Handbuch Lebensmittelhygiene

Praxisleitfaden mit wissenschaftlichen Grundlagen

REPRINT

Indoor Air

1 Hygienic air quality for safe food production

Many manufacturers of food products measure, control and regulate the air quality in their manufacturing facilities. Specific demands are made on the indoor air in production halls, such as temperature, humidity, particle concentration. Certain amounts of supplied fresh outdoor air are needed to ensure safety and workplace comfort. The production of certain foods places particular demands on air quality from a hygiene perspective: for example, to prevent or at least restrict the growth of microorganisms in production or storage areas.

The control and management of air quality and thus of the particle content (dust and microorganisms) in the ambient air leads to a minimizing of product contamination. This in turn makes a significant contribution to safe food production and adequate hygiene.

Airborne contaminants are removed from the air via a filtration process, in which the correct level of filtration and separation efficiency are aligned to the accepted contamination risks. Selection of an optimal system that meets all the requirements can only be achieved through a prior detailed risk analysis and specification, supported by thorough knowledge of the technical design of ventilation systems. Alongside selection of the optimal system, structural design, construction, installation and commissioning play an important role in microbiological product safety and shelf life.

Once the production facility is in operation, it is important that maintenance, cleaning and possibly sterilization can all be effectively and practicably carried out.

In addition to ventilation systems, appropriate hygiene and process control play an important role in the performance capability of food industry processes. This chapter deals with the monitor-

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ing and control of ventilation technology in food-producing facilities. Process air, compressed air and exhaust air (e. g. dust removal and grease filters) have fundamentally different requirements and problems and are covered in other chapters.

2 Terms and definitions

Exhaust air: Air that is transported from a given space out into the atmosphere.

Action value: Value above which corrective actions must be initiated (such as inspection, cleaning, filter change and increasing filter efficiency).

Outside air: Untreated air in the atmosphere; also referred to as 'fresh air'.

ASHRAE: (American Society for Heating, Refrigerating and Air-Conditioning Engineers) is a professional association in the United States for all people professionally involved in the construction of heating, cooling, ventilation and air conditioning installations.

Filter stage: Area immediately in front of and behind the air filters, filter holders, the air filter itself, as well as all measuring instruments used in the context of air filtration.

GPF (gas phase filters): Filters used to selectively separate gaseous components from gases by adsorption, absorption or chemisorption.

HACCP concept (Hazard Analysis and Critical Control Points) is a tool with which potential threats to consumers can be detected and avoided through preventive measures.

Hygiene inspection: Qualified investigation of the hygiene standard of the AHU.

H & S: Abbreviation for yeasts and molds

CFU (colony-forming unit): Unit in which the number of cultivable microorganisms is expressed. [1]

Leakage: Uncontrolled airflow into or out of a space as a result of pressure differences.

Air exchange rate: Calculable rate that describes how often air located in a room is exchanged by ventilation measures. It is calculated by dividing the air supplied to a room per time unit (in m^3/h) by the air volume of the room (in m^3).

Microorganisms: In connection with AHUs, this refers to bacteria (e. g. legionella), algae or fungi that can proliferate in water or on damp surfaces (e. g. humidifier water or condensate).

PM: is the English term for particulate matter.

Process air: Conditioned or treated air in a production process.

AHU (Air Handling Unit) systems and devices: The totality of components required to support the fan-assisted ventilation of one or more spaces. This includes technical component groups, such as centralized and decentralized ventilation and air conditioning equipment, as well as terminal devices.

Circulating air: Circulating air is exhaust air that is fed back into the air treatment system and resupplied as a component of the supply air to at least one space from which it was not removed.

Supply air: Air transported from the atmosphere into a given space.

WHO: World Health Organization.

3 Zone concept regarding product risk categories

Before the start of food production, it is necessary to define product risk categories based on a risk analysis of the intended production area. The result of this analysis is the definition of required degrees of purity and division into zones, which are in turn essential to the design and construction of AHUs. For a food production area, it is important to take an integral approach to the planning, construction and operation of the systems, in which all components that may have an impact on air quality are taken into account. All elements, such as for example doors, gates, intake and outlet flaps, maintenance, servicing, behavior and training of personnel play an important role and must be given due consideration.

Food products show different risks in terms of exposure to microbiological contamination. They range from low risk – for example dry, stable packaged foods – to high-risk such as frozen or ready meals. In the production of such foods, very different raw materials are used under very different process conditions and may introduce, eliminate or control different microbiological hazards. Growth, survival or proliferation of hazardous microorganisms can be greatly affected by air conditioning systems. For these reasons, AHUs in the field of food production must perform the following tasks in particular:

- Slowing or preventing the growth of microorganisms in the immediate area of food production as a result of low temperature and/or humidity
- Preventing the ingress of supply air from higher risk areas, for example as a result of permanent overpressure
- Removing particles on which microorganisms can be transported, for example by means of appropriate air filtration
- Minimizing cross contamination, for example through the proper design of air distribution and extraction systems
- Removing aerosols from the food production area, for example by means of directed airflow distribution
- Not acting as a source of contamination, for example through consideration of appropriate hygiene measures in design, operation and maintenance.

To manage and control risk for producers at the required level while minimizing production costs, it is vitally important that an integral hygiene concept is developed in the early planning and design stages. In this context, all elements of the manufacturing process that may have an impact on hygiene must be involved. This includes ventilation technology and the construction of the building in particular, as these will have a major impact on future hygiene risks. Figure 3-1 schematically depicts risk zones and potential product paths and air flow directions, depending on the requirements of protection against microbial contamination through the production process.

It is common practice to divide the food production area into three risk zones, with normal hygiene risk (**Zone B = “basic”**), medium hygiene risk (**Zone M = “medium”**) and high hygiene risk (**zone H = “high”**).

3 Zone concept regarding product risk categories

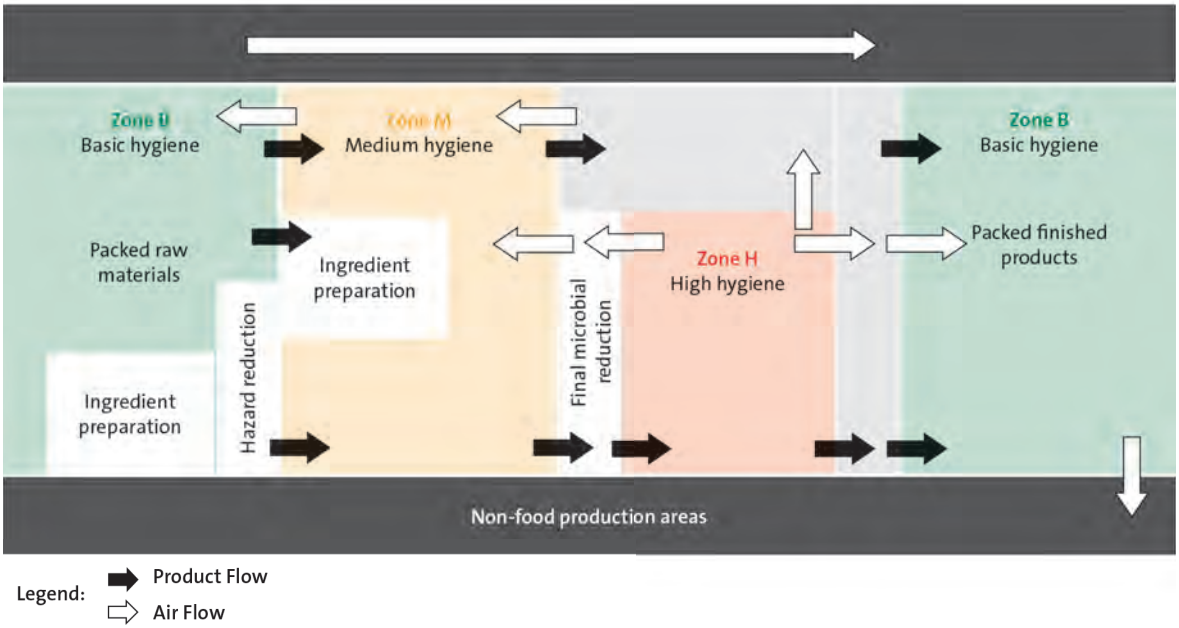

Figure 3-1: Schematic representation of risk zones and potential product paths (black arrows), depending on the product requirements for protection against microbial contamination during the production process and possible air flow directions (white arrows). [20]

- Normal hygiene areas **(Zone B)** are areas with a low hygiene risk and therefore low maintenance requirements. These areas have normal hygiene requirements. The aim here is to avoid product contamination and to control or reduce specific contamination risk sources that may be able to negatively affect areas with higher hygiene requirements. Food should not be stored, processed or transported open, but should be covered or wrapped. A typical example of a Zone B area is a warehouse.

