FILTRATION AND SEPARATION COALITION'S RESPONSE TO THE ECHA PUBLIC CONSULTATION ON THE PFHXA RESTRICTION PROPOSAL

13 May 2020

Section III – Specific concerns

Question 1

We are a coalition of three leading companies in the filtration and separation sector, Ahlstrom-Munksjö, Hollingsworth & Vose and Lydall, with production sites within the European Union, including France, Finland, Germany, Italy, and the United Kingdom. Our companies have set up this joint coalition, "the Filtration and Separation Coalition", to raise common concerns about the restriction proposal for PFHxA, its salts and PFHxA related substances under the REACH Regulation. Our companies value the opportunity to submit the hereby comments to the ECHA public consultation on this restriction proposal.

We are concerned by the absence of an exemption proposal for high performance filtration and separation applications, although the use of C6 fluorotelomer chemistry – hereinafter C6 chemistry– remains without alternatives for these applications. We would therefore like to formally request ECHA to consider the following exemption:

> *Paragraphs 1 and 2 shall not apply to filtration and separation media used in high performance air and liquid applications that require a combination of water- and oil-repellency.*

The hereby non-confidential information summarises the key facts related to our exemption request, i.e. the critical applications of high performance filtration and separation media, the limited releases related to these applications, the absence of suitable alternatives as well as the largely disproportionate negative consequences that the absence of derogation would imply for EU citizens and key industrial sectors of the EU economy.

This contribution will be further underpinned by contributions submitted separately by individual members at a later stage of the public consultation.

High performance filtration and separation media

Filtration and separation media treated with C6 fluorinated polymers consist primarily of non-wovens or paper composed of manmade fibres, natural fibres (or a combination of both), with resins that contribute to the structural or physical properties of the media. Filtration and separation media manufactured with C6 fluorinated polymers play a critical role in the following applications, among others: medical devices, PPE, HVAC (including EPA/HEPA/ULPA), Air Pollution Controls (APC), dust collectors, hydraulic systems, coalescers, gas turbines, and fuel systems.

Medical devices and PPE

Certain medical devices require filtration media. For instance, filters are used for personal respiratory equipment, including respirators and ventilators to assist or replace breathing when a person is unable to breathe adequately on their own. Additionally, in recent decades, Heat and Moisture Exchange (HME) devices have been employed increasingly for short-term use in anaesthesia and long-term use in intensive care units.

For these products, C6-polymers provide highly hydrophobic properties to venting and respiratory filters necessary to provide excellent barrier properties to airborne microbial contaminants, offering protection against bacteria and viruses before they enter the patient's airway and thus bringing a crucial contribution in the prevention of healthcare-associated infection. At the same time, venting filters reduce the number of pathogens a patient exhales into the air and protects equipment from being contaminated, contributing to protecting healthcare staff and other patients.

HVAC and EPA/HEPA/ULPA

Filtration media manufactured with C6 are used for Heating, Ventilation and Air Conditioning (HVAC), including air purification in residential and industrial buildings. Quality of air in buildings is crucial to ensure the protection of personal health for people as well as eliminating contamination of goods throughout industrial production. Filtration media for HVAC applications protect people and processes from harmful pollutants in ambient air, reducing the risk of health issues and airborne contamination. C6 fluorocarbons play an essential role to create the barriers against airborne droplets carrying microbial contaminants like viruses.

EPA/HEPA and ULPA applications have the same purpose as HVAC filters (i.e. purifying ambient air), but with higher purification capabilities. They correspond to different efficiency classes. For this reason, they are used in clean rooms-controlled environment to meet high standards of air quality. EPA/HEPA and ULPA filters play a major role of protection, safety, and productivity in many critical applications such as hospitals, pharmaceuticals, laboratories (P4 laboratories) microelectronics, personal protection, nuclear applications, or food processes.

Air pollution control (APC) and dust collection filter media

Filter media are used in a wide range of industrial applications to reduce or eliminate the emission of particles into the atmosphere from stationary sources, helping protect the environment. C6 polymers ensure excellent pulse self-cleaning properties, and effective removal of particles and dust at a lower pressure drop.

Hydraulic Filter Media

Hydraulic filter media are critical for industrial, mobile, and aerospace applications in order to keep hydraulic fluid contaminant-free. An optimal and reliable filtration performance also reduces maintenance and prevents failures of the fluid power system.

For these applications, C6 chemistry allows the delivery of optimal pressure drop for the required fluid and temperature resistance and the protection of the fluid power system. It also enhances the structural stability of the media. In the case of glass filter media, a light C6-polymer treatment is applied to provide glue repellent properties that are important for lamination and converting steps, both processes involving hot melt glue.

