Expertise
Passion
Automation

Take the safe route

A COMPREHENSIVE APPROACH TO THE SAFETY STANDARDS OF FOOD MANUFACTURING INDUSTRY

01

Introduction

Ensuring food safety is the highest priority for the food manufacturing industry. This white paper explores the crucial aspects of food hygiene and sanitation, emphasizing the regulatory landscape, risk factors, and best practices for maintaining safe production environments. It highlights key global regulations, such as the European Union's Regulation (EC) 852/2004 and the U.S. Food Safety Modernization Act, which mandate strict hygiene controls.

The document also discusses major food contamination risks –physical, chemical, and microbiological– and outlines strategies for mitigating them through hygienic design, proper sanitation, and robust Food Safety Management Systems (FSMS). Additionally, it introduces key frameworks such as Hazard Analysis and Critical Control Points (HACCP) and prerequisite programs (PRPs), which are essential for compliance and risk prevention.

This white paper serves as a comprehensive guide for food manufacturers, engineers, and safety professionals seeking to enhance food hygiene standards, minimize contamination risks, and ensure compliance with evolving safety regulations.

The importance of food safety: be safe, not sorry

Safety is the top priority in the food industry – it forms the foundation of consumer trust. Any decline in trust can have serious consequences for the sector.

To underscore its importance, food safety is enshrined in both European and US law. In Europe, Regulation (EC) 178/2002 establishes the general principles and legal requirements for the food industry, ensuring high standards of human health protection and consumer interest.

For food business operators, **Regulation (EC) 852/2004** outlines general hygiene rules applicable at every stage of food production, processing, and distribution. Additional key regulations include:

- **Regulation (EC) 2073/2005** – Defines microbiological criteria for assessing food safety.
- **Regulation (EC) 1441/2007** – Introduces amendments to Regulation (EC) 2073/2005.

The United States takes an equally stringent approach to food safety. The **Food Safety Modernization Act (FSMA) of 2011** shifts the focus from responding to contamination to preventing it, requiring companies to take proactive measures to ensure a safe food supply.

Additionally, the **U.S. Food and Drug Administration (FDA)** regulates materials that come into contact with food. To achieve FDA compliance, materials must be non-toxic, corrosion-resistant, and capable of withstanding their intended operating environment.

In light of so many legal obligations, a robust and compliant Food Safety Management System is a necessity for food manufacturers around the world. In Europe, this requirement is reflected in Regulation (EC) 187/2002, also known as the **General Food**

Law Regulation. This law covers the entire food chain, from production to retail sale, by establishing procedures for food safety. Manufacturing plants must ensure food is safe for consumption by:

- Providing appropriate information
- Withdrawing unsafe food
- Ensuring traceability.

Who is responsible for food safety? Almost every process stakeholder, including food manufacturers and machine builders, in particular engineers responsible for machine design. Best-practice food safety is necessary to **ensure that people do not become ill** as a result of food contamination. According to the World Health Organization (WHO):

- An estimated 600 million – almost 1 in 10 people worldwide – fall ill after eating contaminated food and 420,000 die every year
- Children under 5 years of age carry 40 % of the foodborne disease burden, with 125,000 deaths annually
- Foodborne diseases impede socioeconomic development by straining health care systems and harming national economies, tourism and trade
- Food safety, nutrition and food security are inextricably linked.

Aside from the potentially disastrous consequences for consumers, food safety matters because production facilities are subject to frequent inspections that have legal consequences. Inspectors will need to see the plant's **HACCP (Hazard Analysis and Critical Control Points)** plan, a legal requirement, and the associated record keeping. The ultimate responsibility for HACCP lies with food producers.

A Food Safety Management System is a global requirement for food manufacturers

With the passage of **US FDA Food Safety Modernization Act in 2011**, more than ever, sites are requirement, by regulations, to have their equipment and premises construction based on hygienic design principles:

21 CFR 117.40-

Equipment & utensils design & maintenance
Equipment and utensils must be designed & constructed to be adequately cleaned or maintained to protect against contamination.

21 CFR 117.20(b)-

Plant construction and design
The facility must be constructed or designed to facilitate maintenance & sanitary operations.

21 CFR 177.2600

Rubber articles intended for repeated use
The articles may be safely used in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food.

Reality check

A compliant food manufacturing facility will carry HACCP approval, as granted by the relevant authorities. Three levels of authority apply:

- **GFSI** (Global Food Safety Initiative), which uses Codex Alimentarius as its foundation (see subsequent section in this introduction)
- **Certified programme owners** (CPOs) such as the BRCGS (Brand Reputation Compliance Global Standard), SQFI (Safe Quality Food Institute), IFS (International Featured Standards) and FSSC 22000, which interpret the benchmark written by the GFSI to prepare their guidelines
- **Auditors** who inspect and review against CPO guidelines.

If the auditors see something of concern, they will issue a non-conformance. If it is of sufficient concern, CPO auditors have the power to close the factory until the issue is resolved and checked. **The top five non-conformances** (based on BRCGS data from 2023) are:

1. Clause 4.11.1: hygienic condition of equipment and premises
2. Clause 4.9.11: use, storage, handling of non-food chemicals
3. Clause 4.6.2: design and construction of equipment
4. Clause 4.4.8: condition of factory doors
5. Clause 4.4.1: condition of factory walls.

Regular audits by external independent bodies should prompt the inclusion of hygienically designed products in the food plant's URS (User Requirement Specification). Visiting auditors will ask to see this document, along with evidence of due diligence following the machine's arrival. For example, if a food plant requires its machine builder to use actuators made from 304 stainless steel with a surface finish of RA 0.8 µm (as specified in its URS), the plant's management team must check compliance. It is the responsibility of the food producer to enforce its URS. Any failures in this regard will result in a non-conformance.

As with all regulations and standards, keeping up with amendments is paramount. For example, in 2020, the GFSI introduced two new guidelines: Scope JI and JII. These guidelines place greater emphasis on hygienic design for both food producers and machine builders. Today, Scope JI (for facility constructors and equipment manufacturers) and JII (for facility and equipment users) are written into auditor's guidance documents.

Codex Alimentarius

Codex Alimentarius (Latin for 'Food Code') is a collection of international standards, guidelines and codes of practice developed jointly by the United Nations' Food and Agriculture Organization (FAO) and the World Health Organization (WHO) to protect the health of consumers. Established in 1963, Codex standards harmonise national food safety regulations worldwide and form the basis of the GFSI benchmark.

The Codex Alimentarius Commission currently comprises 188 member countries, 1 member organisation (the EU) and more than 230 'observers' (inter-governmental organisations, non-governmental organisations and United Nations agencies). It provides help on food safety by:

- **Assisting countries to formulate national legislation based on Codex**, as well as implementing and enforcing food standards harmonised with Codex
- Strengthening national processes for consultation, communication and management of Codex work
- Establishing policy frameworks and the use of Codex as a basis for national food control.

Down to business

Alongside potentially serious risks to public health, a myriad of business reasons outline why food safety must top the list of food plant priorities:

- To avoid loss of business and subsequent falls in revenue
- To avoid unexpected expenses from product recalls and financial penalties
- To avoid legal costs due to outbreaks of foodborne contamination
- To maintain brand reputation
- To maintain consumer loyalty and trust.