- Medium hygiene areas **(Zone M)** are areas with a medium hygiene risk and therefore increased maintenance requirements. There are greater demands on hygiene than in Zone B. The aim here is to avoid product contamination and to control or reduce specific contamination risk sources that may be able to negatively affect areas with higher hygiene requirements. In addition, internal areas of the production facility should be protected against air pollution, where these areas are exposed to the room's atmosphere.

- High hygiene areas **(Zone H)** are areas with a high hygiene risk and therefore very high maintenance requirements. These areas have the highest possible hygiene requirements and must be closed. The aim here is to control or to avoid as far as possible all risks of product contamination, for example by isolating the interior areas of the production facility from the room atmosphere. These areas need to be supplied with sufficiently filtered and cleaned air. Zone H should occupy as little space as possible. System design and accessibility for cleaning and sterilization should be as simple as possible. Hygienic safety clothing, headgear and protective footwear covers must be worn. Cleanroom technology is increasingly being used in these areas (see Chapter 6).

Tables 3-1 and 3-2 provide an overview of system requirements for AHUs in the different hygiene risk areas.

Table 3-1: Overview of system requirements for AHUs

	Zone B	Zone M	Zone H
Air filter recommendations for ambient air	1. Stage ISO ePM10 50 % – ISO ePM1 50 % (M5-F7)[4]	1. Stage ISO ePM2,5 65 % (F7)[4] (+ GPF if necessary)[1] 2. Stage ISO ePM1 80 % (F9)[4]	1. Stage ISO ePM2,5 65 % (F7)[4] (+ GPF if necessary)[1] 2. Stage ISO ePM1 80 % (F9)[4] 3. Stage E10–H13 (depending on risk assessment)
Flow of air from higher to lower stage (controlled overpressure)		optional	✓ essential[2]
Temperature control	optional	✓ essential	✓ essential
Humidity control		optional (depending on risk assessment)	optional (depending on risk assessment)
Minimum air exchange rate needed to maintain required air quality[3]		5	10
Microbiological monitoring (HACCP study)	optional	✓ recommended	✓ essential

[1] GPF = Gas phase filters (e. g. activated carbon or molecular sieves for separation of gaseous components)
[2] Cleanroom standards such as ISO 14644 [3] recommend 10–15 Pa overpressure. The EHEDG directive on building construction recommends 5–15 Pa. Depending on the size of the environment that needs controlling and managing, or the number and size of openings (e. g. access hatches and doors), such high differential pressures could be difficult to achieve and require very large airflows. Alternatively, the positive flow can be detected by measuring the air speed at the openings (speeds of at least 1 m/s are a good reference value).
[3] Values may be higher, for example depending on the number and intensity of heat sources and temperature control.
[4] Filter classes according to DIN EN 779: 2012 (M5-M6, F7-F9) are invalid since July 2018, therefore they are shown in brackets. The filter classification is carried out today in accordance with DIN EN ISO 16890. [31]

Table 3-2: Notes on filter classes in the respective filter stages

100 % separation of particle sizes	General description of the air filter	Choice of filter classes
>10 µm	Primary filter	ISO coarse >60 %– ISO ePM10 50 % (G4–M5)[1]
>5 µm	Secondary filter	ISO ePM10 60 %– ISO ePM1 50 % (M6–F7)[1]
>2 µm	Secondary filter	ISO ePM1 50 %– ISO ePM1 85 % (F8–F9) [1]
>0.5 µm	EPA (Efficient Particulate Air) filter	E11
>0.3 µm	HEPA (High Efficiency Particulate Air) filter	H13

[1] Filter classes according to DIN EN 779:2012 were valid until June 2018. From July 2018 the entire air filter classification was replaced by DIN EN ISO 16890.

4 Air filters

Outdoor air contains a wide variety of dust particles, with the largest proportion composed of particles of a very small size. The air also contains microorganisms and gaseous components. These need to be monitored in the manufacturing of food products in such a way that risks to food can be safely controlled. [4]

Millions of particles are constantly present in every cubic meter of ambient air. Requirements for air filtration and thus for the separation of particles depend primarily on the need to protect the food product. A general representation of the particle size distributions of normal air pollutants is shown in Figure 4-1. [5]

4.1 Function and types of air filters

In general terms, air filters and other air purification systems must be chosen, constructed and operated in such a way that the individual components of the ventilation and air conditioning systems are protected at all times from airborne contaminants. The quality of air provided must at all times comply with the hygiene requirements. In the event that gaseous components need to be separated as well as dust and aerosols, gas phase filters (GPF) such as activated carbon filters or other similar systems can be used in additional filter stages.

At high dust concentrations, cleanable and efficient dust removal systems are often used for technical and economic reasons. Under certain conditions, their clean air can be recirculated [6] and is therefore an additional component of the entire ventilation system.

From a hygiene perspective, only filters that have been tested and certified accord-

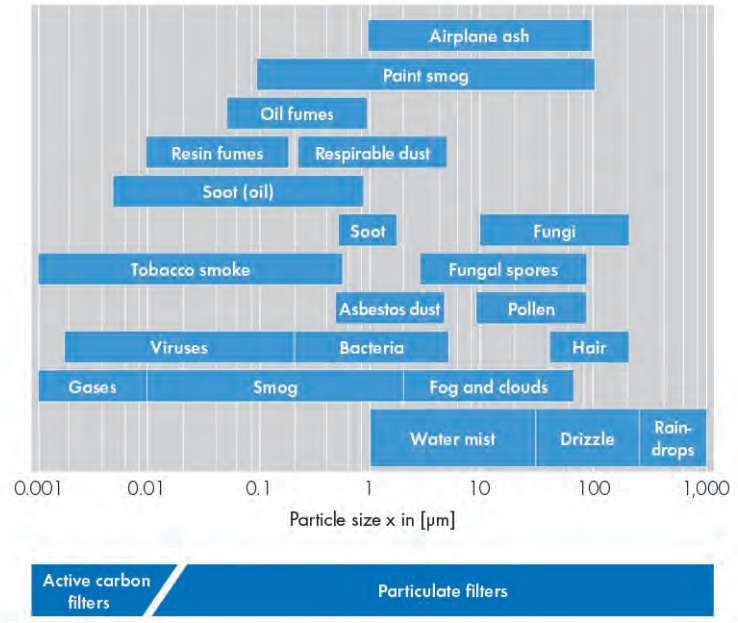

Figure 4-1: General representation of particle size distributions in normal atmospheric pollutants [5]

ing to DIN EN ISO 16890 (or according to DIN EN 779 until June 2018) and DIN EN 1822 or ISO 29463 and are marked accordingly should be used in AHUs and air conditioning systems [7] used for food production. Only fine filters that have been tested and certified by independent institutions such as Eurovent Certification [8] or similar bodies should be chosen and used. Typical designs of fine and HEPA filters are shown in Figure 4-2.