Coalescers

Coalescers are materials used to separate types of materials from each other and can be generally subdivided into Gas/Liquid and Liquid/Liquid applications.

Gas/Liquid separation provides clean, oil-free process air for critical applications in food, pharmaceutical, medical, and paint industries. Manufacturers rely on coalescer to provide clean process fluid, complete aeration, equipment protection, and energy savings. Delivering oil-free compressed air allows low-maintenance, efficient, and safer manufacturing systems in these markets. In order to achieve these critical performance attributes, C6 fluorocarbons are essential. The unique high-level repellency against oil or any other fluid offered by coalescers with these materials are essential to separate out contaminants for processes that rely on clean air flow and reduce energy consumption.

Liquid/Liquid separation (in particular water-oil separation) also relies on these unique properties of fluorocarbon polymers. These coalescer applications support safety and cleanliness of many human activities that rely on clean water. Coalescers help maintain important environmental protections by cleaning and removing oil from the bilge fluid of watercraft and industrial shipping vessels. Additionally, coalescers contribute to other industrial applications including de-watering of hydraulic fluids and removal of quench water in industrial chemical manufacturing operations.

Gas turbine

C6 chemistry is used in the production of filtration media intended to purify the air before entering turbines for energy generation purposes. C6 chemistry allows not only for longer filter lifetime but also ensures the optimal level of pressure drop, a property that helps

maximize output and minimize energy consumption. Furthermore, these filter media rely on a high level of particulate removal efficiency, which protects the turbine against fine dust, soot, and salts. Additionally, high level of hydrophobicity prevents liquid water ingress through the filters and extend filters' lifetime in humid environmental conditions.

In this context, the treatment with C6-polymer plays a critical role in preventing ingress of water, salts and oil droplets in the turbine, providing high humidity resistance, and therefore ensuring the good functioning of the turbines even in challenging environments and protecting them from corrosion and damages. On top of that, C6-polymers demonstrated unique performances in case of fog and icing conditions which cannot be achieved without C6-based hydrophobic treatment.

Nuclear Industry

The nuclear industry is a major user of high efficiency filters with specific requirements. These filters are used to prevent the release of airborne radioactive particles. These particles might be produced due to operations in certain rooms, equipped with exhaust systems. Filter exhaust systems are also used for containment in case of potential accidental releases. The filter media as well as the filters are tested according to specific standards – please, refer to Table 1. C6 is used in these media like it is for HEPA filtration. Besides standard filtration properties these filter media need to respond to specifications include dry and wet mechanical properties prior and after gamma radiation.

Fuel filtration and fuel-water separation

Modern car and truck engines require the removal of water which is naturally dissolved in diesel and bio-diesel due to the nature of the manufacturing processes of these fuels.

State-of-the-art filtration can separate emulsified or finely dispersed water droplets from these fuels in order to avoid corrosion of pits and nozzles in the fuel injection system and cavitation effects during combustion.

Such filter media can be equipped with barrier functionalities against those finely dispersed water droplets in which fluorocarbon-based materials play an important role due to their highly hydrophobic nature, which is an outstanding performance criterion against other chemical materials. It will therefore play an important role to extend the life-time of the filter, the fuel injection system, and finally the whole combustion engine.

Critical properties of C6 and related benefits

C6 chemistry provides essential properties upon which many filter applications depend in order to provide health, safety, and energy efficiency benefits. The essential criteria for filtration and separation may vary slightly depending on the final applications. However, durable water and oil repellency are essential properties of the C6 chemistry that are common to high-performance filtration and separation media applications which

are covered by the hereby exemption request. These properties relate to the unique low surface tension of fluorine. Water and oil repellency provide a strong chemical barrier which is crucial to allow the superior functionality of the abovementioned applications.

Oil-repellency is furthermore strongly correlated with the glue-repellency property, which is important for filter manufacturers that use hot melt glue to fix the pleats of the filters and to give them high mechanical resistance. Without those glue repellent properties, the glue would penetrate inside the media with the risk of clogging the pores that will result in an increase of pressure drop properties as well as a reduced lifetime.

C6 chemistry also ensures reduced pressure drop. Pressure drop means loss of pressure across a filter device in an air (or liquid) flow, due to resistance to flow, which can be caused by filter media, humidity, or contamination. Keeping pressure drop at a low level is key for the good functioning, extended lifetime of filters and maintaining low energy consumption.

Additional benefits include higher dust holding capacity, prevention of microbiological growth, high mechanical strength even in highly humid or rainy environments as well as protection against corrosion and damages. These critical properties also contribute to life- and energy-saving technologies on which many industries depend.

