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Hygienic design and enclosures

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In the food and beverage production industry, electrical enclosure systems are often used that fail to meet the requirements of hygienic design. But which criteria must be used to select enclosures and when can we begin to speak of a “Hygienic Design enclosure”? This White Paper provides a comprehensive overview of the current and relevant directives, regulations and guidelines, as well as describing their practical application.

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1 Introduction

Hardly a month goes by without any warnings or recalls in the foodstuffs industry. Up-to-date information is provided on them on platforms like “lebensmittelwarnung.de” (of the German Federal Office of Consumer Protection and Food Safety). In this context, many consumer protection experts even complain that recalls often occur too late (and sometimes not at all).

Against the backdrop of a highly sensitised public, one thing is certain: Product contamination must be avoided at all costs in the food and beverage industry. The greatest risks are posed by microorganisms such as fungi or bacteria. Only those who can avoid contamination in the manufacturing process and remove these harmful factors from the production environment will have no problems to fear.

Hygiene as a production factor

This all clearly shows how important “hygiene as a production factor” has now become. Consumer confidence evaporates; if hygienic principles are not observed during production, then financial losses for manufacturers and retailers are the logical consequences. And this is where “Hygienic Design” comes in. A variety of specifications must be adhered to, not only during the planning phase but also when operating production facilities.

Hence, for a number of reasons, the food and beverage industry is called upon to design its production processes with an eye to hygienic aspects and to find the best possible solutions for guaranteeing hygiene. Machinery and plant constructors, as well as component makers, offer food manufacturers many solutions, some of them more and some less suitable for the requirements of the food and beverage industry.

Suitable enclosure solutions for hygiene-sensitive areas

Enclosure systems are used in the food and beverage production environment. Although many different systems are used, they do not meet the requirements in full. But which criteria must be used to select enclosures and when can we begin to speak of a “Hygienic Design enclosure”? Who defines these requirements and examines whether they are compatible and in accordance with the – current directives, regulations and guidelines?

This White Paper provides a comprehensive overview of the current and relevant directives, regulations and guidelines, as well as describing their practical application. With the help of this White Paper, you will be able to distinguish more easily between hygienic and non-hygienic enclosure solutions and identify the ideal system to meet your demands.

Figure 1: View of a production line at FrieslandCampina, a food manufacturer in Gütersloh, Germany.

2 Requirements for hygienic design

All the official regulations, directives and guidelines on hygienic design are based on the HACCP quality system. HACCP stands for Hazard Analysis and Critical Control Points. This system originated in the aerospace industry and is based on FMEA ("Failure Mode and Effects Analysis") methodology.

In accordance with the EU Hygiene Regulation (EC) No. 852/2004, the introduction of HACCP plans is demanded by law. The Codex Alimentarius (Alinorm 97/13A) published by the World Health Organization (WHO) is also internationally recognised. The following are the main features of the HACCP system:

1. Analysis of hazards to food safety within the company
2. Determination of the critical points for food monitoring
3. Definition of intervention limits for the critical control points
4. Ensuring the continuous monitoring of food safety
5. Defining corrective measures in the event of any deviations
6. Verification that the system guarantees food safety
7. Documentation of every measure taken

Before the EU adopted general directives for uniform hygiene rules, each EU member state had its own regulations and industrial food manufacturers had to adhere to them. The EU has united these country-specific regulations and defined generally applicable directives. These too are based on the seven points of the HACCP system. In addition, private organisations have produced guidelines based on best practice experience and concrete industry issues. These guidelines can also be used as a basis for hygienic production.

All these directives, regulations and guidelines are aimed at ensuring that food manufacturers' production facilities can be cleaned as easily as possible and – at the same time – as well as possible (process-safe) in order to guarantee the greatest possible safety for the end consumer. Moreover, the industry is under pressure to ensure that end consumers consume products that are as fresh, long-lasting and, above all, as hygienically safe as possible (i.e. harmless to health).

