SOCIO-ECONOMIC ANALYSIS

Impacts of a potential restriction of per-and polyfluoroalkyl substances (PFAS) for electromagnetic actuators, valves, and sensors for dynamic processes in transportation (commercial and passenger vehicles) and industrial applications

SUBSTANCE: **Per- and polyfluoroalkyl substances (PFAS)**

FROM: **[CONF.]**

USE: **in electromagnetic actuators, valves, and sensors**

DATE: **21 September 2023**

PREPARED BY:

EPPA SA/NV

Place du Luxembourg 2

1050 Brussels, Belgium

EU transparency register: 31367501249-92

P U B L I C   V E R S I O N

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DISCLAIMER:

The views expressed in this report are, unless otherwise stated, those of the authors and do not necessarily represent any official view of [CONF.] and/or any other organization mentioned in this report.

Contents

Abbreviations

ABS	Anti-lock braking system
ACM	Ethylene Acrylate Copolymer
ACN	Acrylonitrile
B2B	Business-to-Business
BEV	Battery Electric Vehicles
CA	Competent Authority
CAGR	Compound Annual Growth Rate
CAS	Chemical Abstracts Service
CF	Carbon–Fluorine
CLP	Classification, Labelling and Packaging Regulation
CV	Commercial Vehicle
d.r.	Discount Rate
DIN	German Institute for Standardization
EBIT	Earnings Before Interest and Taxes
EBS	Electronic Braking System
ECHA	European Chemicals Agency
ED	Endocrine Disruptor
EEA	European Economic Area
EINECS	European Inventory of Existing Commercial Chemical Substances
ELV	End-Of Life Vehicles
EoL	End Of Life
EPDM	Ethylene Propylene Diene Monomer
ES	Exposure Scenario
ESP	Electronic Stability Program
EU	European Union
EUR	Euro (currency)
EV	Electric Vehicles
FCEV	Fuel Cell Electric Vehicles
FKM	Fluorine Kautschuk Material
FMEA	Failure Mode and Effects Analysis
FVMQ	Fluorosilicone
GWP	Global Warming Potential
HFPO-DA	Hexafluoropropylene Oxide Dimer Acid
HNBR	Hydrogenated Nitrile Butadiene Rubber
ICE	Internal Combustion Engine
LRTP	Long-Range Transport Potential
MSCA	Member State Competent Authority
NBR	Nitrile Butadiene Rubber
NPV	Net Present Value
OECD	Organization for Economic Co-operation and Development
OEL	Occupational Exposure Limit
OEM	Original Equipment Manufacturer
PBT	Persistent, Bioaccumulative and Toxic
PFAS	Per-and Polyfluoroalkyl Substances
PFBS	Perfluorobutanesulfonic Acid
PFCA	Perfluoroalkyl Carboxylic Acids
PFDA	Perfluorodecanoic Acid
PFHxA	Perfluorohexanoic Acid

PFHxS	Perfluorohexanesulfonic Acid
PFNA	Perfluorononanoic Acid
PFOA	Perfluorooctanoic Acid
PFOS	Perfluorooctanesulfonic Acid
PMT	Persistent, Mobile and Toxic
PNEC	Predicted No-effect-Effect levels
PTFE	Polytetrafluoroethylene
R&D	Research and Development
RAC	Committee for Risk Assessment
SAGA	Suitable Alternatives Generally Available
SEA	Socio-Economic Analysis
SEAC	Committee for Socio-Economic Analysis
SME	Small and Medium Enterprise
SoP	Start of Production
SPERC	Specific Environmental Release Category
SVHC	Substances of Very High Concern
TPE	Thermoplastic Elastomers
TPE-V	Thermoplastic Vulcanizates
VMQ	Silicone rubber
vP	Very Persistent
vPvB	Very Persistent and Very Bioaccumulative
vPvM	Very Persistent and Very Mobile
VVL	Variable Valve Lift
VVT	Variable Valve Timing

1. Summary of the Socio-Economic Analysis

1.1. Purpose and methodology

On 13 January 2023, the Competent Authorities (CAs) of the Netherlands, Germany, Sweden, Denmark, and Norway submitted a joint proposal to ECHA for a restriction under REACH of a broad group of Per- and polyfluoroalkyl substances (PFAS). The proposed restriction aims to limit the risks to the environment and human health from the manufacture, placing on the market and use of a wide range of PFAS through a new entry in Annex XVII of the REACH.[1]

The submission proposal has been sent to ECHA, and both RAC and SEAC will provide an opinion. Once this phase is finalised, the proposal and the opinions of RAC and SEAC will be forwarded to the European Commission for decision-making with the Member States in the REACH committee. The entry into force of a potential restriction is currently anticipated to take place at the earliest in 2027 (year of the proposed entry into force of the proposed restriction plus 18 months of transition period).

PFAS are a group of more than 10,000 synthetic (i.e., man-made) chemicals that are ingredients in various consumer and industrial products. The German authorities proposed in May 2017 criteria for identifying such chemicals in the context of EU REACH Regulation (EC) No 1907/2006. Substances meeting these criteria are referred to as either persistent, mobile, and toxic (PMT) or very persistent and very mobile (vPvM), although those properties do not apply to all the chemicals included in the broad OECD definition used as the basis for the current PFAS restriction proposal. Many PFAS are efficient surfactants or surface protectors because of the perfluoroalkyl moiety's high chemical and thermal stability as well as its ability to repel water and oil. As a result, they have been produced in large quantities and used in a variety of industrial, commercial, and consumer applications since the late 1940s.[2, 3, 4]

The main concern of the lead Member State Competent Authorities (MSCAs) regarding PFAS are their high environment persistence, significantly exceeding the very persistent (vP) threshold set out in Annex XIII of the REACH Regulation. Additional concerns emphasised by ECHA are mobility (M) of compounds, as well as long-range transport potential (LRTP), accumulation in plants, and global warming potential (GWP).

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[1] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

[2] Banks, R.E., Smart, B.E., Tatlow, J.C., 1994. Organofluorine chemistry: Principles and commercial applications. New York (NY): Plenum. ISBN 978-1-4899-1202-2.

[3] Kissa, E., 2001. Fluorinated Surfactants and Repellents, 2nd Edition, CRC Press. ISBN 9780824704728.

[4] Buck, R.C., Franklin, J., Berger, U., Conder, J.M., Cousins, I.T., De Voogt, P., Jensen, A.A., Kannan, K., Mabury, S.A. and van Leeuwen, S.P., 2011. Perfluoroalkyl and polyfluoroalkyl substances in the environment: terminology, classification, and origins. *Integrated environmental assessment and management*, *7*(4), 513-541.

This socio-economic analysis (SEA) focuses on the value of PFAS used in electromagnetic valves, actuators and sensors for a wide variety of applications, in particular dynamic processes in transportation (commercial and passenger vehicles) and industrial applications (i.e., hydraulic systems, pneumatic production and automation technologies, large diesel engines or medical technology). The report has been prepared by EPPA[5] for the socio-economic assessment part, and DEKRA[6] for the emissions assessment part at the request of [CONF.][7] (hereafter 'the Company') with the intention of providing EU regulators with strong evidence-based findings on the social and economic impacts that are expected to occur should this group of substances be restricted under REACH.

The assessment has been conducted in accordance with the existing official guidance from ECHA under REACH,[8] and it is based on information and data gathered from the Company, a leading manufacturer of electromagnetic valves, actuators, and sensors for dynamic processes in transportation (commercial and passenger vehicles) and industrial applications. Furthermore, desk research has been performed.

Notably, the market share covered by this analysis is approximately [CONF.]% of the market for electromagnetic actuators, valves, and sensors that are used in the transportation industry (incl. commercial and passenger vehicles) and industrial applications (e.g., stationary and mobile industrial products for hydraulics). In particular, for actuators for variable valve lift (VVL) and variable valve timing (VVT) in internal combustion engines (ICE) in automotive applications as well as for solenoid valves for brake, transmission, and suspension systems in commercial vehicles. The assessment is, therefore, representative and can serve as a basis for defining the anticipated socio-economic impacts resulting from a restriction of PFAS chemicals for manufacturers of electromagnetic actuators, valves, and sensors that are used in the transportation industry.

In line with the **existing official guidance from ECHA on the preparation of the Socio-Economic Analysis,**[9] **this SEA aims to gather technical and economic information to describe ex-ante in both qualitative and where feasible, quantitative terms the (orders of magnitude of) socio-economic impacts that the Company is expected to face from the ban of PFAS.**

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5 www.eppa.com

6 www.dekra-product-safety.com/en

7 [CONF.]

8 The ECHA Guideline for an SEA to be used in REACH Application for Authorisation is available at: https://echa.europa.eu/documents/10162/23036412/sea_authorisation_en.pdf/aadf96ec-fbfa-4bc7-9740-a3f6ceb68e6e

9 The ECHA Guideline for the SEA preparation as a part of Application for Authorization is available at: https://echa.europa.eu/documents/10162/23036412/sea_authorisation_en.pdf/aadf96ec-fbfa-4bc7-9740-a3f6ceb68e6e ; The ECHA layout for an SEA to be used in Application for Authorization is available at: https://echa.europa.eu/documents/10162/13637/sea_format_with_instructions_v4_en.docx/0cbc5102-6ba2-2170-480a-0061d2798f55

This SEA covers the function of PFAS in electromagnetic valves, actuators and sensors that are used in dynamic processes in transportation and industrial applications as well as the importance of PFAS at the different stages of the manufacturing process. It will also describe the lack of available technologically suitable and economically viable alternatives, the technical difficulties associated with the substitution of PFAS-containing components via alternatives, the social and economic impacts from their restriction, and the broader impacts on society.