According to the WHO, US$110 billion is lost each year in productivity and medical expenses resulting from unsafe food in low- and middle-income countries.

Contamination: a poisonous predicament

Unsafe food is predominantly due to contamination. The principal types of contamination are physical, chemical and microbiological.

Physical contamination refers to fragments of metal, plastic, glass or paint that falls into food. This type of contamination can lead to injuries that include choking, cuts, tooth damage and difficulty in breathing. Faulty or dirty machinery is a common culprit. If machinery does not undergo regular maintenance or features corrosion, there is a high chance of worn seal fragments or metal flakes falling into food. Any components that endure stress can incur wear.

Chemical contamination can come from many sources. Common ones include leaked lubricant from a faulty machine component. Chemicals that leach from polymer seals due to degradation following contact with cleaning detergents are also typical of this contamination type.

Microbiological contamination essentially involves the inadvertent transfer of bacteria/pathogens into food. There are many modes of transfer. A familiar one is the multiplication of bacteria from food trapped in the cavities or recesses of machine components that do not offer hygienic design.

Common pathogens found in food

Salmonella is a common foodborne pathogen that affects millions of people annually, sometimes with severe or even fatal outcomes. Symptoms include fever, headache, nausea, vomiting, abdominal pain and diarrhoea. Foods involved in outbreaks of salmonella include eggs, poultry and other products of animal origin.

Listeria monocytogenes is another bacterial hazard where infections can prove potentially catastrophic, even leading to pregnancy miscarriages or the death of newborn babies. It is found in unpasteurised dairy products and various ready-to-eat foods, including salad vegetables. Listeria can grow at refrigeration temperatures.

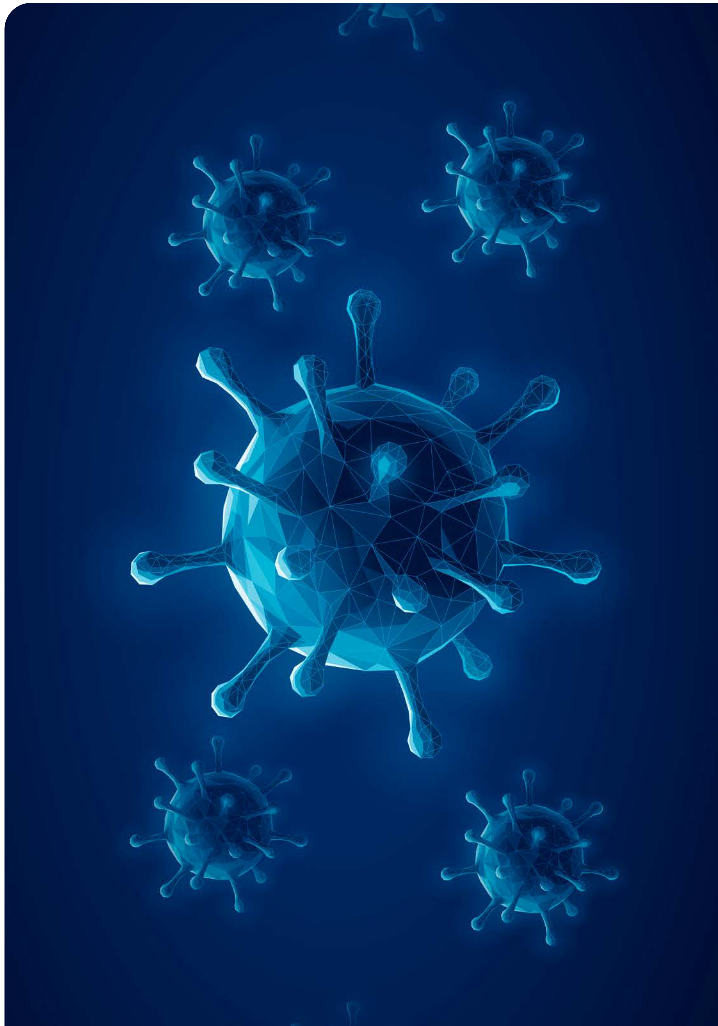
A further common pathogen is E Coli O157, which can prompt diarrhoea, stomach cramps and occasional fever. E Coli O157 is sometimes found in:

- Undercooked ground beef
- Unpasteurised (raw) milk and juice
- Soft cheeses made from raw milk
- Raw fruits and vegetables such as lettuce, other leafy greens and sprouts.

An additional pathogen of note is *clostridium botulinum*, which causes vomiting, diarrhoea and sickness. Paralysis and even death can result without treatment. It can be present in:

- Preserved vegetables such as beets, peppers, asparagus, mushrooms and green beans
- Stored food products like oil, garlic in oil, onions sautéed in butter
- Commercially prepared chilli and traditionally prepared fish or marine mammal meat.

The multiplication rate of bacteria depends on factors like the food type, as well as process and environmental conditions such as temperature (27-37 °C is optimal for bacteria growth) and humidity. It can sometimes take **as little as one day for bacteria to incubate** and contaminate to the subsequent day's production. To make matters worse, the risk is often inconspicuous. For example, bacteria located in the head of machine fastener, which has no direct contact with food, still presents a grave threat. The bacteria can produce spores that carry through the air to contaminate food.



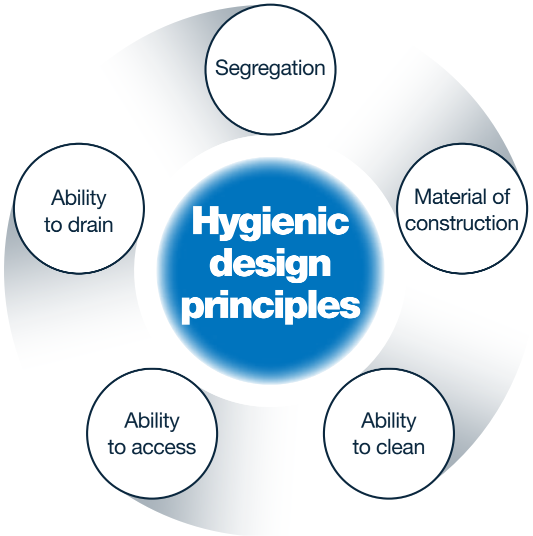
Allergens

Aside from physical, chemical and microbiological contamination, allergens present a further threat. The EU recognises 14 defined allergens:

- Cereals containing gluten: wheat, rye, barley, oats and hybrid cereal strains
- Crustaceans: prawns, crabs, lobsters and crayfish
- Nuts: almonds, hazelnuts, walnuts, cashews, Brazil nuts, pistachios, Macadamia nuts and Queensland nuts
- Eggs
- Fish
- Lupin: found in flour, bread, pastries and pasta
- Milk
- Molluscs: mussels, land snails, squid and whelks
- Mustard
- Peanuts (a legume)
- Sesame
- Soybeans
- Sulphur dioxide and sulphites
- Celery

Hygienically designed

Hygienically designed machine components, **comprehensive sanitation regimes** and **compliance with food safety standards** can help overcome physical, chemical and microbiological contamination, as well as allergen contamination. This is because there are five key principals to hygienic design.