Pre-filters should be positioned as close as possible to the air inlet of the air conditioning plant and should be at least classified as ISO ePM10 50 % (according to DIN EN ISO 16890 [31]). It is an acknowledged rule of the technology to achieve the most effective and economically meaningful pre-filtration possible to maintain clean and hygienic conditions in all areas of the AHUs while simultaneously achieving maximum service life of the subsequent filter stages.

Two filter stages are recommended for the filtration of outside air in Zone M and three filter stages in Zone H. For hygienic reasons, it is recommended to use air filters with higher filter classes to minimize the spread of airborne contaminants in the ventilation and air conditioning systems. On the other hand, more energy is required for the operation of filters with higher separation performance. Choosing the right filter efficiency for the individual filter stages is thus the result of an optimization process based on a risk analysis, as a result of which the hygiene requirements can be met at the lowest possible energy consumption levels. Table 3-1 shows examples of filter selection in various hygiene zones. [2], [7] and [34] provides general information on determining filter selection for different requirements. In particular, the EUROVENT 4/23 Directive [34] recommends filter classifications for different outdoor air and supply air qualities, based on the 2005 WHO PM_{10} and $PM_{2,5}$ limits.

4.2 Requirements for air filters

It should be ensured that the filters themselves are not a source of contaminants or odorous substances, in particular microorganisms, which can find good growth and survival conditions in AHUs or as a result of fiber detachment from the filter materials. The growth of microorganisms can be prevented or at least minimized by selective control of relative humidity and temperature, as well as through appropriate operation and maintenance of the filter stages in AHUs. The use of filters with specific antimicrobial impregnation, for example, is

Pocket filter | Cassette filter (Rigid Fine Filter) | HEPA filter | HEPA filter

Figure 4-2: Typical designs of air filter elements [9]

neither necessary nor recommended. Filter materials that are inert and do not provide a breeding ground for the growth of fungi (measurement method A from ISO 846) and bacteria (measurement method C from ISO 846) are sufficient.

The requirements for the design and manufacture of air filters described below are recommended:

- Closed seals should be used because they remain intact throughout the entire life cycle of the filter element.

- Construction and assembly of air filter elements and mounting frames should be designed to ensure that installation and removal can be carried out easily and safely, in such a way that no damage can occur and the seal remains permanently intact over the entire life cycle of the filter element. Frame structures with cavities must be avoided.

- After the manufacturing process of the filter elements is complete, no residues should remain on or in the filter element that may be released during the filtration operation.

- The strength and stability of the air filter elements and their filter materials must be high enough that they are able to safely withstand all mechanical stresses at all stages of the operation of ventilation and climate control. In particular, it is essential to ensure an airtight, leak-free connection between the filter material (filter bag in pocket filters or bellows in cassette filters) and the filter frame. Under turbulent flow conditions, such as when starting up or shutting down the system, the filter media should not be able to move significantly. This is to ensure that particles already captured in the filters do not become loosened and allowed to contaminate downstream, purified areas of AHUs. So-called “rigid” cassette filters are recommended for this purpose.

- Even in the case of increased moisture content in the air to be filtered, the safety of the installation, the seal and the entire system must at no time be adversely affected or even endangered during operation.

- The filter materials must be free from any damage. Quality inspections should be performed after production of the filter elements and before packaging and transportation, at least in sample batches.

- Filter changing should be possible from the intake air side (dirty side).

- Filter chambers and housings should be constructed in such a way as to offer easy access for cleaning and inspection at any time.

- The inlet for the unfiltered intake air side should have a minimum height of 1.60 meters. The same applies to the clean air side.

- Filters (and especially pockets filters) should not be allowed to lie flat on the floor of the filter chamber, as can be seen in the left-hand photograph in Figure 4-3. For both hygienic and economic reasons, this type of installation should be avoided under all circumstances. Pocket filters should always be installed vertically. In addition, they should be installed in such a way that they do not come into contact with the floor, even when the AHU is switched off: i.e., when no air is passing through them. The right-hand photo in Figure 4-3 shows the correct, vertically oriented installation of pocket filters.

Figure 4-3: Wrongly installed pocket filters – horizontal (left and middle photos) and correctly installed pocket filters (right photo)

- For central air conditioning systems, the following information should always be displayed on the outside of the filter chamber:
  - Actual volume flow (not the values specified for the filters by the filter manufacturer)
  - Number of filter elements in each filter stage
  - Filter group or filter class in accordance with DIN EN ISO 16890 (until June 2018 according to DIN EN 779) or DIN EN 1822 or ISO 29463, as well as energy consumption or energy efficiency class (as indicated by the filter manufacturer)
  - Filter element dimensions (length/width/height)
  - Recommended final pressure drop, at which point the filter elements have to be changed, based on information provided by the system designer or the fan performance curve
- For decentralized ventilation systems, the same data given above should be documented in, for example, operation protocols, installation logbooks or other suitable places.
- Independently of other existing data collection and data monitoring in food production operations, each filter stage within a ventilation, air conditioning and AHU should be equipped with a differential pressure gauge with an adequate measuring range. The gauge should be easy to read.
- Filter mounting frames must be thoroughly and permanently sealed against each other and against the housing.
- The following data should be documented at every filter change and at every routine inspection, for example on a chart that can be fixed visibly on the filter housing. Documentation only in an operating manual, service plan or maintenance plan is not usually sufficient:

– Filter change:

  ◦ Date and the name of the person who performed the change

  ◦ Pressure drop before and after the change

  ◦ Latest date for the next filter hygiene inspection or the next filter change

– Routine inspection:

  ◦ Date and the name of the person who carried out the inspection

  ◦ Pressure values or pressure loss characteristics at the time of the inspection

  ◦ Zero point checked yes/no

4.3 Classification of air filters

In ventilation and air-conditioning technology, different particulate air filters are used to meet specific requirements. These filters are classified according to their performance.

Figure 4-4 shows typical fractional collection efficiency curves in dependence on the particle sizes for different coarse and fine dust filters.

The filter classes G3, M5-M6 and F7-F9 according to DIN EN 779 [10] are invalid. However, the separation efficiency curves clearly show the differences between the air filters with regard to their separation characteristics.

Although DIN EN 779 has been widely accepted in ventilation technology in recent years and has also been referenced in many standards and guidelines with regard to ventilation technology, energy efficien-

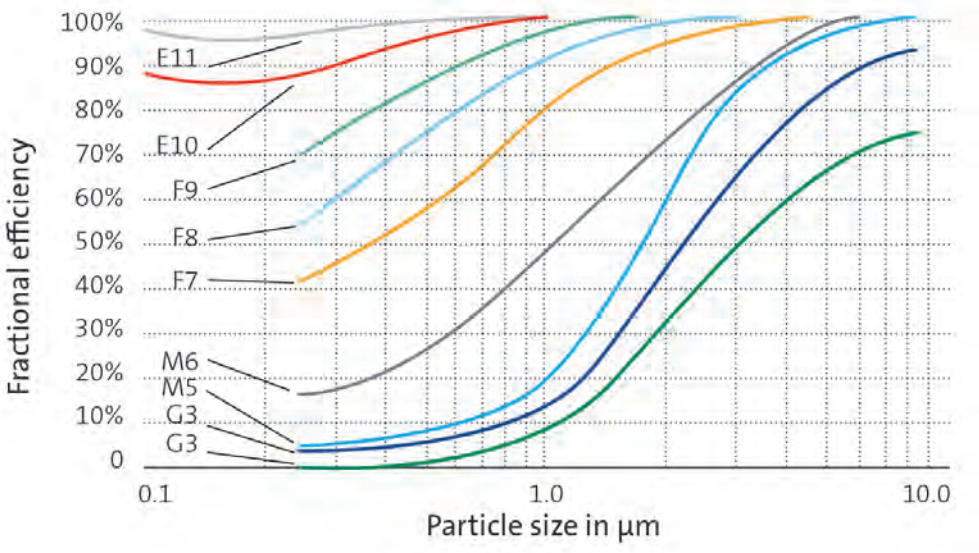

Figure 4-4: Typical examples of fractional collection efficiency curves of new, uncharged air filters with different filtration characteristics

cy, air quality at the workplace, etc., it was generally known that the test methods listed therein showed significant weaknesses. A decisive disadvantage of the laboratory test method according to DIN EN 779 was that the efficiency of an air filter was measured as an average value after several loading steps with a synthetic laboratory test dust (the so-called ASHRAE dust), but only for the particle size 0.4 µm.

