

Contamination Control within the food industry

Summary:

The WHO considers the global lack of food safety to be one of the greatest threats to global health. Market research has led Professional Partners for Controlled Environments (PP4CE) to conclude that a large proportion of Dutch and Belgian companies in the food industry have insufficient knowledge of risk-reducing measures by zoning within their production area. Introducing contamination control measures can be a first step towards gaining a better insight into this risk.

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Introduction

Of course, food safety has been an extremely important topic in the food industry for many decades already. **In principle, the food business operator itself bears full responsibility for safe and hygienic process control!**

Apart from the general hygiene and food safety themes, there are also important requirements with regard to labelling, product recall protocols, and so on.

In the Netherlands, compliance with the Commodities Act (*Warenwet*) is monitored and enforced by the Netherlands Food and Consumer Product Safety Authority (Nederlandse Voedsel- en Warenautoriteit, NVWA). In Europe, the General Food Law Regulation is the leading legislation, which is increasingly being applied in the Netherlands.

Summary of food hygiene requirements

The European regulations on the registration of food businesses provide a great deal of information on the subject of food hygiene.

Regulation (EC) No 853/2004 on the hygiene of foodstuffs lays down general rules for food business operators on the hygiene of foodstuffs, taking particular account of the following principles:

- Primary responsibility for food safety rests with the food business operator.
- It is necessary to ensure food safety throughout the food chain, starting with primary production.
- It is important to maintain the cold chain for food that cannot be stored safely at ambient temperatures, particularly frozen food.
- General implementation of procedures based on the HACCP principles, together with the application of good hygiene practice, should increase the responsibility of food business operators on balance.
- Guides to good practice are a valuable instrument to aid food business operators at all levels of the food chain, promoting compliance with food hygiene rules and the application of the HACCP principles.
- It is desirable to establish microbiological criteria and temperature control requirements based on a scientific risk assessment.
- It is necessary to ensure that imported foods are of at least the same or an equivalent hygiene standard as food produced in the Community.

The Regulation applies to all stages of the production, processing and distribution of food, as well as to exports (under the Dutch Sequential Liability Act (*Wet Ketenaansprakelijkheid*)). It does not prejudice more specific rules on food hygiene.

Why such a focus on food safety?

There are a number of reasons why food safety is receiving increasing attention from the World Health Organisation (WHO) and the UN, among others. We should at least mention the report on this subject commissioned by the WHO in 2015, which showed:

- 600 million registered cases of disease as a result of contaminated food;
- 420,000 deaths (conservative estimate);
- of these deaths, 125,000 children <5 years old.

Problems with food safety have meanwhile been recognised as a global threat.

- There are 200 diseases caused by 31 pollutants (bacteria, fungi, viruses, parasites, and so on).
- Malfunctions in the digestive system can lead to cancer.
- Diseases are a cause of morbidity and mortality,
- as well as a significant obstacle to a country's socio-economic development.

What is the cause of this growing threat?

- The principal cause is the enormous growth of the world population (10 billion people by 2050?).
- Globalisation is stimulating the international movement of food products.
- The food chain is becoming longer and more international.
- Reduced control over the causes of food safety issues, and product recalls are becoming increasingly problematic.

Overall, the WHO ranks shortcomings in food safety among the greatest health risks.

Where are the risks?

We will soon be writing a separate White Paper on developments in global standards and guidelines within the food sector. In any case, a lot has changed in recent years and the question is how the FSSC 22000 standard will develop as a globally recognised benchmark (more than 17,000 companies have now been certified). Above all, how will companies deal with the fact that they can no longer be certified in accordance with the HACCP standard from 2021 onwards?

Whatever standard or directive we apply, a risk analysis will have to be made for the contamination of products in the various stages of the production, storage and transport process. The hygiene regulations mentioned above often relate to the cleaning and disinfection protocols for buildings, equipment and means of production. However, cleaning and disinfection of surfaces and installations alone will not provide the desired result of complete control over the biological risks!

