

# 3 – A Sanitary Standards, Inc.

## 2011 Education Program

Milwaukee, Wisconsin

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# Components of the Act

(some elements extracted)

- Third Party Certification
  - Foreign Countries
  - US not specifically excluded



# Components of the Act

(some elements extracted)

- Mandatory Recall Authority
- Import Requirements
- Inspections
- Plant Registration
- *Hazard Analysis and Preventative Controls*
- Traceability



~~HACCP~~

# Hazard Analysis and Preventative Control (cont.)

## A. Hazard Analyses

- Biological
- Chemical
- Physical
- Radiological

# Hazard Analysis and Preventative Control

## Hazard Analyses

- Natural Toxins
- Pesticides
- Drug residue
- Decomposition
- Parasites
- Allergens
- Unapproved food and color additives
- Intentionally introduced

## Preventative Control

- May include:
  - Sanitation procedures (SSOPs)
  - Environmental monitoring (verification)
  - Allergen Control
  - Recall plan
  - cGMPs
  - Supplier verification

Kill Step? How does that factor into the equation?

# The Seven HACCP Principles

- *Conduct a hazard analysis.*
- *Identify critical control points (CCP).*
- *Establish critical limits for each CCP.*
- *Establish CCP monitoring requirements.*
- *Establish corrective actions.*
- *Establish record keeping procedures.*
- *Establish procedures for verifying the HACCP system is working as intended.*

# Reanalyze

- At least
  - Every three (3) years
  - Before significant changes occur
- Significant changes
  - New hazard – internal or external
  - Intentional hazard
- Document
  - Changes
  - Basis for no revisions required



# FDA Regulates Foods

- FDA does regulate sanitary use of equipment
- 21 CFR 110 – Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food
  - Subpart C - Equipment



# FDA Perspective on Equipment Sanitary Design

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The views expressed do not necessarily represent the official views  
or policies of the agency.

## §110.40 Equipment and utensils

- All plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable...
- The design, construction and use of equipment and utensils shall preclude the adulteration of food with lubricants...or any other contaminants.

## §110.40 Equipment and utensils

- Seams on food contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles...
- Holding, conveying and manufacturing systems...shall be of a design and construction that enables them to be maintained in a appropriate sanitary condition.

## §110.40 Equipment and utensils

- Food contact surfaces shall be maintained to protect food from being contaminated by any source...

“Reasonably appropriate procedures, practices, and processes”

- 3-A Standards ([www.3-a.org](http://www.3-a.org))
- NSF Standards for food equipment ([www.nsf.org](http://www.nsf.org))
- European Hygienic Engineering and Design Group (<http://www.ehedg.org/>)

# Action Against Violations

- If FDA determines equipment is not suitable for its intended use, it will go after the manufacturers that use it.
- This will not be good for business – either manufacturers or their equipment suppliers.

# Embrace Sanitary Design

- Equipment manufacturers have a responsibility with respect to cleaning and sanitation.
- Sanitary design cannot be secondary to functionality of equipment.



# Cooperative Efforts

- Equipment design engineers need to work with sanitarians / quality assurance / microbiologists / food technologists
- Assess designs for areas difficult to clean
- Design to allow quick access to hidden areas
- Easy disassembly, assembly

# Global Food Safety Initiative GFSI

**GFSI** – consortium of approximately 170 companies

- Purpose is to oversee the benchmarking process
- Ensure uniformity of audit content

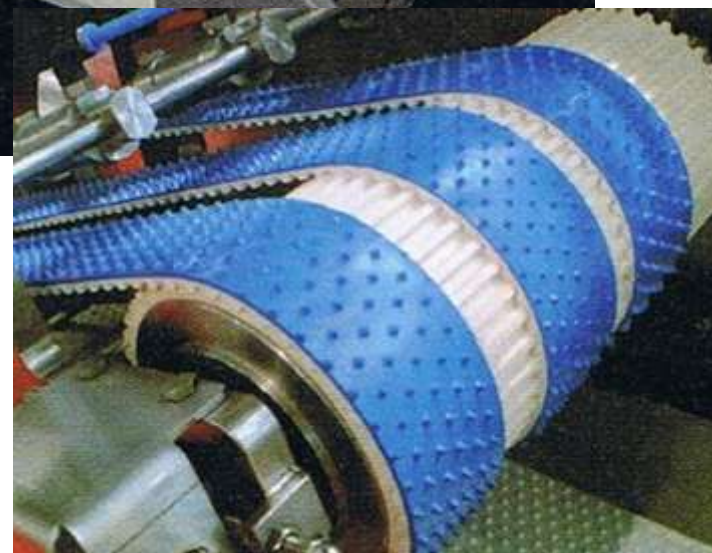
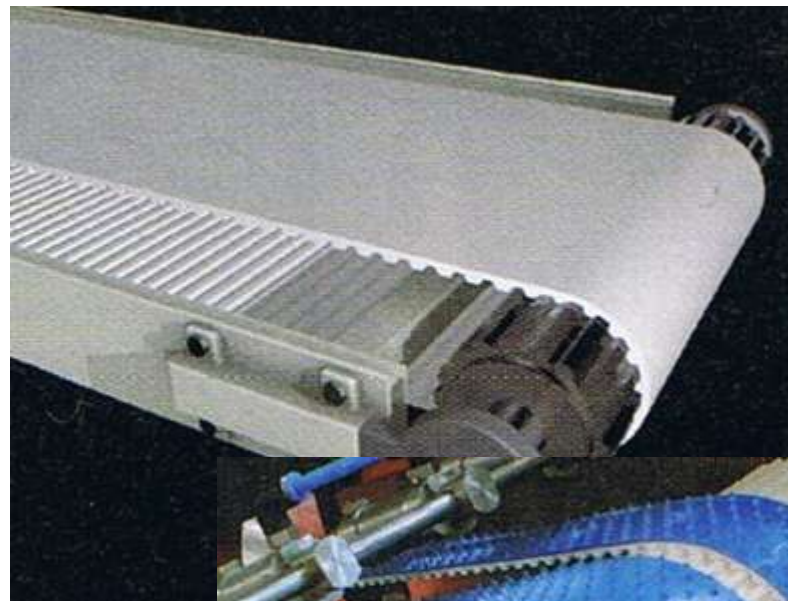
**Standard Owner** – organization that owns the Standard

- BRC, SQF, FSSC22000, IFS, etc
- Design and ensure the scheme
- Consistent with GFSI Benchmarking requirements

# The Standard Requirements

## 4.5 Equipment

- ▶ Suitably designed
- ▶ Properly specified before purchase
- ▶ Tested and commissioned before use
- ▶ Positioned for access
- ▶ Certificates of conformity for direct contact equipment



Thank You

Any Questions?

