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
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)
• NSF Standards for food equipment (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?