The pharmaceutical industry is mainly concerned about the contamination of products by airborne microorganisms. The food industry identifies bacteria, fungi, viruses, yeasts or parasites as threats. Some of these microorganisms occur in the outside air (for example, as fungal spores). The presence of many other microorganisms is a result of human activities, which is why are also often found in buildings. They usually settle on dust particles between 0.3 and 0.5 micron in size. To put this into perspective: one cubic metre of air in a normal Dutch workplace may contain a maximum of 10,000 CFU (Colony-Forming Units such as bacteria and fungi).

In view of the potential impact on foodstuffs that may be exposed to air present in the room after the baking, cooking or steaming process, it is important that this air is filtered and that the microorganisms present are captured in finely meshed filters (e.g. the 'HEPA' filter = High Efficiency Particulate Air filter).

Zoning in production areas

Since the 1980s, it has been common practice for food production spaces to be zoned based on an analysis of the risks present. The aim is to control microbiological risks in particular. Such risks may include:

- Pathogenic microorganisms
- Allergens
- Foreign particles (glass, plastic, insects, and so on)
- Chemicals (e.g. cleaning agents)

Separation of ingredients may also be necessary with regard to handling requirements, labelling or brand protection. Examples include:

- Wet and dry storage and production processes
- Claimed vegetarian products in a mixed farm
- Claimed organic products in a mixed farm
- GMO-free or halal products

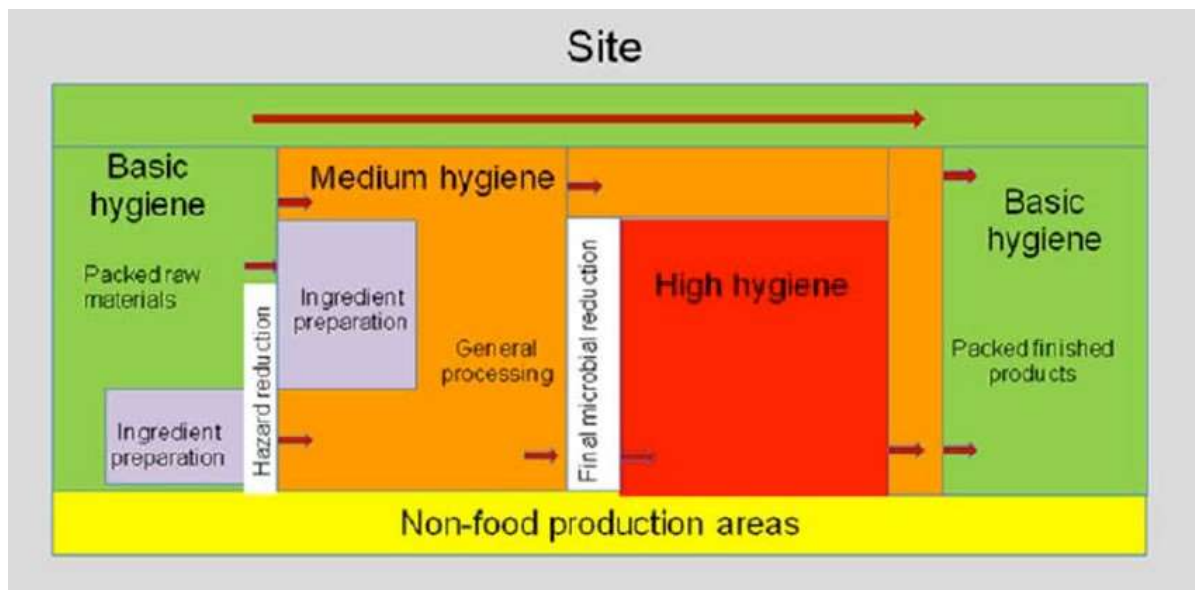


Figure 1. Schematic representation in a flowchart of a process in which the product travels through the various zones

Source: EHEDG Guideline 47.

A food production space can usually be divided into zones by means of a Risk Inventory and Analysis (RIA):

- Zone B = Basic hygiene = Low Care
- Zone M = Medium hygiene = Medium Care
- Zone H = High hygiene = High Care

Low Care:

These are areas where, in principle, there is no threat of contamination of raw materials or finished products. The environment must be suitable for the implementation of GMP (Good Manufacturing Practices) and GHP (Good Hygiene Practices), as well as for effective basic risk control.