1.2. Main findings

This Socio-Economic Analysis & Analysis of Alternatives report concludes that:

- **A broad restriction of PFAS used in electromagnetic valves, actuators and sensors that are used in dynamic processes in transportation and industrial applications will have disproportionate negative impacts on the European economy and society.**

- **The Company supports the phase out of the use of PFAS wherever this is possible. This, however, requires the availability of technically and economically viable alternatives which are to date not readily available. Finding alternatives and substitution (if possible) is a time-consuming process due to the complexity of the affected products. This cannot be achieved in the proposed 18-month transition time; it will take a much longer time period as described in detail in the respective section.**

- **Based on the minimal estimated annual emissions (i.e., less than [CONF.] kg/year), the cost-effectiveness ratio is calculated to be significantly high (> 1.8 million EUR/kg), and the restriction is highly disproportionate. The high socio-economic costs for the Company would offset only a small contribution of the total PFAS input into the environment.**

- **The assessment and conclusions reasonably justify a time-unlimited derogation of PFAS chemicals used in electromagnetic valves, actuators and sensors which are essential for the safety and efficiency in commercial vehicles, passenger cars, and industrial applications, where dynamic processes are present.**

All above-mentioned statements are reasonably founded on the following evidence-based results:

- The Company is a **Tier-2 supplier for pneumatic solenoid valves and pressure sensors in commercial vehicles, and a Tier-1 and Tier-2 supplier for solenoid actuators, valves and pressure sensors in passenger cars**. The company provides electromagnetic actuators, valves, and sensors for situations involving dynamic processes, such as in commercial vehicles, passenger cars, and industrial settings. They offer customized solutions to meet individual customer needs. Their products are specifically designed to meet the demands of highly dynamic processes, prioritizing safety, efficiency, and environmental compatibility.

- The Company uses PFAS to manufacture electromagnetic actuators, valves, and sensors in the EEA. **Approximately [CONF.]% of the product portfolio of the Company contains PFAS**, all of which would have to be removed from the EEA market as of 2027 because of the potential restriction**. The vast majority of these applications are either safety related** (e.g., ABS valves, brake valves for commercial vehicles, levelling systems, automated manual transmissions) **or relevant in terms of positive environmental impact** (efficiency enhancement, for example, through active camshaft control systems).

- **In terms of their total product turnover in the EEA, [CONF.]% of the Company turnover in the EEA comes from PFAS-containing products.** PFAS include PTFE based (wear) coatings, PTFE containing plastic materials, PTFE containing lubricants, FKM sealings, and FVMQ sealings. The primary function of these PFAS in the electromagnetic actuators, valves, and sensors is to reduce tribological wear and abrasion over the service life, enable low friction and thus constant control characteristics over the service life, withstand high operating temperatures (up to 200 °C) and offer resistance to chemicals (e.g., oils, lubricants). Given the high cost of PFAS-based materials, it should be noted that such materials are only used where absolutely necessary, and the requirements do not allow any other material.

- To date, the relevant supply chain for electromagnetic actuators, valves, and sensors has not been able to identify technically suitable and economically viable alternatives to PFAS. **The Company itself performs tests with potential alternative materials on a regular basis – with no suitable alternative identified thus far.** The results of these tests have shown that due to the unique characteristics of PFAS materials, and based on the current state-of-the-art, **no PFAS-free alternative materials for PTFE, FKM and FVMQ with equal performance characteristics are available today and in the foreseeable future**.

- **Implementing a re-design requires long timelines and high costs to convert a high share of the product portfolio.** As downstream users for PFAS based components, substitution timelines are highly dependent on the ability of the supply chain's capabilities to supply adequate information and to offer suitable alternatives. Timelines are difficult to predict and highly subject to uncertainty. **The whole process of identifying suitable alternatives could take decades**.

- In the best-case scenario, **from the moment a successful PFAS-free alternative with equal performance is identified and available on the market, the development and testing of alternative PFAS-free ingredients would necessitate a minimum of 10 years to complete transition activities,** from initiation of a successful discovery phase to the eventual production and product rollout. The Company's experiences have revealed that, especially for tribological systems, testing alternative coatings involves time-consuming endurance tests. Therefore, the 10-year timeline is already an optimistic estimation.

- **A potential broad restriction would have disproportionate socio-economic implications on the EEA manufacturers of electromagnetic valves, actuators and sensors and the relevant transportation supply chain, including the following:**

    - As a consequence of the potential restriction and the aforementioned consequences, in the most likely "non-use" scenario, the Company will have no other option but to halt the production of PFAS-containing electromagnetic actuators, valves, and sensors in the EEA.

- Overall, **the total socio-economic impact of a REACH restriction of PFAS is monetised in the range of [CONF.] EUR** (for the Company alone) **and [CONF.] EUR** (result of the extrapolation for the whole EEA market), consisting of: social impacts from unemployment in the EEA, economic impacts (EBIT loss), and substitution costs (conservative estimates in net losses). The effects of a negative impact upstream would reverberate through the supply chain, causing even larger negative output downstream. Although the company is not in a position to quantify the impacts downstream, user industries that would no longer be able to produce commercial and passenger vehicles in the EEA would face considerable repercussions on sales (turnover) and layoffs (job losses).

- These are conservative estimates (lower boundary), based on the understanding that these are not the sole injury likely to be suffered in the EEA. The market share covered by this impact assessment is approximately [CONF.]% of the whole EEA market for electromagnetic actuators, valves, and sensors that are used in the transportation industry and industrial applications.

- From an EU macroeconomic perspective, a PFAS ban in general – and especially without very long transition periods in selected cases warranted by a glimpse of hope that an alternative could be found – would cause massive damage to the EU in terms of **loss of competitiveness** and resulting **unemployment**, at least in technical/technological areas where the performance characteristics of PFAS cannot be dispensed with. This would probably not be recoverable and would only **increase the EU's dependence on other economies** like e.g., **China**. Components of essential relevance for the safety and performance of commercial vehicles and passenger vehicles as well as selected industrial specialty applications would no longer be available in the EEA, with dire consequences. Eventually, a short-term **ban on PFAS would cost the EU its technological leadership and global competitiveness**.

2. Aims and Scope of the SEA

2.1. Purpose, scope and methodology of SEA

On 13 January 2023, the CAs of the Netherlands, Germany, Sweden, Denmark, and Norway submitted a joint REACH restriction proposal for a broad group of fluorinated substances to limit the risks to the environment and human health from the manufacture and use of a wide range of PFAS in Annex XVII of the REACH based on persistent/very persistent (P/vP) criteria according to REACH Annex XIII and that are not able to degrade under environmental conditions. The opinion-making phase takes 12 to 15 months. After this, the proposal and the opinions of RAC and SEAC are forwarded to the Commission for decision-making by the Commission with the Member States (the entry into force of a potential restriction is anticipated to take place in 2025 and become effective in 2026/2027).

In the proposed restriction, PFAS are defined as any substance containing at least one fully fluorinated methyl (CF_3-) or methylene (-CF_2-) carbon atom (without any hydrogen, chlorine, bromine, or iodine attached to it). The definition is based on OECD definition of PFAS published in 2021 and covers over 10,000 PFAS, including some fully degradable subgroups. In May 2017, The German authorities proposed criteria for identifying such chemicals in the regulatory context of EU REACH Regulation (EC) No 1907/2006. Substances meeting these criteria are referred to as either persistent, mobile, and toxic (PMT) or very persistent and very mobile (vPvM) substances.

Many PFAS are efficient surfactants or surface protectors because of the perfluoroalkyl moiety's high chemical and thermal stability as well as its ability to repel water and oil. As a result, they have been produced in large quantities and used in a variety of industrial, commercial, and consumer applications since the late 1940s.[10, 11, 12]

Certain members of the PFAS chemical family have already been (or are currently in the process of being) restricted under REACH: PFOA, PFHxA, PFHxS, C9-C14 PFCA. Other members of the group are under authorisation procedures (HFPO-DA, PFDA, PFNA), or recognised as SVHC (PFBS). Measures on certain members of the PFAS group are in place also under the Persistent Organic Pollutants Regulations Regulation, Food Contact Materials legislation, new Drinking Water legislation and F-Gas Regulation. The aim of the broad restriction is to move away from this “piecemeal approach”, which has led to “regrettable substitution” of restricted substances by other members of the PFAS chemical family.

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[10] Banks, R.E., Smart, B.E., Tatlow, J.C., 1994. Organofluorine chemistry: Principles and commercial applications. New York (NY): Plenum. 670 p. ISBN 978-1-4899-1202-2.

[11] Kissa, E., 2001. Fluorinated Surfactants and Repellents, 2nd Edition, CRC Press. ISBN 9780824704728.

[12] Buck, R.C., Franklin, J., Berger, U., Conder, J.M., Cousins, I.T., de Voogt, P., Jensen, A.A., Kannan, K., Mabury, S.A., van Leeuwen, S.P., 2011. Perfluoroalkyl and polyfluoroalkyl substances in the environment: Terminology, classification, and origins. *Integr. Environ. Assess. Manag.* 7, 513−541.

This *ex-ante* Socio-economic Analysis aims to identify and assess in both qualitative and (when feasible) quantitative terms the socio-economic impacts that are expected to occur in case of a possible broad REACH restriction to this group of substances.

A survey has been conducted by providing a detailed questionnaire to gather information and data from the Company, a major manufacturer of electromagnetic actuators, valves, and sensors that are used in the industry are likely to be affected by a PFAS restriction in the EEA. The Company has provided socio-economic data in view of extrapolating (based on a large total market share) the impacts for the whole market for actuators, valves, and sensors for transportation applications in a conservative approach, as further detailed below.

Based on the estimated total EEA market for actuators for VVL and VVT in ICE in automotive businesses and solenoid valves for brake, transmission, for suspension systems in commercial vehicles, and in industrial applications (i.e., stationary and mobile industrial products for hydraulics), the market share covered by this survey represents approximately [CONF.]% of the whole EEA market.[13]

The assessment has been conducted in accordance with the existing official guidance on SEA from ECHA under REACH Restrictions.[14] ECHA has developed a solid methodology for conducting socioeconomic assessments in the context of the REACH Regulation, with the support of a dedicated committee, i.e., the Socio-Economic Assessment Committee (SEAC). More specifically, this methodology is consistently applied for REACH applications for authorisation of substances of very high concern (SVHC), and REACH restrictions for certain hazardous substances with a view of forecasting through the SEA the impacts of the different regulatory options.

