

Principles of Hygienic Design In the Dairy Industry



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Principles of Hygienic Design In the Dairy Industry

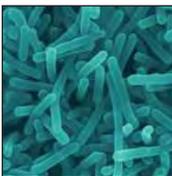
The Dairy industry has some of the harshest operating conditions and most demanding processes in food manufacturing and processing. Manufacturers are under increasing pressure from governments, retailers and consumers to ensure product quality and safety. As a result, many are using inspection tools during production to provide confidence that their products are as safe as possible for consumers.

With a range of product inspection equipment such as metal detectors, checkweighers, x-ray and vision inspection systems being commonly used in the dairy industry, this white paper explores how this equipment should be designed following international sanitary design standards in order to prevent the growth and spread of biological contamination in dairy plants.

1. Why is Sanitary Design Critical?

To prevent biological contamination of dairy products, product inspection equipment must be designed and constructed with sanitary principles in mind.

Potential biological hazards in dairy product manufacturing include microbiological bacteria, which cause a large proportion of all food-borne illnesses – those that are specifically harmful to humans are termed "pathogenic". For most dairy products, the milk pasteurization process removes the majority of potentially unsafe bacteria, including *Salmonella*, *Listeria*, *Staphylococcus aureus* and *Escherichia coli* O157:H7 (E-coli).



Listeria
<http://en.wikipedia.org/wiki/Listeria>.



Salmonella
<http://en.wikipedia.org/wiki/Salmonella>



E-coli
http://en.wikipedia.org/wiki/Escherichia_coli

There is however still some risk that bacteria that can survive pasteurization, such as *Mycobacterium avium subspecies paratuberculosis*, which has been associated with the development of Crohn's disease, and *Bacillus cereus*, which can survive in poorly refrigerated products. The greatest risk is still posed by the production and processing of unpasteurized dairy products, which can harbor a number of infectious bacteria including *Mycobacterium tuberculosis*, *Brucella* and *Campylobacter jejuni*.

With products that are so susceptible to bacterial infection it is critical to ensure that sanitization and sterilization levels are not compromised by the addition of any product inspection equipment to the production line (especially in unpasteurized dairy product processing).

2. Who Sets the Standards?

It is important to avoid the contamination of dairy products whenever possible. This includes inadvertent contamination of raw materials, and from processing procedures and equipment, employees and the environment.

Contamination can be minimized or avoided altogether by following appropriate sanitation procedures, good manufacturing practices, and procedures for employee hygiene. There are several agencies influencing and regulating the sanitation procedures of food manufacturing. In this white paper, we will focus on those with the most influence on the dairy industry today.

Ensuring Product Quality

The European Hygienic Engineering & Design Group (EHEDG), Food & Drug Administration (FDA), 3-A Sanitary Standards Inc. (3-A SSI) and National Sanitation Foundation International (NSF) are probably the best-known international experts in the area of good design practices for sanitary equipment applications.

Each agency has a slightly different approach to making equipment safe for production 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. Later this white paper examines ten keys points which should be considered when evaluating product inspection equipment design for suitability in a RTE Food application. Each of the ten points show an example of favorable and non-favorable construction practices for food applications.

2.1. EHEDG

European Hygienic Engineering & Design Group (EHEDG)



The EHEDG provides practical guidance on the hygienic engineering aspects of manufacturing safe and wholesome food. Founded in 1989, it is a consortium of equipment manufacturers, food companies, research and educational institutes as well as public health authorities, whose common aim is to promote hygiene during the processing and packaging of food products. EHEDG actively supports European legislation which requires that handling, preparation, processing and packaging of food is done hygienically using hygienic machinery and in hygienic premises (EC Directive 98/37/EC, EN 1672-2 and EN ISO 14159).

The principal goal of EHEDG is the promotion of safe food by improving hygienic engineering and design in all aspects of food manufacturing. The EHEDG organization consists of the Main Group, the Executive Committee, the Subgroups and Regional Sections with their chairpersons and members.

► www.ehedg.org

2.2. FDA

U.S. Food & Drug Administration (FDA)



The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, U.S. food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods safer, more effective and more affordable, and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.

