Why is Sanitary Design Critical?
- Protecting your Customers

The three most common culprits for food contamination are Listeria, e-Coli, and Salmonella. Sanitary food equipment and processing is the main defense against contaminated food. It is important because sanitary conditions protect your customers, and protects the livelihood of your employees.

**Listeria**
http://en.wikipedia.org/wiki/Listeria

Commonly found in uncooked meats, uncooked vegetables, unpasteurized milk, foods made from unpasteurized milk, and processed foods. Listeria is killed by pasteurization and cooking.

**Salmonella**
http://en.wikipedia.org/wiki/Salmonella

Commonly found in Poultry, meats and raw eggs. Thorough cooking and washing hands after handling raw meats kills Salmonella.

**E-coli**
http://en.wikipedia.org/wiki/scherichia_coli

Commonly found in unwashed vegetables or undercooked meat. Thorough cooking and washing hands after handling raw meats kills E-coli.
Who Sets the Standards?

There are several agencies involved in the Sanitary Design and the Sanitary Production of food goods. In this publication, we will discuss the five that have the broadest impact on the Food Industry today. They have different histories, different functions, and different levels of legal responsibility. Each has its own publications and websites and further information on the different organizations should be sought through those channels.

Ensuring Product Quality

The American Meat Institute (AMI), United States Department of Agriculture (USDA), and 3-A (an independent organization of equipment manufacturers, food processors, and regulatory agencies) are probably the best-recognized experts in the area of good design practices for sanitary equipment applications. Each of the three has a slightly different approach to the task of making equipment safe for product of Ready-To-Eat (RTE) food. RTE food is anything that the consumer may eat without additional preparation. This includes foods that are normally heated before serving, but could be eaten without preparation because of emergency, or personal preference. This presentation aims to take the keys points of ten different areas considered when evaluating a design for suitability in a RTE Food application, and show examples of good and better construction.
AMI

American Meat Institute

www.meatami.com

AMI is a national trade association that represents companies that process 95 percent of red meat and 70 percent of turkey in the US. Headquartered in metropolitan Washington, DC, AMI keeps its fingers on the pulse of legislation, regulation and media activity that impacts the meat and poultry industry and provides rapid updates and analyses to its members to help them stay informed. In addition, AMI conducts scientific research through its American Meat Institute Foundation designed to help meat and poultry companies improve their plants and their products. The Institute’s many meetings and educational seminars also provide excellent networking and information-sharing opportunities for members of the industry.

The American Meat Institute (AMI) is the nation’s oldest and largest meat and poultry trade association. AMI is dedicated to increasing the efficiency, profitability and safety of meat and poultry trade worldwide.

AMI does not provide third-party reviews of food-packaging equipment, but does provide excellent, current, review tools to assess sanitary design for food producers and equipment manufacturers. METTLER TOLEDO is an AMI member, and their Sanitary Design Checklist was used as a framework in preparing some of the materials for this publication.

AMI does not have legal authority over food production, but its membership which includes the major meat and food manufacturers, gives it a direct and major influence on the industry.
USDA
United States Department of Agriculture
www.usda.gov

USDA Meat & Poultry
The United States Department of Agriculture (USDA) is the federal government agency that is responsible for the safe food supply for the United States. The USDA does this directly through plant inspection, and indirectly by providing evaluation of equipment used in the processing and packaging of food goods. Within USDA, there are two branches of the department that have expertise in sanitary equipment construction - one for Meat and Poultry, and, the other for Dairy.

Dairy grading assists the dairy industry in marketing high-quality dairy products by providing buyers and sellers with an impartial appraisal of product quality and to provide the consumer confidence in buying.

Food Safety Inspection Service (FSIS)
http://www.fsis.usda.gov/

USDA provides a third-party equipment evaluation service through its Food Safety Inspection Services (FSIS). USDA Dairy and USDA Meat and Poultry have separate equipment grading groups, and their standards differ slightly from one another.

USDA has a national responsibility for the safety of food goods in the United States, and several neighboring countries have adopted many or all of the USDA standards as their own. The status as a federal organization with legal authority and responsibility separates the USDA bodies from other Food Safety organizations that have no legal capacity.
During the 1920s, the need for more stringent and uniform standards for dairy processing equipment became evident as the U.S. economy and consumers entered the modern era. Representatives of three interest groups—processors, regulatory sanitarians and equipment fabricators—recognized the need for cooperative action and introduced the first industry standards for equipment. These standards became known as ‘3-A’ standards for the three interest groups that forged a common commitment to improving equipment design and sanitation. Like other types of standards, 3-A Sanitary Standards relate to the cleanability of dairy equipment.