In order to uphold these high-quality standards, food manufacturers are checked by recognised bodies. This involves such standards as the IFS (International Food Standard), whose specifications demand that quality checks are carried out in part on a country-specific basis and partly internationally. Below, some common regulations, directives and guidelines are mentioned that apply to systems and machinery in particular.

EU regulations

- REGULATION (EC) No. 852/2004 OF THE EUROPEAN PARLIAMENT AND THE COUNCIL of 29 April 2004: This regulation covers specific hygiene rules for food of animal origin.
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- REGULATION (EC) No. 854/2004 OF THE EUROPEAN PARLIAMENT AND THE COUNCIL of 29 April 2004: This regulation lays down rules for carrying out official checks on products of animal origin that are intended for human consumption.
- REGULATION (EC) No. 1935/2004 OF THE EUROPEAN PARLIAMENT AND THE COUNCIL of 27 October 2004: This regulation refers to materials and objects that are intended to be brought into contact with foodstuffs.

Organisations

The organisations listed below define the standards, regulations or directives relating to food quality:

- IFS – International Food Standard
- NSF – National Science Foundation
- VSR (Netherlands: Vereniging Schoonmaak Research)
- BGN – Berufsgenossenschaft (Germany)
- BRC Global Standards – Global Standard for Food Safety
- EHEDG – European Hygienic Engineering and Design Group
- FDA – Food and Drug Administration (the US authority responsible for the regulation of foodstuffs and pharmaceuticals)
- 3A Sanitary Standards
- GFSI – Global Food Safety Initiative
- WHO – World Health Organization

Figure 2: Automation technology at FrieslandCampina is safely protected by Hygienic Design enclosures from Rittal.

3 Requirements for materials, design and use

Hygienic Design is the design principle behind a cleaning-friendly or easy-to-clean design of components, machines and entire production plants. The following requirements must be particularly emphasised from the perspective of application areas, material selection and design:

Materials and surfaces

- Corrosion-resistant
- Must be capable of being cleaned and disinfected
- Smooth, no cracks or gaps
- The flow of liquids must be ensured

Connection system

- Sealed, seamlessly welded or glued
- In the food sector, screws and other types of connection must be avoided or at least be hygienically perfect

Angles and corners

– Minimum radius of 3 mm for cleaning
– Niches (i.e. spaces that cannot be examined visually or cleaned) must be avoided at all costs

Wall distance

– A sufficient distance to machines and enclosures must be ensured

Penetration into the machine from outside

– No liquids or other substances may be allowed to penetrate the machine

Lubricants

– Lubricants must not endanger foodstuffs

Maintenance and Cleaning

– Component that could become damaged must be easy to replace (without causing any further damage)