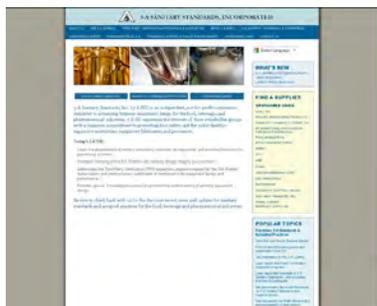
The FDA Food Safety Modernization Act (FSMA), signed into law by President Obama in January 2010, allows the agency to work proactively to prevent food safety problems from occurring, rather than merely responding once food has been found to be unsafe. The new law will also lead to the implementation of new regulations for food producers and suppliers, most importantly the requirements that all food facilities conduct hazard analyses and implement written preventive control plans.

Moreover, FSMA import safety provisions require importers to conduct risk-based foreign supplier verification activities to verify that imported food is not adulterated or misbranded and is produced in compliance with FDA's preventive controls requirements and produce safety standards.

► www.fda.gov

2.3. 3-A

3-A Sanitary Standards Inc. (3-A SSI)



3-A Sanitary Standards were first developed in the late 1920s through the cooperative efforts of the International Association of Food Industry Suppliers (IAFIS), the International Association for Food Protection (IAFP) and the Milk Industry Foundation (MIF). The Food & Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and the 3-A Steering Committee form the leadership of the modern 3-A SSI.

The mission of 3-A SSI is to enhance product safety for consumers of food, beverages, and pharmaceutical products through the development and use of 3-A Sanitary Standards and 3-A Accepted Practices. Further aims include:

- Develop, maintain and publish uniform standards and practices for the sanitary (hygienic) design, fabrication, installation and operation of equipment and machinery.
- Harmonize with global standards and guidelines as appropriate.
- Provide education concerning sanitary design principles, application of 3-A Sanitary Standards, 3-A Accepted Practices, and use of the 3-A Symbol.

► www.3-a.org

2.4. NSF

National Sanitation Foundation International (NSF)



NSF International helps protect you and your customers by certifying products worldwide and writing internationally-recognized standards for food, water and consumer goods. As an independent, not-for-profit, global public health and safety organization, NSF is committed to improving human health and safety worldwide. NSF was founded as the National Sanitation Foundation in 1944 to standardize sanitation and food safety. NSF International provides certification services for equipment used in the processing of dairy products, and Ready-To-Eat foods, against NSF/ANSI/3-A Standards 14159-1, -2 and -3.

NSF has no direct legal authority over food producing organizations. 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).

► www.nsf.org

3. Cleaning Processes and Environments

The industry and environment, as well as the application where a metal detector, checkweigher or x-ray and vision inspection system is being used, dictates which sanitation level is required and will have a direct influence on how the equipment is designed and constructed. Each industry has its own special set of sanitation requirements. A good product inspection equipment manufacturer will have a standard solution which will cater for the majority of sanitary requirements and will offer special versions for all others.

This white paper will primarily cover the sanitary construction and design for product inspection equipment being used in a harsh wash-down environment, commonly found in the dairy industry, where cleaning procedures include regular hosing down of production line equipment.

Recommendations for International Protection Ratings which should be observed as a minimum when constructing equipment for harsh wash-down environments are as follows:

IP65	Conveyor assemblies, sorting devices, spacing devices, sensors and optional add-on components	IP65 – No ingress of dust. Protected from low pressure water jets. Water projected by a nozzle against enclosure from any direction shall have no harmful effect.
IP66	Drive motors	IP66 – No ingress of dust. Protected from powerful water jets. Water projected in powerful jets against the enclosure from any direction shall have no harmful effect.
IP69k	Weighcell, control housing and cabinet containing sensitive electronic components e.g. Industrial PC (IPC)	IP69K – Standard DIN 40050-9 for high-pressure, high-temperature wash-down applications. Such enclosures must be able to withstand high pressure and steam cleaning.

4. Sanitary Design Criteria

This white paper is based on the "10 Principles of Sanitary Design" developed by the EDTF and applies them to product inspection equipment, such as checkweighers, metal detectors, x-ray and vision inspection systems used in the dairy industry.

An appropriate sanitary design ensures that product inspection equipment can be adequately cleaned and that surfaces and components are resistant to contact with corrosive food products and chemicals used for cleaning.