From a geographical perspective, this analysis focuses on the European Economic Area (EEA) territory, comprising the European Union (EU-27), Iceland, Liechtenstein, and Norway. For this study, it has been decided to use a 4-year time horizon to estimate the socio-economic impacts, which is the time period suggested by SEAC when there is no suitable alternative available in general (SAGA)[15, 16]. In other terms, the SEA accounts for the benefits to the EEA society in the event PFAS are prohibited from being manufactured, used, and place on the market, and/or for the socio-economic costs of a complete ban (REACH restriction) starting from the year 2027 (year of the entry into force of the proposed restriction plus 18 months of transition period).

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13 Result of the weighted average of the estimated total market segments and the Company's sales (in EUR) in the EEA.

14 The ECHA Guideline for an SEA to be used in REACH Restrictions is available at: https://echa.europa.eu/documents/10162/2324906/sea_restrictions_en.pdf/2d7c8e06-b5dd-40fc-b646-3467b5082a9

15 https://echa.europa.eu/documents/10162/13637/ec_note_suitable_alternative_in_general.pdf/5d0f551b-92b5-3157-8fdf-f2507cf071c1

16 https://echa.europa.eu/documents/10162/0/afa_seac_surplus-loss_seac-52_en.pdf/5e24c796-d6fa-d8cc-882c-df887c6cf6be?t=1633422139138

Future monetary values have been estimated by using the concept of net present value (NPV), adopting a 3% annual discount rate, which is the standard discount rate, adopted by the European Commission and European agencies (e.g., ECHA) in impacts assessments.[17] All monetized values have been adjusted to a base year, assumed to be 2027. Information and data have been aggregated and anonymized. Statements and estimations from the Company are as close to real data or perception of future changes as possible.

2.2. Overview of the market for electromagnetic actuators, valves, and sensors in the transportation industry and their value chain

As a developer and producer of electromagnetic actuators, valves, and sensors, the Company's products can be found where highly dynamic processes take place. This section starts by an illustration of the typical supply chain in which the Company is active, followed by an overview of the PFAS-containing products.

2.2.1. Typical supply chain

The transportation supply chain is a complex network of companies, organizations, and processes involved in the production and distribution of vehicles and automotive components worldwide. Over the years it has become progressively complex, marked by a rising number of players and interconnected sectors and operations spread across various geographical regions. While a handful of countries/companies dominate the global production of commercial and passenger vehicles, their value chain spans multiple locations worldwide, encompassing not just assembly and manufacturing, but also design, testing, R&D, and innovation that are directly and indirectly interrelated.[18]

The transportation value chain has evolved over time from vertical integration to a multifaceted and geographically distributed production network where different companies and clusters specialise and function as first, second, and third-tier suppliers, manufacturing components that are later assembled into the final vehicle based on the design provided by commercial and passenger car vehicles producers, i.e., the original equipment manufacturers (OEMs).[19]

The supply chain starts with the raw materials suppliers. Raw materials are then sent to Tier-n suppliers, who manufacture various components, such as engines, transmissions, and electronic systems.

Tier-n suppliers, in turn, supply these components to other tiers. OEMs assemble these components into complete vehicles at their manufacturing plants. Once the vehicles are assembled, they are

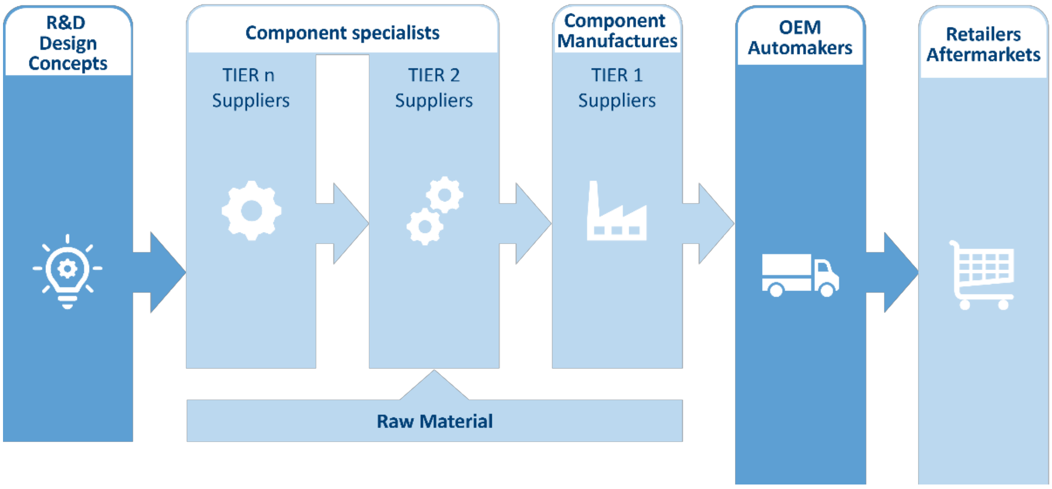
17 European Commission, 2021. Better Regulation Guidelines and Toolbox. https://commission.europa.eu/document/download/9c8d2189-8abd-4f29-84e9-abc843cc68e0_en?filename=br_toolbox-nov_2021_en.pdf

18 Lejarraga, I., A. Kouzul-Wright, A. Primi, M. Toselli and M. Wermelinger (2016), "Upgrading pathways in the automotive value chain", Background document for the 7th Plenary Meeting of the OECD Initiative for Policy Dialogue on GVCs, Production Transformation and Upgrading, OECD, Paris.

19 Ibid.

shipped to wholesalers and distributors for sale to customers. Figure 1 below illustrates the aforementioned process.

Figure 1. Simplified overview of the transportation global supply chain.[20]



In recent years, the transportation supply chain has become increasingly globalized. So does the Company's relevant supply chain. More and more companies source components and services from various countries to take advantage of cost efficiencies and specialized expertise. **The typical supply chain for elastomeric parts involves multiple suppliers located around the world**.

Typically, the longer the value chain, the less control companies have over it. Therefore, **the Company has little influence over its complex and extended supply chain, including for the identification and development of PFAS-free alternatives**.

The Company has several suppliers positioned further up the supply chain. Components containing PFAS are mainly purchased as semi-finished products from the suppliers. Typically, these components include seals, gaskets and O-rings made of FKM and FVMQ, PTFE-coatings on steels, plain bearings and elastomers, as well as foils, cables and strands.

For some passive components where PFAS materials are specified (e.g., O-rings, tubing), the supply chain may be shorter, with the manufacturer of the part supplied to the Company procuring the PFAS material from the producers (upstream). In other instances, for example where PFAS materials are incorporated within components, the supply chain can be several stages long, involving PFAS materials suppliers, and component manufacturers. For vulcanizers, such as sealing elements providers to the Company, Tier 1 suppliers are generally located in [CONF.].

Overall, at least four steps separate the chemical supplier from the Company and then one or two more steps to the vehicles manufacturers. **The Company is a Tier-2 supplier for pneumatic solenoid valves and pressure sensors in commercial vehicles, and a Tier-1 and Tier-2 supplier for solenoid actuators, valves and pressure sensors in passenger cars.** The company supplies electromechanical

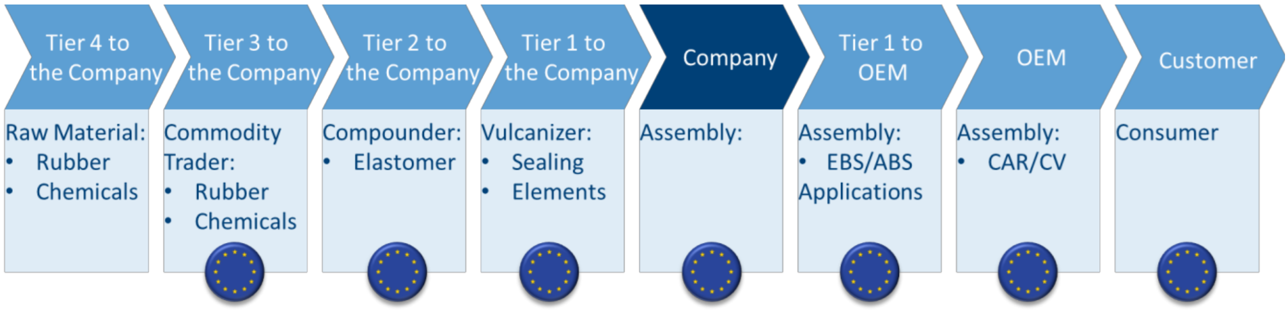
[20] Adapted from Lejarraga, I., A. Kouzul-Wright, A. Primi, M. Toselli and M. Wermelinger (2016), "Upgrading pathways in the automotive value chain", Background document for the 7th Plenary Meeting of the OECD Initiative for Policy Dialogue on GVCs, Production Transformation and Upgrading, OECD, Paris. Figure 12. Automotive Global Value Chain, p. 15.

actuators (solenoids and e-motor drives) and valves for the transportation industry, both to Tier 1 (assemblers) as well as directly to OEMs, and for a wide range of industrial applications.

Many of the products contain PFAS-based components, which are sourced from the suppliers, primarily to maintain the tight fit and seal of valve applications. **The vast majority of the applications are either safety related (e.g., ABS valves, brake valves for commercial vehicles, levelling systems, automated manual transmissions) or relevant in terms of positive environmental impact (efficiency enhancement, for example, through active camshaft control systems).**

Accordingly, the typical supply chain for elastomeric parts is as follows:

Figure 2. Supply chain of elastomeric parts



2.2.2. General overview of impacted products

In the customer's direction, the end products are supplied to the Tier 1 in the commercial vehicle sector or OEM in the automotive sector. This section will provide a general overview of the Company products, distinct according to the business units commercial vehicles, passenger cars, and industry applications.

Commercial vehicles

The Company is a leading producer and supplier of pneumatic solenoid valves and pressure sensors in commercial vehicles. Typical commercial vehicle applications include:

- Anti-lock Braking System (ABS)
- Electronic Braking System (EBS)
- Electronic Stability Program (ESP)
- Retarder brake systems
- Gearbox control units / transmission
- Clutch actuators / transmission
- Air management
- Air suspension
- Standalone valves for various vehicle functions

These are all safety related applications for which compliance with strict technical and quality requirements is mandatory.[21] More generally, technical and quality requirements in the transportation industry are particularly high. The working medium in commercial vehicles is compressed dry air. Therefore, pneumatic solenoid valves (valve types on/off and proportional) are used for the aforementioned applications. These valves modulate the air pressure to, for instance, generate braking forces, to shift gears, and/or to operate the clutch.