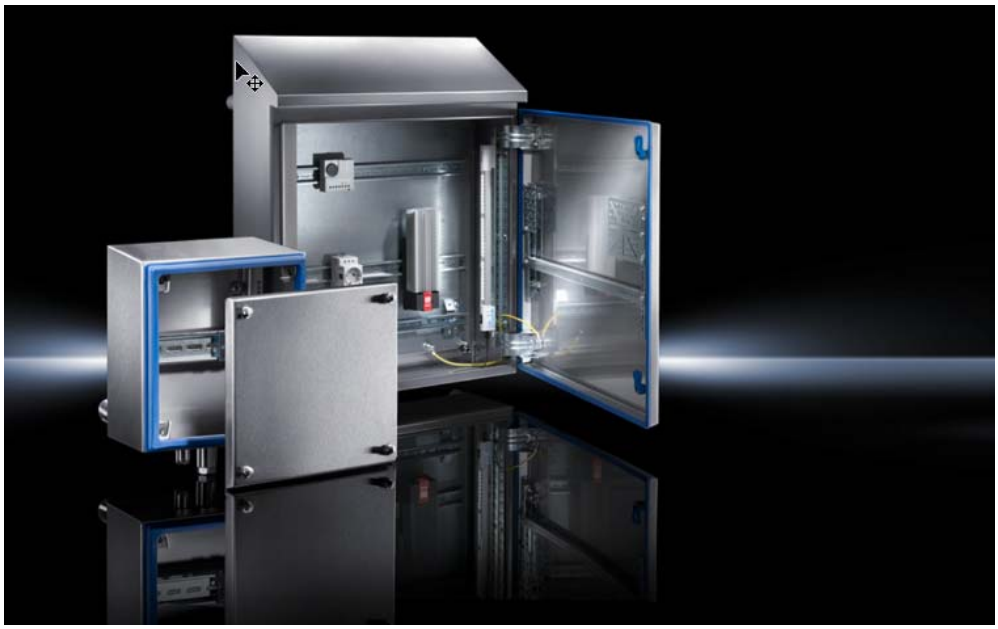

Figure 3: Rittal terminal box and an HD compact enclosure adapted to the requirements of the food and beverage industry.

4 Checklist for enclosures in the food and beverage industry

Firstly, the general electrical enclosure requirements must be observed: Empty housings for electrical enclosures are assigned to a valid EU directive with regard to the CE marking, according to which a marking obligation then exists. In particular, the Low Voltage Directive 2014/35/EU, based on type testing in accordance with DIN EN 62208 (VDE 0660-511): 2005-04 needs to be mentioned at this point. Other relevant directives are the Machinery Directive 2006/42/EC and the EMC Directive 2004/108/EC.

These requirements are placed on all electrical enclosure systems in an industrial environment and they must be met by every mechanical and plant engineer. However, these directives and standards do not provide any information on the enclosure's actual hygienic suitability. Due to the lack of any standardised and recognised test methods, it is up to the enclosure manufacturer, the systems and mechanical engineer, as well as the end user to decide for themselves on which kind of hygienic design should be employed. Nevertheless, the design must comply with the above-mentioned design directives.
The following checklist will help in selecting the right enclosures and housings for hygienic requirements. The most important question is: In which hygiene zone is the enclosure going to be installed?

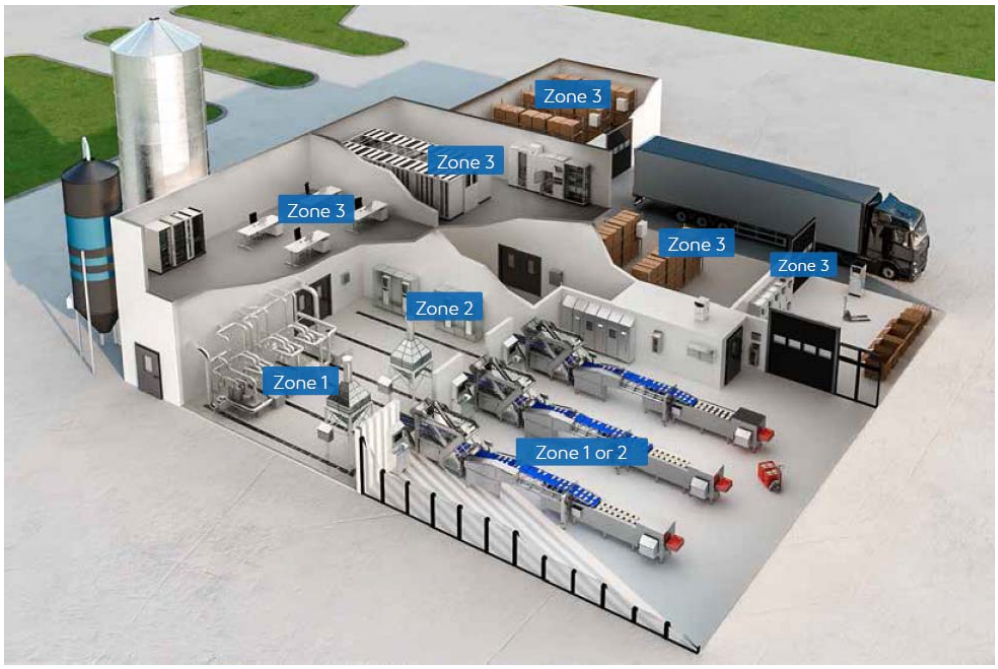

Figure 4: Schematic diagram of the hygiene zones at a company. There are three different types of goods. There are basically three different zones: These are the food zone (zone 1), the spray zone (zone 2) and the packaging and non-food zones (zone 3).