When designing product inspection equipment for the dairy industry, the specific application, the cleaning processes used and environment where the equipment will be installed, all need to be discussed before looking in detail at the sanitary design principles.



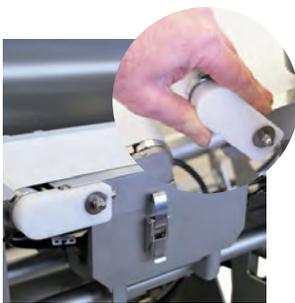
The 10 Principles of Sanitary Design are:

1. Cleanability
2. Construction Materials
3. Accessibility
4. No Liquid Collection
5. Hermetic Sealing
6. No Niches
7. Operational Performance
8. Maintenance Enclosures
9. Hygienic Compatibility
10. Cleaning Validation

4.1. Cleanability

Food equipment must be constructed to ensure effective and efficient cleaning of the equipment over its life span. The equipment should be designed to prevent bacterial ingress, survival, growth and reproduction on both the construction and product. Also important is the ability to easily disassemble the equipment for cleaning and inspection as necessary. All of these criteria lead to a design where every product contact surface that can be touched by product will also be in contact with cleaning solutions at the proper temperature and flow rate so that all product residues are removed.

- Design prevents pathogenic micro-organism growth – smooth, regular surfaces that make sanitation easy
- Surfaces are accessible for cleaning and treatment – trap-free, open construction
- Cleaning protocols provided by the manufacturer ensure that cleaning processes were part of the design process
- Surfaces are clean visually and to touch – the eyes and fingers are your first gauges of cleanliness



Favorable Practice

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



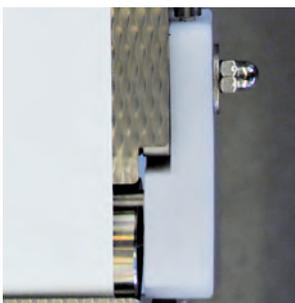
Non-Favored Practice

Surfaces that have small pockets invisible to the naked eye. These indentations can be detected by running your thumbnail across the surface.

4.2. Construction Materials

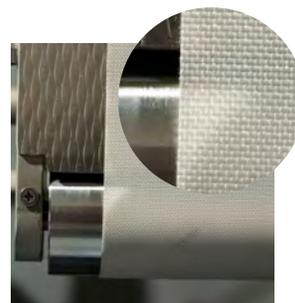
The construction materials for product inspection equipment must fulfill specific requirements for the dairy industry. Materials used for equipment must be completely compatible with the product, environment, cleaning and sanitizing chemicals and the methods of cleaning and sanitation. They must be corrosion resistant, nontoxic, mechanically stable and easily cleaned. Materials should not support pathogenic micro-organism growth, or contribute toxins through breakdown.

- Stainless steel – there are many grades of stainless steel. Each has its own special characteristic but all are inherently corrosion resistant to some degree. Attention should be paid to areas where forming has taken place and on welding seams where stress corrosion may occur, areas of high stress areas with prolonged exposure to high levels of chloride
- No painted components in food area – coatings ultimately fail and contaminate the product
- No cloth belts – cloth draws in moisture, and harbors micro-organism growth
- Careful use of aluminium – untreated aluminium crumbles in harsh sanitation environments
- No chemical interaction – materials must be chemically neutral to prevent contamination
- Product contact barriers/seals – proper use of barriers prevent contamination between product contact zones



Favorable Practice

All stainless and food-grade plastic construction. Plastic coated belts preferred over cloth. Proper fabrication practices to prevent corrosion from weld areas. Bolted joints are properly gasketed.



Non-Favored Practice

Use of fabric belts – stray fibers draw in moisture and microbial material. Use of untreated aluminium – it dissolves in harsh environments. Sealants in lieu of gaskets.

4.3. Accessibility

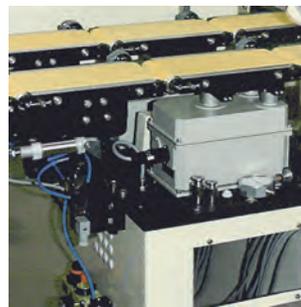
All parts of the product inspection equipment should be readily accessible for inspection, maintenance, cleaning and sanitation without the use of tools. Extra care must be taken during design and construction to avoid all crack and crevice areas where product can seep but cleaning solution cannot reach with sufficient flow to remove all traces. If there are areas where this cannot be accomplished, then those areas have to be identified for disassembly and manual cleaning methods.

