The Impact of New Food Safety Regulations (FSMA) in the US

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Food Safety
A global challenge.

- 1 in 10 people fall ill every year after eating contaminated food (WHO, 2015)
- Children under 5 years old affected the most
- 1.3 billion tonnes of food is lost or wasted every year
- 25% of this is caused by spoilage by microorganisms
- An average cost of a recall is $10 million
- Most recalls are because of microbial contamination
Food Safety concerns all actors along the value chain
Pressure to act builds up from the end product / consumer side
**FOOD SAFETY – Producers’ perspective**

Food producers have the legal obligation to ensure food safety.

- Food producers need to implement appropriate preventive measures to reduce food safety risks.
- Feed producers also need to deliver safe feed to protect animals and the food thereof.
- Producers usually seek Food Safety certification by GFSI, IFS, BRC or FS22000.
- The strongest drivers of food safety standards are retailers and caterers.
- Food Safety cannot be handled at one point in the processing chain and needs a comprehensive value chain approach.

Protect health!

Healthy animals
Food Safety Modernization Act

FSMA signed into Law in January 2011

Premise:
Current food safety has opportunity for improvement
1 in 6 Americans (48 million) sickened, 128,000 hospitalized, 3,000 die each year from foodborne diseases (CDC, 2011)
“Most sweeping reform of our food safety laws in more than 70 years.”

GOAL: “Aims to ensure the U.S. food supply is safe by shifting the focus of federal regulators from responding to contamination to preventing it.”
Paradigm change in food safety management

The past
Just testing........

Today
Preventive risk management (HACCP*)

* HACCP (Hazard Analysis & Critical Control Point)

** Critical Control Point

IAOM-Latin American Region 2020
The Food Safety Modernization Act Consists of four Titled Sections:

**Title I:**
Improving Capacity to Prevent Food Safety Problems

i. Inspection of records
ii. Food facilities registration
iii. HARPC
iv. Sanitary transportation

**Title II:**
Improving Capacity to Detect and Respond to Food Safety Problems

i. Mandatory recall authority
ii. Lab accreditation
iii. Administrative detention of Food

**Title III:**
Improving the Safety of Imported Food

i. Foreign Suppliers Verification Pgm
ii. Importers certification
iii. Inspection of foreign food facil.
iv. Accreditation of Third party aud.

**Title IV:**
Miscellaneous Provisions
Seven Pillars of FSMA

- PCHF
- PCAF
- Produce Safety
- FSVP
- 3rd Party
- Food Defense
- Sanitary Transport
Food Safety Modernization Act

FSMA Food Rule

Requirements established for:
1. A written food safety plan
2. Hazard analysis
3. Preventative controls for **known or reasonably foreseeable** biological, chemical, and physical hazards. It includes process, food allergen, and sanitation controls, as well as supply-chain controls and a recall plan.
4. Monitoring
5. Corrective action
6. Verification
7. Associated records
Identifying Hazards
1.1. Biological (i.e. microbiological)
1.2. Chemical (i.e. mycotoxins)
1.3. Radiological
1.4. Physical
1.5. Economically Motivated Adulteration
1.6. Includes an assessment of the severity of illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.
Where do we start a Food Safety plan?

1) Everything starts with the product(s) being manufactured and its intended use
2) Then, we need to understand the layout of the manufacturing facility
   1) flow charts, diagrams, P&IDs
   2) walking through the facility to verify it
   3) Understanding the overall risk profile
3) Each FS Plan must be customized so it applies to a particular facility, the products produced, the incoming ingredients used and other relevant factors
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<th>Ingredient or Processing Step</th>
<th>Identification</th>
<th>Evaluation</th>
<th>Prevention</th>
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<td>Ingredient or Processing Step</td>
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<td>Determine the Severity for the Food Safety Hazard</td>
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<td>1) Incoming ingredients are tested for mycotoxins based on the type of material received and testing schedule described in SOP-XX. Testing serves as a verification of a supplier meeting our requirements. 2) Testing results from local grain demonstrate concerns for mycotoxins are low for previous growing season. 3) Review of customer complaints shows no concerns in regards to mycotoxins in finished products.</td>
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Food Safety Hazards – Biological

- Bacteria
- Viruses
- Mold
- Insects
We build knowledge for designing safe food & feed processing
Example of bacteria removal or inactivation in wheat processing

Typical microorganism load as Aerobic Plate Count (APC) in wheat products

Some pathogenic microorganism like *Salmonella* are more heat resistant than most of the bacteria that live of wheat. Efficacy of *Salmonella* inactivation needs to be proved by validation.
Food Safety starts with the hygienic layout and zoning of factory

Typical zoning for processing line for wheat flour & refrigerated cookie dough

- Delivery & storage of soft wheat
- Cleaning
- Grading & sorting
- Conditioning
- Grinding & sifting
- Trapping of flour type 400
- Flour storage
- Heat treatment (no steam)
- Dry ingredients mixing
- Dough formation
- Dough packing & refrigeration (5°C)
- Storage at retailer & end consumer
- Home-baking of cookies

- Microbial Kill step
- High extraction flour
- Rejects
- Bran
- High extraction flour
- Rejects
- Water
- Air
- Microbial Kill step

- Basic Hygiene Zone
- Medium Hygiene Zone
- High Hygiene Zone

- Sugar
- Fat
- Water
- Leavening agent
- Emulsifier

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FSMA Inspections: What have we learned?
(Source: FDA Priorities, M. Moorman, Director of Food Safety-CFSAN)

- Majority of Inspections have been focused on CGMP & PCHF
- Domestic: 349 inspections, 203 #483’s issued (58%). Projected FY20, approx. 800 inspections.
- CGMP Top 5 observations:
  - Manufacturing, Processing, Packing, Holding-COMMENTS
  - Equipment & Utensils-Design & Maintenance
  - Sanitary Operations-Plant Maintenance
  - Personnel
  - Pest Control

- PCHF Top 5 observations:
  - Hazard Analysis –Identification Hazard
  - Sanitation Controls Verification Procedures (Establish and Implement)
  - Food Safety Plan
  - Allergen Controls Monitoring Procedures: Establish and Implement
  - Sanitation Controls Monitoring Procedures: Establish and Implement
FSMA Inspections: What have we learned?
(Source: FDA Priorities, M. Moorman, Director of Food Safety-CFSAN)

- Foreign Supplier Verification Program: 159 inspections, 67 #483’s issued (42%)
- Significant Observations
  - Failure to:
  - Develop an FSVP
  - Have a written Hazard Analysis
  - Establish written procedures to ensure that foods are imported only from approved sources
  - Document approval of foreign supplier
  - Have a written evaluation of foreign supplier performance and the risk posed by
Trend: “Feed goes food and food goes pharma”

Closing the gap:
- Preventive food safety approach (HACCP)
- Hygienic design
- Inactivation / elimination of contaminants
- Process validation
- Monitoring & control
- Awareness & training
Thanks for your attention!

For feedback and questions please contact:

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gerardo.morantes@buhlergroup.com