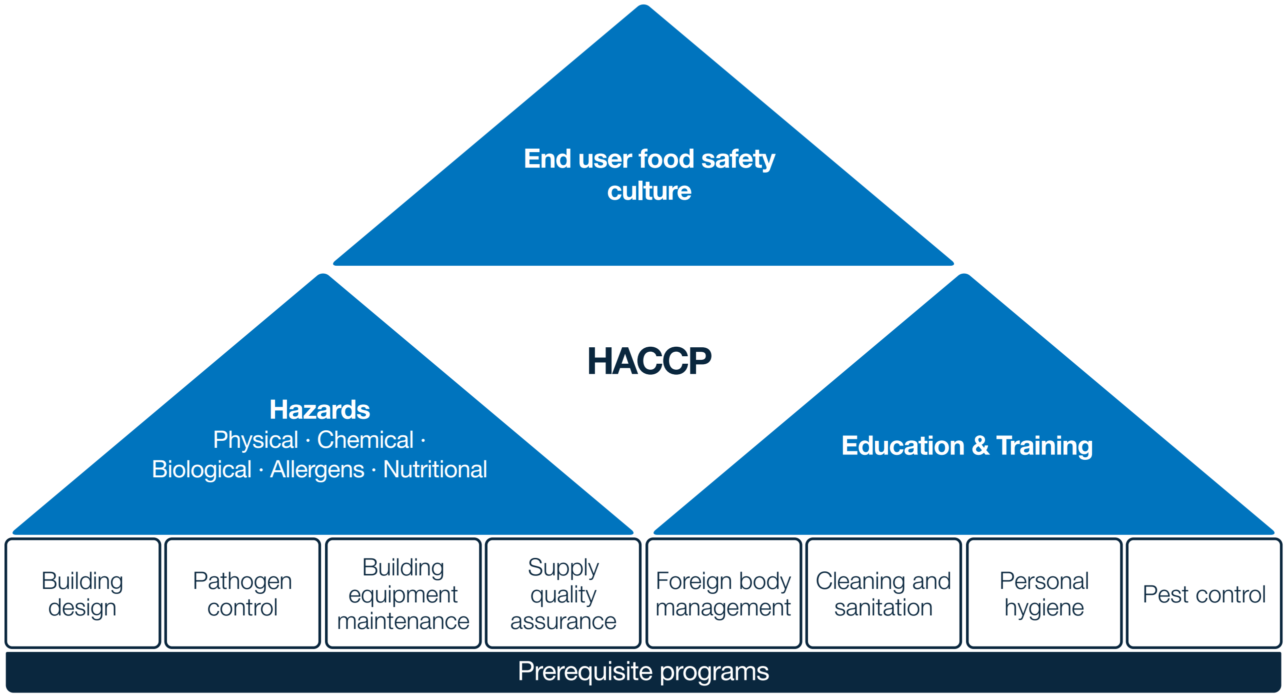


- Material of construction: the right grade of stainless steel or polymer, for example
- Ability to clean: no pooling of water or liquids
- Ability to access: for cleaning purposes
- Ability to drain: to avoid the accumulation of bacteria
- Segregation: to prevent contamination by allergens.

Together, these principles help food processing plants maximise their safety efforts and prevent any potentially costly and catastrophic effects on consumers.

02

Prerequisite programmes (PRPs) and HACCP



Get with the programme

Prerequisite programmes (PRPs) are practices and procedures that ensure food processing facilities are safe and hygienic before commencing operations. PRPs are a base-level necessity for all food-related companies, including manufacturers. They form part of the company's **Food Safety Management System**, which is a **legal requirement**.

ISO/TS 22002-1:2009 details the requirements for establishing, implementing and maintaining PRPs to assist in controlling food safety hazards. It is applicable to all organisations involved in the manufacturing step of the food chain that need to implement PRPs.

The above infographic pyramid shows a typical Food Safety Management System, indicating where PRPs, training and the HACCP (Hazard Analysis and Critical Control Points) plan sit. As a legal requirement, HACCP is central, flanked by awareness requirements such as hazards, education and training. Underpinning the entire Food Safety Management System are the PRPs.

PRPs act as a **preventive measure against potential hazards at an early stage**. They essentially form the cornerstone of a robust food safety management system, establishing a baseline for quality control. ISO/TS 22002-1:2009 specifies PRP considerations that include:

ISO/TS 22002-1:2009 also adds other aspects considered relevant to manufacturing operations, such as:

- Rework
- Product recall procedures
- Warehousing
- Product information and consumer awareness
- Food defence, bio-vigilance and bio-terrorism.

Sounds like a plan

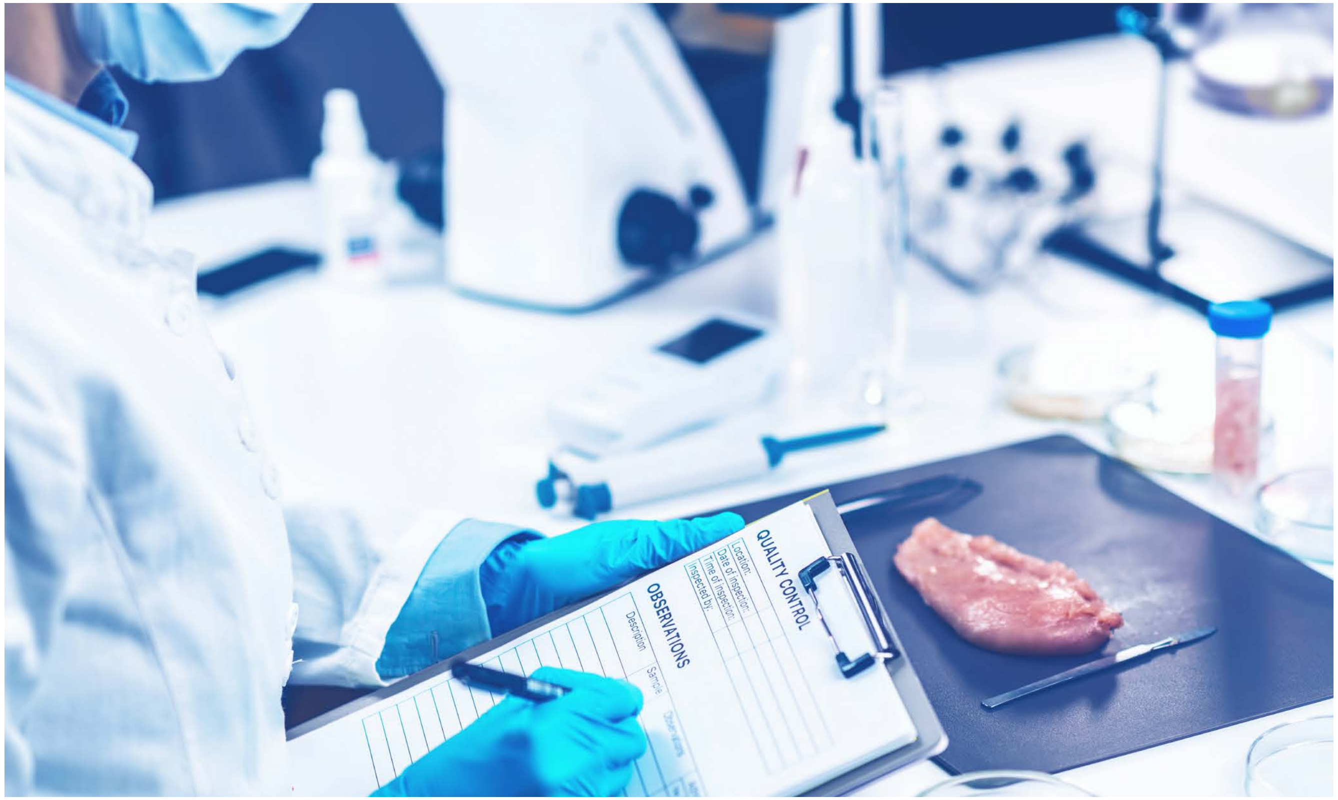
Creating a comprehensive PRP plan involves a number of key steps, the first of which is typically determining the essential hygiene and operational prerequisites specific to the food plant's operation. Facility size, food type and regulatory requirements are all factors here. With this step complete, attention turns to establishing documented procedures for the implementation and monitoring of PRP elements, ensuring clarity and compliance with best practices.

