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Dear Mr. Winther,

Please allow me to write to you on behalf of AAF International, in the perspective of the REACH restriction proposal on PFAS.

AAF International is the world's leading manufacturer of filtration technologies, covering a broad scope of filtration technologies. AAF belongs to the Daikin group.

In addition to the previously submitted contributions of Daikin, AAF has compiled the attached report, focused on PTFE membrane-based air filters.

The report aims to explain the need for an exemption of PTFE membrane-based air filters. It elaborates on the unique properties and benefits of these filters, in terms of filtration but also energy efficiency. These filters are currently used in the terminal stage of multi-stage filtration systems for clean environments required in sectors such as microelectronics, pharmaceuticals or nuclear.

Confidential information included in the report is marked in pink.

While we are aware that the preparatory work on the restriction proposal may soon be completed, we hope you will find the provided information useful and would welcome the opportunity of a meeting to discuss our exemption request in more detail.

We thank you in advance for considering our request and remain at your disposal.

Yours sincerely,
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Opinion Paper regarding an exemption of PTFE based air filters from PFAS restriction

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October 20, 2022

Opinion Paper regarding the exemption of PTFE based air filters from PFAS ban

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1. Report Summary

AAF International is the world's largest manufacturer of air filtration solutions. It belongs to the Daikin Group and has its European headquarter in Germany. The business is covering a broad scope of air filter media technologies including PTFE membrane, C6-based fiber-glass media and synthetic media. AAF International supports all necessary measures to prevent harm to people and the environment and to counteract climate change.

Against the background of the upcoming PFAS restriction proposal, AAF would like to submit the hereby report focused on PTFE-based air filters media, in addition to previous submissions of Daikin.

Purpose of this report is to explain the unique properties, functions and benefits of PTFE filter media in air filter applications, where it is used and the need for continued use.

PTFE membrane-based air filters covered by this report are used in terminal stages of multi-stage filtration systems for clean environments, also called containments, (e.g. cleanrooms, isolator, safety workbenches) which can be classified according to EN1822 (High efficiency air filters (EPA, HEPA and ULPA)) respectively ISO 29463 (High-efficiency filters and filter media for removing particles in air).

For this terminal stage of filtration, PTFE membrane-based air filters have unique properties that make them far superior to C6-based fiber-glass air filters, which are the only alternative today. C6-based filtration media remain nonetheless necessary until a transition to PTFE membrane-based filters can be completed where possible, and for other applications not covered by PTFE media and this report.

PTFE membrane-based air filters are used in semiconductor manufacturing, microelectronics, pharmaceutical industry, nuclear industry and others industry segments, where clean conditions are mandatory for product safety, occupational safety and environmental protection.

Produced according to state-of-the-art standards, PTFE filter media are not expected to release any PFAS during manufacturing, use and are properly handled at waste stage.

A ban of PTFE filter media would result in significant economic damage but also in terms of public health, product safety, environmental protection and increase of greenhouse gas emissions.

PTFE based filter media are a technology platform with further growth potential to meet safety and energy savings goals. A ban would contradict the objectives of the Green Deal, i.e. the efforts of the European Union to reach climate neutrality and the goal of zero net emissions by 2050.

Considering this, a derogation is needed for PTFE filter media for air filtration.

AAF International has every confidence that this report will be duly acknowledged by the responsible authorities in the ongoing PFAS restriction process.

Important remark:

Parts of this report which are marked in pink color are confidential information for the authorities, not for public use.

2. Introduction to AAF

AAF Europe (www.aafeurope.com) is headquartered in Heppenheim, Germany, with about 1.000 employees all over Europe. AAF Europe is part of AAF International (www.aafintl.com), founded in the 1920s in Louisville, Kentucky, who is the world's largest manufacturer of air filtration solutions, operating production, warehousing and distribution facilities in 22 countries across four continents.

AAF International has more than 6.000 employees globally. AAF is committed to protecting people, processes and systems through the development and manufacturing of the highest quality air filters, filtration equipment and containment housings available today.

AAF offers comprehensive, innovative air filtration solutions designed to remove and control airborne particulates and gaseous contaminants in residential, commercial, industrial, clean-room, transportation and nuclear power applications. AAF product portfolio covers a broad range of air filtration technologies including PTFE membrane, C6-based fiber-glass media and synthetic media.

AAF is supported in its international ventures through the resources of our parent company, Daikin Industries Ltd. (www.daikin.com), based in Osaka, Japan, a diversified international manufacturing company and a global leader in air conditioning with globally more than 67.000 employees.

AAF is known as a pioneer in clean air innovation for nearly 100 years. With its combined resources and expertise, it's leading global initiatives that increase productivity, improve processes, products and protect public health for the years to come.

3. Air filtration

Air filtration is normally done in several filtration stages, whereby the separation efficiency increases from filter stage to filter stage. This opinion paper focuses on PTFE membrane filters containing PFAS, as they are typically used in the final (terminal) filter stage of ventilation systems for particular clean environments (e.g. cleanrooms in pharma industry and microelectronics.). In the preceding filter stages, filters are typically used that utilise glass fiber media or those made from other polymers (e.g. polyester, polypropylene, polyethylene...).

In the following, particle separation efficiency is meant when referring to filtration efficiency. This must be distinguished from the energy efficiency of a filter, which is also considered.

3.1 Air filtration of very small particles

PTFE membrane-based air filters are particularly suitable for air filter filtration where extremely high filtration efficiency for very small particles is required. Such particles can be solid or liquid, inorganic but also organic in origin, including bacteria, and viruses. Figure 2.1 illustrates examples for particles and their sizes. The interesting size range is below 10 μm .



Figure 2.1: Relative size of particles.

Tiny particles are harmful for technical process and especially human health, because they are respirable as illustrated in figure 2.2.

Indoor Environmental Quality (IEQ)

Understanding how PM_{2.5} & PM₁ contaminants affect air quality in indoor environments and our health

Consult an AAF Flanders representative to find out how air filter efficiency can help.

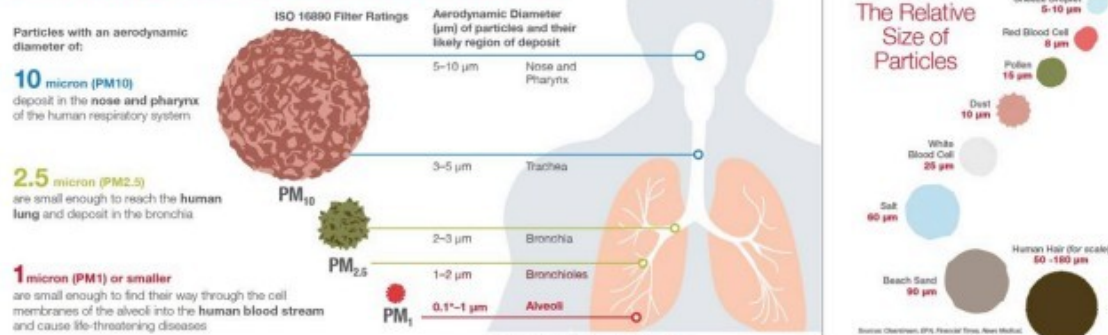


Figure 2.2: Particle sizes and their deposition in human body.

3.2 Air filtration efficiency classes

Air filters for filtration of very small particles are classified according to their separation efficiency in accordance with EN1822 (High efficiency air filters (EPA, HEPA and ULPA) respectively ISO29463 (High-efficiency filters and filter media for removing particles in air). The filtration efficiency averaged over the filter surface is given for the particle size with the highest filter penetration (MPPS: Most Particle Penetration Size (approx. 0,07-1,5 µm)). Air filters are categorised according to a wide range of filter classes (E12-U17), see table 2.1.

filter group	filter class	minimum average efficiency (@MPPS)
EPA Efficient Particulate Air Filter	E10	≥ 85 %
	E11	≥ 95 %
	E12	≥ 99.5 %
HEPA High Efficiency Particulate Air Filter	H13	≥ 99.95 %
	H14	≥ 99.995 %
ULPA Ultra Low Penetration Air Filter	U15	≥ 99.9995 %
	U16	≥ 99.99995 %
	U17	≥ 99.999995 %

Table 2.1: Filter efficiencies for the different filter classes.

The high filtration efficiency of an ULPA filter class U17 means that e.g., from 20.000.000 particles in the size range of 0,07-1,5 µm only maximum 1 particle is not separated in the filter. For particle sizes below or above the specified size range, the separation is physically even better.

PTFE membranes are available in filter classes from E12 to U17. HEPA filters based on micro glass fiber papers can also reach these filter classes but are by far inferior in several crucial properties (pressure drop, mechanical stability, chemical resistance) as described below.

For the sake of linguistic simplicity, the term HEPA filter is used in the following for all 3 filter groups (EPA/HEPA/ULPA).

4. PTFE membrane-based filters

Polytetrafluoroethylene (PTFE) is a synthetic fluoropolymer of tetrafluoroethylene (figure 3.1)

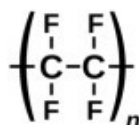


Figure 3.1: Tetrafluoroethylene

Polytetrafluoroethylene is a fluorocarbon solid, as it is a high-molecular-weight polymer consisting of a completely fluorinated carbon backbone, with very strong bonding of the fluorine atoms to the carbon backbone (figure 3.2).

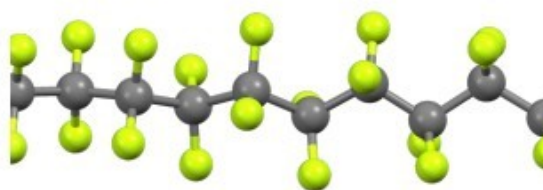


Figure 3.2: Polytetrafluoroethylene (PTFE)

PTFE is hydrophobic and oleophobic: Neither water nor water-containing substances wet PTFE. PTFE has one of the lowest coefficients of friction of any solid. It has numerous applications.

Today Polytetrafluoroethylene is used as a non-stick coating for pans and other cookware. It is non-reactive, partly because of the strength of carbon–fluorine bonds, so it is often used in containers and pipework for reactive and corrosive chemicals. Where used as a lubricant, PTFE reduces friction, wear, and energy consumption of machinery. It is used as a graft material in surgery and as a coating on catheters.