Medium Care:

In these areas, there is some risk of contamination and/or cross-contamination of raw materials or finished products. Here, cleaned raw materials and prepared ingredients are treated, processed and/or packaged. Such areas are already subject to a number of structural and design requirements to ensure compliance with the risk profile.

High Care:

These areas have a high risk of contamination of raw materials or finished products. Such rooms are characterised by the packaging or further treating of ready-made/RTE (Ready-To Eat) food after its last microbiological reduction step, such as heating, steaming or baking. Further activities can only be carried out on the product after it has been packaged in the primary packaging.

Contamination Control in the food sector

Contamination Control evidently presupposes the existence of a decontamination process. Such processes are available for the air in Medium and High Care rooms and tend to be assessed against the ISO 14644 classification of cleanrooms. The usual starting point is that a Medium Care room is categorised as ISO 14644 Class 8 and a High Care room as ISO 14644 Class 7. An overpressure hierarchy with pressure differences of 10–15 Pa is often required in cleanrooms as well.

However, experience has shown that the food sector has given a different interpretation to this requirement. Below is an overview of minimum requirements or technically feasible specifications for the different zoning classes as described in EHEDG Guideline 47.

	Zone B	Zone M	Zone H
Filtration of environmental air (First, second or third filter stage) See also Section 5.8.7	Minimum one filter stage: 1. Stage M5-F7	Minimum two filter stages: 1. Stage F7 (+ GF if required) 2. Stage F9	Minimum three filter stages: 1. Stage F7 (+ GF if required) 2. Stage F9 3. Stage E10-H13 (depending on risk)
Positive air movement from higher to lower zone (Controlled overpressure)	--	optional	✓ essential ¹
Temperature control	optional	✓ essential	✓ essential
Humidity control	--	Optional depending on risk evaluation	Optional depending on risk evaluation
Minimum air changes per hour to maintain air quality ²		5	10

Figure 2. Summary of system recommendations for air treatment in the various zones of a food production system Source: EHEDG Guideline 47.

Just as in pharmaceutical industry cleanrooms, for example, it is necessary for the clothing regime, code of conduct and cleaning protocols within the various zones to be adapted on the basis of the risk analysis.

Another requirement is that a lock is built with an interlock closure system for the doors, especially in the entrances to High Care areas. However, not all architectural requirements can be covered in this White Paper. For in-depth information about hygienic building concepts and the application of air treatment in Medium and High Care areas, we refer to EHEDG Guidelines 44 and 47 respectively.

Conclusion

A market study carried out in the Netherlands within the food industry on behalf of PP4C showed that approximately 50% of the >500 respondents were not familiar with the terms 'Medium' and 'High Care' facilities. This figure rose to 75% in Flanders!

The PP4C partners consider it their task to inform the food industry about the food safety requirements and the supply chain responsibility that is expected of companies active in this market segment. The food sector should take all available risk reducing measures. In addition to jeopardising the continuity of the company concerned, the potential economic and social damage caused by local (let alone international) food poisoning issues can harm the international image – and the economy – of an entire country!

PP4C is a member of EHEDG. This internationally operating body keeps its members informed of developments in the hygienic production of food, drafts and publishes guidelines, advises legislators and regulators, and provides training courses in the field of food safety in the broadest possible sense.

Origin

PP4CE (Professional Partners for Controlled Environments) is a strategic alliance between a number of specialist companies in the design, construction and maintenance of cleanrooms and laboratories in a wide range of market segments. PP4CE is also active in Medium and High Care areas within the food industry.

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For more information, see [http: www.pp4ce.com](http://www.pp4ce.com)

References:

- Report by Wolting Marketing dated 21 November 2017 on food risk reduction ('Risicoreductie voedsel'), commissioned by PP4C
- Regulation (EC) No 852/2004 on the hygiene of foodstuffs (29 April 2004)
- EHEDG R.L. 44 Hygienic design principles in the food industry ('Hygiënische ontwerpprincipes voor voedingsmiddelenbedrijven')