Limited releases related to these applications

As shown below, we expect very limited releases to the environment from the use of C6 chemistry in filtration and separation media.

Filtration and separation media are commonly produced via wet-laid processing. According to this process, fibres are initially suspended in an aqueous solution (1) and then formed into a sheet on a moving screen where the water is removed (2). The web is then further dewatered and dried (3). After drying, filtration media undergo relevant mechanical and/or chemical finishing treatments (4) to be tailored or functionalised to meet specific properties. Finally, the media manufacturing ends with large rolls of product. Converters transform these large rolls into smaller rolls to be later assembled as part of a final filter article by filter manufacturers.

C6 fluorinated polymers can be used at different stages of the process, e.g. during stage (1) or (4), depending on the process and performance requirements.

Wastewater from the process is recovered and treated in wastewater treatment plants according to environmental legislation. Those wastewater treatment plants can be equipped with e.g. physicochemical treatments and/ or biological treatments. About air emissions, no air emission releases are expected from the drying process since C6 polymers are very stable chemicals and the temperature remains below degradation possibility. Regarding solid waste from the process –e.g. media production, filter manufacturing–, it should be noted that residuals are fully captured, including the ones containing C6, and then disposed according to their corresponding waste code. There

are several codes possible depending on the type of waste/residual (e.g. Waste Codes 150202 –absorbents, filter materials (including oil filters not otherwise specified), wiping cloths, protective clothing contaminated by hazardous substances– and 150203 – absorbents, filter materials, wiping cloths and protective clothing other than those mentioned in 150202).

It is worth noting that C6 is well embedded in the filter matrix and, therefore, there is no risk of C6 getting airborne downstream in the value chain.

Question 10

Assessment of alternatives

Difficulty of substitution

Filtration applications present technical limitations in terms of potential approaches to achieve water-repellent and oil-repellent properties. Normally, such properties could be achieved by two approaches: (1) a physical barrier where there are no pores in the media and a specific coating treatment avoids or reduces the diffusion of water or oil throw the media, and (2) a chemical barrier where the unique low surface energy tension of fluorine turns the surfaces into repellent surfaces for water and oil.

In case of filtration and separation applications, the physical barrier approach is not usable because the presence of pores and the ability to filter is the fundamental characteristic for a filter. Only the chemical barrier approach is possible.

Depending on the applications, customers need certain specifications to be met. The typical customer requirements are listed below:

- Water repellency (Hydrostatic head, Hydrodynamic resistance);
- Oil repellency;
- Compatibility with glue / glue repellency;
- High durable filtration efficiency (against viruses, bacteria, oil, water, dust, etc.) in all types of environments;
- Resistance against microbiological contaminants;
- Performance in difficult operating conditions (high moisture content at high temperatures);
- Compatibility with other chemistries, final applications and processes.

Alternatives previously assessed/ under assessment

The key alternative fluorine-free repellents that are most widely used in the EU and which could be regarded as potential alternatives include:

- Flat modified polymers,

- Hyperbranched functionalized polymers,
- Paraffin,
- Silicones,
- Polymeric compounds,
- Plasma treatment

However, these candidate alternatives show a lower level of water repellency and no oil repellency. Therefore, there are no alternatives available to provide filtration and separation media with a combination of these two essential properties.

The abovementioned substances also fail to meet other typical customer standards. Paraffin, in particular, does not provide sufficient temperature resistance. Silicones cause damage to the air fume treatment in RTO systems and are not accepted in certain applications. In fact, both paraffin and silicones have been identified as paint wetting impairment substances by the German Mechanical Engineering Industry Association (VDMA). As a consequence, these substances are not allowed for HVAC filters, not just for the painting industry but for many other sectors including for instance automotive production. Due to their interference with paint adhesion, silicones are restricted by the automotive industry and their absence is verified in all air supply equipment through specific test methods.

In addition, potential candidates for substitution may not have a more favourable hazard profile, or not much information is currently available. Silicones may degrade to D4, D5, D6 which are listed as SVHCs, and are subject to a separate REACH restriction proposal.[1]

Finally, on C4 fluorotelomer chemistry, undertaking a similar transition from C6 to C4 as it was done for C8 to C6 is not a realistic option. With all PFAS being under regulatory scrutiny, C4 is not seen as a long-term potential replacement, which is what our industry and downstream users require.