Typically, customers are responsible for the system (e.g., ABS/EBS brake system) that has to be compliant with several harmonised standards. The Company, as component supplier (pneumatic valves) receives a component specification from the customer. The customer derives the requirements for the component from his system architecture and from the associated harmonized standards (e.g., DIN EN 61508-1:2011-02 on Functional safety of electrical/electronic/programmable electronic safety-related systems).[22]

In terms of safety, the Company receives Failure Mode and Effects Analysis (FMEA) severities for component functions from the customer or functional safety requirements for the component.

Typical requirements for on/off valves can be as high as [CONF.] switching cycles and reproducible switching time over service life. In other words, as they are safety-relevant applications, their expected service life is longer than the service life of a typical vehicle. These requirements can only be met by very few materials, many of which are PFAS.

For example, it is mandatory that the armatures/plungers of the solenoid valves are coated with a wear coating that contains PTFE. Sealings are typically made of FKM to withstand temperatures up to 180 °C ([CONF.]) and to withstand air contaminations, such as oils, lubricants.

At present, there is no indication from the global market that the working medium compressed air and pneumatic solenoid valves will be replaced by an alternative technology for commercial Battery Electric Vehicles (BEV) or commercial Fuel Cell Electric Vehicles (FCEV), even in the long term.

The EU could remain the world leader in commercial vehicle technology based on inert PFAS materials as used today (PTFE, FKM, FVMQ). PFAS-free substitutes with the same performance characteristics in terms of temperature resistance, chemical resistance, corrosion resistance, wear resistance, low friction and permeation tightness are **not currently available** and have **yet to be developed**. It is a long-term process, as outlined in Section 3.4. **Therefore, a short-term ban on PFAS would cost the EU its technological leadership and global competitiveness, while at the same time it is not certain that alternatives could even be found.**

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[21] With the only exceptions of air suspension and standalone valves for various vehicle functions, which could be safety relevant as well.

[22] https://www.beuth.de/en/standard/din-en-61508-1/135302584

Passenger Cars

Another major application of the Company's products is in solenoid actuators, valves, and pressure sensors in passenger cars. Typical passenger car applications include:

- Active camshaft control systems, including:
  - valve stroke control, variable valve timing intake and exhaust camshaft, cylinder deactivation (leading to a reduction of fuel consumption and CO_2 emissions)
  - camshaft phaser
- Engine oil pumps
- Transmission
- Camshaft phaser control
- Engine water pumps
- Air suspension systems
- Power steering pumps

Similar to the above description, there are strict requirements that can only be met by very few materials, many of which are PFAS. For example, bearings typically contain PTFE to fulfil durability requirements and control characteristics over service life. Yet, sealings are typically made of FKM to withstand temperatures up to 180 °C and to withstand contaminations, such as oils, lubricants.

Industrial applications

Finally, the Company supplies solenoids, valves, actuators, switches and sensors used in a wide variety of industrial applications, including stationary hydraulics, mobile hydraulics, rail technology, large diesel engines, medical technology, energy technology, automation technology and pneumatics. Typical industry applications include:

- Proportional solenoids with position sensors
- Control solenoids
- Inductive position switches
- Hydraulic switching solenoid

PFAS are crucial for these applications. For instance, sleeve bearings and sliding foils contain typically PTFE in order to fulfil durability requirements and control characteristics for proportional solenoids over service life. Again, sealings are typically made of FKM to withstand temperatures up to 180 °C and to withstand contaminations, such as oils, lubricants.

3. Analysis of Alternatives

This section provides a closer look at the use, function, and requirements of PFAS chemicals used in electromagnetic actuators, valves, and sensors that are used in the transportation industry (particularly, but not exclusively focusing on commercial vehicles and passenger vehicles) as well as selected and specialised industrial applications. It covers the technical obstacles that prevent substitution via potential alternatives to PFAS, the typical timelines related to the re-design of pneumatic solenoid valves and pressure sensors, and the complex challenges related to a transition towards PFAS-free products.

A review of alternatives as regards the uses was included. Through this analysis, using a robust methodology from guidance available at European level, the unique value of PFAS-based options vis-à-vis potential alternatives is demonstrated – including a perspective of negative impacts that would arise from a negative regulatory scenario. The alternatives identified are listed and described, followed by a comprehensive analysis.

The analysis of alternatives concludes that there are no appropriate chemical alternatives that could substitute PFAS in these uses and applications. In the best-case scenario, substituting PFAS will easily require up to 10 years, from the moment a successful candidate (alternative) substance is identified. Thus, this estimate is subject to high uncertainty and highly dependent on the time to find, if possible, a successful candidate (alternative) substance. Also, system re-designs (like e.g., alternative valve concepts) have been explored and analysed for their potential of replacement, with non-satisfactory results.

The following paragraphs describe the function and technological advantages of PFAS for all uses in electromagnetic actuators, valves, and sensors. Unless clearly specified, all below information are sourced from the Company's replies to the survey conducted in the context of this Socio-Economic Analysis. Additional desk research has been performed.

3.1. Function and technical performance requirements in applications where PFAS are used

It is important to understand the requirements in the different uses to develop a perspective on the importance of PFAS and on potential alternatives. For this, it is necessary to understand both, the requirements towards the material itself as well as the role it plays in their final technical performance as a part in a use / application.

Overview of key technical performance and function requirements

Overall, it is important to understand that the technical and quality requirements in the transportation industry – both, for passenger vehicles as well as commercial vehicles – are exceptionally high. The durability requirements for the commercial vehicle valves, for example, range up to [CONF.] cycles that these products must withstand. As they are safety-relevant, their expected service life is longer than the service life of a vehicle. These requirements can only be met by very few materials.

The following table provides an overview of the key requirements:

Table 1. Overview of the key function and performance in general as well as more specific to key sectors

Sector	Key function and performance
Commercial vehicles (in particular pneumatic solenoid valves and pressure sensors)	- The uses in this area are directly linked to components of commercial vehicles that are essential for the safety of these vehicles (e.g., braking systems, stability programs, gearbox control units, air management, etc.). Therefore, no compromise can be made related to performance requirements. - The working medium for all these systems in commercial vehicles is compressed dry air. The valves modulate the air pressure in order to generate the breaking forces, to shift gears, to operate the clutch etc., and these valves must fulfil up to [CONF.] on/off switching cycles and reproducible switching time over the service life (due to the safety relevance, the expected service life if longer than the service life of a vehicle. This is a requirement by the industry and the end-users for safety reasons. There is no indication that the working medium compressed dry air combined with pneumatic solenoid valves will be replaced by an alternative technology for electrified commercial vehicles (be it battery-based or fuel-cell based). - In order to function properly, the valves need to be coated with a wear coating; this coating contains PTFE to fulfil the requirements. - The main requirements are wear resistance and corrosion resistance, combined with temperature resistance, chemical resistance, low friction and permeation tightness. - The sealings need to withstand temperatures of up to 180 °C ([CONF.]). - The sealings needs to withstand chemical air contaminations such as oils and lubricants coming from both, inside the system and from the outside.

Passenger vehicles (in particular, solenoid actuators, valves and pressure sensors)	- The uses in this area are of key importance to the performance of the vehicle (e.g., active camshaft control systems, valve stroke control, camshaft phaser, engine oil and water pumps, air suspension systems, power steering pumps). So, they are critical for the proper functioning of the vehicle systems (and in certain areas also for their safety), and likewise, they contribute to the reduction of fuel consumption and thus GHG-emissions. Therefore, no major compromise can be made related to performance requirements. - Bearings need to fulfil durability requirements and control characteristics over their service life. - The sealings need to withstand temperatures of up to 180 °C ([CONF.]). - The sealings needs to withstand exposure to chemicals such as oils and lubricants.
Industrial applications (such as solenoids, valves, actuators, switches and sensors)	- The uses in this area cover functions such as solenoids supporting position sensors and control units as well as inductive position switches and hydraulic switching solenoids. - Sleeve bearings need to fulfil durability requirements and control characteristics for proportional solenoids over their service life. - The sealings need to withstand temperatures of up to 180 °C ([CONF.]). - The sealings needs to withstand exposure to chemicals such as oils and lubricants.

3.2. Function/technological advantages of PFAS in relevant uses in transportation and industrial applications

As described before, the relevant applications served by the Company are in the area of transportation (including, but not limited to passenger vehicles and commercial vehicles) as well as industrial applications. Amongst the many functions and requirements, the most characteristic ones related to PFAS are shown in the following table:

Table 2. Function/technological advantages of PFAS by type of application / use

Type of application / use	Description of the differentiating functionality
PTFE based wear coatings on armatures/plungers, sliding foils and bearings	- Reduce of tribological wear and abrasion over service life ([CONF.] switching cycles) - Enable low friction and thus constant control characteristics over the service life ([CONF.] switching cycles) - Withstand high operating temperatures (up to 200 °C) - Resistance to chemicals (e.g., oils, lubricants)
PTFE based coating on dynamic sealings	- Reduce of tribological wear and abrasion over service life ([CONF.] switching cycles) - Enable very low leakage over the service life - Enable excellent switching characteristics at very low temperatures (inhibit sticking of dynamic sealings to valve seats at ambient temperatures down to -40/-50 °C)
PTFE containing plastic materials	- Reduce of tribological wear and abrasion over service life ([CONF.] switching cycles) - Enable low friction and thus constant control characteristics over the service life ([CONF.] switching cycles)
PTFE containing lubricants as installation aids	- Installation aids for assembling/mounting O-rings, sealings
FKM sealings	- Excellent resistance to chemicals (e.g., oils, lubricants) - Especially for dynamic sealing best compromise of low temperature characteristics (-30 °C) and high temperature performance (up to 200 °C) as well as mechanical performance
FVMQ sealings	- Good resistance to chemicals (e.g., oils, lubricants) - Especially for static sealing best compromise of very low temperature characteristics (-50 °C) and high temperature performance (up to 200 °C)

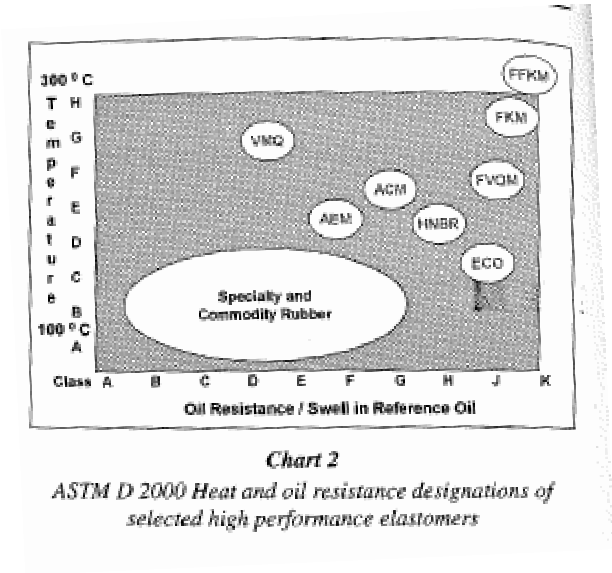
3.3. Challenges with substitution by potential alternatives

This section will further elaborate on identified non-PFAS alternative materials and their ability to fulfil the function and performance requirements in the high demanding operating environments relevant here.