3-A does provide a third-party evaluation for some food producing equipment, including some conveyors. It has no government authority like that with USDA. 3-A Sanitary Standards provide material specifications, design criteria and other necessary information for equipment types to satisfy public health concerns. 3-A Sanitary Standards are available for many equipment types, from fittings to silo tanks. At this writing, standards for conveyor design are limited to use of the conveyor for dry foods and powders.
NSF
NSF International
www.nsf.org

NSF was founded as the National Sanitation Foundation in 1944 to standardize sanitation and food safety. NSF International is a non-profit, non-government organization that provides certification services for equipment used in the processing of meat and poultry, and Ready to Eat foods, against NSF/ANSI/3-A Standards 14159-1, -2 and -3. These standards have been cited by the USDA for the evaluation of equipment used in processing meat and poultry.

NSF has no direct legal authority over food producing organizations like the USDA. The “NSF 14159” standard aligns with the European Norm (EN) NSF 14159, to advance a harmonized Sanitary Design Standard between Europe and North America.

NSF is more oriented towards the process side of the business than the other agencies cited, providing training and accreditation for Hazard Analysis Critical Control Points (HACCP).
Criteria for Sanitary Designs

Cleanability

- **Design prevents microbial growth** - Smooth, regular surfaces that make sanitation easy
- **Surfaces are accessible for cleaning and treatment** - trap-free, open construction
- **Cleaning protocols provided by manufacturer** - means that cleaning wasn’t an afterthought in the design process
- **Surfaces are clean visually and to touch** - the eyes and fingers are your first gages of cleanliness

**Favorable Practice**

Smooth finish, free of pockets or stray material that can collect or harbor microbial infestation. Easily disassembled and assembled.

**Non-Preferred Practice**

Surfaces (such as bead-blast) that have small pockets invisible to the naked eye (USDA Dairy does not allow bead-blast because of this trait). Surfaces with indentations that can be detected by running your thumbnail across the surface.
Compatible Materials

- **Resist corrosion, non-toxic, non-absorbent** - materials can’t hold microbial growth, or contribute toxins through breakdown
- **300 Series Stainless** - inherently corrosion resistance, and properly handled to prevent corrosion from forming or welding
- **No plating or coating in food area** - coatings ultimately fail and contaminate the product
- **No cloth backed belts** - cloth wicks moisture, and harbors microbes
- **No aluminum** - Aluminum crumbles in typical sanitation solutions
- **No chemical interaction between materials, or the product** - must be chemically neutral to prevent contamination
- **Seals minimize product contact** - proper use of barriers prevents contamination of product contact zone from less-controlled area

Favorable Practice

All stainless and food-grade plastic construction. Single layer plastic belt preferred over cloth-backed or modular. Proper fabrication practices to prevent corrosion from weld areas. Bolted joints are properly gasketed.

Non-Preferred Practice

Clothed backed belts should not be used - stray fibers wick moisture and microbial material. Aluminum should not be used as it dissolves in harsh environments. No sealants in lieu of sanitary gaskets.
No Liquid Collection

☐ Surfaces are designed to prevent pooling - surface are convex over concave
☐ Framework is round, or turned 45 degrees - with no flat undersurfaces that are difficult to see or clean
☐ Surface areas and belts do not warp or change shape to collect liquid - no temporary ponding from thermal buckling
☐ No dead spaces - flat spaces are less expensive to make, but more costly to clean

Favorable Practice
Start with the product contact zone and ensure that everything flows down and away from there.

Non-Preferred Practice
Concave surfaces, or large surfaces with tendency to buckle. Pockets between bearings and conveyors. Frames with large upper or lower surface areas that encourage moisture retention.
Sanitary Operational Performance

- **Buttons on controls are easily cleaned** - no buttons means the easiest cleaning
- **Air contacting product is dry and 0.3 micron filtered** - can be done at the machine, but sanitary air is ultimately dependent on plant air source
- **No bearings in the product zone** - USDA Dairy 153 mm min gap, or *4”/3 mm/1” rule
- **Areas near the product zone should be considered as the product zone** - considered “splash” areas
- **Product zones prevent product buildup** - construction should defeat product buildup

**Favorable Practice**

Drives and bearings are well-removed from the product contact zone. Proper separation of product and non-product contact zones. User friendly, button-free, or buttons that are easily cleaned and properly protected.

