GLOBAL FOOD SAFETY: Hygienic Design & Food Safety Audits
Regulatory Perspective

Allen Sayler
Managing Partner
Center for Food Safety & Regulatory Solutions
3-A SSI 2016 Education Program May 17, 2016
Clarion Hotel, Milwaukee, WI
Allen R. Sayler
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**Background:**
- 30 years serving the US Dairy Industry as government regulator & industry advocate
- 12 years w/International Dairy Foods Association (IDFA) serving as primary HACCP, SQF and food safety trainer, advocating industry views with FDA, USDA and state dairy regulatory agencies and writing industry position papers
- Certified HACCP Trainer
- Experienced SQF & BRC Trainer & Consultant
- 2009 IAFP Harold Barnum Award Winner

**Education:**
BSc Biology & Human Physiology, University of Mary
Additional Course Work in Civil Engineering
2016 CFSRS Workshop Schedule

1. **Official FSMA Preventive Controls Qualified Individual Workshops**
   - May 31st, June 1st & 2nd @ 8:30 a.m.–5:00 p.m. MDT, Utah State, Logan, Utah
   - June 6th, 7th & 8th @ 8:30 a.m.–5:00 p.m. PDT, Fresno, California
   - July 19th, 20th & 21st @ 8:30 a.m.–5:00 p.m. EDT, Reston, Virginia

2. **CFSRS Advanced HACCP/HARPC Workshop**
   - May 23rd & 24, 8:30 am – 5:00 pm, MDT, Utah State, Logan, Utah

3. **Implementing SQF 7.2 Systems Workshop**
   - May 25th & 26th @ 8:30 a.m. - 5:00 p.m. MDT, Utah State, Logan, Utah
2016 CFSRS Webinar Schedule
(see www.cfsrs.com for current list, & dates):

1. FSMA Preventive Controls, FSV, TPC & Intentional Contamination Update
2. Crisis Readiness: How to Prepare for Operational Failures, Large-Scale Disasters and Everything in Between
3. Food Defense Strategies & FSMA’s Intentional Contamination Reg.
4. The Microbiology of Milk
5. Overview of Changes: 2013 Grade A Pasteurization Milk Ordinance
6. HTST & VAT Pasteurization Technology for Fluid Processors
7. Food Processing Instrumentation: Improving Control, Data Capture and Cost Management
8. Computerized Solutions for Food Processing Quality Assurance Programs
9. Industry Rights & Responsibilities During an FDA Investigation
10. SQF Practical Implementation Strategies
11. Survival Strategies on Managing a Recall
What Is Keeping Food Processing Company Executives Up At Night

America’s food industry has a $55.5 billion safety problem. – Forbes Magazine, May 2016

GROWTH IN RECALLS

USDA-regulated (meat and poultry products)
2004: 48
2014: 94

FDA-regulated (non-meat products)
2004: 240
2014: 565

REASON FOR RECALL

<table>
<thead>
<tr>
<th>Reason</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microbiological Contamination</td>
<td>47%</td>
</tr>
<tr>
<td>Labeling Issue</td>
<td>26%</td>
</tr>
<tr>
<td>Processing Defect</td>
<td>13%</td>
</tr>
<tr>
<td>Physical Contamination</td>
<td>7%</td>
</tr>
<tr>
<td>Chemical Contamination</td>
<td>6%</td>
</tr>
<tr>
<td>Unapproved Ingredients</td>
<td>1%</td>
</tr>
</tbody>
</table>

Recall Cost Calculator*

Retail cost of recalled product × Quantity of recalled product + Notification costs 4% + Transportation costs 10% = Direct cost of recall

*approximation formula

Swiss RE; USDA; FDA
Define: Risk (Hazard)

Biological

- Vegetative Pathogens
- Parasites
- Intentional Bioterrorism
Define: Risk (Hazard)

Chemical

- Antibiotics
- Natural Toxins
- Pesticides
- Allergens
- Unapproved Additives
- Intentional Bioterrorism
Define: Risk (Hazard)

Physical

- Metal
- Wood
- Glass
- Intentional Bioterrorism
WHAT ABOUT THESE EXAMPLES? USED IN MARCH 2003 FOOD SAFETY MAGAZINE ARTICLE
### EXAMPLES OF EQUIPMENT DESIGN CHALLENGES