The state-of-the-art situation is that there are **no PFAS-free alternative materials for PTFE, FKM and FVMQ with equal performance characteristics available today and in the foreseeable future**. This is confirmed by regular technology discussions between the Company and its technology leading global suppliers. Furthermore, as described further below in the section related to innovation, **the Company itself performs tests with potential alternative materials on a regular basis – with no suitable**

alternative identified thus far. The following chart visualizes the challenge well – there are only very few materials that fulfil the necessary performance requirement combinations (in this case e.g., temperature and oil resistance / swell in reference oil):

Figure 3. Heat and oil resistance



Source: This is a copy paste of Chart 2 in Beswick (2000)[23]

Potential alternatives for O-rings and sealings:

The following table summarises the key challenges of potential alternative materials for O-rings and sealings:

Table 3. Identified potential alternatives and identified challenges

Alternative	Comparison and challenges
NBR	Limited temperature range and not resistant to chemicals, e.g., oils, lubricants
HNBR	Limited temperature range. Either low temperature HNBR -45° C to 100 °C or high temperature HNBR -25 °C to 125 °C. Broad temperature range from -40 °C to 200 °C not possible. Chemical resistance against oils, lubricants limited.
EPDM	Not resistant to chemicals, e.g., oils, lubricants.
ACM	Bad compression set characteristics.
FMVQ	Bad mechanical properties and limited oil resistance in comparison to FKM, only capable for static sealing functions. Also, a PFAS-based material.

[23] Beswick, R., 2000. An overview of the high-performance elastomer industry. High performance elastomers 2000 (Berlin, 10-11 October 2000).

TPE	Limited temperature range, insufficient compression set characteristics and limited chemical resistance.

Further details of these key potential alternative materials can be described as follows:

Material and acronym	**NBR (Nitrile Butadiene Rubber) and HNBR (Hydrogenated NBR)**
Brief description	NBR is a synthetic rubber derived from acrylonitrile (ACN) and butadiene. HNBR is a synthetic elastomer that is created by hydrogenating NBR.
Strengths and Weaknesses	**HNBR** is a versatile material and used in many industries for its basic resistance to heat, chemicals, oil, and abrasion, while maintaining its strength. However, while HNBR shows a level of oil resistance that is higher than average elastomeric materials, it at the same time shows significant volume swell after exposure to oil, which exceeds acceptable levels by far (e.g., with a factor 5x for oil seals). Therefore, even though HNBR outperforms other non-PFAS materials in oil resistance, it would still not be able to deliver the function required. In general, the range of HNBR grades covers a continuous performance temperature range of approx. -40 °C to 130 °C or even 150 °C. Low temperature performance is achieved by using low ACN grades, and high temperature range performance is achieved by using highly ACN-saturated grades plus adding significant levels of fillers. Both characteristics cannot be combined, thus a grade that fulfils the entire temperature range required does not (and likely cannot) exist. Also, a higher level of ACN content negatively impacts dynamic properties (such as e.g., reduced elasticity). Thus, HNBR does not allow a combination of all requirements. Furthermore, HNBR typically degrades faster at temperatures between 120-150 °C, limiting it to a level of an expected 1000 hours service life, which is completely incompatible with the requirements described before. **NBR** is inferior in its performance compared to HNBR when it comes to temperature range (approx. -40 °C to 100 °C) and does not show adequate resistance to chemicals (e.g., oils and lubricants). It is therefore not suitable and hence not further described here as all aspects have already been covered in the section related to HNBR.
Material and acronym	**EPDM (ethylene propylene diene monomer)**
Brief description	EPDM is made from ethylene, propylene, and a diene comonomer that enables crosslinking via vulcanization.
Strengths and Weaknesses	**EPDM** exhibits superior resistance to heat, light, and ozone exposure and is therefore used e.g., in external harsh environments. Examples in the

	transportation industry include seals for door, windows, trunks and hoods. Similar to HNBR, EPDM can be formulated to perform in a temperature range from -40 °C to 150 °C. It has some of the same challenges described for HNBR. However, the key characteristic that prevents it from being a suitable alternative is its lack of adequate resistance to relevant chemicals (e.g., oils and lubricants). It also degrades in contact with bituminous materials (e.g., asphalt).
Material and acronym	**ACM (ethylene acrylate copolymer)**
Brief description	ACM is based on copolymers and terpolymers of acrylate monomers in combination with variable carbons in the alkyl structure.
Strengths and Weaknesses	**ACM** is used in mid-performance requirements areas e.g., in the transportation industry. This can be e.g., sealings for simple parts of the engine and transmission system. Its service temperature range typically is between -30 °C to 150 °C (special grades up to 175 °C), which is not completely fulfilling the requirement range, but making it a close candidate. However, its performance at low temperatures is not sufficient. The resistance to oil is adequate. Its resistance to chemicals (e.g., hydrocarbons) is relatively poor, and also its resistance to water (hydrolysis as well as swelling) is inadequate – both are key factors preventing it from being a realistic alternative. Another key factor is its relatively poor dynamic properties – e.g., the compression set is not meeting requirements in the relevant applications.
Material and acronym	**FVMQ (fluoro silicone rubber or fluorovinylmethylsiloxane)**
Brief description	Silicone rubber (VMQ) is a type of synthetic elastomer. The term silicone often refers to a group of polymers. In FMVQ, the methyl group of the material is replaced by fluoro-alkyl groups.
Strengths and Weaknesses	**FVMQ** possess rubber-like characteristics, exhibit resistance to heat, are non-reactive, and resistant to harsh conditions. Some grades of silicone rubber are already used in seals in demanding environments. VMQ is the most thermally resistant non-PFAS substance, with temperature resistance ranging from -70 °C to 200 °C. However, at temperatures between 150 °C to 200 °C, the performance begins to deteriorate, impacting the life-span of the material and thus its suitability for the relevant applications. VMQ shows significant volume swell after exposure to oil, which exceeds acceptable levels by far (e.g., with a volume increase above 50% after a

	relatively short exposure time of 2-3 days). Therefore, it would not be able to deliver the function required, especially not in dynamic sealing applications. FMVQ is also in the scope of the proposed PFAS restriction and will therefore not be analysed further as an alternative.
Material and acronym	**TPE (thermoplastic elastomers such as TPE-S (Styrenic Block Copolymers), TPE-V (Thermoplastic Vulcanizates) etc.)**
Brief description	Thermoplastic elastomers (TPE) use a mix of polymers to combine the elastic behaviour of elastomers with the meltable crosslinks of plastic material. There are two groups of TPE, block-copolymer and elastomer blends.
Strengths and Weaknesses	**TPE** allows easy production processes similar to plastic materials, because there is no vulcanization (chemical connection of polymers). TPE parts can be molten and reused. TPE has a good resistance to chemicals and oil. Compression set and thermal stability do not meet the requirements (max temperature of 120 °C). High amount of softener can lead to shrinkage after production, which is unacceptable.

Source: Industry experts as well as Beswick (2000)[24]

Potential alternatives for PTFE containing wear coatings on armatures/plungers of solenoids:

Over the past decades, customer demands for durability have continued to increase. Fifteen years ago, the demand for durability of clutch control solenoid valves was [CONF.] switching cycles and since 2017 the requirement is [CONF.] switching cycles (mainly for safety reasons). These requirements are expected to further increase in the future. The goal is smarter and smoother clutch control with the effect of higher demands on the service life of control solenoid valves.

In order to follow the increasing customer demands the Company has been testing and validating since 2007 various types of wear coatings in durability tests. This includes various wear coatings with a wide range of binding agents (e.g., [CONF.]) in combination with a wide range of dry-film lubricants (e.g., [CONF.]) as well as the potential alternative coating (e.g., [CONF.]). The test results clearly show that only the options that include PTFE are capable to fulfil durability demands up to [CONF.] switching cycles, all others failed.

[24] Beswick, R., 2000. An overview of the high-performance elastomer industry. High performance elastomers 2000 (Berlin, 10-11 October 2000).

Alternative system design options

Naturally, also different system design options must be considered when looking at potential alternatives. This is the "daily bread" of engineers in the highly innovative transportation sector, as constant improvement is a must.

In the relevant applications here, so-called pivot valves are known as a potential alternative to using PTFE containing wear coatings, bearings or sliding foils. In this concept, the armature makes no transaortic movement, but a rotation. But this concept has significant drawbacks or limitations in terms of increased leakage, big orifice size (nominal width) and small installation space. Therefore, the pivot valves are not considered a viable alternative, and they are not used in the market in any significant manner. Furthermore, also in this concept, FKM or FVMQ sealings are still required. This is independent of the application.

3.4. Efforts towards innovation and potential suitable alternatives

The following chapter describes the typical innovation and development processes for the relevant uses and applications. Furthermore, it describes the efforts done by the Company to identify, develop and test potential alternatives to PFAS-based options.