The evaluation of the performance of fine filters for other particle sizes was not allowed. The stored amount of test dust significantly influenced the measurement result. If the filter stores a lot of dust and ensures this load for a strong increase in efficiency, this was resulting in a high average efficiency. In practice, however, the same filter usually behaves differently. Its efficiency remains rather constant with the storage of atmospheric dust. It may even lose efficiency slightly, eventually increasing less after a while than the ASHRAE dust suggests. For this reason, in the new DIN EN ISO 16890, which has replaced DIN EN EN 779 since July 2018, the separation efficiency of a fine filter is evaluated in the laboratory without dust loading [35].

The characterization of a filter for only one particle size with only one filter class, which is then still not the most relevant particle size for most air filter applications, has made the handling seemingly simple, but had little meaningful significance.

In the course of global filtration standardization, the DIN EN ISO 16890 standard was developed for coarse and fine filters, which also takes into account the hygiene-relevant particle size range between 0,3 and 10 µm. Thus, it is now possible to make much more practical statements regarding the filter efficiency in the particulate matter classes PM_{10}, $PM_{2,5}$ and PM_1, which are also used by the WHO (World Health Organization) and local environmental authorities such as the UBA (German Federal Environmental Agency), EEA (European Environmental Agency) and EPA (Environmental Protection Agency, USA).

The DIN EN ISO 16890 “Air filters for general ventilation” is divided into four parts:

Part 1: Technical specifications, requirements and classification system based upon particulate matter efficiency (ePM).

Part 2: Measurement of fractional efficiency and air flow resistance.

Part 3: Determination of the gravimetric efficiency and the air flow resistance versus the mass of test dust captured.

Part 4: Conditioning method to determine the minimum fractional test efficiency.

The sequence of a filter test in accordance with ISO 16890 takes place in several steps. First, the fractional separation efficiency of an untreated air filter in the particle size range of 0,3 µm to 10 µm is measured with an aerosol. Thereafter, the complete prefabricated filter element is exposed to an isopropanol vapor atmosphere for 24 hours to evaluate the extent to which the separation efficiency is based on electrostatic mechanisms. The fractional separation efficiency is measured again, resulting in a deposition curve from which the minimum efficiency for the respective particle size ranges is determined. From the mean value of both curves, the efficiency values ePM_{10} for the particle size range up to 10 µm, $ePM_{2,5}$ for the particle size range up to 2,5 µm and ePM_1 for the particle size

Table 4-1: Filter groups according to ISO 16890

Group name	Requirement			Class Specification Value
	$ePM_{1,min}$	$ePM_{2,5,min}$	ePM_{10}	
ISO Coarse	-	-	<50 %	gravimetric initial efficiency
ISO ePM10	-	-	≥50 %	ePM_{10}
ISO ePM2,5	-	≥50 %	-	$ePM_{2,5}$
ISO ePM1	≥50 %	-	-	ePM_1

Table 4-2: Orientation guide for a translation of filter grouping from DIN EN ISO 16890 into "old" filter classes of DIN EN 779

acc. to EN 779	acc. to ISO 16890			
	Coarse	ePM_{10}	$ePM_{2,5}$	ePM_1
G1	-	-	-	-
G2	**30–50** %	-	-	-
G3	**45–65** %	-	-	-
G4	**60–85** %	-	-	-
M5	**80–95** %	**40–70** %	10–45 %	5–35 %
M6	>90 %	**45–80** %	**20–50** %	10–40 %
F7	>95 %	80–90 %	**50–75** %	**40–65** %
F8	>95 %	90–100 %	75–95 %	**65–90** %
F9	>95 %	90–100 %	85–95 %	**80–90** %

Table 4-3: North American air filter classification according to ASHRAE 52.2

MERV	Average degree of separation across the particle size range			Average separation A_m (gravimetric)
	Range 1 0.3–1 µm	Range 2 1–3 µm	Range 3 3–10 µm	
1	–	–	$E_3 < 20$ %	$A_m < 65$ %
2	–	–	$E_3 < 20$ %	$65\ \% \le A_m < 70\ \%$
3	–	–	$E_3 < 20$ %	$70\ \% \le A_m < 75\ \%$
4	–	–	$E_3 < 20$ %	$75\ \% \le A_m$
5	–	–	$20\ \% \le E_3 < 35\ \%$	–
6	–	–	$35\ \% \le E_3 < 50\ \%$	–
7	–	–	$50\ \% \le E_3 < 70\ \%$	–
8	–	–	$70\ \% \le E_3$	–
9	–	$E_2 < 50$ %	$85\ \% \le E_3$	–
10	–	$50\ \% \le E_2 < 65\ \%$	$85\ \% \le E_3$	–
11	–	$65\ \% \le E_2 < 80\ \%$	$85\ \% \le E_3$	–
12	–	$80\ \% \le E_2$	$90\ \% \le E_3$	–
13	$E_1 < 75$ %	$90\ \% \le E_2$	$90\ \% \le E_3$	–
14	$75\ \% \le E_1 < 85\ \%$	$90\ \% \le E_2$	$90\ \% \le E_3$	–
15	$85\ \% \le E_1 < 95\ \%$	$90\ \% \le E_2$	$90\ \% \le E_3$	–
16	$95\ \% \le E_1$	$95\ \% \le E_2$	$95\ \% \le E_3$	–

range up to 1 µm are calculated. In addition, the minimum fractional efficiencies $ePM_{1,min}$ and $ePM_{2,5,min}$ are calculated only from the precipitation curve measured after isopropanol treatment. All of the measurements described here take place without dust feeding.

Based on the measured and calculated filtration efficiencies, filters are divided into four groups. The prerequisite for a filter belonging to the group ISO ePM 1 or ISO ePM 2,5 is that this filter deposits at least 50 % of the corresponding particle size range after discharge. The condition for the classification in ePM_{10} is that the filter element achieves a mean separation efficiency (mean value of the new state and after isopropanol discharge) of at least 50 %. If a filter removes after discharge for example more than 50 % PM_1, it may be grouped as an ISO ePM 1 filter. For this purpose, the respective average separation efficiency is given, rounded off in 5 % steps. As an example, this filter is then classified as an ISO ePM1 55 % filter. Filter classes, as specified in DIN EN 779, no longer exist. Frequently, filters satisfy the conditions for multiple classes. So it is possible that a filter achieves ISO ePM1 50 %, ISO ePM2,5 70 % and ISO ePM10 95 %. The manufacturer decides for his filter, which information makes sense on his filter.