<table>
<thead>
<tr>
<th>Bearing Auger / Mixer Shaft Non-Drive Side:</th>
<th>Interior of Auger / Mixer:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Flush mounted bearing. Limited access to back side of bearing to clean old grease. Lap joint = opportunity for harborage. 2. Painted carbon steel bearing block will not hold up to wash down environment. Compatible material deficiency. 3. Over time, oxidation could contaminate the stainless steel and impact product contact surfaces directly.</td>
<td>1. Welds are not free of pits. Inconsistent bead width creates a potential niche. Welds need to be redone and polished to a product contact surface requirement with a 1/4 inch radius.</td>
</tr>
</tbody>
</table>
Stainless steel plate as received from the mill w/cracks and crevices. After use in a food plant, microbes have settled into those cracks and crevices.

Photos 5, 6 and 7 illustrate a sanitary butt weld. In the first photo, we see a flat plate welded on one side without backer rod—and the depression that is a hiding place for microbes and soils. In the second shot, the plate is welded with backer rod but it has not yet been ground and polished and thus still poses some food safety risk. Finally, we see the ground and polished sanitary weld.
ROLLED EDGES

EQUIPMENT LEGS

HOLLOW CONVEYOR ROLLER

PUMPS & MOTOR MOUNTING MAKES CLEANING DIFFICULT

Black stuff in drive roller after disassemble from frame and shaft taken apart.
Data taken prior to the two day Kollmorgen Advisory Council meeting at Virginia Tech

- 25 participants (we sent to 50 and got 25 to participate)
- 44 total questions...pretty extensive
Q12: Which of these best describes how you feel about the cleanliness of components that are bagged and wiped instead of washed down?

- Answered: 23    Skipped: 2
Q13: Do you feel you are compromising your sanitation process to ensure reliability of the machines by protecting sensitive components?

- Answered: 23  Skipped: 2
Q16: Do you find yourself at odds with your production goals as you drive better hygienic sanitation processes?

- Answered: 23   Skipped: 2
Q38: What is your biggest barrier to procuring a cleanable, hygienically designed piece of equipment?

- Answered: 20    Skipped: 5
<table>
<thead>
<tr>
<th>3A Sanitary Standards</th>
<th>FDA FSMA Preventive Controls for Human Foods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food contact surface is any surface that has direct contact with food residue, or where food residue can drip, drain, diffuse or be drawn and surfaces that touch the product contact surfaces (as per Dr. Ron Schmidt’s Food Safety article 2013)</td>
<td><strong>Food-contact surfaces</strong> are those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. “Food-contact surfaces” includes utensils and food-contact surfaces of equipment</td>
</tr>
</tbody>
</table>
Department of Health and Human Services

Food and Drug Administration

Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food; Final Rule
(d) All food-contact surfaces, including utensils and food-contact surfaces of equipment, must be cleaned as frequently as necessary to protect against allergen cross-contact and against contamination of food.

(1) Food-contact surfaces used for manufacturing/processing, packing, or holding low-moisture food must be in a clean, dry, sanitary condition before use. When the surfaces are wet-cleaned, they must, when necessary, be sanitized and thoroughly dried before subsequent use.

(2) In wet processing, when cleaning is necessary to protect against allergen cross-contact or the introduction of microorganisms into food, all food-contact surfaces must be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment must be cleaned and sanitized as necessary.
21 CFR 117.40 Equipment

(a) (1) All plant equipment and utensils used in manufacturing, processing, packing, or holding food must be so designed and of such material and workmanship as to be adequately cleanable, and must be adequately maintained to protect against allergen cross-contact and contamination.

(2) Equipment and utensils must be designed, constructed, and used appropriately to avoid the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.

(3) Equipment must be installed so as to facilitate the cleaning and maintenance of the equipment and of adjacent spaces.

(4) Food-contact surfaces must be corrosion-resistant when in contact with food.
(5) Food-contact surfaces must be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds, sanitizing agents, and cleaning procedures.

(6) Food-contact surfaces must be maintained to protect food from allergen cross-contact and from being contaminated by any source, including unlawful indirect food additives.

(b) Seams on food-contact surfaces must be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact.

(c) Equipment that is in areas where food is manufactured, processed, packed, or held and that does not come into contact with food must be so constructed that it can be kept in a clean and sanitary condition.
(d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, must be of a design and construction that enables them to be maintained in an appropriate clean and sanitary condition.

(f) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food must be accurate and precise and adequately maintained, and adequate in number for their designated uses.

