addressed at every stage of the supply chain. These hazards are:

- Allergenic
- Biological
- Chemical
- Physical
- Radiological



8226/0773 (4x 03)
Pectinatus cerevistipitius
bacteria



What initiated the Food Safety Modernization Act (FSMA)?

- Prevalence of food-borne pathogen contamination in produce
- Rise in major outbreaks of food-borne illnesses in humans and animals
- Global sourcing of fresh food and ingredients
- New and evolving food safety science and methodologies
- Identification of new food safety risks
- Changing food consumption patterns
- Consumer demand for fresh and safe food

First Major Rule Mandated by FSMA

Produce Safety: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption



FDA reported that outbreaks and outbreak-related illnesses.....

1996	2010
23.3%	42.3%

The likely point of original contamination occurred when the produce was in the raw agricultural commodity (RAC) form

Produce is one of the highest food categories for food-borne illnesses in United States!

Produce Safety

Requirements and Goals

- Implement preventative practices to prevent fresh produce safety risks
- Prevention of biological hazards

Exemptions

- Based on sales/annum
- Based on farm size
- **Produce not consumed raw**

Covered

- Ninety percent (90%) of produce grown and consumed by Americans

Comments

- Due 22nd November 2013

Brewing Industry Concerns...

- FDA described hops as “edible flowers”
- Hops were not exempted
- Hops anti-microbial properties, substantiated by peer-reviewed and sound technical literature, have apparently gone unnoticed.....



Second Major Rule Mandated by FSMA

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



- **Company:** Peanut Corporation of America
- **Recall Year:** 2009
- **Commodities:** 3,913
- **Production Dates:** 1/1/2007 – 2/8/2009
- **Executives knowledge of issue:** 2006
- **Status:** 76 counts of criminal indictment for 4 Officials – 2/21/13

- **Biological Hazard:** *Salmonella*
- **Deaths:** 9
- **Confirmed Illnesses:** 19,000
- **States:** 43

The largest food recall in United States history!

Human Food

Requirements and Goals

- Risk-based preventative controls and current good manufacturing practices (CGMP) to prevent human food safety risks
- Protection of public health
- Prevention, or control of a food-borne illness outbreak

Exemptions

- Based on sales/annum
- Seafood and Juice
- **Alcohol beverages at “certain alcohol-related facilities”**

Covered

- **Majority FDA registered facilities**
- Manufacturers and Processors
- Warehouses and Storage Tanks
- Grain Elevators

Comments

- Due on 22nd November 2013

Brewing Industry Concerns...



- Beverage alcohol products were not “fully” exempted
- FDA suggested that beer companies are in 2 businesses:
 - Brewing beer/selling beer
 - Producing/selling spent grains
- Spent grains are the natural by-product, or residue of brewing beer
- **There is no compelling scientific reason to legislate spent grains as human food**
- If spent grains are legislated under human food rule, it can potentially become a huge economic burden for brewers, for a commodity not sold as such
- **Note:** Spent grains will also be addressed under the Animal Food Rule.

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Third and Fourth Major Rules Mandated by FSMA

Imports:

- (1) Foreign Supplier Verification Program (FSVP)*
- (2) Accredited Third Party Certification (will not be addressed)*



- **Company:** Beaver Valley Mall Chi-Chi's
- **Date of Outbreak:** November 2003
- **Commodity:** Green onions
- **Country of Origin:** Mexico
- **Immunization to prevent HAV:** 9,000

- **Biological Hazard:** *Hepatitis A Virus (HAV)*
- **Deaths:** 4
- **Confirmed Illnesses:** 650
- **State:** Pennsylvania

The worst Hepatitis A Virus outbreak in United States history!

Foreign Supplier Verification Program

Requirements and Goals

- Preventative practices to prevent imported food safety risks
- Proven compliance with U.S. laws and regulations

Exemptions

- Seafood and Juice
- Foods trans-shipped for export
- **Alcoholic beverages**

Covered

- Importers of foreign food commodities
- Importers of foreign food contact packaging materials

Comments

- Were due in 31st March 2014

Foreign Supplier Verification Program

Brewing Industry Concerns...

- Imported food commodities (e.g. specialty hops or malts) used in the brewing process were not exempted



- Imported food contact packaging materials (e.g. crowns and caps) used in the packaging of beverage alcohol products were not exempted



Fifth Major Rule Mandated by FSMA

Good Manufacturing Practices and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals



- **Companies:** 12 including Menu Foods
- **Date of Outbreak:** March 2007
- **Commodities:** Pet, Fish, Farm Animals Food
- **Brands:** 180
- **Country of Origin of Ingredients:** China
- **Findings:** Intentional contamination of wheat and rice gluten protein from China
- **Status:** Chinese and US Companies indicted



- **Chemical Hazard:** *Melamine*
- **Deaths:** 17 confirmed during taste test at Menu Foods, Canada
- **Confirmed Illnesses:** Uncertain
- **Region:** North America, Europe and South Africa

The largest pet food recall in North America!