It is one of the most well-known and widely applied PFAS. In 1969 Bob Gore accidentally discovered the possibility to stretch (expand) a PTFE tape 1000 times its original length (figure 3.3).



Figure 3.3: Bob Gore stretching (expanding) a PTFE tape [2].

It turned out that the tape did not simply break but opened into a network of ultra-fine fibers (figure 3.4).

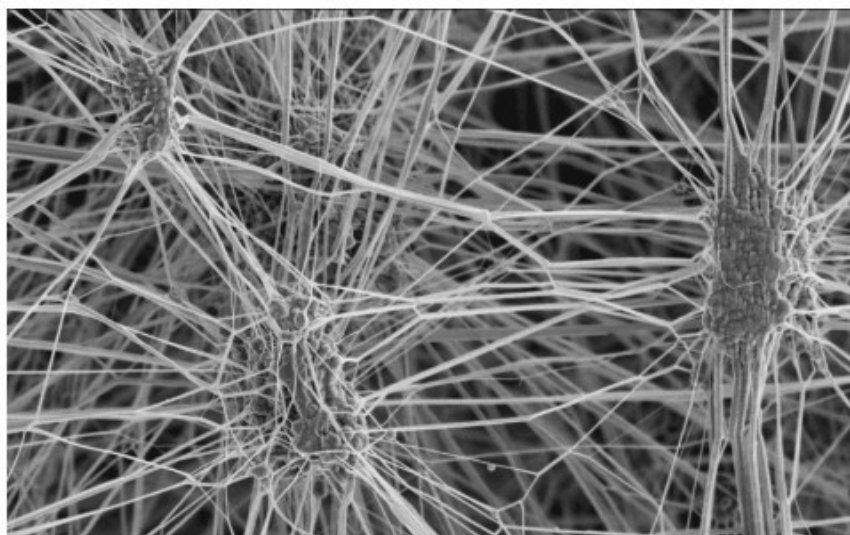


Figure 3.4: Scanning electron microscope photo of ePTFE [2].

In 1976 the use of expanded PTFE membranes in breathable functional apparel started.

In 1973 the use of expanded PTFE membranes in filtration started, initially for bag filters in the surface filtration of large quantities of dust from the exhaust gas of technical processes. In 1994 HEPA filters with expanded PTFE membranes were introduced for clean environments in micro-electronics.

4.1 Expanded PTFE membrane

PTFE membrane-based HEPA filters use filter media containing expanded PTFE membranes. Such a membrane consists of a network of ultrafine fibers in the nanometer range (figure 3.5) on which the particles are deposited (figure 3.6).

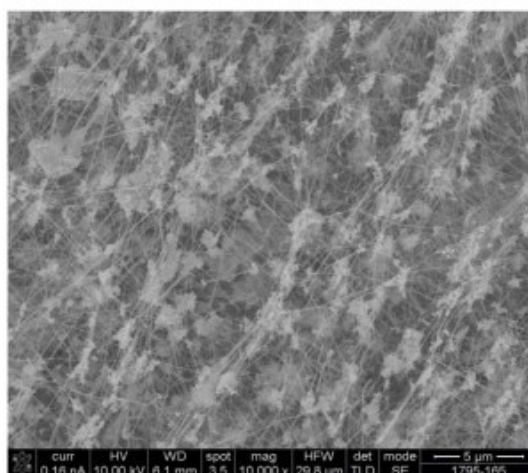


Figure 3.5: SEM photo of expanded PTFE membrane.

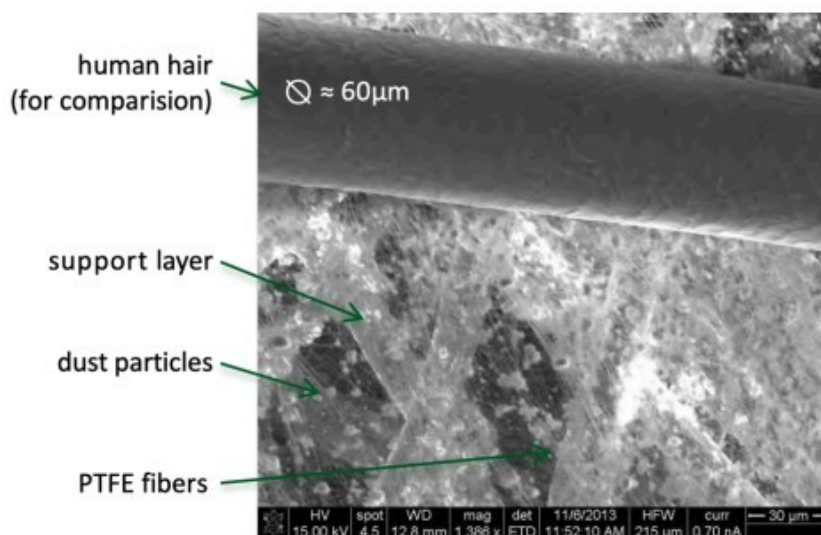


Figure 3.6: PTFE membrane with deposited particles.

PTFE membrane-based filter media consist of one or two layers of expanded PTFE membranes sandwiched between a support layer and a cover layer, which are normally made of a standard polymer, e.g. polyester or polypropylene.



Figure 3.7: Designs of PTFE-based Filters.

Figure 3.7 shows typical designs of PTFE-based filters. The central element is a package of folded filter medium, which is glued airtight into a frame made of e.g. plastic or metal.

AAF refers to filter media with one layer of PTFE membrane as ePTFE media, and those with two layers of PTFE membrane as eFRM media. The two-layer medium is used in applications where a certain amount of VOC (Volatile Organic Components) or soot must be expected in the supply air. These are applications with a lot of fresh air content (in contrast to pure recirculation operation), e.g. air handling units. It is also used in pharma industry where often a photometer, which requires relatively high concentrations of test aerosol, is used to test the filter for leaks (more about leak testing can be found in Chapter “Applications”).

4.2 Last filter stage in a multistage filter system

PTFE based filters are used for highly efficient particle filtration of air. They are typically used as the terminal (last) filter stage in a multi-stage filter system (figure 3.8 and 3.9).

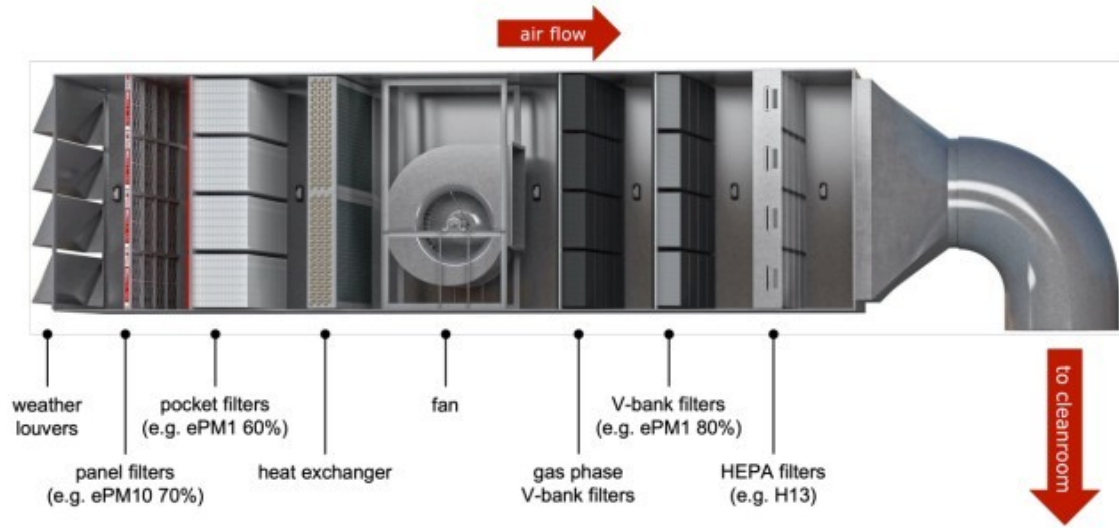


Figure 3.8: Schematic structure of an AHU (air handling unit) with different filter stages.



Figure 3.9: Cleanroom ventilation system.

The preceding filter stages protect the terminal filters from excessive dust exposure. In these stages, synthetic filter materials (e.g. made of polyester, polypropylene...) or also glass fiber-based filter media, which are hydro- and oleophobic by means of C6 compounds, are used.

4.3 Technical properties and functions

a) Slip-flow effect and resulting energy efficiency gain

Due to its porous structure, the filter medium resists the air flowing through it, which must be overcome by the fan of a ventilation system. The power required for this can be determined using equation 3.1.

$$P = \frac{V \cdot \Delta p}{\eta} \quad (\text{eq. 3.1})$$

P power (W)
 V volume flow (m³/s)

$\overline{\Delta p}$ average pressure drop (Pa)
 η fan efficiency (-)

To minimise the required power, fans with high efficiency must be used on the one hand, and filters with the lowest possible pressure drop on the other. PTFE membrane is providing the lowest possible pressure drop due to its nano-scale fibers, which are much finer than the fibers used in micro-glass media. The reason for that is the so call slip-flow effect.

The fibers in the filter medium cause significant drag to air flow. This aerodynamic behavior of air flow around fibers dramatically changes when the fiber diameter is reduced to nanoscale (< 100 nm) resulting in dramatically reduced pressure drop. Air molecules adjacent to each other are separated by a mean spatial distance of 0,0034 μm in standard temperature (25°C) and atmospheric pressure (1,01 x 10⁵ N m⁻²). The mean free path between air molecules can be described by λ as shown in equation 3.2.

$$\lambda = \frac{k T}{(\sqrt{2} \pi d^2 p)} \quad (\text{eq. 3.2})$$

k Boltzman constant (1,38 x 10⁻²³ J/K)
 d effective diameter of air molecules (nm)
 T temperature of air (K)
 p atmospheric pressure (Pa)

A cubic micron volume of air has 2,54 x 10⁷ air molecules and the mean free path λ is calculated to 65,3 nm. If the fiber encountered by the airflow has a fiber diameter close to or smaller than the mean free path of the air molecules, only a fraction of the air molecules will come into contact with the nanofiber. This will result in a significantly reduced drag force experienced by the fiber, which results in reduced pressure drop of the filter medium.