(g) Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment must be treated in such a way that food is not contaminated with unlawful indirect food additives.
(c) Manufacturing operations.

(1) Equipment and utensils and food containers must be maintained in an adequate condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment must be taken apart for thorough cleaning.

(7) Equipment, containers, and utensils used to convey, hold, or store raw materials and other ingredients, work-in-process, rework, or other food must be constructed, handled, and maintained during manufacturing, processing, packing, and holding in a manner that protects against allergen cross-contact and against contamination.
Part III

Department of Health and Human Services

Food and Drug Administration


Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals; Final Rule
Animal food-contact and non-contact surfaces of utensils and equipment must be cleaned and maintained and utensils and equipment stored as necessary to protect against the contamination of animal food, animal food-contact surfaces, or animal food-packaging materials. **When necessary, equipment must be disassembled for thorough cleaning.**
(a) The following apply to plant equipment and utensils used in manufacturing, processing, packing, and holding animal food:

(1) All plant equipment and utensils, including equipment and utensils that do not come in contact with animal food, must be designed and constructed of such material and workmanship to be adequately cleanable, and must be properly maintained;

(2) Equipment and utensils must be designed, constructed, and used appropriately to avoid the adulteration of animal food with non-food grade lubricants, fuel, metal fragments, contaminated water, or any other contaminants;

(3) Equipment must be installed so as to facilitate the cleaning and maintenance of the equipment and adjacent spaces;
Animal food-contact surfaces must be:

(i) Made of materials that withstand the environment of their use and the action of animal food, and, if applicable, the action of cleaning compounds, cleaning procedures, and sanitizing agents;

(ii) Made of nontoxic materials; and

(iii) Maintained to protect animal food from being contaminated.

Holding, conveying, manufacturing, and processing systems, including gravimetric, pneumatic, closed, and automated systems, must be designed, constructed, and maintained to protect against the contamination of animal food.

Instruments and controls used for measuring, regulating, or recording temperatures, pH, aw, or other conditions that control or prevent the growth of undesirable microorganisms in animal food must be accurate, precise, adequately maintained, and adequate in number for their designated uses.

Compressed air or other gases mechanically introduced into animal food or used to clean animal food-contact surfaces or equipment must be used in such a way to protect against the contamination of animal food.
Human food by-products held for distribution as animal food will protect against contamination, including the following:

1. **Containers and equipment** used to convey or hold human food by-products for use as animal food before distribution must be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of human food by-products for use as animal food;

2. Human food by-products for use as animal food held for distribution must be held in a way to protect against contamination from sources such as trash; and

Shipping containers (e.g., totes, drums, and tubs) and bulk vehicles used to distribute human food by-products for use as animal food must protect against the contamination of animal food when the facility is responsible for transporting the animal food itself or arranges with a third party to transport
21 CFR 507.28 Holding & Distribution of Human Food By-Products for Use as Animal Food

(a) Human food by-products held for distribution as animal food will protect against contamination, including the following:

(1) Containers and equipment used to convey or hold human food by-products for use as animal food before distribution must be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of human food by-products for use as animal food;

(2) Human food by-products for use as animal food held for distribution must be held in a way to protect against contamination from sources such as trash; and

(b) Shipping containers (e.g., totes, drums, and tubs) and bulk vehicles used to distribute human food by-products for use as animal food must protect against the contamination of animal food when the facility is responsible for transporting the animal food itself or arranges with a third party to transport
Sanitation controls. Sanitation controls include procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens and biological hazards due to employee handling. Sanitation controls must include, as appropriate to the facility and the animal food, procedures, practices, and processes for:

(i) Cleanliness of animal food-contact surfaces, including animal food-contact surfaces of utensils and equipment; and
Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 1 and 11
Sanitary Transportation of Human and Animal Food; Final Rule
Carrier means a person who physically moves food by rail or motor vehicle in commerce within the United States. The term carrier does not include any person who transports food while operating as a parcel delivery service.

Shipper means a person, e.g., the manufacturer or a freight broker, who arranges for the transportation of food in the United States by a carrier or multiple carriers sequentially.
21 CFR 1.906 Vehicle & Transportation Equipment

**Bulk vehicle:** means a tank truck, hopper truck, rail tank car, hopper car, cargo tank, portable tank, freight container, or hopper bin, or any other vehicle in which food is shipped in bulk, with the food coming into direct contact with the vehicle.