Further PRP development stages include the provision of training and education for relevant personnel. The implementation of robust monitoring and review processes are also key to assess the effectiveness of a PRP and address any gaps or non-conformities.

While PRPs are the building blocks for food safety plans, they do not guarantee absolutely safety and are not a replacement for more sophisticated food safety systems such as HACCP (Hazard Analysis and Critical Control Point) plans.

Take control

HACCP forms part of the mandatory Food Safety Management System in helping identify, evaluate and control potential hazards in food. It represents a comprehensive approach that can help **prevent foodborne illnesses and protect consumer health**.



Key pieces of legislation here include the FDA Food Safety Modernization Act (FSMA), which shifts the focus from responding to foodborne illness to preventing it. The US Government signed the FSMA, which includes the HACCP food safety regulation, into law in 2011. It serves as a mandate that requires comprehensive, preventive control standards across the food supply chain, covering those for the safe production, harvesting, packing and storage of raw agricultural commodities, including produce.

In Europe, Regulation (EC) 852/2004 on the hygiene of foodstuffs states that food businesses must have a food safety management system based on HACCP principles. HACCP helps businesses to:

- Critically assess their processes
- Identify potential hazards
- Implement necessary controls
- Improve food safety
- Enhance operational efficiencies.

As a point of note, the UK retained the regulation after leaving the EU in 2020, so it remains part of UK law.

A food plant's HACCP plan is subject to review every 1-3 years by certified programme owners such as the BRCGS (Brand Reputation Compliance Global Standard), SQFI (Safe Quality Food Institute), IFS (International Featured Standards) or FSSC 22000.

Stay one step ahead

The first key step to establishing a HACCP plan is appointing a **multi-disciplinary HACCP team** that includes senior site leads, technical managers, QA personnel, sanitation specialists and others. The team can then set about identifying any physical, chemical or biological hazards that may compromise food safety. To complete this task successfully it is necessary to define a hazard. **A food hazard is anything that could make food unsafe or unfit to eat.** A common way forward is to scrutinise the entire manufacturing process from start to finish and ask the question: what has the potential to go wrong?

Another key aspect of HACCP plan creation is determining critical control points (CCPs) in the food manufacturing process, where hazards require either:

- Prevention (after all, prevention is better than cure)
- Reduction to a safe level
- Complete removal.

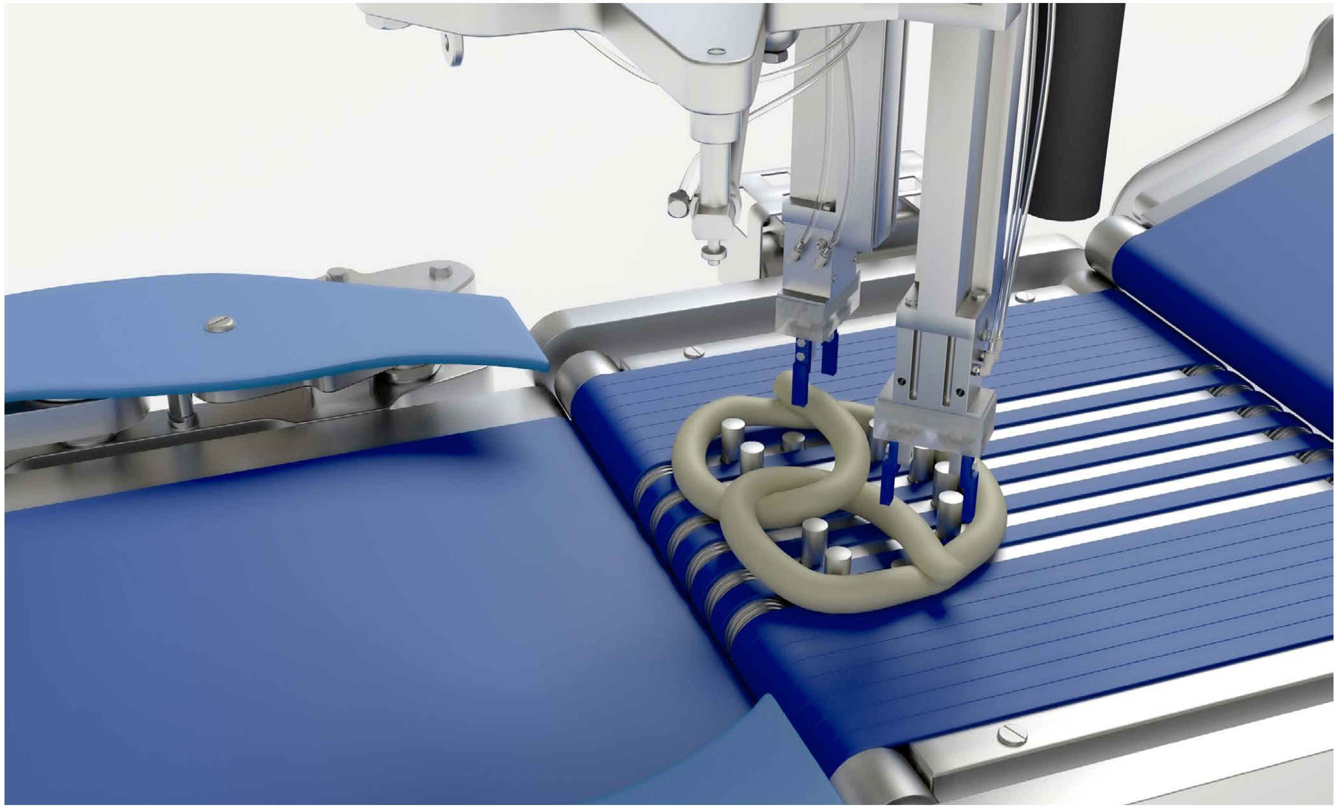
This is also known as a 'kill step', namely the last point in the food production process where it is possible to eliminate (or mitigate to an acceptable level) a potential food safety hazard.