Figure 3.10 shows a conceptual schematic of a partial boundary layer of 2 μm fiber (e.g. glass fiber) relative to a 60 nm PTFE nanofiber; air molecules are randomly distributed in the air flow.

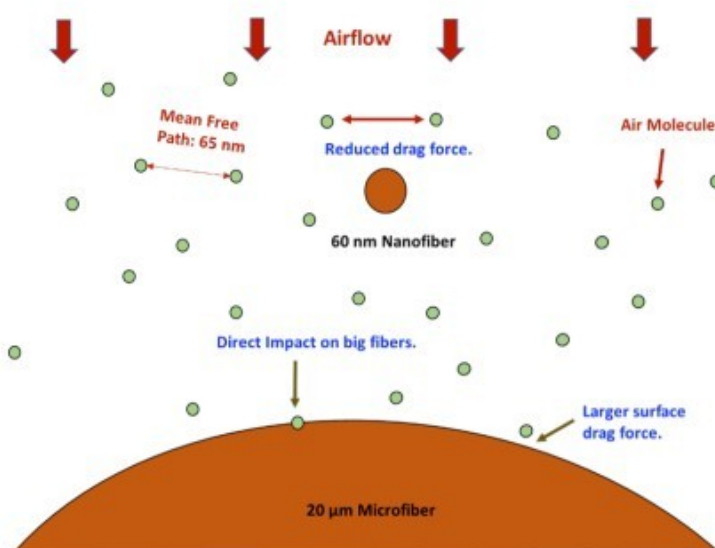


Figure 3.10: Schematic of a partial boundary layer of 2 μm micro-glass fiber relative to a 60 nm PTFE nanofiber with air molecules are randomly distributed in the air flow.

For thicker fibers (e.g. glass filter media), the air molecules hitting the 2 μm micro-glass fiber will encounter the surface of the microfiber and acquire the same velocity as the fiber. An elemental

volume of the air that is encountered at the surface of the microfiber will lead to all molecules in that volume to change their motion, with respect to the bulk volume. The average velocity will be zero if the fiber is stationary as the sum of all velocity vectors of the molecules will be zero.

On the other hand, the PTFE nanofiber is so small, that when an elementary volume of air passes through it, only a fraction of the air molecules encounters the surface of the nanofiber. Hence only a fraction of molecules experiences a change in velocity. The rest of the molecules retain the same velocity as the bulk flow velocity. This movement of air molecules across the PTFE nanofibers without hitting the nanofiber is called “slip-flow”.

In addition to lowering the pressure drop, slip flow effect also improves the capture efficiency of small particles on nanofibers. This is due to the fact that particles following the air flow streamlines pass closer to the surface of the nanofiber compared to a microfiber and get captured on the nanofiber.

The effects of the low pressure drop on energy consumption, energy costs and CO₂ footprint are quantified and discussed in chapter 6 in comparison to fiberglass-based filter media.

b) Mechanical stability

HEPA filters are used in critical applications where their mechanical integrity is of paramount importance.

Although HEPA filters are tested by the manufacturer to check absence of leaks before delivery (for details see EN1822 resp. ISO 29463), they can easily be damaged during transport or installation and thus rendered unusable. When installed, damage can also be caused by careless handling, e.g. during regular leak testing. Even a light contact with the filter medium is sufficient for this.

Damaged and thus leaking HEPA filters compromise the integrity of the containment (i.e., the high-purity environment). This can lead to uncontrolled product leakage or product contamination, as a result of which neither product safety nor occupational or environmental safety can be guaranteed.

This is in contrast to the low mechanical stability of glass fiber-based HEPA filter media.

PTFE-based HEPA filters are mechanically significantly more stable than glass fiber based filter media. This leads to increased safety for products produced in clean environments, the employees working there and the environment.

The increased mechanical stability of PTFE membrane filter media is quantified and discussed in chapter 6 in comparison to fiberglass-based filter media.

c) Chemical resistance

Often aggressive chemicals (e.g. acids, alkalis, solvents) are handled in containments (clean-rooms, isolator, safety workbenches...). Many containments are regularly cleaned or even sterilised to guarantee high purity working conditions. By their very nature, equally aggressive chemicals are used for this purpose, e.g. H₂O₂, ClO₂, CH₂O.

To ensure the integrity of the containment, it must be ensured that HEPA filter media can withstand contact, even accidental, with aggressive chemicals.

Damaged and thus leaking HEPA filters compromise the integrity of the containment (i.e., the high-purity environment). This can lead to uncontrolled product leakage or product contamination, as a result of which neither product safety nor occupational or environmental safety can be guaranteed.

In aggressive environments in the chemical industry, PTFE is the material of choice because of its high chemical resistance.

PTFE-based HEPA filters are chemically significantly more resistant than glass fiber based filter media. This leads to increased safety for products produced in clean environments, the employees working there and the environment. For more details see Chapter 6.

d) Low outgassing

In microelectronic production processes, even a trace of impurities in the ppb range can lead to defects in the lattice structure of semiconductors, resulting in malfunctions and thus defective batches. The result is lower productivity, higher costs and more waste.

Particularly harmful is the element boron (B), which is a companion of silicon (Si), found in glass (SiO₂) based materials and outgases in trace amounts.

In contrast to glass fiber-based filter media, PTFE-based HEPA filters do not emit any boron. This makes them suitable for use in microelectronic production. For more details see Chapter 6.

e) Hydrophobicity and oleophobicity

Due to their chemical structure and fluorine content PTFE membranes are hydrophobic, i.e. they are water-repellent and cannot be wetted by aqueous substances. If they come into contact with aqueous liquids either through condensation of atmospheric moisture or through careless handling in a containment, for example, they do not become saturated with them, and block nor is the mechanical stability reduced.

PTFE membranes are oleophobic as well, i.e. they are oil-repellent and cannot be wetted by oily substances. This is important in applications where oily substances are handled in a containment but even more during the production process of the filter. Here the oleophobicity prevents hot melt adhesive (spacer between the folds of the filter media) or polyurethane (potting compound to bond the filter media to the frame) from being completely absorbed by the filter media and thus unable to perform its function.

To achieve hydrophobicity and oleophobicity, C6-containing chemicals must be used in glass fiber-based filter media.

5. Applications

5.1 High purity environments

HEPA filters are used in high purity environments where cleanliness and lowest particle concentrations are crucial for safety of people, quality of products and safety of the environment. The maximum permissible particle concentrations in high purity environments are specified in the ISO14644-1 standard ("Classification of air cleanliness", see table 8) and can be achieved by using HEPA filters.

		Maximum Concentration Limits (Particles/m³)					
		0.1 µm	0.2 µm	0.3 µm	0.5 µm	1.0 µm	5.0 µm
ISO 14644-1 Classification Number (N)	1	10					
	2	100	24	10			
	3	1,000	237	102	35		
	4	10,000	2,370	1,020	350	83	
	5	100,000	23,700	10,200	3,500	832	
	6	1,000,000	237,000	102,000	35,200	8,320	298
	7				352,000	83,200	2,930
	8				3,520,000	832,000	29,300
	9				35,200,000	8,320,000	293,000

Major change from 1999 is the elimination of the max concentration limit of 29 particles at 0.5 µm in the ISO 5 space.
*This does not apply to EU GMP Annex 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100, 101, 102, 103, 104, 105, 106, 107, 108, 109, 110, 111, 112, 113, 114, 115, 116, 117, 118, 119, 120, 121, 122, 123, 124, 125, 126, 127, 128, 129, 130, 131, 132, 133, 134, 135, 136, 137, 138, 139, 140, 141, 142, 143, 144, 145, 146, 147, 148, 149, 150, 151, 152, 153, 154, 155, 156, 157, 158, 159, 160, 161, 162, 163, 164, 165, 166, 167, 168, 169, 170, 171, 172, 173, 174, 175, 176, 177, 178, 179, 180, 181, 182, 183, 184, 185, 186, 187, 188, 189, 190, 191, 192, 193, 194, 195, 196, 197, 198, 199, 200, 201, 202, 203, 204, 205, 206, 207, 208, 209, 210, 211, 212, 213, 214, 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2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017, 2018, 2019, 2020, 2021, 2022, 2023, 2024, 2025, 2026, 2027, 2028, 2029, 2030, 2031, 2032, 2033, 2034, 2035, 2036, 2037, 2038, 2039, 2040, 2041, 2042, 2043, 2044, 2045, 2046, 2047, 2048, 2049, 2050, 2051, 205

Figure 4.1 shows a schematic diagram of a clean room where the entire ceiling, or even just part of it, is covered with HEPA filters for clean air ventilation. The persons shown illustrate testing of the filters for freedom from leaks.

Note the HEPA filters in the exhaust air of the room, which prevent harmful particles from entering the environment or being distributed throughout the building by the ventilation system.

If only a part of the room requires particularly clean air, only a part of it can be separated, e.g. with curtains. HEPA filters are installed in the ceiling within the separated area (Figure 4.2).



Figure 4.2: Highly clean cleanroom area separated with curtains.

Particularly clean zones can also be created by using RABS (Restricted Area Barrier Systems) or isolators (Figure 4.3). In this case, the air supplied to the closed area is also specially cleaned by HEPA filters on top of the RABS or isolator.



Figure 4.3: Isolator in cleanroom (source: Optima).

If only a small area where something is handled needs to be protected, safety cabinets are used. Figure 4.4 shows such a safety cabinet and scheme of air flow for two different configurations.