In addition to fine dust filters, DIN EN ISO 16890 also rates coarse dust filters. These are termed “ISO Coarse” if they deposit less than 50 % of the PM_{10} particle fraction. This measurement procedure is comparable to the previous standard DIN EN EN 779, but using a different laboratory test dust (ISO A2 according to ISO 12103-1). It measures the gravimetric precipitation and evaluates the dust holding capacity of the filter. This measurement is additionally carried out for filters of the ISO ePM groups in order to include an evaluation of the energy efficiency of the

Table 4-4: Classification of EPA, HEPA and ULPA filters in accordance with ISO 29463 and EN 1822

	Filter classes according to		**Integral values**		**Limit for leak determination**	
	EN 1822	ISO 29463	Efficiency at MPPS	Penetration at MPPS	Efficiency at MPPS	Penetration at MPPS
E	E10	–	≥85 %	≤15 %	–	–
(EPA)	E11	ISO 15 E	≥95 %	≤5 %	–	–
		ISO 20 E	≥99 %	≤1 %	–	–
	E12	ISO 25 E	≥99.5 %	≤0.5 %	–	–
		ISO 30 E	≥99.9 %	≤0.1 %	–	–
H	H13	ISO 35 H	≥99.95 %	≤0.05 %	≥99.75 %	≤0.25 %
(HEPA)		ISO 40 H	≥99.99 %	≤0.01 %	≥99.95 %	≤0.05 %
	H14	ISO 45 H	≥99.995 %	≤0.005 %	≥99.975 %	≤0.025 %
		ISO 50 U	≥99.999 %	≤0.001 %	≥99.995 %	≤0.005 %
U	U15	ISO 55 U	≥99.9995 %	≤0.0005 %	≥99.9975 %	≤0.0025 %
(ULPA)		ISO 60 U	≥99.9999 %	≤0.0001 %	≥99.9995 %	≤0.0005 %
	U16	ISO 65 U	≥99.99995 %	≤0.00005 %	≥99.99975 %	≤0.00025 %
		ISO 70 U	≥99.99999 %	≤0.00001 %	≥99.9999 %	≤0.0001 %
	U17	ISO 75 U	≥99.999995 %	≤0.000005 %	≥99.9999 %	≤0.0001 %

filters considered from the data obtained. Tab. 4-1 clearly shows the filter groups according to DIN EN ISO 16890.

The measurement and evaluation procedures of DIN EN EN 779 and DIN EN ISO 16890 are fundamentally different. The category in which the filters are classified in DIN EN ISO 16890 depends on their nature and must be determined individually for each filter. Therefore, the old filter classes of DIN EN 779 cannot be translated directly into the new evaluation scheme of DIN EN ISO 16890 groups. The decisive factor is that the particle size range critical for the application is known for the selection of suitable air filters. Due to the considerable public interest in a simple translation, with which the new filter grouping of DIN EN ISO 16890 can be attributed to the "old" filter classes of DIN EN EN 779, the guideline EUROVENT 4/23 [34] in Tab. 4-2 gives a useful guidance.

In North America, the generally accepted US standard ASHRAE 52.2 [13] applies. It classifies coarse and fine filters by means of so-called MERV classes (Minimum Efficiency Reporting Values), as shown in Tab. 4-3. Here, the particle size range between 0,3 and 10 µm is taken into account, which was fundamentally adopted in the DIN EN ISO 16890.

If the highest air purity is necessary due to the highest hygiene requirements, for example in food industry cleanrooms, EPA, HEPA and ULPA filters are used. These are tested and classified in Europe in terms of separation efficiency and absence of leakage on the basis of DIN EN 1822 [11], whereby HEPA and ULPA filters are individually tested. The international ISO 29463 standard [12] is based in its essential elements on the European standard EN 1822 and is expected to replace it. Both standards are based on modern particle counting methods and are each divided into five parts:

Part 1: Classification, performance testing and identification

Part 2: Aerosol production, measuring equipment and particle-count statistics

Part 3: Determination of minimum separation grade

Part 4: Testing for the absence of leakage

Part 5: Determination of integral filtration efficiency

An overview of the filter classes of DIN EN 1822 and ISO 29463 is shown in Table 4-4.

4.4 Recommendations for filter classes in designated applications

There are numerous recommendations from various associations and manufacturers for the use of coarse and fine filters classified according to DIN EN ISO 16890 in various applications of ventilation technology. In some cases these recommendations are contradicting. Therefore, it is advisable to consider each case in detail and to examine.

The most comprehensive and to date the most accurate presentation is the EUROVENT 4/23 [34]. It is shown in Tab. 4-5. Here minimum efficiencies are recommended for filters depending on the available outdoor air quality and demanded supply air qualities and numerous examples are given.

An overall representation of the commonly used filters of different classification in the food sector is shown in Tab. 4-6.

Table 4-5: Recommended minimum efficiencies for air filters according to Eurovent 4/23

	Supply Air Quality				
Outdoor Air Quality	**SUP 1**[1] $PM_{2,5} \leq 2,5\ \mu g/m^3$ or $PM_{10} \leq 5\ \mu g/m^3$	**SUP 2**[1] $PM_{2,5} \leq 5\ \mu g/m^3$ or $PM_{10} \leq 10\ \mu g/m^3$	**SUP 3**[2] $PM_{2,5} \leq 7,5\ \mu g/m^3$ or $PM_{10} \leq 15\ \mu g/m^3$	**SUP 4** $PM_{2,5} \leq 10\ \mu g/m^3$ or $PM_{10} \leq 20\ \mu g/m^3$	**SUP 5** $PM_{2,5} \leq 15\ \mu g/m^3$ or $PM_{10} \leq 30\ \mu g/m^3$
ePM-Bereich	**ePM_1**	**ePM_1**	**$ePM_{2,5}$**	**ePM_{10}**	**ePM_{10}**
ODA 1 $PM_{2,5} \leq 10\ \mu g/m^3$ oder $PM_{10} \leq 20\ \mu g/m^3$	70 %	50 %	50 %	50 %	50 %
ODA 2 $PM_{2,5} \leq 15\ \mu g/m^3$ oder $PM_{10} \leq 30\ \mu g/m^3$	80 %	70 %	70 %	80 %	50 %
ODA 3 $PM_{2,5} > 15\ \mu g/m^3$ oder $PM_{10} > 30\ \mu g/m^3$	90 %	80 %	80 %	90 %	80 %

[1] Last filter stage must be at least ISO ePM1 50 %.
[2] Last filter stage must be at least ISO ePM2,5 50 %.

Outdoor Air Classes	
ODA 1	Outdoor air, which is only temporarily dusty. Used when the WHO guidelines (2005) are met ($PM_{2,5} \leq 10\ \mu g/m^3$ and $PM_{10} \leq 20\ \mu g/m^3$).
ODA 2	Outdoor air with high dust concentrations. Used when the WHO guidelines (2005) are exceeded by a factor of 1.5 ($PM_{2,5} \leq 15\ \mu g/m^3$ and $PM_{10} \leq 30\ \mu g/m^3$).
ODA 3	Outdoor air with very high dust concentrations. Used when the WHO guidelines (2005) are exceeded by more than a factor of 1.5 ($PM_{2,5} > 15\ \mu g/m^3$ and $PM_{10} > 30\ \mu g/m^3$).