**Transportation equipment** means equipment used in food transportation operations, e.g., bulk and non-bulk containers, bins, totes, pallets, pumps, fittings, hoses, gaskets, loading systems, and unloading systems. Transportation equipment also includes a railcar not attached to a locomotive or a trailer not attached to a tractor.

**Vehicle** means a land conveyance that is motorized, e.g., a motor vehicle, or that moves on rails, e.g., a railcar, which is used in transportation operations.
(a) Vehicles and transportation equipment used in transportation operations must be so designed and of such material and workmanship as to be suitable and adequately cleanable for their intended use to prevent the food they transport from becoming unsafe, i.e., adulterated within the meaning of section 402(a)(1), (2), and (4) of the Federal Food, Drug, and Cosmetic Act during transportation operations.

(b) Vehicles and transportation equipment must be maintained in such a sanitary condition for their intended use as to prevent the food they transport from becoming unsafe during transportation operations.
(c) Vehicles and transportation equipment used in transportation operations for food requiring temperature control for safety must be designed, maintained, and equipped as necessary to provide adequate temperature control to prevent the food from becoming unsafe during transportation operations.

(d) Vehicles and transportation equipment must be stored in a manner that prevents it from harboring pests or becoming contaminated in any other manner.
<table>
<thead>
<tr>
<th>Proposed section (§)</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.906(a)</td>
<td>Specifies that vehicles and transportation equipment must be designed and of such material and workmanship to be suitable and adequately cleanable for their intended use to prevent food from becoming adulterated.</td>
</tr>
<tr>
<td>1.906(b)</td>
<td>Specifies that vehicles and transportation equipment must be maintained in such sanitary condition for their intended use to prevent food from becoming adulterated.</td>
</tr>
<tr>
<td>1.906(c)</td>
<td>Specifies that vehicles and transportation equipment used for food requiring temperature control for safety must be designed, maintained and equipped, as necessary, to provide adequate temperature control to prevent the food from becoming adulterated.</td>
</tr>
<tr>
<td>1.906(d)</td>
<td>Specifies that freezers and mechanically refrigerated cold storage compartments to be equipped with an indicating thermometer, temperature measuring device, or temperature recording device to show the temperature accurately with the compartment.</td>
</tr>
<tr>
<td>1.906(e)</td>
<td>Specifies that vehicles and transportation equipment must be stored in a manner that prevents harborage of pests or becoming contaminated in any other manner that could result in food becoming adulterated.</td>
</tr>
</tbody>
</table>
Consequences: New Prohibited Acts

It is a prohibited act to:

- Fail to establish or maintain records
- Refuse access to or verification or copying of any such required record
- Fail to make records available to FDA as required by section 414 or 704(a) of the act and this regulation
SQF 7.2 Code

2.4.6 Non-conforming Product or Equipment

2.4.6.1 The responsibility and methods outlining how non-conforming product, raw material, ingredient, work-in-progress, packaging or equipment detected during receipt, storage, processing, handling or delivery is handled shall be documented and implemented. The methods applied shall ensure:

ii. Non-conforming equipment is effectively repaired or disposed of in a manner that minimizes the risk of inadvertent use, improper use or risk to the integrity of finished product; and

iii. All relevant staff is aware of the organization’s quarantine and release requirements applicable to equipment or product placed under quarantine status.

2.4.6.2 Quarantine records, and records of the handling, corrective action, or disposal of non-conforming product or equipment shall be maintained.
11.2.1 Materials and Surfaces

11.2.1.1 Product contact surfaces and those surfaces not in direct contact with food in food handling areas, raw material storage, packaging material storage, and cold storage areas shall be constructed of materials that will not contribute a food safety risk.

11.2.9 Premises and Equipment Maintenance

11.2.9.4 Equipment located over product or product conveyors shall be lubricated with food grade lubricants and their use controlled so as to minimize the contamination of the product.

11.2.9.5 Paint used in a food handling or contact zone shall be suitable for use and in good condition and shall not be used on any product contact surface.
11.2.12.1 Equipment and utensils shall be designed, constructed, installed, operated and maintained so as not to pose a contamination threat to products.

11.2.12.2 Benches, tables, conveyors, mixers, mincers, graders and other mechanical processing equipment shall be hygienically designed and located for appropriate cleaning. Equipment surfaces shall be smooth, impervious and free from cracks or crevices.