Requalification process

The performance characteristics are not the only parameter to consider. Any changes in the product require its requalification, not only for C6-related properties but for all key performance requirements such as fire behaviour, energy efficiency, etc. This requalification process varies depending on the end-use sector's protocols –e.g. nuclear industry, pharmaceutical industry. Nonetheless, it usually involves four main steps: converting, internal testing, third-party certification as well as field testing. Third party

[1] https://echa.europa.eu/de/-/echa-s-committees-conclude-on-two-restrictions-and-10-harmonised-classification-and-labelling-opinions?utm_source=echa-weekly&utm_medium=email&utm_campaign=weekly&utm_content=20191211&_cldee=bXNjaG9AcmFtYm9sbC5jb20%3d&recipientid=contact-346530e323d5e9118112005056b9310e-16d35c59f893459da1528a376f161569&esid=61cd7bf3-f11b-ea11-8115-005056b9310e

certification may also be required, not only for filtration and separation media producers, but also for customers as well as the Original Equipment Manufacturer (OEM). Requalification of materials comes with its own costs, including time, resources, development of novel chemistry, risks to product performance, and failures in critical product uses.

Please see below a list of common sectoral standards which need to be met in a requalification process. Certain standards relate specifically to performance in terms of repellency, for filtration and separation media as well as filters. At present, there is no candidate that can meet all the current performance and industry requirements. Other standards, as those listed below, relate to the overall performance or other aspects of media / filters. They nonetheless belong to the requalification process, contributing to the complexity and costs of this process.

Table 1 – *Standards for filtration and separation media and filters*

Filtration and separation media - Performance in terms of repellency	Performance Standards
Water repellency	EN20811 (Hydrostatic pressure)
	ISO811 (Hydrostatic pressure)
	EDANA NWSP 080.6 (Hydrostatic pressure)
	Mil Std 282 (Q-101) (Hydrostatic pressure)
	NWSP 080.11.R0 (15) (Mason Jar)
	WSP 80.11 (09) (Mason Jar)
	ASME-AG-1-2017; FC-I-3241 (prior to gamma irradiation)
	ASME-AG1-2017; FC-I-3242 (after gamma irradiation)
Oil repellency	ISO 14419
	Tappi T559
	Dupont Kit test
	3M Kit test
Wet strength	ASME-AG-1-2017; FC-I-3233 (Wet tensile strength)
	Tappi T494 (Wet tensile strength)
	ISO 2758 (Wet burst strength)

Filters – Performance related to repellency	Filter Performance Standards
Repellency standards	ISO/PWI 29461-4 — Part 4: Test methods for static filter systems in marine and offshore environments (in development)
	ISO/AWI 29461-7, AWI, Filter element endurance test in Fog and Mist environments (in development)
Other performance requirements per application	**Filter Performance Standards**
Medical devices and PPE (masks)	EN143
	EN149
	NIOSH 42 CFR Part 84
	ISO846
	VDI6022
	Military, country specific standards
	General, country specific standards
Medical devices and PPE (surgical masks)	ASTM 1862-05
	EN14683
HVAC	EN779:2012
	ISO16890
	ASHRAE52.2
	ISO846
	VDI6022
EPA/HEPA/ULP	EN1822
	ISO29463
APC and dust collection filter media	TRGS 727:2016
	VDI3926-2004
	ISO11057-201

Hydraulic Filter Media	ISO/DIS 23369
	ISO16889
Coalescer	ISO12500
Gas Turbines	ASHRAE 52.2
	EN779:2012
	ISO29461
	ISO11057-201
	VDI3926-2004
	ISO846
	VDI6022
Nuclear industry	ASME AG-1
	CTHEN
Fuel filtration	ISO19438
	ISO4020
	ISO 19612 (under evaluation)
Fuel-water separation	SAEJ 1488: Emulsified Water/Fuel Separation Test Procedure
	ISO 16332: Diesel engines — Fuel filters — Method for evaluating fuel/water separation efficiency
Automotive Paint Applications	VDMA24364
Fire behaviour relevant to media and final products for a wide range of applications	UL900
	DIN53438
	DIN4102
	ISO11925
	ISO53568

	EN13501
	NP P92-503, -504, -505

To sum up, there are no candidates to replace C6 chemistry in high performance filtration and separation applications. After the identification of the substances, both filtration media and filtration products will require requalification by manufacturers, and customers/OEMs. Given the wide array of filtration applications, the length of the process might also vary. Therefore, it is not possible to provide a clear timeline for potential substitution in case it would be possible.

Socio-economic implications

As shown by the analysis of alternatives, there are at present no viable alternatives that can be used in high performance air and liquid filtration and separation which require a combination of water- and oil-repellency.