**Non-Preferred Practice**

Bearings in the product zone or internal to pulleys. User interfaces or buttons that require protection during cleaning. Use of no-sanitary guides for product zone separation.

* The “4”/3 mm/1” Rule” is a USDA Dairy requirement that permits a construction where the bearings and drive of a conveyor can be closer than standard 6” (153 mm) from the product contact area. It states that product guided by sanitary guides that are 4” minimum height, no more than 3 mm from the belt surface, and no less than 1” from the edge of the belt, permit drive components up to 1” from the product contact area.
Hygienic Design of Maintenance Enclosures

☐ No drives, guards, or enclosures above the product zone - and sloped away from the product contact zone

☐ Control boxes are mounted in a sanitary manner - using the same design principles as the machine

☐ Conduit and supply lines are 12” from the floor, and easily cleaned - cables that are movable are easier to clean around

☐ No conduit or cable over the product zone - condensate with microbes collects and drains from the exterior

☐ Enclosures must be able to withstand direct cleaning and sanitation - no plastic shields allowed

Favorable Practice

Operator interface on same side as the operator. Conduits and cables are freely supported. Enclosures are smooth surfaces and drain away from the product area.

Non-Preferred Practice

Operator reaches over conveyor, or UI extends across conveyor. Enclosures and UI are lower IP rating than machine components. Drive assemblies are part of the product zone.
Accessible for Inspection, Cleaning and Maintenance

- Surfaces accessible for cleaning and inspection - easy to see and easy to clean
- Inaccessible parts are easily disassembled and reassembled - difficult tasks are poorly done or ignored
- CIP is preferred over COP - means the equipment designer considered cleaning in the design
- COP parts should be mounted to the machine - or trays provided to collect for cleaning
- Catch bins or pans are easily removed - reject collections are often overlooked as product contact areas
- Belt is removable and tensioned without tools - more likely to be thoroughly cleaned and free of threads
- Product contact areas are 18” above the floor minimum floor clearance of 12” - prevents splash and makes clean out easier
- Tubing is easily removed for cleaning - especially where used to convey food

Favorable Practice
Open construction for cleaning and visual inspection. Intuitive field-assembly.

Non-Preferred Practice
Field maintenance requires tools. Areas are concealed from cleaning, inspection. Narrow gaps hide areas requiring sanitation.
No Niches

- **Product surface 32 µ-in or better** - for all surfaces, including welds
- **Non product surface 64 µ-in or better** - for areas outside product contact zone
- **135° internal angles or with 1/8" or large radii** - area between the surfaces can’t be seen or cleaned
- **No lap joints** - area between the surfaces can’t be seen or cleaned
- **Welds are flush, and free of pits, occlusions, and corrosion** - tight corners are difficult to clean and trap food material
- **No press or shrink fits** - press and shrink fits have inherent gaps and are subject to leak. Some standards allow for dissimilar materials where one material flows into the other
- **No fasteners in the product zone** - fasteners are harborage areas
- **No exposed threads** - even outside the Product Contact Zone, exposed thread is a contamination risk
- **Fasteners require a positive locking method** - if used in the product contact zone, they cannot become free
- **Belt support are single-part construction** - multi-part conveyor beds require lap joints and fasteners
- **Bolted joints are gasketed with gasket visible** - for verification of presence and security

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**Favorable Practice**

Brushed #4 or better. Minimum contact between support surfaces. Smooth surfaces, and large enough radii to help cleaning.

**Non-Preferred Practice**

Pockets for product buildup. Unsealed gaps between assemblies. Fasteners and threads in product area.
Validated Cleaning and Sanitation

- What needs to be cleaned, how, and what materials are compatible for cleaning?
- What Cleaning and Sanitation Protocols are provided by the equipment supplier?
- What maintenance tasks are required after cleaning and sanitation?

- The equipment supplier has considered the cleaning and maintenance of the machine at the start of the design, and not as an afterthought.

Favorable Practice

A planned sanitation protocol that addresses the specific equipment, for the customer to incorporate into the plant sanitation process.

Non-Preferred Practice

Sanitation instructions that don’t consider the type of equipment, or the environment in which the equipment will be placed.
Hermetically Sealed

- Solid construction preferred over tube
- If tube, then welded closed with dye-trace as means to trace failure
- IP69K compliant Electronics
- Monolithic preferred over parts combinations, laminates, or fabric-reinforced
- Standoffs with blind holes and gaskets where welding is not possible or practical to attach hardware

Favorable Practice
Minimize tube or all tube closed-welded. Pulleys solid stainless or plastic, or with food dye-tracer.