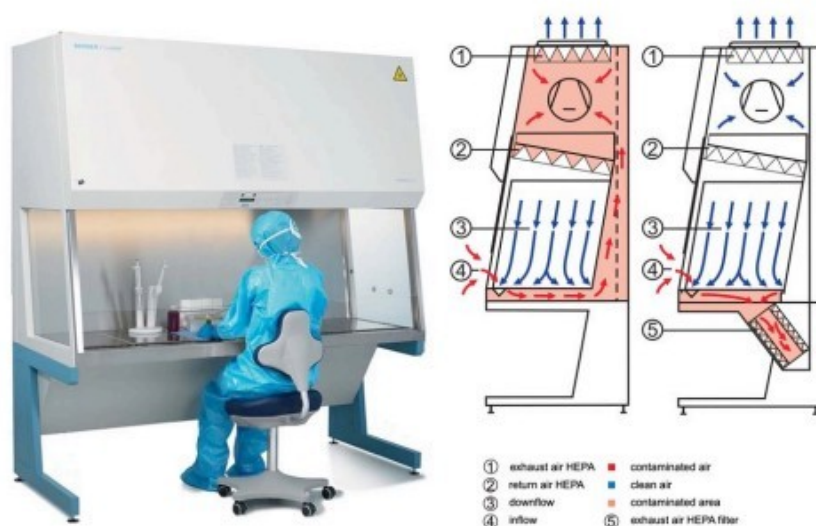


Figure 4.4: Safety cabinet with air flow scheme for two different configurations (source: Berner).

a) Microelectronics

A typical application for PTFE membrane-based HEPA filters is the microelectronic industry. The production process in this industry is highly complex and places the highest demands on air purity.

Here we have a broad range of applications from cleanroom, isolators and safety workbenches up to ultra-clean environments inside lithography machines in wafer production. Figure 4.5 shows such a lithography machine.



Figure 4.5: Lithography machine (source: ASML).

Today, the state of the art are structure widths of 5nm, and 3nm structures have also been shown. It is immediately obvious that even the smallest particulate impurities have devastating effects on the production of microelectronic components (Figure 4.6).

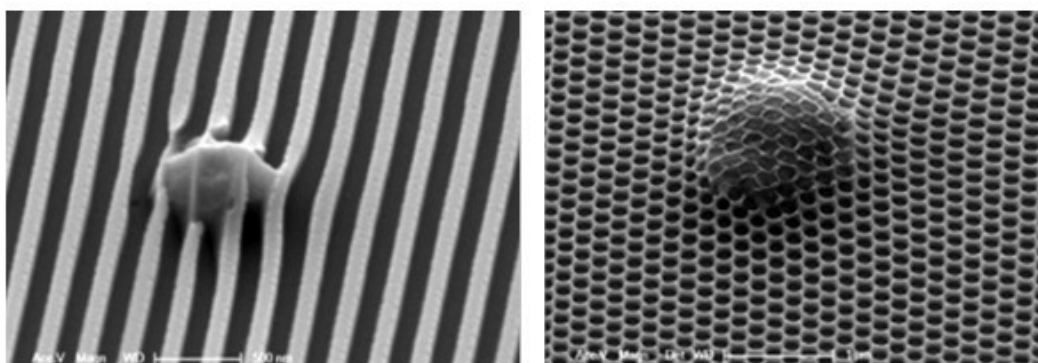


Figure 4.6: Nanoscale microelectronic structures and particulate impurities (source: Source: P1 Verschuuren et al., SCIL Nanoimprint Solutions)

In microelectronics applications, very high filtration efficiency coupled with minimum outgassing are decisive factors. Unwanted outgassing leads to disturbances in the crystal lattice of nanoscale semiconductor structures. The result is malfunctions that cause reduced production yield and increased waste.

Furthermore, the high mechanical stability and chemical resistance of PTFE membrane-based HEPA filters offer the required safety for microelectronic production processes with the requested quality and production reliability.

Since PTFE membrane-based HEPA filters are providing all these features, they have been used in this industry for decades.

b) Pharmaceuticals

In this application cleanrooms, RABS, isolators and safety workbenches are widely used. The production of pharmaceutical substances involves protection against foreign particles and cross contamination. In addition to product safety, it is also a matter of occupational safety for employees and protection of the environment from unintentional contamination through uncontrolled particle release. European guidelines for Good Manufacturing Practice (GMP) [3] as well as FDA regulations require the use of HEPA filters for the reasons mentioned.

Examples of sensitive processes that take place in specially protected environments include vaccine production (Figure 4.7), insulin filling (Figure 4.8), and handling, filling and packaging of solid drugs (Figure 4.9).

In all these applications, the aim is to achieve high filtration efficiency while minimising risk and pressure drop.

Since PTFE membrane-based HEPA filters are providing high filtration efficiency, high mechanical stability and chemical resistance combined with low pressure drop, they are predestined for use in the pharmaceutical industry.



Figure 4.7: Production of vaccines at Biontech in Marburg (Germany) (source: AFP).



Figure 4.8: Filling line in pharmaceutical production (source: Synthegon)



Figure 4.9: Solid handling device in pharma production (source: GEA).

c) Others (Biological Safety Labs BSL, healthcare etc.)

Another application with highest requirements regarding contamination protection are biological safety laboratories (BSL) where pathogens and toxins are handled. Clean rooms, RABS, isolators and safety cabinets are also used here.

BSL are classified according to Table 4.2. HEPA filters are used in all four BSL classes. Safety of the personnel as well as the environment from uncontrolled release of pathogens and toxins have the highest priority.

Biosafety Level	BSL-1	BSL-2	BSL-3	BSL-4
Description	- No Containment - Defined organisms - Unlikely to cause disease	- Containment - Moderate Risk - Disease of varying severity	- High Containment - Aerosol Transmission - Serious/Potentially lethal disease	- Max Containment "Exotic," High-Risk Agents - Life-threatening disease
Sample Organisms	E.Coli	Influenza, HIV, Lyme Disease	Tuberculosis	Ebola Virus
Pathogen Type	Agents that present minimal potential hazard to personnel & the environment.	Agents associated with human disease & pose moderate hazards to personnel & the environment.	Indigenous or exotic agents, agents that present a potential for aerosol transmission, & agents causing serious or potentially lethal disease.	Dangerous & exotic agents that pose a high risk of aerosol-transmitted laboratory infections & life-threatening disease.
Autoclave Requirements	None	None	Pass-thru autoclave with Bioseal required in laboratory room.	Pass-thru autoclave with Bioseal required in laboratory room.

*Table 4.2: Classification of biological safety laboratories
(source: Consolidated Sterilizer Systems).*

Since PTFE membrane-based HEPA filters are providing high filtration efficiency, highest mechanical stability and chemical resistance combined with low pressure drop, they are predestined for use in the biological safety labs.

Another application of HEPA filters in healthcare and veterinary medicine is the ventilation of operation theaters (figure 4.10). It goes without saying that high demands are placed on air quality here.

HEPA filters are placed in the ceiling of the operating theater supplying clean air to the operating table. It's about protection of the patient in the state of highest sensitivity for particulate contaminations. Clean air during operations minimises the risk of infection and is thus a basic prerequisite for successful healing.

Since PTFE membrane-based HEPA filters are providing high filtration efficiency, highest mechanical stability and chemical resistance combined with low pressure drop, they are predestined also for use in the operation theater ventilation.



Figure 4.10: Operation theater with HEPA filter above the operating table.

There are countless other applications which require clean air, calling for HEPA filters and where the property profile of PTFE membrane-based HEPA filters comes into play: micromechanics or optical production, aerospace engineering, food & beverage industry etc.

This always involves the combination of high filtration efficiency, highest mechanical stability and chemical resistance combined with low pressure drop.

5.2 Ventilation units

The applications described so far are primarily concerned with minimising risks for people, quality of products and safety of the environment. The low pressure drop of PTFE membrane-based HEPA filters makes a positive contribution but is not necessarily the main feature for the applications mentioned above.

The low pressure drop of PTFE membrane-based filters is particularly noticeable for installations in ventilation units, where significantly larger volume flows are usually moved, and the largest energy and CO₂ footprint savings are achieved.

According to equation 4.1, the power required to operate the fan is proportional to the product of volume flow and pressure drop:

$$P \sim V \cdot \overline{\Delta p} \quad (\text{eq. 4.1})$$

P	power (W)
V	volume flow (m ³ /s)
$\overline{\Delta p}$	average pressure drop (Pa)

This means that low pressure drop has a positive effect in terms of lower power consumption, especially with large volume flows.

a) Stationary ventilation units

Figure 4.11 shows the schematic structure of a ventilation system for a building. The air is drawn in by an air handling unit, cleaned by filters, conditioned in terms of temperature and humidity, and distributed in the building by means of fans via ventilation ducts.



Figure 4.11: Schematic structure of a ventilation system for a building.

Figure 4.12 shows an example of the schematic structure of an air handling unit (AHU) with multiple filter stages and terminal HEPA filters. Today's technology only allows PTFE membrane-based filters in efficiency range E12-U17. The filters in the stages before the terminal filters are made of synthetic fibers or glass fibers.

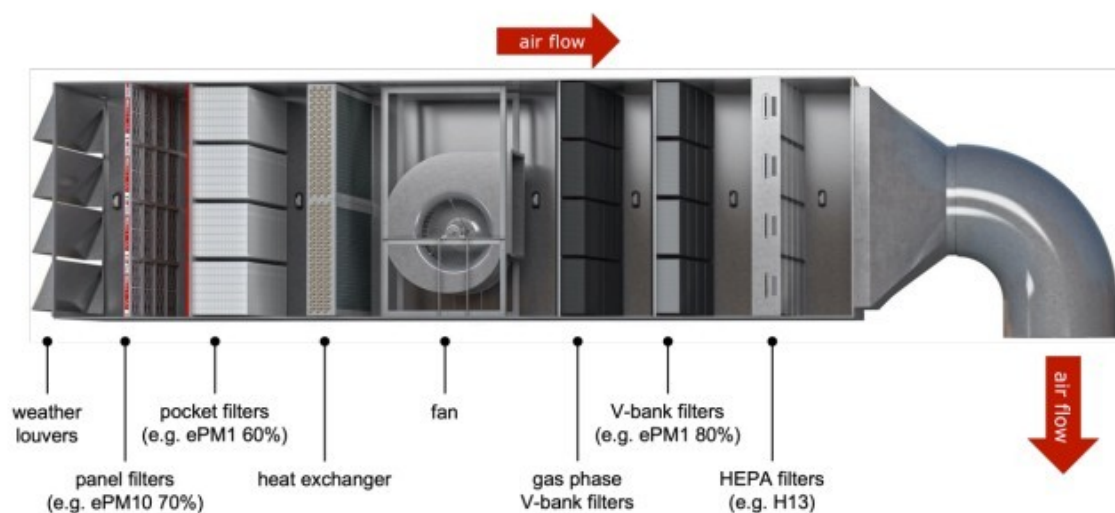


Figure 4.12: Schematic structure of an air handling unit with different filter stages.