11.2.12.3 Product containers, tubs, bins for edible and inedible material shall be constructed of materials that are non-toxic, smooth, impervious and readily cleaned.

11.2.13.8 A record of pre-operational hygiene inspections, cleaning and sanitation activities, & verification activities shall be maintained.
11.7.5.3 The use of temporary fasteners such as string, wire or tape to fix or hold equipment shall not be permitted.

11.7.5.6 Loose metal objects on equipment, equipment covers and overhead structures shall be removed or tightly fixed so as not to present a hazard.
GLOBAL STANDARD

FOOD SAFETY
<table>
<thead>
<tr>
<th>2.2</th>
<th>Prerequisite programmes</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.2.1</td>
<td>The site shall establish and maintain environmental and operational programmes necessary to create an environment suitable to produce safe and legal food products (prerequisite programmes). As a guide these may include the following, although this is not an exhaustive list:</td>
</tr>
<tr>
<td></td>
<td>• cleaning and sanitising</td>
</tr>
<tr>
<td></td>
<td>• pest control</td>
</tr>
<tr>
<td></td>
<td>• <strong>maintenance programmes for equipment</strong> and buildings</td>
</tr>
<tr>
<td></td>
<td>• personal hygiene requirements</td>
</tr>
<tr>
<td></td>
<td>• staff training</td>
</tr>
<tr>
<td></td>
<td>• purchasing</td>
</tr>
<tr>
<td></td>
<td>• transportation arrangements</td>
</tr>
<tr>
<td></td>
<td>• processes to prevent cross-contamination</td>
</tr>
<tr>
<td></td>
<td>• allergen controls</td>
</tr>
</tbody>
</table>

The control measures and monitoring procedures for the prerequisites must be clearly documented and shall be included within the development and reviews of the HACCP.
In addition to the internal audit programme there shall be a programme of documented inspections to ensure that the factory environment and processing equipment is maintained in a suitable condition for food production. These inspections shall include:

- hygiene inspections to assess cleaning and housekeeping performance
- fabrication inspections to identify risks to the product from the building or equipment.

The frequency of these inspections shall be based on risk but will be no less than once per month in open product areas.
3.5.3.1 There shall be a documented procedure for the approval and monitoring of suppliers of services. Such services shall include, as appropriate:

- pest control
- laundry services
- contracted cleaning
- contracted servicing and maintenance of equipment
- transport and distribution
- off-site storage of ingredients, packaging or products
- laboratory testing
- catering services
- waste management.
### BRC ISSUE #7 – Global Food Safety Standard

<table>
<thead>
<tr>
<th>4.6</th>
<th>Equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Statement of Intent</strong></td>
<td>All food-processing equipment shall be suitable for the intended purpose and shall be used to minimise the risk of contamination of product.</td>
</tr>
<tr>
<td><strong>4.6.1</strong></td>
<td>All equipment shall be constructed of appropriate materials. The design and placement of equipment shall ensure it can be effectively cleaned and maintained.</td>
</tr>
<tr>
<td><strong>4.6.2</strong></td>
<td>Equipment which is in direct contact with food shall be suitable for food contact and meet legal requirements where applicable.</td>
</tr>
<tr>
<td>4.7</td>
<td>Maintenance</td>
</tr>
<tr>
<td>-------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Statement of Intent</strong></td>
<td>An effective maintenance programme shall prevent contamination and reduce the potential for breakdowns.</td>
</tr>
<tr>
<td><strong>4.7.1</strong></td>
<td>There shall be a documented planned maintenance schedule which includes all plant and processing equipment. The maintenance requirements shall be defined when commissioning new equipment.</td>
</tr>
<tr>
<td><strong>4.7.2</strong></td>
<td>Where there is a risk of product contamination by foreign bodies, the equipment shall be inspected at predetermined intervals, inspection results documented and appropriate action taken.</td>
</tr>
<tr>
<td><strong>4.7.3</strong></td>
<td>Temporary measures shall be permanently repaired as soon as practicable and within a defined timescale.</td>
</tr>
<tr>
<td>4.7.4</td>
<td>The site shall ensure that the safety or legality of product is not jeopardised during maintenance and subsequent cleaning operations. Maintenance work shall follow a documented hygiene clearance procedure, which records that product contamination hazards have been removed from machinery and equipment.</td>
</tr>
<tr>
<td>4.7.5</td>
<td>Maintenance activities undertaken in high-risk and high-care areas shall respect the segregation requirements of the area with dedicated tools retained in the area whenever possible.</td>
</tr>
<tr>
<td>4.7.6</td>
<td>Materials used for equipment and plant maintenance and that pose a risk by direct or indirect contact with raw materials, intermediate and finished products, such as lubricating oil, shall be food grade and of a known allergen status.</td>
</tr>
</tbody>
</table>
4.11 Cleaning systems shall ensure appropriate standards of hygiene are maintained at all times and the risk of product contamination is minimized.