According to the EN 1672-2:2005 standard, a company can be divided into three different hygiene zones:

Food zone: This covers all the surfaces that come into direct contact with food and all the surfaces from which the food returns to the product stream through drainage, dripping, outflow or leakage.
Spray zone: This covers all the surfaces that come into direct contact with food and from which the food does not return to the product stream.
Non-food zone: This can be understood as all other surfaces and areas.

Figure 5: Washdown inserts require enclosures that are maximum leak-proof.

Below, zones 1 and 2 are considered in order to refine the checklist even further. This makes it possible to derive specific requirements for hygienic enclosures.

The following points must be considered when selecting enclosure solutions for hygienic environments:

1. Stainless steel (V2A, a nickel chromium steel type) with a corresponding surface roughness (peak-to-valley height < 0.8 µm).
2. All the surfaces and the folded edges of the roofs and doors must be visible. Liquids must be able to drain off, and it must not be possible to place objects on them. This leads to the requirement that the roof and door must have a slope of 30 and 10 degrees, respectively.

3. Liquids or foodstuffs must be prevented from penetrating when the door is open (e.g. during maintenance of the system). This means that an overhang edge (drip edge) is needed.
4. There must be no dead spaces or undercuts that are difficult or impossible to see. For this purpose, a suitable gasket must be provided.
5. In practice, the gasket proves to be a key factor. A gasket on the outside creates a radius between the enclosure and the door. No microorganisms must not be allowed to settle on it. The factors of the interchangeability and durability of the gasket must also be taken into account. This is because material fatigue aspects come into play as a result of the closing and opening cycles, as well as the environmental conditions.
6. There must be no “hard edges”: All the edges (for example, the welds, folded edges, seals or complex geometries) must have a radius of at least three millimetres and guarantee an even transition or else they must lie within the sealing area. This can be achieved by having the fittings on the inside and with welding seams that have been ground.
7. Every non-metallic object must be resistant to cleaning agents. Consequently, only FDA-compliant gasket material may be used.
8. It must be possible to replace all the replaceable components by components of the same quality. This can be achieved by using a replaceable gasket; in other words, all the components must be available as spare parts.
9. The protection category must be adapted to the cleaning and environmental conditions. A corresponding declaration of conformity and suitable documentation is vital.

Figure 6: For example, the hinges are located outside the sealing area in an enclosure that is not of hygienic design.

Figure 7: The blue gaskets, which extend to the outside, are clearly visible on this HD series enclosure.

Figure 8: The gaskets of an HD enclosure can be easily replaced.

Figure 9: The slope of the enclosure's roof ensures that liquids can drain off.

5 Proof of the hygienic suitability of enclosures

Proof of the hygienic suitability of enclosures needs to be provided by a recognised testing institute that has the expertise needed for hygienic applications.

The following process represents one possible test procedure:
1. The test object is contaminated with a fluorescently labelled milk product
2. Then it is cleaned
3. It is then dried and
4. The residues are identified by fluorescence.

The general conditions such as temperature, test distance and drying time should therefore be as realistic as possible and logged. It makes sense to carry out comparative tests in order to be able to make a comparison with conventional enclosures.

Following a realistic cleaning process with defined times and cleaning agents, the hygiene enclosure must be cleaned until no residue is left.

The following illustrations show the possible results of such a test:

Figure 10: The HD enclosure before contamination.

Figure 11: The contamination of the HD enclosure in the test.

Figure 12: Not all the contamination is removed after a conventional enclosure is cleaned.

Figure 13: This is how the HD enclosure looked near the upper hinge prior to the experiment.

Figure 14: After the test has been performed on an HD enclosure, all the contamination is removed without leaving any residues.

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