3.4.1. Typical innovation process and timing

Product development or innovation processes are generally initiated through two approaches:

- **Market pull**: This occurs when a customer submits a request for a quotation along with specific tailored requirements to the Company. This leads to the initiation of a product development project following the implemented development process according to IATF 16949, as depicted in Figure 4. Development review checklists ensure compliance with laws, regulations, and product standards. Throughout the product development process, various sample states undergo validation. Positive validation results are essential for gate release and serve as a prerequisite for progressing to the next development phase;

- **Technology push**: In this scenario, the outcome of the product management or business development management process gives rise to a new and innovative product idea that no customer has requested before. A project for product development is initiated to explore this idea, and it follows the process outlined in Figure 4.

As illustrated in Figure 4, the Company's typical project structure for development projects progresses through several phases:

- Project definition (Phase 1): [CONF.];
- Concept (Phase 2): [CONF.];
- Product development (Phase 3): [CONF.];
- Sample qualification and validation of B samples (Phase 4): [CONF.];

- Series development phase, involving validation of C samples and building the production line (Phase 5): [CONF.];
- Production ramp-up phase, involving the release of D samples, internal production release until SoP (Phase 6): [CONF.];
- Series production, involving implementation of lessons learned and project closure (Phase 7): [CONF.].

[redacted]

Figure 4. Project structure of the Company's development projects

The typical timeline for customer-specific product development is [CONF.] years, while the development of a new generation of platform valves, suitable for many customers, can take up to [CONF.] years.

Regarding the potential PFAS restriction, it is anticipated that **the validation and transition of affected series products to PFAS-free alternatives with equivalent performance will extend beyond a 10-year timeframe from their market availability**. Validation tests, specifically durability tests, can last up to [CONF.] for a single test run. Each product within the product family must undergo this crucial validation step, demanding substantial engineering and testing efforts. The duration for one test run of a durability test, consisting of [CONF.] switching cycles, is as long as [CONF.]. Typically, before customer release, 2 to 4 test runs are required, adding up to a testing period of up to [CONF.]. This extensive testing is crucial, particularly when evaluating the performance of wear coatings. Customers usually conduct their field tests simultaneously with the Company's testing process. Additionally, the utilization of specialized test equipment, such as temperature chambers and shakes, might present potential bottlenecks.

The development and testing of alternative PFAS-free ingredients would necessitate a minimum of 10 years from the initiation of a successful discovery phase to the eventual production and product

rollout. The Company's experiences have revealed that, especially for tribological systems, testing alternative coatings involves time-consuming endurance tests. Therefore, the 10-year timeline is already an optimistic estimation.

Previous experience also shows that this assumption is correct – this is from the past case of a ban on surface coatings with Hexavalent chromium (Cr(VI)). In that situation, it was a relatively simple change as several coating alternatives were available. Also, the duration of the required corrosion tests was short and cost efficient. Nevertheless, it took 5 years to change the affected series products.

3.4.2. Significant efforts performed so far to develop and test potential alternatives

As part of its innovation and performance optimisation process, the Company has been searching for potential alternatives to PFAS-based options in a structured and professional way, investing significant time and effort into these processes and related analysis and testing.

Besides the constant strive for innovation and constant improvement processes that is part of the "genes" of the Company, there is also a natural commercial interest: the transportation industry is characterised by its constant search for technical and commercial optimisation, which means also constant pressure to optimise the relationship between performance and price.

Given the high cost of PFAS-based materials (e.g., FKM are [CONF.] times more expensive than HNBR), it should be noted that such materials are used only used where absolutely necessary and the requirements do not allow any other material. This important difference is also visualized in the following chart:

Figure 5. Price bonds for high performance elastomers

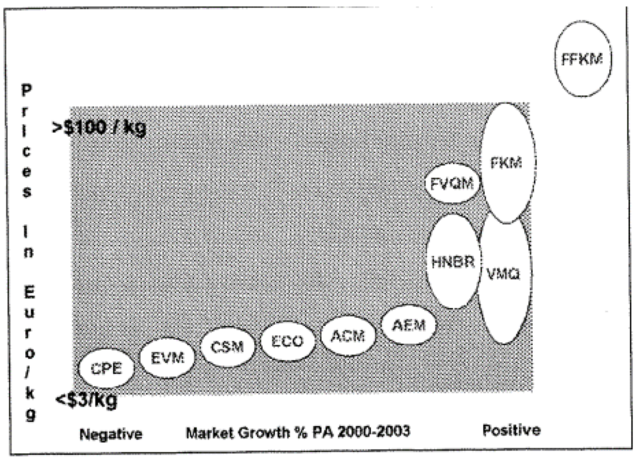


Chart 10

Price bands for high performance elastomers

(Source: Compilation of Industry Data)

Source: This is a copy paste of Chart 10 in Beswick (2000)[25]

[25] Beswick, R., 2000. An overview of the high-performance elastomer industry. High performance elastomers 2000 (Berlin, 10-11 October 2000).

Over time, many materials and material combinations have been tested by the Company. So far, none of them was identified as a suitable candidate for replacing the PFAS-based materials used – none of the alternatives explored has provided the performance characteristics required for these critical and in many cases also safety-relevant applications. And unfortunately, the Company is not aware of any new promising materials that are expected to fulfil the requirements.

Various wear coatings with the binding agents [CONF.] were verified in durability tests. The combination of binding agents [CONF.] and dry-film lubricant PTFE is the only one that was found capable to fulfil durability demands up to [CONF.] switching cycles. Wear coatings based on [CONF.].

3.5. Overall conclusion on suitability and availability of alternatives

Based on the results of this analysis, it is considered very unlikely that materials containing PFAS can be replaced by PFAS-free materials in the relevant applications described due to unique combination of performance characteristics of PFAS – not even in the long term. **We therefore conclude that materials containing PFAS should be considered an indispensable substance for the uses and applications described above.**

A PFAS ban in general – and especially without very long transition periods in selected cases warranted by a glimpse of hope that an alternative could be found – would cause massive damage to the EU in terms of loss of competitiveness and resulting unemployment, at least in technical/technological areas where the performance characteristics of PFAS cannot be dispensed with. This would probably not be recoverable and would only increase the EU's dependence on other economies like e.g., China. Components of essential relevance for the safety and performance of commercial vehicles and passenger vehicles as well as selected industrial specialty applications would no longer be available in the EEA, with dire consequences.

Based on the review and analysis performed, the relevant PFAS should be considered an indispensable substance for its uses and applications as described in this document. None of the potential alternatives reviewed are comparable nor preferable from an environmental, technical or cost efficiency perspective, and do not fulfil technical function requirements.

The assessment and conclusions therefore reasonably justify the request for time-unlimited derogations for critical industrial applications as described.

Therefore, the Company requests a time-unlimited derogation (exemption from the proposed restriction) for fluoropolymers including FKM, PTFE, and PFA in transportation (including, but not limited to, automotive and commercial vehicles) as well as industrial manufacturing uses.

4. Exposure Assessment and Emission Evaluation

4.1. Executive Summary of the Chemical Safety Report

Environmental emissions and worker exposure of PTFE, FKM and FVMQ were assessed for six uses at the Company, their supplier for PTFE coating, the following supply chain, service life and end of life. The polymer production process itself is not subject to this assessment. The assessment was done in four Exposure Scenarios: PTFE spraying, assembly phase, use phase and emissions from waste treatment.

The aggregate annual emissions are minimal (i.e., less than [CONF.] kg/year). Thereof, [CONF.]% occurs during the manufacturing phase (PTFE coating), [CONF.]%, during use phase, and [CONF.]% during end-of-life phase.

Based on hazard information in literature and in the Annex XV dossier, the following risks were assessed:

Human health:

For human health, the possible inhalation of PTFE particles was considered to be the most sensitive endpoint. Of the 6 uses assessed, the PTFE coating process was identified as the process with the highest exposure. The exposure was modelled with ART1.5 to be 0.0063 mg/m^3 (95% percentile). Compared to the OEL (Occupational Exposure Level) for respirable particles which is 1.25 mg/m^3, we see a safety factor of 200. Therefore, we do not see a health risk for workers.

Particle emissions into the environment:

No substance-specific hazards in ecotoxicology or man-via-environment toxicology have been identified so far for the fluoropolymers PTFE, FKM and FVMQ. The reasoning in the Annex XV dossier is based on the persistence of fluoropolymers and the possible effects of microplastics which could be PTFE, FKM and FVMQ. Therefore, the emission of particles was assessed in the Exposure Scenarios (ES) for PTFE spraying, assembly phase, use phase and waste treatment.

- ES1 PTFE Spraying: As no measured values were available, we decided to calculate the emissions of PTFE using the conservative SPERC (Specific Environmental Release Category), which gave a result of [CONF.] kg/year. We assume that the emissions are actually significantly lower but can only be assessed by on-site measurements.

- ES2 Assembly Phase: According to the assessment, there are no relevant emissions into the environment at this stage.

- ES3 Service Life: The typical service life scenarios have been assessed. As most of the parts containing PTFE, FKM and FVMW are used for sealing (e.g., O-rings), no relevant emissions will have to be considered here. The only use where emissions are happening is from the PTFE coating of the armature operating the brake valves, especially in commercial vehicles as these brakes are operated by pressurized air. Based on the number of parts and the maximum wear of the PTFE surface, a total emission of [CONF.] kg/year PTFE particles was calculated.

- ES4 Waste treatment: Emissions from the treatment of waste streams of the previous scenarios have been assessed. A specific treatment (ISODRY®) for wet waste from the PTFE spraying process has been assessed in detail. The emissions were estimated to be [CONF.] kg/year. For solid waste, incineration will be the prevalent treatment. There is a scientific study (Alexandrov et al., 2019) stating that municipal incineration of PTFE using best available technology should be considered an acceptable form of waste treatment.[26] Regarding the landfilling of solid waste, we assume that the emissions from landfills are very low, provided that the landfills are operated and maintained properly and in accordance with the relevant regulations. Therefore, no contribution from landfills to the total emissions was calculated.

For details, please see the full Chemical Safety Report attached in Annex I.