Fundamental Statement Of Intent

4.11.1 The premises and equipment shall be maintained in a clean and hygienic condition.

4.11.2 Cleaning procedures for processing equipment, food contact surfaces and environmental cleaning in high-care/high-risk areas shall include the:

- responsibility for cleaning
- item/area to be cleaned
- frequency of cleaning
- method of cleaning, including dismantling equipment for cleaning purposes where required
- cleaning chemicals and concentrations
- cleaning materials to be used
- cleaning records and responsibility for verification.
4.11.3 Food contact surfaces, processing equipment and for environmental cleaning in high-care/high-risk areas, limits of acceptable and unacceptable cleaning performance shall be defined. Acceptable levels of cleaning may be defined by visual appearance, ATP bioluminescence techniques (see glossary), microbiological testing or chemical testing as appropriate. Where cleaning procedures are intended to control the risk of a specific hazard, the cleaning and disinfection procedures and frequency shall be validated and records maintained. This shall include the risk from cleaning chemical residues on food contact surfaces.
4.11.4 Where it is necessary to dismantle equipment for cleaning purposes or to enter large equipment for cleaning, this shall be appropriately scheduled. Engineering support provided where access within equipment is required for cleaning.

4.11.5 The cleanliness of equipment shall be checked before equipment is released back into production. The results of checks on cleaning, including visual, analytical and microbiological checks, shall be recorded and used to identify trends in cleaning performance and instigate improvements where required.
4.11.6 Cleaning equipment shall be:

- hygienically designed and fit for purpose
- suitably identified for intended use (e.g. colour coded or labelled)
- cleaned and stored in a hygienic manner to prevent contamination.

Equipment used for cleaning in high-care and high-risk areas shall be visually distinctive and dedicated for use in that area.
4.11 A schematic diagram of the layout of the CIP system including process piping circuits shall be available. There shall be an inspection report or other validation that:

- systems are hygienically designed with no dead areas, limited interruptions to flow streams and good system drain ability
- scavenging/return pumps are operated to ensure that there is no build-up of CIP solutions in the vessels
- spray balls and rotating spray devices effectively clean vessels by providing full surface coverage and are periodically inspected for blockages
- CIP equipment has adequate separation from active product lines (e.g. through the use of double seat valves, manually controlled links, blanks in pipework or make-or-break connections with proxy switches as interlocks) to prevent or safeguard against cross-contamination.
- The system shall be revalidated following alterations or additions to the CIP equipment. A log of changes to the CIP system shall be maintained.
4.11 The CIP equipment shall be operated to ensure effective cleaning is carried out:

- The process parameters, time, detergent concentrations, flow rate and temperatures shall ensure removal of the appropriate target hazard (e.g. soil, allergens, vegetative microbes, spores). This shall be validated and records maintained.
- Detergent concentrations shall be checked routinely.
- CIP process verification shall be undertaken by analysis of rinse waters and/or first product through the line for the presence of cleaning fluids or by tests of ATP (bioluminescence techniques), allergens or micro-organisms as appropriate.
- Detergent tanks shall be kept stocked up and a log maintained of when these are drained, cleaned, filled and emptied. Recovered post-rinse solutions shall be monitored for a build-up of carry-over from the detergent tanks.
- Filters, where fitted, shall be cleaned and inspected at a defined frequency.
| 6.1.4 | Where variation in processing conditions may occur within equipment critical to the safety or quality of products, the processing characteristics shall be validated and verified at a frequency based on risk and performance of equipment (e.g. heat distribution in retorts, ovens and processing vessels; temperature distribution in freezers and cold stores). |
What Keeps You Up At Night

May 4, 2016
Blue Bell Ice Cream Recalled Due To Packaging Mistake

Who Has the First Question?

Thank You! Allen R. Sayler
asayler@CFSRS.org