

# SANITARY AND HYGIENIC DESIGN STANDARDS FOR SAFETY COMPONENTS



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The food-processing industry includes many mechanically performed process steps, such as harvesting, drying, filleting, heating, shredding, crushing, mixing, filling, and packing. During these process steps, industry sanitary and hygienic standards and directives must be upheld, to prevent food borne illnesses. But machinery safety regulations must also be observed. It is highly important when selecting safety devices or command devices for food processing machines that they meet hygienic or sanitary standards.

Sanitary and hygienic are both terms used to describe a clean environment free of areas that cultivate microbial growth. Canada and USA are split between the use of the terms in their regulations.

Canada has recently released and enforced the Safe Food for Canadians Regulation (SOR/2018-108). Section 50.1 outlines that all conveyance and equipment must be maintained in a sanitary condition. The regulation does not instruct how to ensure a design is sanitary apart from making sure it “does not present a risk of contamination of a food” (50.2). It goes on to specify that equipment used in the “manufacturing, preparing, storing, packaging or labelling” (53) of food must be constructed of materials suitable for their intended use and capable of withstanding repeated cleaning and sanitizing. Furthermore, the Ontario Ministry for Agriculture, Food, and Rural Affairs (OMAFRA) goes on to explain sanitary as

the treatment of a clean surface with chemical or physical agent to reduce pathogenic microorganisms. OMAFRA also spotlights control buttons and HMI, ensuring a proper procedure to clean and sanitize those devices should an inherently unsanitary product design is used.

In the United States there is the Food Safety Modernization Act (FSMA), which has been rolling out since 2011. It defines hygienic design standards in terms of following current Good Manufacturing Practices. One such practice is found in the American Meat Institute standard AMI2003 7.1 “Human/Machine interfaces such as push buttons, valve handles, switches and touch screens, must be designed to ensure product and other residues (including liquid) do not penetrate or accumulate in or on the enclosure or interface.” Other industry standards define the need for smooth surfaces (EN1672-2) and cleanability (EN1672-2, NSF 5.1, AMIF 2013). The National Sanitary Foundation (NSF) has a voluntary standard, uniformly enforced by health departments, which goes into detail about ventilation, cleanability, grease removal, and safety shut off.



In both countries, the bottom line for sanitary/hygiene is cleanability. Machine components must be able to withstand various cleaning conditions, such as high temperature/high pressure wash downs, steam cleaning, and/or harsh cleaning agents.

Some certifications to look for are:

**IP69(K) Rating** – certified for high temperature (to 176° F/80°C) and high pressure (to 1450 PSI) wash downs, a method typically used to sterilize equipment.

**ECOLAB certification** – ECOLAB tests the efficacy of cleaning agents and certifies products for resistance to approved cleaning agents.

**3A Sanitary** – design criteria for equipment and processing systems developed using ANSI requirements to promote acceptance by USDA, FDA and state regulatory authorities.

**DGUV certified hygienic** – Deutsche Gesetzliche Unfallversicherung (German Social Accident Insurance) tests products based on European standards.

**EHEDG** – European Hygienic Engineering & Design Group, another group which tests products based on European standards.

**IPA cleanroom approved** – cleanrooms are an indispensable infrastructure and a mandatory requirement for high quality and product safety in the pharmaceutical and biotechnology industries, in addition to semiconductor, optics, aerospace, and electronics production.

For more on the Safe Food for Canadians regulations, check:  
<https://laws-lois.justice.gc.ca/eng/regulations/SOR-2018-108/page-7.html#h-844197>

For more on the Food Safety Modernization Act, check:  
<https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/food-safety-modernization-act-fsma>

### Examples of hygienic/sanitary designs

Features include smooth surfaces and transitions, concealed mounting, special seals that are IP69K rated, and/or ECOLAB approved materials. Other considerations include use of stainless steel or blue colored gaskets that are easily identifiable if they fall into food lines.



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