Supply Air Classes	
SUP 1	Supply air, which has very low particle concentrations. The WHO guidelines (2005) are undercut by a factor of 0.25 ($PM_{2,5} \leq 2,5\ \mu g/m^3$ and $PM_{10} \leq 5\ \mu g/m^3$). **Examples:** Rooms with highest hygienic requirements: hospitals, pharmacy, electrical and optical industry, cleanrooms, High Risk & High Care Zones in food industry.
SUP 2	Supply air, which has low particle concentrations. The WHO guidelines (2005) are undercut by a factor of 0.5 ($PM_{2,5} \leq 5\ \mu g/m^3$ and $PM_{10} \leq 10\ \mu g/m^3$). **Examples:** Rooms with permanent use: kindergarten, offices, hotels, residential buildings, meeting rooms, exhibition halls, conference rooms, theaters, cinemas, concert halls, food industry.
SUP 3	Supply air having average particle concentrations. The WHO guidelines (2005) are undercut by a factor of 0.75 ($PM_{2,5} \leq 7,5\ \mu g/m^3$ and $PM_{10} \leq 15\ \mu g/m^3$). **Examples:** Rooms with temporary use: warehouses, shopping centers, washrooms, server rooms, copy rooms, food industry with low hygiene requirements.
SUP 4	Supply air, which has high particle concentrations. The WHO guidelines (2005) are fulfilled ($PM_{2,5} \leq 10\ \mu g/m^3$ and $PM_{10} \leq 20\ \mu g/m^3$). **Examples:** Rooms with short-term use: toilets, storage rooms, stairwells, automotive industry areas.
SUP 5	Supply air, which has very high particle concentrations. The WHO guidelines (2005) are exceeded by a factor of 1.5 ($PM_{2,5} \leq 15\ \mu g/m^3$ and $PM_{10} \leq 30\ \mu g/m^3$). **Examples:** Rooms and spaces with limited use: waste management, computer centers, parking garages, heavy industry production.

Table 4-6: Air filter classification and possible use in the food industry

General Filter Description	Test and Classification Standard		Typical use in food industry
First filter stage for removal of course dust (larger than PM_{10} fine dust fraction)	**ISO 16890** ISO coarse	**ePM_{10} efficiency** <50 %	Not recommended for 1-stage filtration in the food industry. Recommended as pre-separator in multi-stage filtration.
Fine filter, often used in the first filter stage, depending on the hygiene risk. (normally 50–80 % for PM_{10} fine dust fraction)	**ISO 16890** ISO ePM10	**ePM10 efficiency** ≥50 %	Use as the first filter stage in multi-stage filtration. Use in less critical food production areas (Zone B).
Fine filter for the second filter stage, depending on the hygiene risk. (normally 50–80 % for $PM_{2,5}$ fine dust fraction)	**ISO 16890** ISO ePM2,5	**ePM2,5 efficiency** ≥50 %	Use in less to medium critical food production areas (Zone M).
Fine filter for the second filter stage, depending on the hygiene risk. (normally ≥65 % for PM_1 fine dust fraction)	**ISO 16890** ISO ePM1	**ePM1 efficiency** ≥50 %	Use if only one filter level exists. Use as a second filter stage in Zone M or to protect downstream EPA / HEPA filters in Zone H. ISOePM1 85 % are often used as final filters in production halls classified as High Care (target is to minimise bacterial contamination).
EPA[1] and HEPA[2] for high demands on separation performance	**EN 1822** E10 E11 E12 H13 H14	**Integral value minimum separation efficiency at MPPS[4]** ≥85 % ≥95 % ≥99,5 % ≥99,95 % ≥99,995 %	Initial Efficiency for synthetic test aerosol in MPPS, usually 0.1 to 0.3 µm, resulting in an initial efficiency of 100 % for particle sizes > 0.5 µm. HEPA filters of filter classes H13 and H14 are 100 % leak tested by the manufacturer. Filter for high demands on hygiene and sterility.
ULPA[3] Filter	**EN 1822** U15 U16 U17	**Integral value minimum separation efficiency at MPPS[4]** ≥99,9995 % ≥99,99995 % ≥99,999995 %	Filter for highest requirements, usually outside food production, e. g. in microelectronics, pharmaceutical industry. ULPA U15 PTFE filters used in Aseptic Filling Machines for dairy & beverage products.

1 EPA = **E**fficient **P**articulate **A**ir filter
2 HEPA = **H**igh **E**fficiency **P**articulate **A**ir filter
3 ULPA = **U**ltra **L**ow **P**enetration **A**ir filter
4 MPPS = **M**ost **P**enetrating **P**article **S**ize

4.5 Energy efficiency in air filtration

Hygiene has top priority in the production of foodstuffs. Even tiny amounts of air pollutants may contaminate food, which affects shelf life and brings with it the risk of endangering the health of consumers. There is also a business management and ecologically significant aspect: **energy efficiency**. Rising energy costs and the need to reduce CO_2 emissions mean that the energy consumption of air conditioning systems is becoming increasingly important. In Europe, between 10 % and 20 % of the electrical energy used in the industrial and commercial sectors is absorbed by the operation of fans in ventilation systems. In cleanrooms, the power consumption of ventilation and air conditioning systems may account for as much as 80 % of the total energy needs of a building.

Approximately one third of the energy consumed is used to overcome the flow resistance (pressure loss) of air filters. Alongside capital investments such as conversion to high-efficiency, frequency-controlled fans within existing installations, efficiency optimization of the filters used and employing high quality, energy-efficient air filters is a relatively simple way to achieve significant energy savings. However, it must not be forgotten that any optimization must ensure that target protection levels can still be achieved. In other words, achieving increased energy efficiency in air conditioning systems should never come at the expense of hygiene.

The energy requirement for the perfusion of two air filters can be graphically illustrated by their pressure drop over the course of a specified period of use (Figure 4-5). When using a filter with lower pressure drop, energy savings are evident when comparing both areas below the curves. The mark of an energy-efficient filter is that pressure difference only increases slowly, resulting in a favorable energy balance. As Figure 4-5 shows, in individual cases, a filter with a slightly higher initial pressure drop (Filter B in this case) can be the most economically efficient variant. The savings achieved by the lower initial pressure drop of the Filter A (yellow area on the left) is significantly lower than the savings achieved through the flatter pressure difference of Filter B (blue area to the right). An additional positive effect of a flat pressure difference increase is longer service life. This also represents a major cost effect for the food industry with its high cleanliness requirements.

To make it easier for users to select energy-efficient air filters, the European association of manufacturers of air conditioning and drying systems, EUROVENT, has developed a European energy efficiency classification system for air filters as part of EUROVENT certification in 2011. The Guideline Eurovent 4/11 Energy Efficiency Classification System gave the user the opportunity for the first time to quantitatively compare the different design aspects of different filters with regard to their energetic operating behavior. The laboratory test method used was essentially based on the filter test standard DIN EN 779:2012. Due to the withdrawal of the filter test standard DIN EN 779:2012 in June 2018 and replacement by DIN EN ISO 16890:2017-08, the energy efficiency classification system had to be updated. It is now based on the filter test standard DIN EN ISO 16890:2017-08 and described in the Eurovent document 4/21 [30].

For each air treatment system, the individually required protection target needs to be set in accordance with the requirements for air purity. Overachieving this target by choosing unnecessarily high filter efficien-

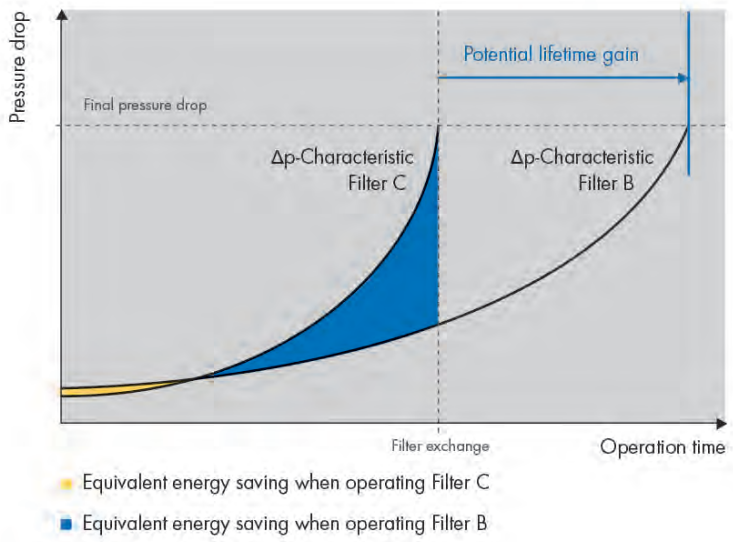

Figure 4-5: Pressure drop – comparison of two filters

cy will tend to lead to excessive energy consumption. The higher the filter class, separation or efficiency level, the denser the filtration medium and the more pronounced the expected pressure difference. On the other hand, while more open filters with lower separation performance have a reduced energy requirement due to their lower flow resistance, they may not reach the required protection target and thus the required hygiene level.