- Clean-in-place (CIP) is preferred over clean-out-of-place (COP) – a clear indication that the method of cleaning was part of the initial design planning stage to avoid time-consuming disassembly and reassembly (Difficult tasks are poorly done or ignored)
- COP parts – these should be easily removable by hand or with the use of simple hand tools
- Catch bins or pans – these are often overlooked as product contact areas and should be easily removable
- Tool-free belt removal and tensioning – allows quick and easy sanitation, service and replacement
- Open construction – free lines of sight to all components and high ground clearance



Favorable Practice

Open construction for cleaning and visual inspection. Intuitive field-assembly. Tool-less removal of components and high ground clearance.



Non-Favored Practice

Field maintenance requires tools. Areas are concealed from cleaning, inspection. Narrow gaps hide areas requiring sanitation.

4.4. No Liquid Collection

Equipment should be self-draining to ensure that liquid from the product, cleaning process or condensation, which can harbor and promote the growth of bacteria, does not accumulate or pool on the equipment. This is of particular importance where wet wash-down routines are used or the ambient working environment is prone to large temperature fluctuations or high humidity.

- Surfaces are designed to prevent pooling – predominantly convex and rounded surfaces to actively promote the flow rate of product spillage and cleaning solutions
- Framework is round, or inclined at 45 degrees – avoid flat undersurfaces that are difficult to see or clean
- High structural integrity of construction materials – surface areas and belts do not warp, change shape or buckle and cause temporary pooling when subject to large temperature fluctuations

Flat surfaces are less expensive to make, but more costly to clean.



Favorable Practice

Predominantly sloping and rounded surfaces. Start with the product contact zone and ensure that everything flows down and away.



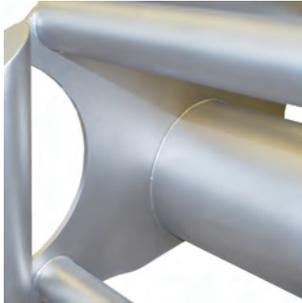
Non-Favored Practice

Concave and flat 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.

4.5. Hermetic Sealing

Hollow areas of equipment such as frames must be eliminated whenever possible or permanently sealed. Bolts, studs, mounting plates, brackets, junction boxes, name plates, end caps, sleeves and other such items should be continuously welded to the surface, not attached via drilled and tapped holes.

- Solid construction preferred over hollow tube
- IP69K sealing of compartment containing electronic components
- Monolithic preferred over parts combinations, laminates, or fabric-reinforced
- Standoffs with blind holes and gaskets where welding (to attach hardware) is not possible or practical



Favorable Practice

All tubing closed-welded.



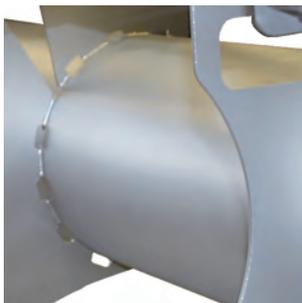
Non-Favored Practice

Internal bearings, socket-head or other fasteners with pockets, hollow pulleys or press-fit plastic cap assemblies capping hollow areas.

4.6. No Niches

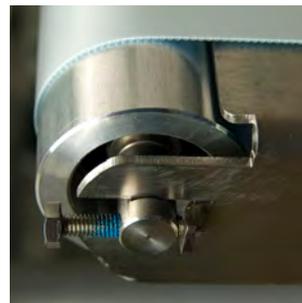
Equipment parts should be free of niches such as pits, cracks, corrosion, recesses, open seams, gaps, and protruding ledges. Welds should be flush, and free of pits, occlusions, and corrosion. Tight corners are difficult to clean and trap food material. It is quite often that parts are constructed to be compatible with various product inspection equipment designs. These parts normally have several series of non-functional tapped holes to accommodate the different designs. The tapped holes not in use need to be correctly filled.