In the example shown, each filter stage consists of 16 filters. With a nominal volume flow of $3.400 \text{ m}^3/\text{h}$ per filter, this results in a total volume flow of $54.000 \text{ m}^3/\text{h}$. A typical fiberglass-based H13 HEPA filter in the final filter stage has a pressure drop of 370 Pa at $3.400 \text{ m}^3/\text{h}$, while a PTFE membrane-based H13 HEPA filter has a pressure drop of only 220 Pa . That means 150 Pa less. Assuming fan efficiency η of 50%, this results in a power saving for the whole AHU of $4,53 \text{ kW}$ (eq 1).

Assuming further a yearly operation time of 8.700 h , this results in yearly energy savings of $1,42 \cdot 10^{11} \text{ J}$ (eq. 3).

Assuming the CO_2 emission factor for Germany according to table 5, the yearly energy savings above are equivalent to CO_2 emission savings of $12,27 \text{ t/year}$ (eq. 4).

Assuming an electricity price of 0,5 €/kWh, this results in annual electricity cost savings of € 19.720 € for AHU (eq. 5).

As background information:

So far, there has only been talk of PTFE membrane-based HEPA filters. However, there are developments that have not been fully completed, which make PTFE-based pocket filters, e.g. of efficiency class ePM1 60% as shown in figure 21, seem possible.

A conventional pocket filter of this efficiency class has a pressure drop of about 75 Pa. A PTFE-based pocket filter of only 45 Pa, which corresponds to a pressure drop difference of 30 Pa.

If the above calculations are carried out, these PTFE based pocket filters result in energy savings of $2,84 \cdot 10^{10}$ J, equivalent to CO₂ emission savings of 2,45 t/year and electricity cost savings of 3.944€.

Adding both stages together, PTFE-based air filters contribute to energy savings of $1.70 \cdot 10^{11}$ J, equivalent to CO₂ emission savings of 14,72 t/year, and electricity cost savings of 23.664€.

b) Mobile Ventilation units

Besides stationary ventilation systems, HEPA filters are also used in mobile ventilation systems. These have proven to be a flexible and quick-to-implement measure to reduce the risk of infection, especially in times of pandemic.



Figure 4.13: Mobile air purifier.

Figure 4.13 shows such an air purifier for use in schools, offices and public buildings. The air is sucked in at the bottom, passed through a pre-filter and blown out through a HEPA filter to the top by means of a fan. The volume flow of this unit is 2.000 m³/h. The HEPA filter of efficiency class H14 can be a glass fiber-based HEPA filter (V-type) or a PTFE membrane-based filter (deep pleated type).

Assuming 1.170 h yearly operation time in a classroom, a fan efficiency of 50%, specific electricity cost of 0,5 €/kWh and doing the same calculations as for the stationary ventilation units, the savings by using a PTFE-membrane based HEPA filter vs. a glass fiber-based HEPA filter are shown in table 8.

Let's further assume 30.000 schools in Germany with an average of 10 classrooms per school and that only 50% of these classrooms were equipped with one of such an air purifier. The results of the calculations as mentioned above are also shown in table 4.3.

Yearly savings by PTFE-based filter H14 HEPA filter	1 Air Purifier	Estimation for 50% of all classrooms in Germany equipped with 1 Air Purifier
pressure drop	37 Pa	37
power	41 W	6,17 MW
energy	1,73*10 ² MJ	2,60*10 ⁷ MJ
electricity cost	24 €	3.607.500 €
CO ₂ equivalents	15 kg	2.244 t

Table 4.3: Yearly savings by using PTFE-based filter H14 HEPA filter.

It is obvious that significant energy savings and reductions in CO₂ emissions can be achieved by using PTFE-based filter HEPA filter in such mobile ventilation units. It should be noted that the example calculation was performed only for Germany and the application in schools.

6. Risk assessment

6.1 Production of filters

a) PTFE membrane production process

AAF Europe is importing the complete PTFE membrane from its sister company American Air Filter (Suzhou) Co., Ltd. in China.

There the production process of the PTFE membrane starts with purchased PTFE fine powder obtained by emulsion polymerization. The PTFE powder may contain only very few percent of other fluor polymers (FEP (fluoroethylene propylene), PFA (perfluoroalkoxy alkanes). Therefore, the PTFE/PEF/PFA compound can be considered as only PTFE fluoropolymer.

In the past, fluoropolymers were manufactured using PFOA (perfluorooctanoic acid). However, PFOA is not used anymore in production of fluoropolymers by manufacturers that comply with REACH regulations. Strict analysis result of PFOA content is N.D. (Not Detectable, i.e. < 1ppb).

For more information, see the fluoropolymer manufacturers' contributions.

The fine powder is blended with some extrusion aid to impart fluidity in the following processes. The extrusion aid is a synthetic hydrocarbon oil, not containing any fluorine.

The resulting PTFE paste is extruded through a die and calendered between hot rolls to form a thin tape. At this stage the PTFE forms closed foil, which is also used, for example, as a commercial sealing tape for fittings in the household. (figure 5.1).



Figure 5.1: Sealing tape for fittings in the household.

After removing oil from the tape, it is stretched in machine direction and then in biaxial direction to make porous fiber structure (see figure 3.5).

At the end the membrane is heat treated in a high temperature oven to complete the expanded PTFE membrane. Figure 5.2 shows a schematic diagram of the PTFE membrane production process.

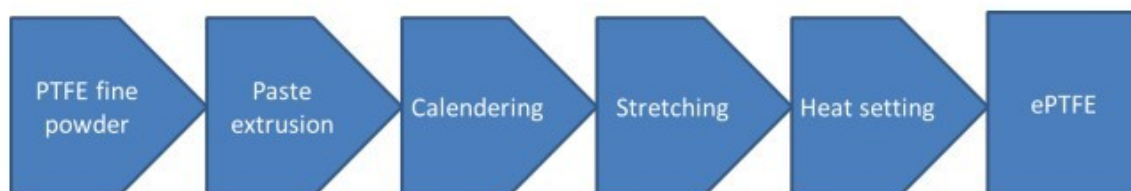


Figure 5.2: Diagram of the manufacturing process of a PTFE membrane.

To finish the PTFE membrane-based filter media the expanded PTFE membrane is laminated between carrier layer and a cover layer. These layers are usually polyester or polypropylene.

b) Filter production process

In AAF plants in within the European Union (e.g. in Latvia or Slovakia) the filter medium is processed into a pleat pack by means of a pleating machine. The pleats are separated from each other, e.g. with the help of aluminum separators, and thus kept open during operation. The pleat pack is then glued to the frame without leakage using polyurethane adhesive. Figure 5.3 shows a schematic of such a deep pleated HEPA filter.

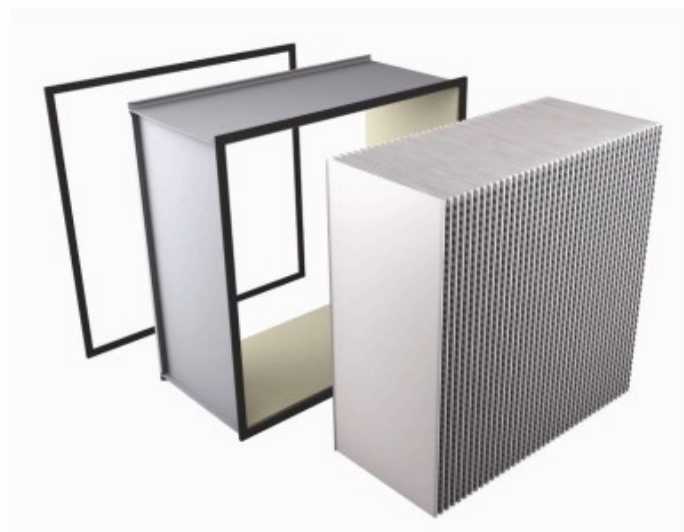


Figure 5.3: Scheme of a deep pleated HEPA filter.

Other designs with less deeply folded pleat pack, so-called mini pleats, follow the same principle. Only the aluminum separators are replaced by lines of hot-melt glue (figure 5.4).

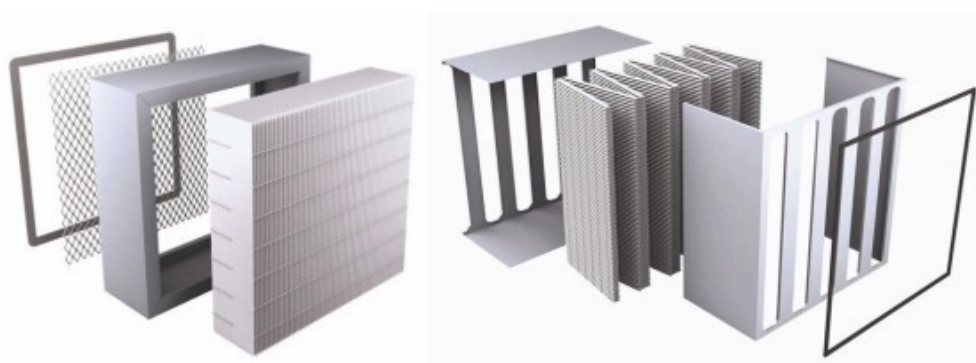


Figure 5.4: Scheme of mini-pleated HEPA filters.

If necessary, gaskets are attached to the frame to seal it against an external installation frame in the later installation situation.

Depending on the respective filter class, the finished filters are still individually tested for absence of leaks. The filters are then packed and ready for shipment to the customer.

6.2 General emissions assessment

a) Manufacturing of PTFE-membrane media and filters

The manufacturing of PTFE membrane filter media is done in an AAF plant in China. It's done in a cleanroom under very clean conditions. The cleanroom class is class 8 (acc. ISO14644-1). This is equivalent to classification EU GMP D according to European guidelines for Good Manufacturing Practice (GMP) [4]. This means that such a room in pharmaceutical production is suitable in terms of product and occupational safety for the preparation of products and components for subsequent filling.