From a food production perspective, **typical CCPs** might include processes such as **cooking, reheating, thawing or chilling**. Other examples could include testing ingredients for chemical residues, product formulation control and testing product for metal contaminants. Cross contamination and segregation is another common CCP in food production. With the CCPs determined, further HACCP tasks include:

- Establishing **limits** for the CCPs
- **Monitoring** the CCPs
- Establishing **corrective procedures** if a problem arises with a CCP
- **Maintaining records** for regulatory compliance and to demonstrate that procedures are operating correctly
- Establishing adequate **verification procedures**.

As a particular point of note, hygienic design is a vital part of the HACCP approach to food safety, and it requires the attention of both food plants and machine builders. When designing a process line or machine, there must be consideration for the use of components that offer hygienic design.

Designing a machine component to be hygienic is a detailed process, but there is a founding principle: is it easy to clean? Food plants and machine builders must consider this fact when specifying components for use on their lines or machines.



03

Cleaning and sanitation

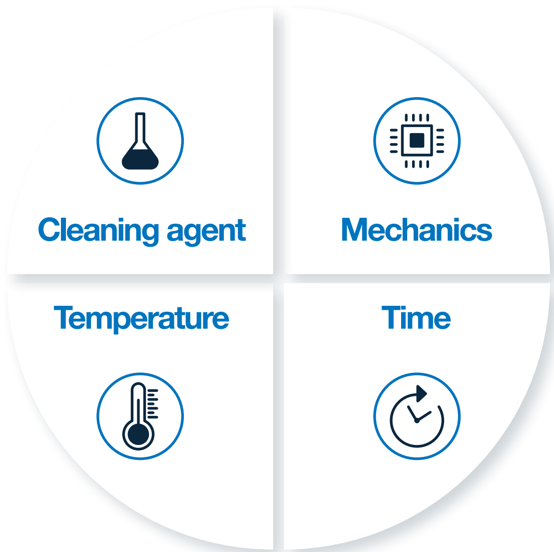
Clean, rinse, sanitise

The Machinery and Equipment Manufacturers Association (VDMA) in Germany suggests that food manufacturing plants spend up to 20 % of machine production time on cleaning and sanitising. In a highly competitive era when OEE (overall equipment effectiveness) is king, poor production line/machine availability is extremely damaging to food businesses.

Efficient and effective cleaning therefore becomes a priority. The so-called 'Sinner's Circle', named after German chemical engineer Dr Herbert Sinner, indicates the four variables of the process:

- **Cleaning agent**: the type and amount of detergent used to remove soil
- **Mechanics**: the action used to dislodge soil, such as brushing, scrubbing or jet washing
- **Time**: the length of time the cleaning chemical remains in contact with the surface
- **Temperature**: the temperature used to help loosen grease and accelerate chemical reactions.

As a rule of dynamics, an increase in one of the four variables prompts a reduction in the other three.



Sinner's circle

Finding the 'sweet spot' means identifying the right balance of these variable for the specific machine and linking it to total cost of ownership (TCO). Minimising all four variables, without jeopardising cleanliness or food safety, will save money.

This is where the importance of hygienic design comes to the fore. Hygienically designed machines reduce TCO as their components are easier to access and clean. Fast and easy cleaning routines meet with a core food plant ambition: clean, rinse, sanitise and back into production without any compromise to food safety. But take note, it is far easier to **impart hygienic design at the beginning of a design process**/capex project than try and accommodate it later in the project.

Trust the process

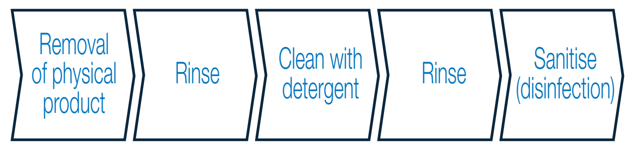
Cleaning and sanitising processes are not the same. The definitions provided below serve to clarify the principal difference:

- Soil: unwanted matter on a surface prior to start up
- Cleaning: removal of visible soil
- Sanitising: removal of invisible soil (micro-organisms)

Cleaning, which takes place first, helps increase the effectiveness of subsequent sanitation efforts by removing organic materials that include soil and dirt visible on surfaces. By following-up with sanitising procedures, food manufacturing facilities reduce the number of bacteria and other micro-organisms to levels considered safe for human health.

Exact procedures will vary from plant to plant, depending largely on factors such as the type of food and throughput rates. To meet the requirements of HACCP plans, a typical list of process steps might be:

- **Removing soil** and dirt from food-contact surfaces
- **Rinsing away residues** from machines/equipment using warm water
- **Applying chemical cleaners/detergents** to remove soil such as fat and protein
- Undertaking a **thorough rinse** to remove detergent
- **Inspecting surfaces**
- Applying a **sanitising or disinfecting chemical**
- **Rinsing and drying**.



Wet or dry?

Cleaning processes in food plants typically fall into two categories: wet cleaning and dry cleaning. Each has its own advantages and disadvantages.

Wet cleaning

Advantages

- Superior cleaning **power**: wet cleaning, with the use of appropriate cleaning solutions, is generally more effective at removing food particles, grease and allergens from surfaces due to the ability of detergents to penetrate and lift grime
- **Flexibility** in cleaning agents: users can add contaminant-specific cleaning chemicals to the water to target more effective results
- **Visible results**: wet cleaning supports visual confirmation of cleanliness.

Disadvantages

- Drying time: wet cleaning requires a period of time for drying, extending production downtime
- Water damage risk: improperly sealed or sensitive electrical equipment can suffer damage from wet cleaning
- Potential for water waste: without careful management, wet cleaning can lead to high water usage.

Types

- **Manual scrubbing** using tools like brushes, scrapers and squeegees
- **Foam-based** cleaning solutions
- **Clean-in-place (CIP)** procedures (no equipment disassembly necessary)
- **Clean-out-of-place (COP)** procedures (requires some level of disassembly).

As a point of note, large food manufacturing plants running batch-mode production lines typically deploy automatic clean-in-place (CIP) and sanitise-in-place (SIP) routines between batch runs. **Critical machine components must be able to withstand these cleaning regimes, including:**

- Actuators
- Valve manifolds
- Connectors
- Sensors
- Switches.

Dry cleaning

Advantages

- **Reduced** or no drying **time**: dry cleaning methods minimise downtime
- **Safer for electronic systems** on the food line: dry cleaning is generally considered safer for electrical equipment as it avoids direct water contact
- **Low or no water usage**: as the name suggests, dry cleaning will see a dramatic reduction in water usage compared with wet cleaning.

Disadvantages

- May not remove stubborn soils: dry cleaning might not be as effective as wet cleaning for removing heavy food residue, particularly sticky or greasy contaminants
- Potential for incomplete cleaning: without due care and attention, dry cleaning might only remove surface dirt, leaving behind deeper contaminants
- May require special cleaning agents: depending on the type of dry cleaning method, specific cleaning agents might be necessary to achieve the results required.

Types

- Vacuuming
- Brushing
- Wipes
- Dry steam: heated to over 100 °C, dry steam becomes invisible and acts like a hot gas.