- Internal angles of less than 55° are to be avoided – the area between the surfaces can't be seen or cleaned
- No press or shrink fits – press and shrink fits have inherent gaps and are subject to leak. Some standards allow the use of dissimilar materials where one material overlaps another
- No fasteners in the product contact zone – fasteners are harborage areas
- Minimal exposed threads – even outside the product contact zone, exposed threads are a contamination risk
- Welded flanges – gaps in welded seams allow free flow of cleaning solutions
- Bolted joints are gasketed with gasket visible to verify presence and security



Favorable Practice

Minimum contact between support surfaces. Smooth surfaces with large enough radii to help cleaning. All seams with a smooth high quality weld.



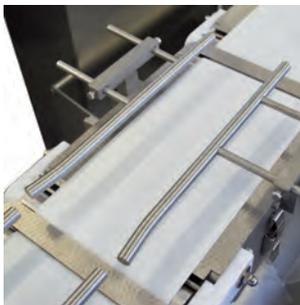
Non-Favored Practice

Pockets allowing product buildup. Unsealed gaps between assemblies. Fasteners and threads in the product contact area.

4.7. Operational Performance

During normal operation, the product inspection system must perform in such a way that does not contribute to unsanitary conditions or the harborage and growth of bacteria. The characteristics of the product being produced will have the greatest impact on the equipment's operational construction specifications. Avoidance of spillage and the effective separation of product contact and non-contact zones are of paramount importance. To ensure hygienic operation, it is essential that the design also takes into account components and parts which will be touched by the operator who will almost certainly have had contact with the product, minimizing the possible spread of contamination.

- Buttons and control elements are easily cleanable
- Sanitary air source – ideally dry and 0.3 micron filtered but is ultimately dependent on the plant environment
- "Splash" areas near the product zone should also be considered as the product zone
- Avoidance of product build-up – the construction design should defeat product build-up



Favorable Practice

Drives and bearings are well-removed from the product contact zone. Proper separation of product contact and non-contact zones using guides.



Non-Favored Practice

Bearings in the product zone or internal to pulleys. User interfaces or buttons that require protection during cleaning. Use of non-sanitary guides for product contact zone separation.

4.8. Maintenance Enclosures

Product inspection equipment maintenance enclosures and Human Machine Interfaces (HMI) such as push buttons, valve handles, switches and touch-screens must be designed to ensure food product, water or product liquid does not penetrate or accumulate in or on the enclosure or interface (IP69K recommended). Also, physical design of the enclosures should be sloped or pitched to avoid use as storage area. A special control function to temporarily disable the touch-screen during cleaning is extremely advantageous as it prevents mis-operation.

- No drives, guards, cable conduits or enclosures above the product zone
- Control cabinets are mounted in a sanitary manner using the same design principles as, for example, the checkweigher with a sloped top surface to prevent collection of moisture and debris
- Power and network supply lines are well above floor level and connections to and from the control cabinet are firmly affixed and able to withstand direct cleaning and environment sanitation processes
- Enclosures and HMI must be able to withstand direct cleaning and environment sanitation processes



Favorable Practice

Sealed touch-screen HMI with no protruding buttons. Control cabinet has a sanitary design with a sloping top surface. IP rating of all connections to and from the cabinet adequate to withstand sanitation process.



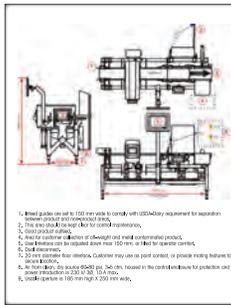
Non-Favored Practice

Operator reaches over conveyor, or HMI extends across conveyor. Enclosures and HMI are lower IP rating than machine components. Drive assemblies are part of the product zone.

4.9. Hygienic Compatibility

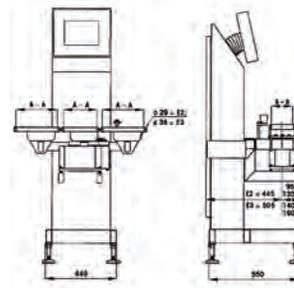
Product inspection systems, such as metal detectors, x-ray inspection devices and checkweighers, generally don't have a "hygienic compatibility" requirement with other systems. Where special plant conditions and sanitation requirements are known in advance, it is possible to introduce certain design features to ensure hygienic compatibility with other equipment and systems such as electrical, hydraulics, steam, air and water.