The air entering the cleanroom is filtered by a multi-stage system consisting of the stages panel filter G4, pocket filter F7, air conditioner, gas phase filter and as terminal filter a H13 HEPA filter. The exhaust system is equipped with a gas phase filters.

Filter assembly is done in an AAF plant in Latvia. It's done in a cleanroom of class 7 (acc. ISO14644-1). This is equivalent to classification EU GMP C according to European guidelines for Good Manufacturing Practice (GMP) [4]. This means that such a room in pharmaceutical production is suitable in terms of product and occupational safety for filling of products or preparation of solutions that are unusually at risk of contamination.

The air entering that cleanroom is filtered by a multi-stage system with H14 HEPA filters as terminal filters.

The employees in the cleanrooms wear cleanroom clothing.

All processing steps as described above are processed at temperatures well below the decomposition temperature of fluoropolymers. The fluoropolymers therefore do not decompose during processing, no degradation products are produced.

Under these conditions, no PFAS emissions to the environment are to be expected.

b) Use of filters

Once PTFE membrane-based HEPA filters are installed, they clean particles from the air flowing through them. The air is usually pre-filtered and pre-conditioned and corresponds to normal ambient conditions. Due to the adhesives used in filter construction, the operating temperature is limited to < 70-80°C.

Depending on the application, HEPA filters are checked for leakage at regular intervals (e.g. 6 or 12 months).

They are usually in use for many years before they are replaced. A HEPA filter is replaced either because it leaks (which is extremely unlikely with PTFE membrane-based HEPA filters due to their high mechanical stability and chemical resistance), or because of general hygiene considerations. Another reason to change HEPA is the reconstruction of a cleanroom.

Typically, HEPA filters are used for several years. The market expects service lives of minimum 2 to 4 years. There are also known cases of use where the filters were only replaced after 15 years.

Under the above-mentioned conditions of use of PTFE membrane-based HEPA filters, no PFAS emissions into the environment are to be expected.

c) End of life

At the end-of-life phase, the vast majority of HVAC filters (over 98% corresponding to non-residential applications) as fluorine containing waste are collected by professional companies and subject to incineration in incinerating plants.

PTFE membrane-based HEPA filters can be assigned to European waste code 150202:

- Absorbent and filter materials (including oil filters if not otherwise specified), wiping cloths and protective clothing contaminated by hazardous substances.

Combustion typically takes place at temperatures of around 1200°C. In the process, PTFE decomposes to form gaseous hydrogen fluoride (HF).

These incineration plants are equipped with flue gas cleaning technology that includes multi-stage wet scrubber using calcium hydroxide ($\text{Ca}(\text{OH})_2$, also called lime milk) to wash the flue gas. The hydrogen fluoride (HF) will be transformed to calcium fluoride (CaF_2). CaF_2 is the principal source of hydrogen fluoride, a commodity chemical used to produce a wide range of materials. Among others it's used as raw material for PTFE production. They comply with applicable legislation on emissions.

Figure 28 shows the process scheme of such an incineration plant [4].

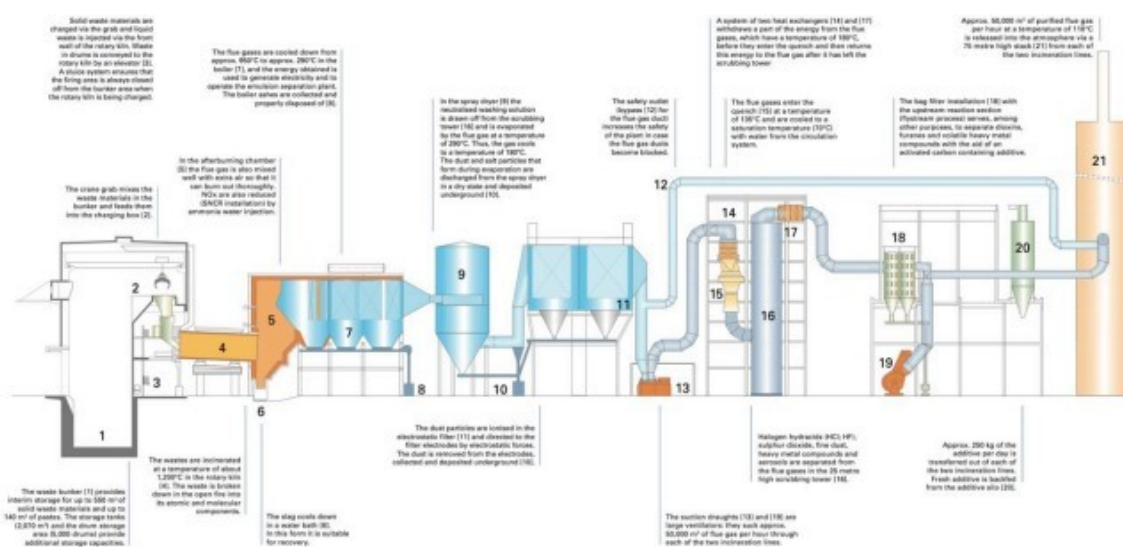


Figure 28: Process scheme of an incineration plant for industrial waste [4].

Under these conditions, no PFAS emissions to the environment are to be expected.

7. Assessment of alternatives

For aerosol physical reasons, fine fibers are necessary for highly efficient separation of particles in the submicron range. Thus the decisive task in filter material development is to process fine fibers into an air-permeable, leakage-free and pleatable sheet material with hydrophobic and oleophobic properties.

7.1 AAF R&D work on alternatives

Following information in pink color is marked as confidential:

In order to be able to replace C6-containing glass fiber filter media also for filter classes below the EPA/HEPA/ULPA range, AAF and Daikin are engaged in the development of PTFE-based filter media also for filter classes covered by ISO16890.

Together with media suppliers the development of C6 free glass fiber filter media is discussed. So far, no satisfactory materials are in sight or even available. This is also due to the fact that the usually silicone-based alternative PFAS free hydro/oleophobicizing agents cannot be used for application-related reasons.

7.2 PFAS containing alternatives (C6 glass fiber filter media)

a) Introduction to C6 glass fiber filter media

One way of producing fine fibers is the spinning of thin glass fibers from its melt and processing them into a filter material in a process similar to paper production.

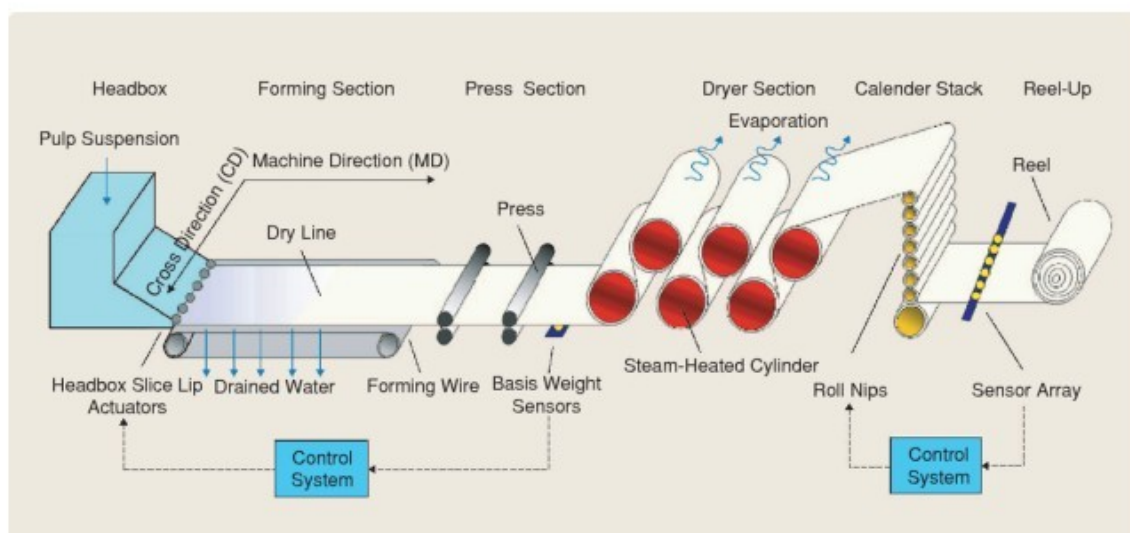


Figure 6.1: Scheme of filter paper production process (source: FiberLean Technologies).

Figure 6.1 shows the Scheme of filter paper production process. In a first step, glass fiber chips made of so-called textile glass are brought into suspension with surfactants and polymer binders.

This suspension is applied to a sieve belt to be first mechanically dewatered. Thermal contact drying using steam-heated cylinders is followed by calendaring to smooth the surface before the material is wound up.

The polymer binder contains fluorine-containing substances to hydro- and oleophobicise the filter material. On the one hand, this is necessary to prevent PU glue and hotmelt from penetrating

the filter medium during the production of filters. On the other hand, the filter materials in later installations need to maintain their mechanical stability and filtration efficiency under the influence of moisture.

In the past, these hydro/oleophobic agents were based on PFOA related substances, (abbreviated to C8). After their restriction they are now based on PFHxA related substances (abbreviated to C6). A separate REACH restriction procedure is currently pending for PFHxA, which foresees an exemption for C6-based filtration media. It includes a derogation proposal for C6-based filtration media. We support this derogation. As already explained, C6-based filtration media are used in combination with PTFE-based filters, in particular in the preceding stages of filtration, but they can also be used in other filtration applications not covered by PTFE or this report. Additionally, where possible, a transition from C6- to PTFE-based filters can take several years.

b) Comparison between PTFE and C6-glass fiber media

PTFE membrane-based filter media for HEPA filter applications is far superior to glass fiber media for HEPA filters, for the terminal filtration stage of filtration systems, as described in Chapter III b, (Description of ePTFE filters/Technical properties and functions).

In all the following aspects PTFE membrane-based HEPA filters are superior to glass fiber-based HEPA filters. PTFE membrane-based HEPA filters are the benchmark for the terminal stage of air filtration systems in clean environments.

1. Low pressure drop, energy consumption/cost and low CO₂ footprint

PTFE-based HEPA filters have significantly lower pressure drop due to the slip flow effect as described before.

The slip-flow results in a dramatically reduced pressure drop of about 50% compared to fiber based HEPA filters!