[26] Aleksandrov, K., Gehrmann, H. J., Hauser, M., Mätzing, H., Pigeon, D., Stapf, D., & Wexler, M. (2019). Waste incineration of Polytetrafluoroethylene (PTFE) to evaluate potential formation of per-and Poly-Fluorinated Alkyl Substances (PFAS) in flue gas. *Chemosphere*, *226*, 898-906.

5. Analysis of Impacts

The sections below provide a general overview of the socio-economic impacts, including business impacts on manufacturers of electromagnetic actuators, valves, and sensors, social impacts (i.e., unemployment as a result of the restriction), substitution costs, and broader macroeconomic consequences resulting from a potential restriction of the PFAS used in electromagnetic actuators, valves, and sensors for the transportation as well as industrial manufacturing industries. Based on the estimated total socio-economic impacts and emissions, the section concludes with a high cost-effectiveness factor, indicating that the measure would be disproportionate.

5.1. Socio-economic impacts

5.1.1. Business impacts

A detailed questionnaire has been used to gather SEA data and information from a manufacturer of PFAS-containing electromagnetic actuators, valves, and sensors that are utilised in transportation and industrial applications. The market share covered by this impact assessment is approximately [CONF.]% of the market for electromagnetic actuators, valves, and sensors that are used in the transportation industry (incl. commercial and passenger vehicles) and industrial applications (incl. stationary and mobile industrial products for hydraulics). This market share can be used to obtain estimates for the total EEA market via extrapolation, as detailed below for the assessment of the business impacts.

The Company does not produce the PFAS-containing components itself, but these are instead, sourced and purchased as semi-finished products from suppliers and procured in the context of an extended value chain, as illustrated in Section 2.2.1. Yet, a substantial share of the Company's product portfolio contains PFAS.

In the financial year of 2022, a total of about [CONF.] parts were manufactured in the EEA, encompassing [CONF.] different products. **On aggregate, around [CONF.]% of the product portfolio of the Company was based on PFAS, all of which would have to be removed from the EEA market as of 2027 (year of the entry into force of the proposed restriction plus 18 months transition period).**[27]

The manufacturing of the final products in the EEA takes place in Germany and Poland. The final PFAS-containing products produced in the EEA – a total of about [CONF.] products, mainly produced for the EEA market – are subsequently sourced to [CONF.] customers ([CONF.]% in the EEA) at [CONF.] different locations (>[CONF.] in the EEA). Only ~[CONF.]% of the PFAS-affected products manufactured in the EEA were exported to non-EEA customers.

[27] Out of [CONF.] parts, ~[CONF.]% ([CONF.]) contained PFAS, spread across [CONF.] different products.

Overall, the lion's share of the total company turnover in the EEA (i.e., [CONF.]%) is from the sale of PFAS-containing products. Thus, a PFAS restriction would have major repercussions on the Company's business and continued operability in the EEA.

The direct cost of a PFAS restriction is represented by the loss of the contribution to the EEA economy of the Earnings Before Interests and Taxes (EBIT) generated by manufacturers of electromagnetic actuators, valves, and sensors that are used in the transportation industry. The relevant economic measure to quantify this economic impact is given by EBIT. The monetization (net present value, NPV, with 3% discount rate)[28] of this economic impact (lost EBIT) is reported below.

If the PFAS restriction would materialize,[29] it is estimated that the Company, as a manufacturer of PFAS-based products and components, would face **total net EBIT loss of approximately [CONF.] EUR/year (rounded, in annualised terms).**

Over four years (i.e., the time horizon suggested by SEAC when there is no suitable alternative available in general), the **total impact for the Company is expected to be approximately [CONF.] EUR** (NPV, 3% d.r.).[30]

One can use the market share of the Company to extrapolate the total economic impact in the EEA across all manufacturers of electromagnetic actuators, valves, and sensors that are used in the transportation industry in the EEA. The market share covered by this survey represents [CONF.]% of the total EEA market for electromagnetic actuators, valves, and sensors that are used in the transportation industry and industrial applications. This market share is used for the extrapolation of the impacts for the whole EEA in a conservative approach.

The total monetised impact for the EEA market of electromagnetic actuators, valves, and sensors that are used in the transportation industry (incl. commercial and passenger vehicles) would therefore be in the range of [CONF.] EUR, as derived above, and **[CONF.] EUR** (viz., the result of the extrapolation: [CONF.] / [CONF.]%).

It ought to be highlighted that the survey covers only the downstream level of the supply chain. Other companies may benefit from a negative regulatory outcome for PFAS, especially, competitors based outside the EEA. Because the REACH restrictions would affect equally the whole EEA electromagnetic actuators, valves, and sensors industry, the corresponding loss in value added (i.e., loss in EBIT) can be considered an EEA industry-wide impact.

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28 In accordance with European Commission, 2021. Better Regulation Guidelines and Toolbox. https://commission.europa.eu/document/download/9c8d2189-8abd-4f29-84e9-abc843cc68e0_en?filename=br_toolbox-nov_2021_en.pdf

29 The Company was asked to project lost sales and EBIT under the assumption that a restriction of PFAS used in electromagnetic actuators, valves, and sensors were to be fully adopted as of 2027.

30 Using the Excel function =PV(3%,4,- [CONF.],0,0).

Thus, as a result of a highly conservative approach, these figures result in an underestimation of the impact and should be considered as a minimum (lower boundary) of the expected impacts of a restriction in the EEA electromagnetic actuators, valves, and sensors that are used in the transportation industry's supply chain.

Substitution costs and time

From the time PFAS-free alternatives with equal performance are available on the market, this will necessitate a validation and transition process for affected series products, which is expected to take more than 10 years. The validation entails conducting extensive tests, particularly durability tests, lasting up to [CONF.] per test run. Each product within the product family must undergo this crucial validation proves, requiring substantial engineering efforts and specialized test equipment like temperature chambers and shakers. This test equipment might pose potential bottlenecks in the system.

Developing and testing PFAS-free alternatives would require at least 10 years from beginning of a successful discovery phase to production and product rollout. Based on the Company‘s experiences, endurance testing for alternative coatings, especially in tribological systems, is time-consuming. Hence, the 10-year timeframe provided already is an optimistic estimate.

Not only is it time-consuming, the whole PFAS-free transition operation will also be cost-expensive. The total projected costs for transitioning all PFAS-affected series products and product families are estimated to be over [CONF.] EUR (rounded) due to additional investments in regulatory processes if using existing PFAS ingredients, including development costs to identify suitable alternatives, costs for reformulation and quality assurance, and costs for the transition to a full-scale production using the alternatives or altered formulations.

In reality, the switching costs across the total industry of the manufacturers of electromagnetic actuators, valves, and sensors are likely to be much larger than this estimate. By making use of the [CONF.]%-market share covered in this SEA, one can extrapolate a total switching cost for the manufacturers of electromagnetic actuators, valves, and sensors that are used in the transportation industry and industrial applications of **[CONF.] EUR** (viz., result of the extrapolation via market share: [CONF.] EUR / [CONF.]%).

5.1.2. Social impacts: unemployment

In general, it is difficult to estimate the unemployment because this depends on whether the end user market will accept completely different PFAS-free parts and materials in the EEA markets for automotive, commercial vehicle, and stationary and mobile industrial products for hydraulics industries.

The scale of impact on employment is expected to be lower than the impact on EBIT. However, it is estimated that, assuming a REACH restriction is implemented, on average over [CONF.] FTEs directly involved in the manufacturing and supply chain of the Company's PFAS-containing electromagnetic valves, sensors, and actuators in the EEA would face layoff. The vast majority of these FTEs are located in Germany ([CONF.] FTEs), while the remaining [CONF.] of these employees are located in Poland. This is equivalent to [CONF.]% of the Company's workforce in the EEA (i.e., more than [CONF.] employees in Europe).

In this section, we report the monetization of the likely social costs of unemployment for these workers.

A well-known guideline in monetizing the social impact of unemployment has been developed by the European Chemicals Agency (ECHA) for evaluating such impact in different regulatory processes. Estimates have been made in accordance with the ECHA document on the evaluation of unemployment (SEAC/32/2016/04)[31] and the paper of Dubourg (2016)[32] endorsed by ECHA. Therefore:

- The average annual salaries across these European workers (including the employer's social security contributions) are reported below.[33]
- Using Table A7 (column G, considering the gross wages including the employer's social security contributions) in Dubourg's paper, the total social cost of unemployment in Germany is equal to 2.18 times the annual gross salary, and 1.95 in Poland.[34]
- Table 4 and Table 5 present the statistics from Eurostat (data for 2023-Q1) on the average duration of unemployment for both men and women between the ages of 15-64 years, for Germany and Poland respectively.[35]
- Only 75% of the average duration of employment is considered, to reflect the fact that some affected workers are highly skilled and could find employment sooner.

31 ECHA (2016). The Social Cost of Unemployment. Available at: https://echa.europa.eu/documents/10162/13555/seac_unemployment_evaluation_en.pdf/af3a487e-65e5-49bb-84a3-2c1bcbc35d25

32 Richard Dubourg, 2016. Valuing the Social Costs of Job Losses in Applications for Authorization. The Economics Interface Limited.

33 For the calculation of the average annual salaries in Germany (including the employer's social security contributions), the weighted average of the average salaries across the three locations in Germany was taken.

34 This value is greater than 1 because it takes into account the following components: lost wage, costs of job searching, recruitment costs, the impact of unemployment status on future wages (scarring effect) and employment possibilities, and leisure time (which is a benefit and therefore subtracted from the previous components).

35 Data extracted from: https://ec.europa.eu/eurostat/web/products-datasets/-/lfsq_ugad

Table 4. Duration of unemployment in Germany

Duration Grouping	Thousand units	Proportion (A)	Assumed duration (B)	Weighted average (A*B)
Less than 1 month	199.8	0.151317782	0.5	0.075658891
From 1 to 2 months	319.1	0.241669190	1.5	0.362503787
From 3 to 5 months	233.1	0.176537413	4.5	0.794418358
From 6 to 11 months	172.4	0.130566495	8.5	1.109815208
From 12 to 17 months	99.0	0.074977280	14.5	1.087170554
From 18 to 23 months	65.4	0.049530445	20.5	1.015374129
From 24 to 47 months	116	0.087852166	35.5	3.118751893
48 months or over	115.6	0.087549228	48	4.20236292
Total	1320.4	1		**11.76605574**

The social costs of unemployment for workers employed in Germany would therefore be equal to: [CONF.] EUR x [CONF.] FTEs x 2.18 x 11.76605574/12 x 75% = [CONF.] EUR (rounded).