It is also important to touch on **typical cleaning agents** and their effect on production line systems and components, specifically their material of construction. The graphic below sets out the factors to consider:

Nature of chemical	Suitable for use on	Not suitable	Common issues
Alkaline	Stainless steel	Cooper, use with care on Al and Zn	—
Alkaline-inhibited	All metals and plastics	—	May leave residual inhibitor on surfaces
Caustic	Stainless steel	Soft metals and alloys	Pitting of surfaces
Chlorinated	Stainless steel, some plastic	Soft metals, e.g. aluminium	Pitting or de-lamination
Acidic	Stainless steel	Care on mild steel and soft metals	—
Neutral	All metals and plastics (care of stress cracking on some plastics)	—	Residual grease or oil

Engineered for protection

Among common misconceptions is that the specified **IP (ingress protection) rating** relates to the level at which a component can withstand cleaning, but this notion is incorrect. The IP rating merely infers the **ability of a component to resist the penetration of water and dust**. It is the design of the component that determines its ability to withstand cleaning detergents and high temperatures, as already outlined in the hygienic design section of this report.

The food manufacturing sector typically requires the use of IP66-rated components to protect against the ingress of water during cleaning at medium pressure. However, the trend for IP ratings is upwards. Most of industry is moving towards IP67, particularly in full washdown environments such as the processing of protein-based products (meat, fish, cheese). Thorough washdowns need components with an appropriate IP rating. Many consider the ultimate as **IP69K**, which means a component can **withstand high-pressure, high-temperature jets of water**.

It is worth reiterating that even a component with a high IP rating may not be able to withstand harsh cleaning chemicals or water temperatures of 50-60 °C. A holistic approach to hygienic component design is therefore paramount in all applications.

Ingress protection (IP) ratings guide

IP ratings are represented by combining the first and second digits of the below columns

1st numeral – solid foreign objects

0 No protection

1 Protected against solid foreign objects of 50 mm Ø and greater

2 Protected against solid foreign objects of 12.5 mm Ø and greater

3 Protected against solid foreign objects of 2.5 mm Ø and greater

4 Protected against solid foreign objects of 1 mm Ø and greater

5 Dust-protected

6 Dust-tight

2nd numeral – water

0 No protection

1 Protected against vertically falling water drops

2 Protected against vertically falling water drops when enclosure tilted up to 15°

3 Protected against spraying water

4 Protected against splashing water

5 Protected against water jets

6 Protected against powerful water jets

7 Protected against the effects of temporary immersion in water

8 Protected against the effects of continuous immersion in water

9 Protected against high pressure and temperature water jets

Example:

IP 6 5

5 – Protected against water jets

6 – Dust-tight

04 Hygienic design

Setting the standard

Directives, regulations and standards governing hygienic design concepts for the food industry include:

- The Machinery Directive 2006/42/EC, which was repealed and replaced by Regulation (EU) 2023/1230 on machinery, which applies from 20 January 2027
- Regulation (EC) 852/2004 on the hygiene of foodstuffs to ensure safety for consumers
- EN1672-2:2020 standard for food processing machinery that outlines the basic concepts for hygiene and cleanability.

These documents set out the **stipulations for machines, systems and components** used within the food industry, where smooth, easy-to-clean surfaces minimise the risks of contamination and contagion.

Hygienically designed, easy-to-clean components are paramount to food plants and machine builders. In fact, a gold-standard hygienically designed component will not only support the easy washing away of soil, it will also present the opportunity to lower the temperature of the cleaning process and reduce the amount of water and detergent. These outcomes are **beneficial from both a sustainability and cost perspective**. In addition, easy-to-clean components reduce the time required to perform cleaning regimes, potentially contributing to higher machine availability and OEE (overall equipment effectiveness).

If an existing machine does not feature hygienic design, the cost to improve it and maximise food safety is typically extremely high. A far more cost-effective strategy is to impart hygienic design from the outset. Although the upfront cost may be a little higher, it pales into insignificance compared with the potential costs associated with:

- Consumer health issues
- Legal action
- Product recalls
- Loss of business
- Damage to brand reputation.

Indeed, the topic of hygienic design is trending across industry as increasing numbers of food plants see this concept as a way to minimise total cost of ownership (TCO) and support competitiveness.

As a further point of note, most consider hygienic design as a holistic approach to food safety. It forms a centrepiece that segues with other factors that include:

- Food Management Safety System
- Equipment and process design
- Cleaning and disinfection
- Building design
- Utilities
- Personnel hygiene.

EHEDG

With reference to hygienic design, the key body in Europe is EHEDG (European Hygienic Engineering & Design Group), a non-profit organisation founded in 1989 that produces guidelines for the hygienic design of food processing equipment. The US equivalent of EHEDG is 3-A Sanitary Standards. Machine builders and food plants should identify components designed according to EHEDG or 3-A guidelines.

So, what does an EHEDG-compliant automation component look like? Take the example of pneumatic insert fittings. As a concept, an EHEDG-compliant fitting will **feature a rounded design for better flow of the wash solution and less liquid pooling**. More specifically, EHEDG design guidelines applicable to such a component might include:

- External surface roughness of RA 0.8 µm or less
- Either corner radii of 3 mm or more, or internal angles of 135°
- Stainless steel material with high anti-corrosion performance: 316 stainless steel
- No direct contact of external metal parts
- Gasket seals made of rubber materials compliant with US FDA standards or Regulation (EC) 1935/2004.

Hygienic design, when applied properly, leads to **optimal product safety** and **high product quality**. It will also serve to reduce downtime, maintenance costs, cleaning costs and environmental impact. EHEDG certification requires renewal every five years, involving a new design review and re-testing if necessary.

EUROPEAN HYGIENIC ENGINEERING & DESIGN GROUP
EHEDG
MEMBER SINCE 2013

SMC's insert fitting, FDA compliant, EHEDG compliant, male connector +

Out of harm's way

All machine components – including cylinders, valves, valve manifolds, pressure sensors and flow meters – must offer ease of cleaning in their installed position to comply with EDHEG. They must be easy to clean, and easy to see they are clean.

In the first instance, components, pipes, connections and seals should be as simple and residue-free as possible. Cylinders, for example, must offer a design that is free of:

- Grooves and indentations
- Dead spaces like crevices, recesses and gaps
- Trap points
- Socket-head fasteners.

A good source of reference here is EHEDG Guidelines Document 8: hygienic design principles.

Material world

A major factor in successful hygienic design is the material of construction, which must be **non-toxic, non-absorbent and resistant to cleaning agents**. Materials should also be compatible with one another and the environment.

All components intended for use on food production lines must be made from the right grade of corrosion-resistant stainless steel. This material is necessary due largely to the use of cleaning chemicals like chlorinated caustic, which can cause incorrectly-specified component materials to corrode and potentially contaminate food.

As its name suggests, this cleaning chemical combines chlorine with a caustic base to clean and sanitise equipment and surfaces in food processing plants. It works by chemically oxidising organic molecules, such as proteins and colours, into smaller molecules for easy removal and rinsing away from surfaces. Only by using the appropriate grade of stainless steel is it possible to avoid degradation or damage to the surfaces of components - and subsequent contamination.

A case in point is pneumatic cylinders, which divert, collate, sort and dispense food during automated manufacture. Cylinders also see use further downstream, in processes such as automated sealing, labelling, wrapping and box erecting. Cleaning techniques at food plants running batch-mode production lines typically involve:

- Alkalis
- Acids
- Disinfectants
- Saturated steam.