The power required to operate a filter can be determined using equation 6.1.

$$P = \frac{V \cdot \overline{\Delta p}}{\eta} \quad (\text{eq. 6.1})$$

P	power (W)
V	volume flow (m ³ /s)
$\overline{\Delta p}$	average pressure drop (Pa)
η	fan efficiency (-)

According to equation 1, **50% less pressure drop means 50% reduction in power consumption for the same volume flow and the same ventilator efficiency!**

This leads to lower operation cost, lower energy consumption and lower CO₂ footprint of their operation.

To calculate the energy consumption, the power consumption (eq. 6.2) only needs to be multiplied by the operating time:

$$E = P \cdot t \quad (\text{eq. 6.2})$$

E	Energy consumption (kWh)
t	operating time (h)

If the power consumption is reduced to 50%, the yearly energy consumption for operation of such a PTFE membrane-based filter is also reduced by 50%!

Today, energy is still generated from fossil fuels in most European countries. That means most power generations are accompanied by certain CO₂ emissions. This is commonly referred to as the CO₂ footprint:

$$FP_{CO_2} = E \cdot F_{EM\ CO_2} \quad (\text{eq. 6.3})$$

FP_{CO_2} CO₂ footprint (kg_{CO2})

E Energy consumption (kWh)

$F_{EM\ CO_2}$ CO₂ emission factor (kg_{CO2}/kWh)

The level of CO₂ emissions depends on the energy mix of the respective country. Fossil energy sources (coal, gas, oil) naturally generate higher CO₂ emissions than regenerable energy sources (wind, sun, water).

For the same electricity consumption, the resulting CO₂ emissions therefore vary greatly from country to country, depending on the nationally determined energy mix. Table 3.1 shows the level of CO₂ emissions from electricity generation in different countries. Naturally, countries with a high use of renewable energy sources or nuclear energy, such as Sweden or France, have relatively low CO₂ emissions for electricity generation.

$F_{EM\ CO_2}$ - CO ₂ emission factors	Sweden	France	Finland	Spain	Italy	Germany	Poland
g/kWh	9	51	69	156	213	311	710

Table 6.1: CO₂ emissions from electricity generation in different countries in 2020 [5].

However, due to the very low energy consumption when using PTFE membrane-based filters, their CO₂ emission equivalents are always lower than those of micro-glass fiber filters.

The CO₂ savings are in the order of 50% as well!

Energy cost EC for operating a filter can be calculated by multiplying energy consumption E (eq. 6.2) with specific energy cost c_E :

$$EC = E \cdot c_E \quad (\text{eq. 6.4})$$

EC Energy cost (€)

E Energy consumption (kWh)

c_E specific energy cost (€/kWh)

That means 50% of energy consumption results in 50% lower operation cost!

II. Mechanical resistance

A crucial property in which PTFE membrane are far superior to glass fiber media is mechanical resistance and stability. That's why, depending on the filter class, HEPA filters are leak tested before leaving the manufacturer's plant as well as after installation on-site in the clean environment (containment).

In comparison of PTFE membrane-based HEPA filters, glass fiber HEPA filters are very sensitive in handling. Even a light touch during filter installation, filter validation, cleaning of ceiling, cleanroom modifications and working activities in the cleanroom can cause damage to the filter medium (figure 6.2).



Figure 6.2: Glass fiber media can be easily damaged.

Tensile strength tests on flat and folded glass fiber and PTFE membrane have shown significantly greater mechanical stability of the PTFE membrane (figure 6.3).

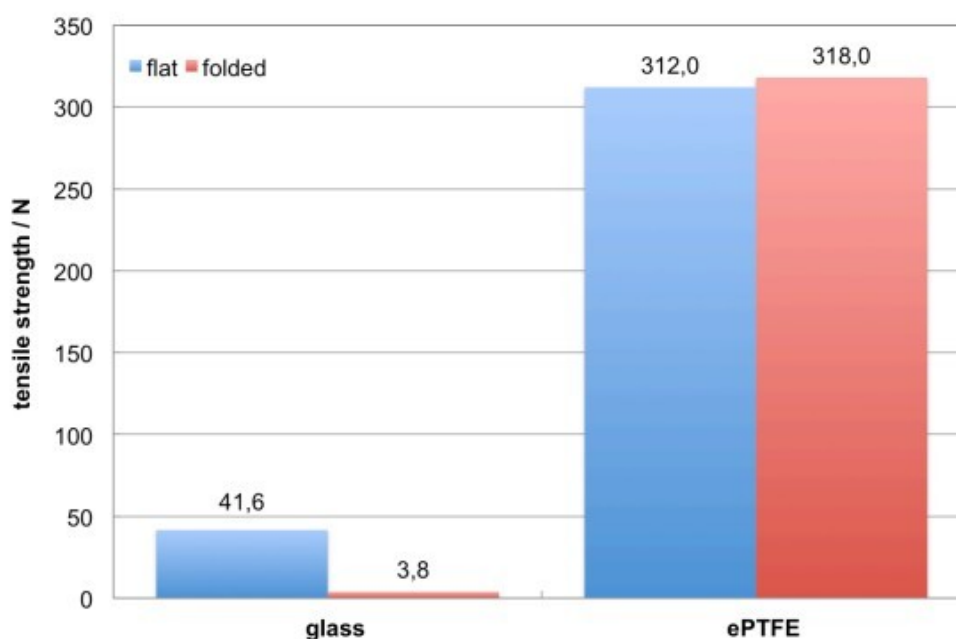


Figure 6.3: Tensile strength of flat and folded glass fiber and PTFE membrane.

In the case of flat specimens, the values for PTFE membrane are larger by a factor of 7,5x and in the case of folded media even by a factor of 84x.

High mechanical stability of PTFE membrane media is not only demonstrated by tensile strength measurements, but also by burst tests, in which a flat material sample is clamped in an apparatus and burst by overpressure on one side. Measurements of the burst pressure show even greater differences in favor of the mechanical stability of PTFE membrane media. As a direct result of this significantly higher mechanical stability of PTFE membrane, the risk of filter damages decreases, resulting in lower cleanroom downtimes, higher productivity, less unscheduled replacements, less costly recovery actions, less waste, less cross contamination and less uncontrolled release of harmful substances.

III. Chemical resistance

PTFE membranes are also extremely chemically resistant. They are insensitive to moisture, direct water contact and even harsh chemicals. Table 6.2 shows the results of test done by soaking of filter media for 24h in water, acids, alkalis and organic solvents. Afterwards the samples were tested for filtration efficiency, pressure drop and weight.

In no case was the filtration efficiency affected. With acetone the pressure drop was slightly increased, with concentrated sulphuric acid the weight was slightly reduced. In both cases, the carrier layer and the cover were affected, but not the PTFE membrane.

solvent (dipped in for 24h)		efficiency	pressure drop	weight
water	pure water	✓	✓	✓
	conc. hydrochloric acid (35%)	✓	✓	✓
acid	conc. sulphuric acid (95%)	✓	✓	reduced*
	conc. nitric acid (60%)	✓	✓	✓
	conc. hydrofluoric acid (47%)	✓	✓	✓
	ammonia solution (28%)	✓	✓	✓
alkalis	sodium hydroxide (10%)	✓	✓	✓
	isopropyl alcohol	✓	✓	✓
	toluene	✓	✓	✓
organic solvents	acetone	✓	increased*	✓
	benzene	✓	✓	✓
	xylene	✓	✓	✓
	hexane	✓	✓	✓

* Only the carrier or cover layer was affected, not the PTFE membrane.

Table 6.2: Chemical resistance of PTFE membrane.

In some pharmaceutical, healthcare and veterinary applications, clean environments (clean rooms, Restricted Area Barrier Systems, safety cabinets, etc.) must be disinfected periodically. The chemicals used (e.g. chlorine dioxide ClO_2 , formaldehyde CH_2O , hydrogen peroxide H_2O_2) are very aggressive and can attack and decompose non-resistant materials.

Tables 6.3 – 6.5 are showing tests of PTFE membrane regarding resistance to the mentioned chemicals. In all cases the PTFE membrane is resistant and consequently guarantees the integrity of the clean environment.

ClO_2	before exposure	after 24h exposure in 0,2% ClO_2 solution	notes	result
efficiency @ 0,3µm PSL	99,9995%	99,9992%	at 5,3 cm/s	✓
pressure drop	119 Pa	119 Pa	at 5,3 cm/s	✓
weight	98 g/m ²	99 g/m ²	-	✓

Table 6.3: Chemical resistance of PTFE membrane to ClO_2 .

CH ₂ O	before exposure	after 24h exposure in 36% CH ₂ O solution	notes	result
efficiency @ 0,3µm PSL	99,9998%	99,9996%	at 5,3 cm/s	✓
pressure drop	125 Pa	124 Pa	at 5,3 cm/s	✓
weight	97 g/m ²	101 g/m ²	-	✓

Table 6.4: Chemical resistance of PTFE membrane to CH₂O.

H ₂ O ₂	sample	before exposure	after 24h exposure in H ₂ O ₂ solution	notes	result
efficiency @ 0,1~0,2µm	#1	99,9998%	99,9999%	at 5,3 cm/s	✓
	#2	99,9999%	99,9998%		✓
pressure drop	#1	255 Pa	276 Pa	at 5,3 cm/s	✓
	#2	257 Pa	286 Pa		✓
weight	#1	2,729 g	2,738 g	135x200 mm	✓
	#2	2,603 g	2,609 g		✓

Table 6.5: Chemical resistance of PTFE membrane to H₂O₂.

IV. Outgassing

Clean environments particularly in microelectronic production (e.g. of wafers) do not only require extremely low dust particle concentrations but must also be free from disturbing gaseous impurities. In order to filter such gaseous impurities from the supply air, absorption filters based on activated carbons or other absorbents are usually used. Since the HEPA particle filter is the last barrier stage directly before the high-purity environment, care must be taken to ensure that this filter itself does not cause any gaseous contamination.

Of particular importance, as highly disruptive to production, are impurities due to the element boron (B) und phosphorus (P). Boron is a companion element of silicon (Si), which as SiO₂ is the base material for glass fiber media.

Since these glass-fiber based HEPA always outgas disturbing traces of boron, they were replaced in wafer production by PTFE membrane-based filters already decades ago.