Our companies count several production plants for filtration and separation media in the EU, representing several hundreds of jobs. As a result, an absence of derogation for these applications will put at risk these manufacturing facilities located in the EU. It would furthermore result in a supply interruption of filtration and separation media within the current technical specifications until adequate alternative candidates are identified and completion of subsequent requalification.

The socio-economic implications of such a supply interruption can only be expected to be very large due to the applications at stake and the timeline for potential substitution.

High performance air and liquid filtration and separation are used in safety-critical applications which require requalification of equipment including third party certifications. It must be noted that more than 80% of applications that require requalification have a link to other industrial activities – e.g. medical, pharmaceutical, food and nutrition, protective equipment electronics, energy, chemistry. The table below describes the main implications of an absence of C6-treated media on the functioning of downstream applications.

Table 2 – *Safety implications resulting from the absence of derogation*

Filtration and Separation Applications	Safety Implications of Absence of Derogation
Medical devices and PPE (including RPE)	The absence of highly hydrophobic properties to venting and respiratory filters would lead to an increase in the number of air contaminants a patient exhales, putting healthcare staff and other patients at risk. It would also lead to contamination of the medical equipment.

HVAC/ EPA/HEPA/ULPA	The absence of a proper barrier against harmful pollutants in ambient air would increase the risk of health issues and airborne contamination for people. It would lead to lower productivity of industrial applications relying on clean air.
	In the case of EPA/HEPA and ULPA, filters would be unable to meet high standards of air quality required in many critical applications, such as hospitals, pharmaceuticals, laboratories, microelectronics, personal protection, nuclear applications, or food processes. Additionally, increased pressure drop would result in a shorter lifetime of filters would force HVAC and HEA systems to use more energy to push the air through, leading to increasing costs and higher environmental damage – 40% of the global energy consumption is being used in buildings and 35% of this power consumption is used in air conditioning.
APC and dust collection filter media	Increased emissions of pollutants / particulates from industrial facilities.
Hydraulic Filter Media	Increased pressure drop would lead to lower fluid and temperature resistance, impacting the protection and performance of the fluid power system.
Coalescers	Low-level repellency against oil or any other fluid would not allow to separate out contaminants for processes that rely on clean air flow –i.e. medical, pharmaceutical and food industries.
Gas Turbines	Liquid water ingress resulting from the absence of highly hydrophobic properties would reduce the products' lifetime under humid environmental conditions, lead to engine stops, and provoke serious risks for operating platforms and supply of energy or transport of gas.
Nuclear industry	Risk of media failure under extreme conditions that could result in radioactive material to contaminate the environment.
Fuel filtration/ Fuel-water separation	The lack of highly hydrophobic properties resulting in a shorter lifetime of filters would undermine the functioning of the fuel injection system and the whole combustion engine. We can therefore assume a high impact in terms of productivity.

In terms of timeline, there is no certainty at this stage on when suitable alternatives will be found despite R&D work being conducted for years. The sector just completed its transition from C8 to C6 which already took 5 to 10 years depending on applications and represented a heavy economic burden on the industry – in terms of tens of millions of euros. Transitioning to non-fluorinated chemistry will take even more time and be

significantly costlier. The duration of the requalification by customers (customer internal testing/ field testing) might also take longer depending on the sector, the value chain, and the intended applications. And this period would start once a good candidate has been identified by filtration and separation media producers.

In absence of a derogation, and give the lack of proper enforcement, the restriction would penalise European producers that have transitioned to C6 and operate under strict emission control conditions, compared with non-EU producers, potentially still using C8. Additionally, end-users will be penalised as a result of the lack of materials to meet critical performance specifications, increasing their dependence on imported products.

In conclusion, the absence of derogation would be disproportionately costly and represent significant risks in terms of safe operations of applications relying on high performance filtration and separation media.

Annex I – List of acronyms

APC	Air Pollution Control.
CTHEN	Technical Center for Nuclear Equipment Certification.
EPA	Efficiency Particulate Air filters.
HEA	High-Efficiency Air.
HEPA	High-Efficiency Particulate Air filters.
HME	Heat and Moisture Exchange.
HVAC	Heating, Ventilation and Air Conditioning.
ISO	International Organization for Standardization.
GT	Gas Turbine.
OEM	Original Equipment Manufacturer.
P4 Laboratories	Laboratories with the highest level of biosafety precautions.
PPE	Personal Protective Equipment.
RPE	Respiratory Protective Equipment.
RTO	Regenerative Thermal Oxidiser.
ULPA	Ultra-Low Penetration Air filters.
VDMA	Mechanical Engineering Industry Association *(Verband Deutscher Maschinen- und Anlagenbau).*