These elements create an extremely aggressive environment for components such as cylinders. Only **electro-polished, high-quality stainless steels provide the required CIP** (clean-in-place) **capabilities** on batch-mode food production lines.

Aside from corrosion resistance and compatibility with detergents and disinfectants, additional hygienic design considerations regarding materials of construction include:

- Inert to food products
- Non-toxic
- Non-tainting
- Mechanical stability (resistant to cracking, splintering and flaking)
- Non-absorbent
- Avoids crevices or blind ends (these serve as soil traps)

Seal of quality

The choice of construction materials is equally critical when selecting food-safe, regulation-compliant plastics and elastomers, such as seals and gaskets. In the European Union **(EU), EC 1935/2004** sets safety and inertness standards for food-contact materials, while in the United States, CFR 177 specifically governs polymers used in such applications.

Plastics and elastomers must resist chemical leaching, which can occur when exposed to cleaning agents like chlorinated caustic detergents. Selecting an unsuitable material can compromise the integrity of seals—for instance, on an actuator—leading to surface cracks that create an ideal environment for bacterial growth. Over time, a deteriorating seal may also shed debris, posing a risk of food contamination.

To mitigate this, an increasing number of food equipment designers are opting for machine components with **blue seals**, making contaminants more easily detectable in the event of contamination.

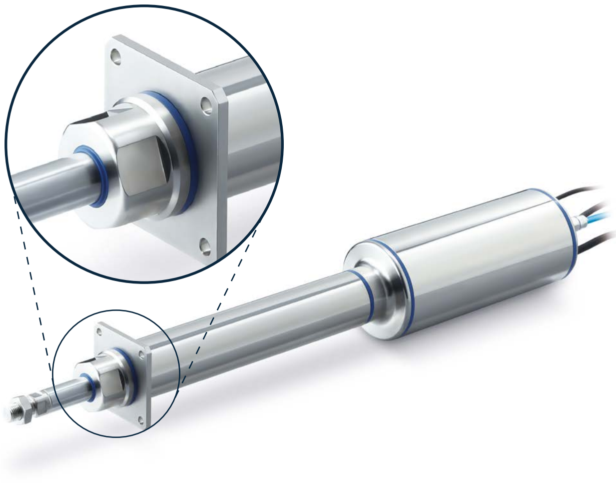
Good on the surface

Another key aspect of hygienic design is the **surface finish** of components. Many actuators and valves, for instance, are manufactured through machining, which can leave surfaces rough and prone to bacterial buildup. To prevent this, surfaces must be sufficiently smooth, **minimizing crevices where bacteria could reside**. A smooth finish also facilitates thorough and effective cleaning. Common surface finishing techniques include:

- **Polished steel**: abrasive belts or discs even out the surface to produce a brushed or lined finish
- **Electropolishing**: metal immersed in phosphoric electrolyte bath where a low-voltage current passes through the solution to remove a uniform layer of metal particles
- **Pickling**: hydrochloric or sulphuric acid removes impurities
- **Glass bead blasting**: Ceramic or plastic beads smooth the surface, aiding in the removal of bacteria and viruses.

Beyond surface finishes, designers of machines and food production lines must also specify components that use **suitable lubricants**. NSF H1 food-grade grease is the industry standard for food applications, ensuring safety in the event of accidental contamination or consumption.

Another important consideration is labelling. Traditional labels can degrade or detach under rigorous cleaning, posing a contamination risk. A more reliable alternative is **laser marking**, which provides permanent, tamper-resistant identification.



SMC's dust-tight/water-jet-proof (IP69K) electric actuator +

05

Compressed air filtration

Filtering out the risks

The food industry is highly influenced by strict legal regulations, even more so if the machine or equipment comes into contact with food. In such applications, materials that come into food contact must comply with regulations that include:

- Regulation (EC) 1935/2004: a general safety framework applicable to all possible food contact materials and articles
- Regulation (EC) 2023/2006: a good manufacturing practice (GMP) guide for materials and articles intended to come into contact with food
- Regulation (EU) 10/2011: specifically for plastic materials and articles intended to come into contact with food
- FDA CFR Title 21 (USA).

SMC's air combination units for food & packaging

Automation components also need to feature a hygienic design in accordance with HACCP plans and other standards.

An example of a direct-contact application is the blowing of compressed air over food products. Air is perceived as free and clean, but little could be further from the truth. Sure enough, it is free to take air from the atmosphere but there is a cost to compress and deliver it to the point of application in the optimal way. **Compressed air is also unclean**. It passes through a mechanical compressor, then moves along pipelines that may be many years old.

On the danger list

Untreated compressed air contains many potentially harmful contaminants. Blowing compressed air directly over food products or food packaging therefore necessitates filtration at different locations. However, not all filtration products are made equal. In the first instance, filtration solutions should comply with **ISO 8573-1**, which specifies the various purity classes of compressed air with respect to particles, water and oil (independent of the location in the system at which the air is specified or measured). Filtration products compliant with ISO 8573-1 and tested at a third-party test house in accordance with ISO 12500 (test methods for compressed air filters) can help support a food manufacturing plant's PRP and HACCP requirements.

The British Compressed Air Society (BCAS) is among numerous trade associations around the world that makes recommendations regarding the quality of compressed air. It proposes three components to remove:

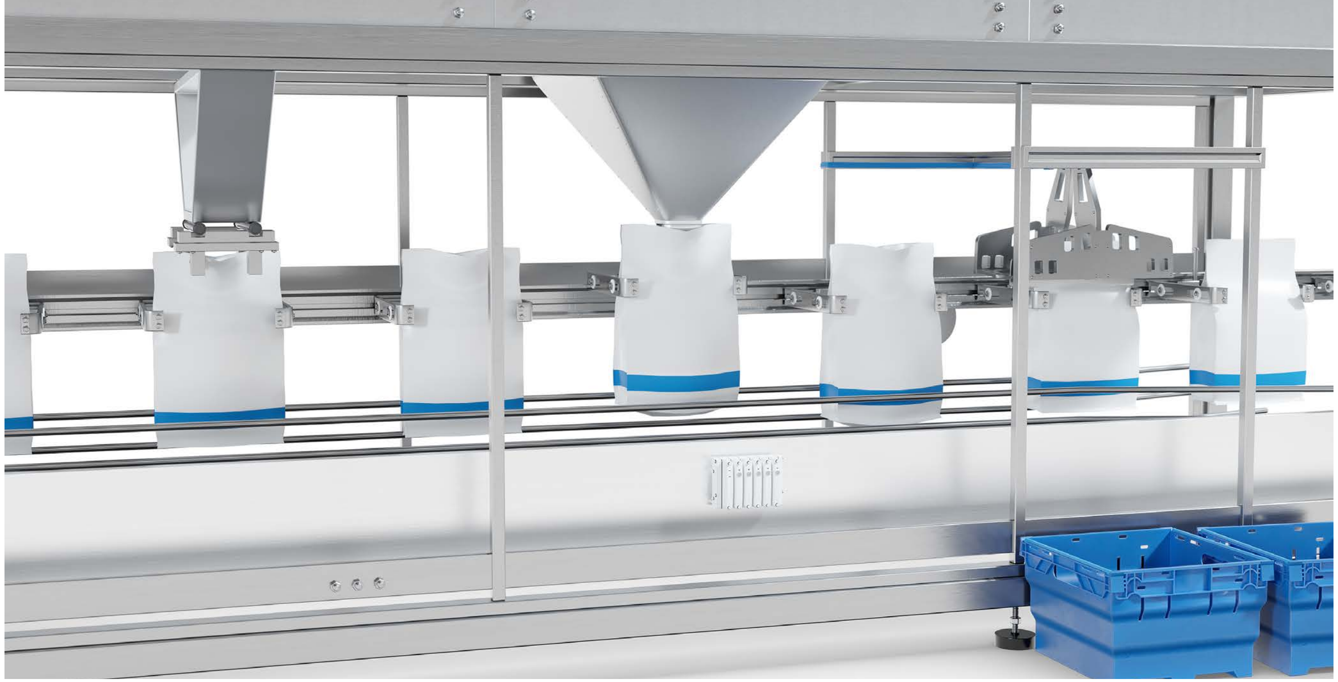
- Particulate
- Water
- Oil.