Animal Food

Requirements and Goals

- Risk-based preventative controls and current good manufacturing practices (CGMP) to prevent animal food safety risks
- Animal food safety for animal consumption
- Animal food safety for humans handling animal food

Exemptions

- Based on sales/annum
- Low-acid canned animal foods
- Warehouses that store packaged animal foods

Covered

- **Majority FDA registered facilities**
- Manufacturers and Processors
- Packers and Holders

Comments

- Were due 31st March 2014

Brewing Industry Concerns...

- Why are spent grains and other by-products of the low risk brewing industry not included on the exemption list?
- Why add such an economic burden on the U.S. brewing industry in terms of compliance costs, possibly in the order of possibly \$128.75 million per annum?
- If the ingredients used in the brewing process are safe for humans, why would the resultant by-products, such as spent grains, not be safe for animals?
- *Please attend the Food Safety Workshop I on Thursday 5th June, 10:00 a.m. – 11:45 a.m. to learn more.....*



Sixth Major Rule Mandated by FSMA

Protecting Food Against Intentional Adulteration



Intentional Adulteration

Requirements and Goals

- Address hazards that may be intentionally introduced by acts of terrorism which can cause massive harm to the public health
- Protection of key activities that indicate significant vulnerability

Exemptions

- Based on sales/annum
- **Alcoholic beverages “under certain conditions”**

Covered

Manufacturing process steps:

- Bulk receiving and loading
- Liquid storage and handling
- Secondary ingredient handling
- Mixing and similar activities

Comments

- **Due on 30th June 2014**

Intentional Adulteration

Brewing Industry Concerns.....

- FSMA includes the phrases:
 - Alcoholic beverages at “certain alcohol-related facilities” or “under certain conditions”
- This suggests limitation in the scope of exemption
- Instead the phrase “manufacturing, processing, packing and holding of alcoholic beverages,” should be used as:
 - There is no evidence that facilities producing alcoholic beverages present any higher risk of impact on human health from adulteration caused by acts of terrorism

Seventh and Final Major Rule Mandated by FSMA

Sanitary Transport



- **Company:** The Schwan's Food Company
- **Date:** October 1994
- **Biological Hazard:** *Salmonella enteritidis*
- **Commodities:** Ice-cream pre-mix
- **State:** Southern Minnesota
- **Findings:**
 - The contamination was caused by a contractor's truck that delivered an ice cream pre-mix to Schwan's
 - The truck had previously carried raw, unpasteurized eggs and the tank had not been properly washed between loads

Sanitary Transport

Requirements and Goals

- Practices to prevent food safety risks during transportation
- Temperature control
- **Cleaning between loads**
- Separation of items in a load
- Carrier personnel training (e.g. food safety, documentation)
- Prior commodity certificate
- Vehicle inspection
- Written procedures
- **Dedicated carriers**

Comments

- **Due 30th July 2014**

Exemption

- Based on sales/annum
- Foods trans-shipped for export
- **Shelf stable food completely enclosed by a container**

Covered

- The transportation of all human and animal food
- Shippers
- Receivers
- Carriers (air, rail, road, sea)

Sanitary Transport

Brewing Industry Concerns....

- Finished beverage alcohol products are shelf-stable, completely enclosed by a container and should be exempted.
- Profitability
 - FDA estimates the total cost for the first year to comply at \$149.1 million
- Personnel
 - Additional personnel required to comply with requirements
- Transportation practices and partnership between transportation companies
 - The recordkeeping, information-exchange and training requirements, may be new to some carriers of food and could present challenges.
- Facility Upgrade
 - Loading and unloading bay areas to comply with Good Manufacturing Practices (GMP)

Summary

Summary...

For information on FSMA: <http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm>

It is expected that that the **Revised** and **Final Rules will** include the concerns raised by the Brewing Industry. The dates are as follows:

- **Summer 2014**
 - Animal Food - Clarification and revision for animal feed and by-products
- **30th August, 2015**
 - Preventive Controls for Human Food and Preventive Controls for Animal Food
- **31st October, 2015**
 - Produce Safety
 - Foreign Supplier Verification Program
 - Third-Party Accreditation (not included in this presentation)
- **31st March, 2016**
 - Sanitary Transport
- **31st May 2016**
 - Intentional Adulteration



Acknowledgements/Questions

- ASBC
- MillerCoors
- Cecil Giarrantano
- You, the audience
for listening!