Table 6.6 shows the result of a flow test of a PTFE membrane-based HEPA filter compared to a glass fiber-based HEPA filter.

element	PTFE membrane-based HEPA filter			Micro glass fiber-based HEPA filter			detection limits
	up- stream	down- stream	contami- nation	up- stream	down- stream	contami- nation	
Boron	< 0,002	< 0,002	< 0,002	< 0,002	0,25	0,25	< 0,002
Phosphorus	< 0,02	< 0,02	< 0,02	< 0,02	< 0,02	< 0,02	< 0,020

Table 6.6: Contamination of air flow by B and P after passing a PTFE membrane-based and a glass fiber-based HEPA filter; all concentrations in $\mu\text{g}/\text{m}^3$.

While both filters do not produce phosphorus contamination, the glass fiber-based HEPA filter shows clear contamination with boron. In the case of the PTFE membrane-based HEPA filter, no contamination is detected.

V. Hydrophobicity and oleophobicity

Air filter media require hydrophobicity and oleophobicity, i.e. depending on their application they must be water and oil repellent for the following reasons:

- Use of filters:
 - Mechanical resistance in wet and oily environments.
 - Avoiding high pressure drop due to blockage of the filter medium by absorbed liquids.
- Production of filters:
 - Keeping hotmelt glue (separating the pleats) on the surface of the media. If it's sucked into the media the pleat separating function is lost.
 - Keeping PU potting compound (fixing and sealing the filter media towards the frame) on the surface of the media. If it's sucked into the media, filtration area and sealing function are lost.

PTFE membrane-based filter media are hydrophobic and oleophobic due to their chemical structure and fluorine content.

With glassfiber-based filter media the required repellency is achieved by treating with C6 containing chemicals (replacing former used C8 chemistry), which is today the best chemistry currently available for hydro-/oleophobicisation of glassfiber media in air filter applications.

7.3 PFAS-free alternatives

a) PFAS-free glass fiber HEPA media

The challenge is to achieve hydrophobic or oleophobic properties without chemicals containing PFAS. In principle, this is conceivable through the use of silicones. However, this is opposed by the fact that silicones are wetting inhibitors even in traces. For this reason, many customers, especially from the automotive industry, request silicon-free filter production in order to avoid subsequent paint damage due to the release of silicon traces.

Glass fiber based PFAS-free HEPA filter media are not known so far.

b) Meltblown

In the so-called meltblown process, very fine fibers can be achieved by strong stretching when spinning fibers from a polymer melt. In principle, high efficiencies up to the HEPA range can be achieved with such filter media. Such media are used, for example, for non-clean environments

such as FFP2 filter masks or also HEPA filters for household vacuum cleaners, where small leaks in the filter media are accepted.

But even small leaks are not accepted in HEPA filters for high-purity environments (cleanrooms, isolators, safety workbenches...). Leaking HEPA filters compromise the integrity of the containment (i.e. the high-purity environment). This can lead to uncontrolled product leakage or product contamination, as a result of which neither product safety nor occupational or environmental safety can be guaranteed.

The definition of a leak, its detection and classification are described in the standards EN1822 (High efficiency air filters (EPA, HEPA and ULPA)) resp. ISO 29463 (High-efficiency filters and filter media for removing particles in air). In addition to simple damage to the filter material, inhomogeneities in the filter material itself can cause leaks.

In contrast to PTFE membrane-based filter media, meltblown filter media do not have the necessary uniformity to guarantee the required freedom from leakage in the sense of EN1822 or ISO29463. That's why meltblown HEPA filters are unsuitable for use in clean environments (cleanrooms, isolators, RABS etc.).

c) Nanofibers

Very fine fibers with diameters in the nanometer range can be produced by various processes, e.g. spinning from its solution or electrospinning.

Here, too, high efficiencies can be achieved in principle but these filter media lack the homogeneity to be used for leak-free HEPA filters for high purity environments.

As already mentioned above, even small leaks are not accepted in HEPA filters for high-purity environments (cleanrooms, isolators, safety workbenches...). Leaking HEPA filters compromise the integrity of the containment (i.e. the high-purity environment). This can lead to uncontrolled product leakage or product contamination, as a result of which neither product safety nor occupational or environmental safety can be guaranteed.

In contrast to PTFE membrane-based filter media, nanofiber filter media do not have the necessary uniformity to guarantee the required freedom from leakage in the sense of EN1822 or ISO29463. That's why nanofiber HEPA filters are unsuitable for use in clean environments (cleanrooms, isolators, RABS etc.).

d) Other membranes

Years ago, the company Lydall provided a membrane filter medium based on UPE (ultra high molecular weight polyethylene). However, it was only available for efficiency classes below the HEPA range and has disappeared from the market.

Other membrane-based air filter media for the HEPA range are not known.

8. Socio-economic implications in case of absence of derogation

Based on the unique property profile of PTFE membrane-based filter media (Chapter 3) and the assessment of alternatives (Chapter 6), it must be concluded that a ban on PTFE membrane-based filter media would have significant and adverse socio-economic consequences for AAF as well as for the downstream sectors and the society at large.

In the event of a ban on PTFE membrane-based filter media, there would be no other solution than to rely on other PFAS (C6) containing glass fiber media for the terminal stage of filtration. Time and cost frame for developing an alternative to this are not foreseeable.

8.1 Impact on AAF and Daikin Group

Costs for the decades-long development of PTFE membrane-based filter media and the filters made from it as well as the production facilities concerned would have to be written off. This amount certainly exceeds € 100 million and thus causes serious economic damage.

AAF would also be forced to rely on the sole use of fiber-based filtering media losing competitive advantage in a key market segment.

Both, i.e. depreciation and losing competitive advantage, together with the unforeseeable cost and time frame for developing an alternative would put the company in serious difficulties, even threatening its existence.

8.2 Impact on downstream users and society

Following information in pink color is marked as confidential:

AAF estimates approx. 5 Mio pcs HEPA filters in use in the EU, thereof 5% (i.e. ≈250,000 pcs) using PTFE based filter media. Today the majority is still using C6 containing glass fiber based filter media. The amount of PTFE polymer in these filters is estimated to be in the range of 30 – 40 t.

AAF market share of PTFE based HEPA filters is estimated to be around 50%.

The distribution between the different application segments is estimated to be 80% microelectronic (thereof the vast majority based on PTFE), 10% pharma, 10% other applications.

Growth rate of PTFE based HEPA filters is estimated as +10% per year.

A ban of PTFE membrane-based filter media would have the following negative consequences for all downstream users which need clean environments (e.g. microelectronic, pharma industry) and society at large.

1. Loss of jobs

There is a risk that AAF, other suppliers of PTFE based filters and downstream users get into economic difficulties that threaten their existence. This means that more than 1,000 jobs are affected in the EU alone. This does not include the impact on other suppliers and downstream users.

2. Higher energy consumption

Significant higher energy consumption of ventilation systems as glass fiber based HEPA filters have a significant higher pressure drop (≈100%). The missed power savings are estimated to be in the range of 16.3 MW, the missed energy savings are estimated to

be in the range of 390 TJ (Terra Joule) per year. This estimation is based on current installation base of PTFE membrane filters, which is continuously growing.

3. **Larger CO₂ footprint contradicting the European “Green Deal”**

The higher energy consumption by using glass fiber based HEPA filters lead to higher CO₂ emissions, which is contradicting the European “Green Deal”. The missed CO savings are estimated to be in the range of 33.600 t per year. This estimation is based on current installation base of PTFE membrane filters, which is continuously growing.

4. **Reduced product safety**

The lower mechanical stability and chemical resistance of glass-fiber based filter papers increases the risk of contaminated, defective or unusable products which are manufactured in clean environments. The pharmaceutical, food, microelectronics and nuclear industries would be particularly affected.

5. **Reduced workplace safety**

The lower mechanical stability and chemical resistance of glass-fiber based filter papers increases the risk of exposing employees in clean environments to health risks from contamination with harmful substances. The pharmaceutical, food, microelectronics, nuclear industries and biological safety laboratories would be particularly affected.

6. **Reduced environmental safety**

The lower mechanical stability and chemical resistance of glass-fiber based filter papers increases the risk of release of harmful substances into the environment. The pharmaceutical, food, microelectronics, nuclear industries and biological safety laboratories would be particularly affected.

7. **Loss of innovation potential and competitiveness of the EU filtration sector**

The development of PTFE based HEPA filtration media will surely go on and be dominated by Chinese companies.

8. **More waste**

Reduced product safety leads to reduced yield in production processes, increased defective or unusable products.

9. **Higher cost**

Due to the lower mechanical stability and chemical resistance of glass fiber-based HEPA filters compared to PTFE membrane-based filters, higher costs are incurred due to:

- defective or unusable, because contaminated, products,
- increased waste,
- increased cleanroom validation costs and downtime due to increased replacement of leaking HEPA filters.

9. Conclusions

PTFE membrane-based air filters covered by this report are used in terminal stages of multistage filtration systems for clean environments (containments) and classified according EN1822 (High efficiency air filters (EPA, HEPA and ULPA)) resp. ISO 29463 (High-efficiency filters and filter media for removing particles in air). They are used in semiconductor manufacturing, microelectronics, pharmaceutical industry, nuclear industry and others industry segments, where clean conditions are mandatory for product safety, occupational safety and environmental protection.

These PTFE membrane-based air filters have unique properties that make them far superior to fiberglass and C6-based air filters, which are the only alternative today. Having said that, a separate derogation for C6-based air filters is necessary to ensure transition from C6 to PTFE-based filters where possible, as well as to cover other filtration applications, either not suitable for PTFE or not covered by this report.

Produced according to state-of-the-art standards, PTFE filter media are not expected to release any PFAS during manufacturing, use and are properly handled at waste stage.

A ban of PTFE filter media would result in significant economic damage but also in terms of public health, product safety, environmental protection and increase of greenhouse gas emissions.

A ban would contradict the objectives of the Green Deal, i.e. the efforts of the European Union to reach climate neutrality and the goal of zero net emissions by 2050.

PTFE based filter media are a technology platform with further growth potential to meet safety and energy savings goals.

In light of this, a derogation is needed for PTFE filter media for air filtration.

10. References

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