For further information about ISO air purity class, check our guide for **air treatment.**

BCAS recommends 1:2:1 air quality for direct food contact - particulate class 1, water class 2, oil class 1 - as based on the ISO 8573-1:2010 standard.

- Particle size class 1: no more than 20,000 particles in the 0.1-0.5 μm range; 400 particles in the 0.5-1 μm range; and 10 particles in the 1-5 μm range per cubic metre
- Water content class 2: a pressure dewpoint of -40 °C or better, with no liquid water present
- Oil content class 1: no more than 0.01 mg of oil per cubic meter, including vapour.

The type of food manufacturing process is a major influencer when it comes to specifying the necessary level of filtration. Please note, while the machine builder or component supplier can provide advice regarding air quality, it always the responsibility of the food manufacturing plant to specify its desired quality of compressed air.



Alive and kicking

Another focus area is **bacteria**. Unlike particles, bacteria are alive. With temperature and humidity, bacteria can thrive and pass certain filters. The first thought is to employ a dryer that reduces the dew point of the compressed air to remove moisture. Typically, bacteria cannot reproduce in such environmental conditions. In reality however, bacteria can still be present in certain situations, perhaps where the level of heating is insufficiently high to eliminate all moisture, or where the dryer is not functioning correctly. Food manufacturing processes require dry air down to a pressure dew point of at least -26 °C, a level that renders bacteria inactive.

For these reasons, food manufacturing should install **antibacterial filters** to ensure full food safety. As a point of note, it is worth seeking out an inline anti-bacterial filter that does not require cartridge cleaning. Conventional filters often require daily cartridge cleans, typically using an autoclave, leading to extra cost. Certain applications, however, such as those involving dairy products, must use cartridge-based filters in support of aseptic cleaning processes.

Spot checks

The filtration efforts of food plants are of increasing interest to auditors. An auditor will frown upon a food manufacturing process that only features filtration in the compressor house on the other side of the factory. In such applications, the compressed air might travel 500 m through old, unclean pipes that harbour bacteria, before blowing on to food. Although filtration is always advisable at the compressor, the optimal location is at the point of air blow.

A risk analysis is necessary in all applications, with thought given to the intended use of the product. Plants can then decide whether it is a critical control point (last point in a process where it is possible to kill any bacteria/risk), or implement suitable prerequisites for compressed air.

Filter out non-compliance

So, what might represent an optimal specification for an anti-bacterial filter? Key factors to look out for include:

- LRV (log reduction value)
- Nominal filtration rating
- Filtering efficiency.

LRV is a measurement of how well a filter captures bacteria or other materials. Seek out an LRV ≥9 in order to blow safely in food processes. Another important metric is filtering efficiency.

Products with a nominal filtration rating of 0.01 μm are able to deliver 99.99c filtering efficiency to avoid any impurities in the process air. It is also worth checking that the filter uses NSF-H1 food-grade lubrication for the flow path. In cost terms, investing in a bacteria-removal filter is appealing to food plants because the alternative of generating sterile air is typically far more expensive.

Of course, filters are just one component of systems intended for food contact. Tubing, for example, is also available that complies with both EC1935 and FDA standards to ensure there is no chemical leaching. Many other products are suitable for direct or incidental food contact, using the appropriate materials, elastomers and grease.

06

Executive summary

There are many factors to consider in support of successful food manufacturing operations, but top of the priority list is food safety. **Consumer health, business prosperity, reputation, compliance and effects on the global food chain** are just some of the reasons why food safety is so important. Achieving food-safe manufacturing means specifying machines, equipment and components that offer hygienic design. **Expert advice and support from key technology suppliers** is therefore a vital ingredient of project success.

Problem

Put simply, poor food safety increases the likelihood of contamination, the three principal types of which are physical, chemical and microbiological. The dangers of these contaminants to human health include:

- **Physical contamination**
  - Choking
  - Cuts to mouth and/or gums
  - Broken teeth
  - Illness.
- **Chemical contamination**
  - Vomiting
  - Potential long-term conditions such as organ damage or cancer
  - Poisoning.
- **Microbiological contamination**
  - Foodborne illnesses such as diarrhoea, nausea, vomiting, fever, abdominal pain and even death in certain instances.

Add to this the financial implications that can arise from legal settlements, regulatory failures, product recalls, loss of business and damage to reputation – and the seriousness of food safety issues soon becomes very apparent.

Solution

Many initiatives can have a positive impact on food safety. Arguably top of the list is adopting a **cultural approach** to food safety that cascades throughout business, from board level directors to production line operatives. This top-to-bottom ethos of course includes engineers, who must think carefully about their production line machines and equipment. Are they food-safe? To answer affirmatively means taking advantage of hygienically designed components.

There are two **key questions** to ask when assessing a component for hygiene-based applications like food manufacturing:

- Is it easy to clean?
- Has it been designed in line with the appropriate regulations and guidelines?

Only by adopting a mantra of hygienic design as part of a corporate-wide strategy will it be possible to satisfy auditors and become a food-safe manufacturing facility.

Value proposition/ result

Partnering with a proven expert in the design and manufacture of automation components for food manufacturing applications will ease the pathway to food-safe operations.

Highly experienced automation specialist **SMC can advise on individual applications, entire machines and full production lines**, ensuring hygienic design is part of the solution from the outset. But how can food plants ensure this happens? The answer is simple, they must specify the need for hygienically designed components in their user requirement specification (URS), as set out by new CPO guidelines in BRCGS Global Standard Food Safety Issue 9 and FSSC 22000 Version 6.0. The implications and cost of overlooking this inclusion are potentially catastrophic and enormous.

Expert advice from SMC

With subsidiaries and distributors at hundreds of locations in more than 80 countries worldwide, SMC offers a global presence on a local level. The company's highly **qualified engineers - trained in HACCP principles and EHEDG hygienic design guidelines** - are ready to provide prompt advice and solutions to the diverse needs of both machine builders and food production plants.

A broad and rapidly expanding range of **hygienically designed automation components** are available from SMC in support of food-safe manufacturing operations, including those involving direct food contact. The company has extensive experience in many industry segments, including protein, dairy, baking, chocolate, snack, beverage and brewing.

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