5 Hygiene requirements for ventilation systems (VDI 6022)

The VDI Society for Building and Construction Technology has published various VDI guidelines on "room air". An overview is given in the flyer "VDI ventilation code of practice" [7].

AHUs, air filters and air filter stages need to be designed, built and operated in such a way that a spread of microorganisms, organic and inorganic dusts is minimized or avoided. Avoiding transmission applies to downstream components and process steps and to areas into which the filtered air is passed. It also applies to both the filtration operation as well as activities such as filter installation, filter inspection and filter replacement. Under no circumstances should contamination increase as a result of the operation of AHUs or other system components.

The VDI 6022 (Part 1–7) series of guidelines [7] describe the hygiene requirements for AHUs and equipment in terms of design, manufacture, construction, operation and maintenance. In the process, they make direct reference to the quality of room air and thus respiratory air. This guideline applies to all air conditioning systems and devices and their central and decentralized components, which influence the supply air quality. The mentioned requirements serve primarily the health protection of persons.

The minimum aim is that air quality should not be made worse by the AHUs or devic-

es. Requirements include, for example, that the content of the supply air in terms of organic, inorganic or biological ingredients may not exceed that of the comparative air in any category. Furthermore, it is not permitted to add odor-active substances without the consent of users. AHUs are not allowed to cause impaired health, mood disorders, thermal comfort or unpleasant odors.

VDI 6022 stipulates that responsibility resides with the operator to ensure hygienic operation and the maintenance necessary to achieve it. He or she must keep an AHU logbook (or similar), which should be in the keeping of the person responsible for the building. This person must be made known. The representative of those using the system has the right to inspection.

Contents of the document include:

- Date, name and address of the person carrying out the work
- Repairs to the AHUs with information on the date, name and address of the person carrying out the work
- Where and which cleaning agents or disinfectants were used in the AHUs, including humidifier water treatment and recooling plant

The hygienic design of AHUs plays a crucial role in the air quality achieved. Systems need to be operated in such a way that microbial proliferation is avoided. To achieve this, the following aspects need to be given special consideration:

- Choosing the right air flow rates to meet all possible external conditions
- Location of the inlet and outlet grilles
- Dimensioning and placement of the air duct system
- Avoidance of leaks
- Ensuring accessibility for cleaning and inspection
- Material, equipment and process selection
- Hindrance of damp areas being created
- Prevention of contamination
- Ensuring relative humidity of <80 %

VDI 6022 lists all components for AHUs or equipment that are either specified or recommended for implementation, operation and maintenance. Issues regarding humidifiers, for example, include accessibility, positioning in the plant, inspection openings, water quality, disinfection methods, condensate tray, supply shutdown/dry running, disassembly, dimensioning, max. humidity, visual inspections, regular cleaning/disinfection, orientating microbiological tests, functional tests.

Materials intended for use in damp areas are not allowed to provide a breeding ground for microorganisms. Sealants and sealing materials must be closed-pore and are not permitted to absorb moisture or emit odors. Materials in air-conducting areas must not emit hazardous materials (e. g. also coatings and sealants). They should prevent any capture or deposition of contaminants: for example, porous, open-pore linings, gaskets or insulation materials (except soundproofing) are not allowed.

To ensure that hygiene standards are adhered to, regular checks need to be carried out on AHUs, especially in the food production area.

6 GMP and cleanroom technology in food production

The management and control of microbiological conditions in the ambient air is strongly geared to the GMP (Good Manufacturing Practice) standard [18]. This involves guidelines that apply to quality assurance for the production processes and production environment in the production of medicines and drugs, but also in cosmetics, food and feedstuffs. A GMP-compliant quality management system is used to ensure product quality and the fulfillment of the binding requirements for commercialization and marketing.

The GMP guideline, which was originally developed for production in the pharmaceutical industry, can be fairly transferred to the food industry and serves as an orientation option. Thus in accordance with EN ISO 14644-1 [3], different risk levels and requirements are divided into zones and classified according to the maximum permitted number of particles in the ambient air. This classification, together with details of the respective maximum allowable number of particles, is shown in Table 6-1.

Because particles are always potential carriers of microbiological contaminants such as bacteria, spores or other microorganisms, cleanroom technology for the control of contamination problems in the food sector is now widespread. Cleanrooms are typically associated with cleanroom technology in the production facilities of the pharmaceutical industry or in microelectronics. However, cleanrooms in the different sectors vary significantly and are also evaluated differently.

Fluid mechanics plays a major role in cleanroom technology because in areas of high hygienic risk, for example, germs, spores, or microorganisms deposited on surfaces can be stirred up again by unsuitable flows. Laminar flow systems have proven their value in the food industry. These systems suck up the room air, filter it and then selectively blow it in large masses in a laminar manner back over areas to be protected. Examples include FFUs (Fan Filter Units); small, modular systems that are installed locally and which selectively ventilate areas in need of protection.

Table 6-1: Maximum allowable number of particles according to GMP

	Maximum number of particles per cubic meter of ambient air			
	Idle state[1]		Operational state[2]	
Class	**0.5 µm**	**5 µm**	**0.5 µm**	**5 µm**
A[3]	3,520	20	3,520	20
B[4]	3,520	29	352,000	2,900
C[5]	352,000	2,900	3,520,000	29,000
D[5]	3,520,000	290,000	Not established	Not established

[1] Idle state = ".. the state in which the installed production equipment is in operation without the presence of operating personnel." [18]
[2] Operational state = ".. the state in which the system is operated as intended by the specified number of people." [18]
[3] Class A: Local zone for high-risk operations
[4] Class B: Zone for aseptic preparation or bottling
[5] Class C and D: Clean areas for less critical steps in the manufacture of sterile products

Table 6-2: Cleanroom classes according to DIN EN ISO 14644-1 [3]

Cleanroom classes according to EN ISO 14644-1						
	Number of particles per m³					
Class	**≥0.1 µm**	**≥0.2 µm**	**≥0.3 µm**	**≥0.5 µm**	**≥1.0 µm**	**≥5.0 µm**
ISO 1	10	2				
ISO 2	100	24	10	4		
ISO 3	1,000	237	102	35	8	
ISO 4	10,000	2,370	1,020	352	83	
ISO 5	100,000	23,700	10,200	3,520	832	29
ISO 6	1,000,000	237,000	102,000	35,200	8,320	293
ISO 7				352,000	83,200	2,930
ISO 8				3,520,000	832,000	29,300
ISO 9				35,200,000	8,320,000	293,000

Further examples of cleanroom solutions used in food production are “mini-environments” or “flow boxes”. These are closed or partially closed cleanroom areas, as implemented in protective enclosures, transport system tunnels or machine housings. Manufacturers of bottling plants, for example, are making increased use of processes based on cleanroom technology. Here, for example, carbonated beverages and soft drinks are bottled in germ-free environments (aseptic cold filling). Most clean rooms operate at ISO 7 or ISO 8. Aseptic filling machines usually operate at ISO 5.

All of these systems can be assessed on the number of airborne particles in accordance with DIN EN ISO 14644-1. Cleanroom classes according to DIN EN ISO 14644-1 are shown in Table 6-2.

Cleanrooms in the food industry are usually implemented in ISO classes 5, 6 or 7 – more rarely in ISO class 8. ISO Class 5 is considered “germ-free”.