- Design features for hygienic compatibility should be identifiable in the graphic overview of the design
- Product inspection equipment interfaces and connections to all electrical, mechanical, pneumatic, and mounting interfaces need to be defined to enable integration into the production line, environment and sanitary processes.
- Access for maintenance, plant cleaning and sanitation processes need to be known
- Product characteristics, and how they will flow into and out of the product inspection equipment need to be taken into account
- Specific biological contamination risks must be identified and taken into account during construction design



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-Favored Practice

A generic drawing of a machine-type, without instruction on integration fundamentals and hygienic compatibility

4.10. Cleaning Validation and Sanitizing Protocols

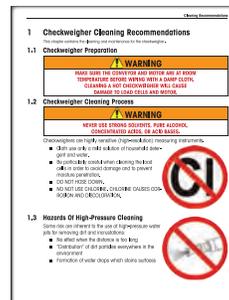
Procedures for cleaning and sanitation must be clearly written, designed and proven effective and efficient. Chemicals recommended for cleaning and sanitation must be compatible with the product inspection equipment construction materials, contamination risk and manufacturing environment, and must be able to remove product residue as non-aggressively as possible. The product inspection equipment supplier must consider the cleaning and maintenance of the machine at the start of the design, and not as an afterthought.

- What needs to be cleaned and how (CIP/COP)?
- Which cleaning process should be used and are there restrictions on sensitive components?
- What cleaning and sanitation protocols are provided by the product inspection equipment supplier?
- What maintenance tasks are required after cleaning and sanitation?



Favorable Practice

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



Non-Favored Practice

Sanitation instructions that don't consider the type of equipment or the environment in which the equipment will be placed.

5. Sanitary Design Assessment

For your use – a tool for critical review of product inspection system conveyors and components by functional areas

Conveyors

- Easily disassembled/re-assembled for CIP/COP
- Surfaces with relief pattern to prevent belt adhesion
- Drives external to the product contact area and separated by barrier or distance
- No exposed threads
- Plastic coated belt materials preferred over cloth

Frames

- Minimize tube in favor of solid, where practical
- Internal angles 55° or greater
- Sloped surfaces to minimize material accumulation
- Welds closed, complete, free of pits, occlusions, spatter, and discoloration
- Blind-holes with standoffs for any bolted attachment
- Minimize horizontal surfaces

Bolted Joints

- Minimize bolted joints in favor of one-piece, or weldments
- Gaskets visible for inspection, proper position, and function
- Minimize surface area between bolted parts
- No fasteners with recessed heads

Clamps

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

User Interfaces

- Accessible without reaching over the product contact zone where practical
- Minimum IP69K rating
- No buttons, niches, or traps that collect debris
- Positioned outside the product contact zone where practical

Floor Interface

- No exposed threads
- Adjustable to permit proper installation
- Minimize points of contact
- Minimize horizontal surfaces facing the floor
- Horizontal surfaces far enough from floor to support cleaning

Rejectors

- Clean air source provided
- Filtered and dried

Transfers and Guides

- Easily removed, disassembled, and re-assembled for cleaning COP or CIP
- Easily adjusted to encourage proper use

Sensors

- IP rated appropriately for the environment
- No niches or traps that collect debris
- Removed from product contact zone

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

Further Information

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Building an Effective Metal Contamination Detection Program

Led by METTLER TOLEDO Safeline experts in metal detection technology, this FREE 1 hour webinar will cover the basic principles of metal detection through to the implementation of a comprehensive program.

How Safe is X-ray Inspection of Food?

Some of the popular misconceptions about x-ray inspection of food are tackled in this webinar. It is an indispensable webinar for food manufacturers who are considering x-ray inspection to comply with food safety regulations and legislations.

Effective Checkweighing for Challenging Times

In today's ever changing dairy industry we are challenged with making the most out of our time, material and our processes. This webinar has been developed to provide you insights on how to best use checkweighing to make every gram count!

Implementing a Label Mix-up Prevention Program

Vision experts from CI-Vision will discuss vision technology and how it can be proactively applied to your packaging line to prevent product mislabelling.

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