Non-Preferred Practice
Internal bearings, socket-head or other fasteners with pockets, hollow pulleys or press-fit assemblies that foster microbe growth.
Hygienic Compatibility With Other Systems

Inspection equipment generally doesn’t have a “hygienic compatibility” requirement with other systems. The equipment should identify in the graphic overview of the design:

- All electrical, mechanical, pneumatic, and mounting interfaces that define how the equipment will interface to the surroundings
- All access for maintenance, cleaning and sanitation
- How material will flow into and out of the equipment

**Favorable Practice**
A definition of the specific equipment provided along with the customer interfaces for all utilities and communications, maintenance, product transfers, and product segregation.

**Non-Preferred Practice**
A generic drawing of a machine-type, without instruction on integration fundamentals.
Cited References:

- Wikipedia
- American Meat Institute: http://www.meatami.com
- 3-A “Sanitary Standards, Inc”: www.3-a.org
- NSF International: www.nsf.org
Sanitary Design Assessment
For Your Use – A Tool for Critical Review of Conveyor Equipment by Functional Areas

Conveyors
- Pulleys – solid stainless or closed-welded with dye trace, 32 µ-inch finish or better. No internal bearings or recesses
- Bearings – external, lube capable, sealed for water protection, stainless or poly housings. Spaced from support surface or sealed with approved gasket
- Top plates or Beds - 32 µ-inch finish or better
- Easily disassembled/assembled for CIP/COP
- Surfaces relieved to prevent belt adhesion
- Drives external to the product contact area and separated by barrier or distance
- No exposed threads
- Solid belt materials preferred over cloth-backed or modular plastic

Enclosures
- Removed from the floor to allow cleaning
- Smooth surfaces, particularly facing the product contact zone
- Sloped away from the product contact zone
- IP rated appropriate for the environment
- Switches and conduit interfaces IP rated appropriate for the environment
- Seals and gutters enhanced for high pressure
- Hyperbaric or hyperthermal to prevent internal condensation

Frames
- Minimize tube in favor of solid, where practical
- Internal angles 135° or greater
- Sloped surfaces to minimize material accumulation
- Finish to 64 µ-inch for areas outside of product contact area and 32 µ-inch for areas in splash area
- Welds closed, complete, free of pits, occlusions, spatter, and discoloration
- Blind-holes with standoffs for any bolted attachment
- Minimize horizontal surfaces

User Interfaces
- Accessible without reaching over the product contact zone
- IP rating suitable to support cleaning environment
- No buttons, niches, or traps that collect debris
- Positioned outside the product contact zone

Bolted Joints
- Minimize bolted joints in favor of one-piece, or weldments
- Bolted joints secured with gaskets to prevent microbial growth between surfaces
- No exposed thread
- Gaskets integrated to fasteners to prevent separation
- Gaskets visible for inspection, proper position, and function
- Minimize surface area between bolted parts
- No fasteners with recessed heads

Floor Interface
- No exposed threads
- Adjustable to permit proper installation
- Minimize points of contact
- 64 µ-inch finish minimum for all surfaces and welds
- Minimize horizontal surfaces facing the floor
- Horizontal surfaces far enough from floor to support cleaning

Clamps
- Easy to use to support cleaning
- Open construction to allow cleaning
- No exposed thread
- Minimize contact area between surfaces to support cleaning
- No traps or niches that collect debris

Rejectors
- Clean air source provided
- Filtered and dried
- USDA Accepted cylinders for product contact and splash areas
- 32 µ-inch finish for all constructions in the product contact and splash zones
- No exposed threads

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Sanitary Design Assessment

Transfers and Guides
- 32 µ-inch for all constructions in the product contact and splash zones
- Easily removed, dis-assembled, and assembled for cleaning COP or CIP
- Easily adjusted to encourage proper use
- Meet 25 mm, 100 mm, 3 mm rule for separation

Sensors
- IP rated appropriately for the environment
- No niches or traps that collect debris
- No exposed thread
- Removed from product contact zone
- Metal detector apertures guttered and gasketed to prevent debris from falling into product area

Cable and Conduit
- Cable appropriate for environment and power rating
- Interfaces to enclosures IP rated for the environment
- Open cable preferred over conduit to prevent water entrapment
- Wires and cables loosely supported in open rack to permit thorough cleaning