A clear presentation of the relationships between ISO cleanroom classes according to DIN EN ISO 14644 [3] and GMP classes according to the GMP standard is shown in the diagram in Figure 6-1. Here, the maximum permissible particle number in the air as a function of particle size is shown in a double logarithmic representation. The right-hand side of the diagram shows the GMP classes that correspond to the ISO classes for 5-micron particles.

7 Microbiological tests and limit values

The measurement of airborne germs can be carried out both by microbiological methods (this happens especially with the use of fine filters in the 1st and 2nd filter stages) as well as by particle measurement or application of test aerosols (the latter is usually performed for EPA, HEPA and ULPA filters).

Several methods are available for microbiological testing [21, 22]. In the simplest case, this involves the preliminary microbial count by time exposure fired with nutrient sedimentation plates. Other, more elaborate methods are based on the filtration of intake air quantity, the introduction

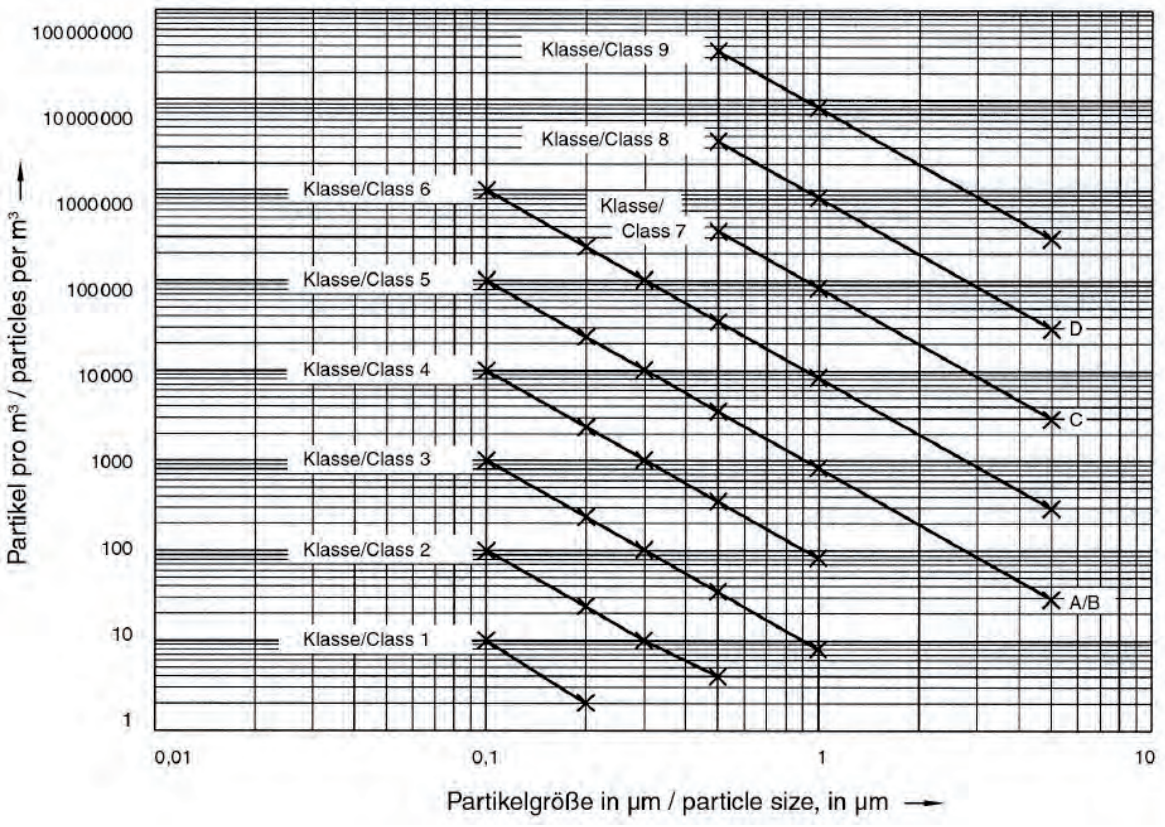

Figure 6-1: Particulate cleanliness classes of air in accordance with DIN EN ISO 14644-1

of sucked-in air in liquids (impingement) with subsequent microbial count, and on the impaction of airborne germs from an accelerated air stream on breeding ground surfaces and microbial counting. In the latter method, so-called centrifugal collectors are used in which airborne germs are deposited by a rapidly rotating rotor by centrifugal force on the agar strips (breeding strips). This enables a quantitative determination in air volumes of 10–1,000 liters. There are marked differences in the informational value and the precision of the measurement methods [24] that may require validation [25].

In contrast to regulations for outdoor air (for example, production equipment, waste disposal plants, landfills, biogas plants, etc.), there are no microbiological limit values for indoor air in food industry businesses, or mold content in indoor air [26, 27].

As part of their statutory duty of care, it is the responsibility of producers to take all necessary measures to ensure that the ambient air in production facilities represents no danger to either employees or to the products manufactured. Compliance with the requirements of VDI 6022 for AHUs and their testing (AHU Hygiene Inspection [28]) is the responsibility of the operator and can be ensured by the involvement of a certified service company for maintenance, servicing and testing. Monitoring is a governmental task of labor inspectorates or offices for labor protection.

The setting of obligatory microbiological limits is not possible due to the very different characteristics of foodstuffs and their special production technology. However, there are a number of recommendations, policies and guidelines for microbiological air quality in the food industry [23, 29]. Some areas of the food industry with hygienically sensitive or extended shelf life products have largely been oriented on the manufacture of pharmaceutical products and the guide to Good Manufacturing Practice (GMP) [18] guidelines that need to be applied. However, it is not strictly necessary to assume these measures, because substantial differences exist between the pharmaceutical and food industries.

Zones with normal hygiene (Zone B) should not exceed values of >1,000 CFU/m³ for bacteria and 500 CFU/m³ for yeasts and molds (H & S). If exceeding these levels cannot be avoided, inspection and corrective measures must be initiated and a filter change carried out. In addition, the filter class in the first filter stage should be increased to at least ISO ePM1 50 % according to DIN EN ISO 16890 [31] (in the past F7 in accordance with DIN EN 779 [10]).

In general, a value of <200 CFU/m³ for bacteria and <100 CFU/m³ for H & S is scheduled for medium hygiene zones (Zone M). The action value should be >2,000 CFU/m³ for bacteria and >1,000 CFU/m³ for H & S. The corresponding recommendations for high hygiene areas (zone H) are <100 CFU/m³ for bacteria and <50 CFU/m³ for H & S with action values of >1,000 CFU/m³ and >500 CFU/m³.

For aseptic equipment and aseptic filling with clean air, DIN EN 1822 [11] requires at least filter class H13. Particle measurements must be carried out according to the manufacturer's instructions, but there is no requirement for routine microbiological controls. One maximum value that may be applied for bacteria and H & S is <5 CFU/m³. These data are clearly summarized in Table 7-1.

8 HACCP concept (Hazard Analysis and Critical Control Points)

Room air conditioning and control is, just as for example personal hygiene, cleaning, disinfection and hygienic design, an inherent part of the so-called Prerequisite Programs. These form the foundation of an effective HACCP system. Detailed explanations of risk analysis and the HACCP concept can be found in other chapters.

Table 7-1: Recommended values for colony forming units

Maximum number of colony forming units (CFU)	For bacteria	For H & S
Zone B (normal hygiene)	<1,000 CFU/m³	<500 CFU/m³
Zone M (medium hygiene)	<200 CFU/m³	<100 CFU/m³
Zone H (high hygiene)	<100 CFU/m³	<50 CFU/m³
Aseptic equipment/aseptic filling with clean air	<5 CFU/m³	<5 CFU/m³

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