Table 5. Duration of unemployment in Poland

Duration Grouping	Thousand units	Proportion (A)	Assumed duration (B)	Weighted average (A*B)
Less than 1 month	19.5	0.039062500	0.5	0.01953125
From 1 to 2 months	133.3	0.267027244	1.5	0.400540865
From 3 to 5 months	85.8	0.171875000	4.5	0.773437500
From 6 to 11 months	108.5	0.217347756	8.5	1.847455929
From 12 to 17 months	97.8	0.195913462	14.5	2.840745192
From 18 to 23 months	14.5	0.029046474	20.5	0.595452724
From 24 to 47 months	26.2	0.052483974	35.5	1.86318109
48 months or over	13.6	0.027243590	48	1.307692308
Total	499.2	1		**9.648036859**

The social costs of unemployment for workers employed in Poland would therefore be equal to: [CONF.] EUR x [CONF.] FTEs x 1.95 x 9.648036859/12 x 75% = [CONF.] EUR (rounded).

Overall, the social impacts of the Company's business linked to the EEA countries would therefore be equal to [CONF.] EUR.

Although companies along the supply chain would face a reduction in sales over the years, we assume for simplicity that the entire workforce will continue working for further three years. Therefore, we discount the monetized impact derived above by three years due to the assumed delay in the layoff, using discount rate of 3% per year, as follows: [CONF.] EUR x $(1 + 0.03)^{-3}$ = [CONF.] EUR.

One can affirm with a high likelihood that the total social impact of a restriction of PFAS used in the production of electromagnetic actuators, valves, and sensors *along the whole supply chain* would be larger than [CONF.] EUR, once one considers competitors and all other economic operators having business linked to the Company's electromagnetic actuators, valves, and sensors that are used in the transportation industry.[36]

5.1.3. Wider economic impacts

It is also important to consider the wider macroeconomic impacts and consequences on the EU society at large, by focusing on the expected consequences for the EEA market. In particular, there are concerns on the overall EU trade balance and on the competitiveness of the EEA market.

Impacts on the market – Quality and costs

If PFAS would no longer be available in electromagnetic actuators, valves, and sensors, sectors and consumers such as users of passenger cars and commercial vehicles in the transportation industry relying on these goods, would be particularly affected. In the EEA, the Company's PFAS-containing products are sold to [CONF.] customers located in [CONF.] locations in the EEA. These customers would all be affected as a result of the PFAS restriction.

It is expected that end-customers would not change their functional requirements, but they will likely expect their suppliers to bear the costs of developing, validating, and releasing PFAS-free alternatives, given that substitution is even possible. The electromagnetic actuators, valves, and sensors are mainly found in highly dynamic processes where safety, efficiency, and environmental compatibility are of high importance. **Therefore, the adverse impact on both the quality and costs of electromagnetic actuators, valves, and sensors that are used by the transportation industry in safety relevant applications would therefore have widespread social impacts.**

Impacts on the market – Competitiveness

A broad restriction of PFAS used in the production of electromagnetic actuators, valves, and sensors would put European markets at a competitive disadvantage with the rest of the world. Non-EEA companies would not be subject to any restriction on PFAS. As such, they would be able to supply and place on the international market a wider range of products, currently preferred and purchased by consumers without incurring any reformulation costs.

[36] Once again, the market share covered by this survey represents [CONF.]% of the whole EEA market for electromagnetic actuators, valves, and sensors that are used in the transportation industry and industrial applications. For the social impacts on unemployment, we refrain from using the EU market share (revenue-based) to extrapolate social costs from two different countries with different sales rates. Consequently, the social impacts derived above only cover the company's business.

In addition, the costs of EEA products would increase more than the costs for non-EEA suppliers. While EEA companies would have to use unplanned engineering resources to redesign of existing products, **non-EEA competitors would have a commercial competitive advantage in terms of both product cost and engineering effort**. The EEA industry for electromagnetic actuators, valves, and sensors would therefore face significant hurdles. The EEA would **face a loss of competitiveness** vis-à-vis the rest of the world.

Impacts on the market – Innovation and R&D

The transportation industry, in particular related to electromagnetic actuators, valves, and sensors, has invested in **extensive R&D to create products** that meet end-consumers' requirements. It is expected that investments in further development of components and systems at customers and at the Company's EEA plants will be significantly be reduced, as the basis for further development and meeting end-customer requirements would be lacking. If serial products cannot keep the functional requirements anymore, this may subsequently result in a loss of sales.

As a result of the potential restriction, current R&D efforts and resources would inevitably be redirected towards re-formulating, re-qualifying, and re-certifying the portfolio. **This will require R&D resources to support efforts to redevelop portfolios, stalling innovation and new product development**. At similar components costs and in the same installation space, the development of a non-PFAS alternative is time-consuming (i.e., at least 10 years), involves a significant amount of costs (i.e., over [CONF.] EUR), and involves the risk that the same required performance at the end will not be achieves. **In the event of a potential PFAS restriction, the Company currently lacks the revenues to finance these unplanned engineering resources.**

Impacts on the market – Trade

A broad restriction of PFAS used in the production of electromagnetic actuators, valves, and sensors that are used for the transportation industry in the EEA would disadvantage European companies in their trade with the rest of the world. The costs of products from the EEA would increase more than the costs for non-EEA suppliers. Therefore, this would make non-EEA countries more competitive in exporting electromagnetic actuators, valves, and sensors. Moreover, if the serial products cannot keep their functional requirements anymore, this would in turn also result in a loss of sales and may even result in a loss of complete business in the EEA. As a result, **the overall EU trade balance would be adversely impacted**.

Impacts on the market – Suppliers and subcontractors

As described in Section 2.2.1, the supply chain for PFAS is extensive. A wide number of actors is involved in the supply chain linked to electromagnetic actuators, valves, and sensors, including raw material suppliers, commodity traders, compounders of elastomers, sealing of elements, and the assembly. This extensive supply chain is only located in the EEA. **If the PFAS restriction is implemented, there would be a decreased demand for the services of each actor.** These suppliers are at a risk of losing these sales in the EEA while bearing high reformulation costs to develop new technologies to replace their existing PFAS based products.

The Company purchases PFAS-containing components (e.g., O-rings and seals made out of FKM or FVMQ and coated armatures or plungers containing PTFE) from suppliers that are nearly all located in the EEA. A ban of PFAS would result in a fundamental challenge for their business, as they would either be able to develop a PFAS-free alternative with similar technical performance, or lose their business completely.

5.2. Cost effectiveness ratio

A potential broad restriction would have disproportionate socio-economic implications on the EEA society. Overall, at the level of manufacturers of electromagnetic actuators, valves, and sensors, **the total socio-economic impact of a REACH restriction of PFAS is monetised in the range of [CONF.] EUR** (for the Company alone) **and [CONF.] EUR** (result of the extrapolation via [CONF.]%-market share) as shown earlier in this chapter, consisting of: social impacts from unemployment in the EEA, economic impacts (EBIT loss), and substitution costs for manufacturers of electromagnetic actuators, valves, and sensors (conservative estimates in net losses).

The estimates reported in this socio-economic analysis should be considered as a minimum (lower boundary) of the expected impacts of a restriction of PFAS. The impacts cover only one level of the extensive typical supply chain for elastomeric parts. Moreover, it does not include the high costs to identify and establish an alternative for the suppliers and the overall industry.

Notably, the economic impacts downstream in the supply chain can be substantial. In fact, the socio-economic impacts typically follow a magnification effect along the supply chain so that the (downstream) manufacturers of finished products are expected to have larger impacts. In other words, **the effects of a negative impact upstream would reverberate through the supply chain, causing larger negative output downstream. Such impacts may include decreased sales and layoffs (job losses).**

As shown in Section 4, the aggregate annual emissions are minimal. Taking into account the total estimated PFAS particle emissions into the environment for the Company, which have been estimated at [CONF.] kg/year[37], **a theoretical full ban would be highly disproportionate:**

[CONF.] EUR / ([CONF.] kg/year x 20 years) = **1.8 million EUR/kg** (rounded)

[37] Particle emissions into the environment:
- ES1 PTFE Spraying: [CONF.] kg/year;
- ES2 Assembly Phase: N/A;
- ES3 Service Life: [CONF.] kg/year;
- ES4 Waste treatment: [CONF.] kg/year.

This cost-effectiveness ratio can be compared with the benchmark of 50,000 EUR/kg, which is the threshold beyond which a restriction is clearly unproportionate and should not occur (Oosterhuis et al., 2017).[38] This study is always referenced as a benchmark by SEAC in REACH restriction opinions for substances with environmental concerns (e.g., ED, PBT).

Therefore, in the case of a REACH restriction of PFAS used in actuators, valves, and sensors for transportation applications (incl. commercial and passenger vehicles), the cost per kg of avoided PFAS emissions is estimated to be much higher than the threshold of 50,000 EUR/kg for all releases (i.e., 1.89 million EUR/kg).

This cost-effectiveness ratio is considered high enough to justify a time-unlimited derogation of PFAS in actuators, valves, and sensors for transportation and industrial applications unavoidable.

[38] Oosterhuis, F., Brouwer, R., Janssen, M., Verhoeven, J., Luttikhuizen, C., 2017. Towards a proportionality assessment of risk reduction measures aimed at restricting the use of persistent and bioaccumulative substances. Integrated Environmental Assessment and Management, 13, 1100-1112.

6. Conclusions

This SEA identifies the main potential negative consequences that the EU society at large would face in the framework of the potential upcoming REACH Restriction of PFAS. It has been performed in line with existing ECHA guidance for the preparation of the Socio-Economic Analysis. The results are based on a survey focused on the EU industry for electromagnetic actuators, valves, and sensors that are used in dynamic processes, with market share coverage of approximately [CONF.]% of the EEA market for electromagnetic actuators, valves, and sensors that are used in the transportation industry (incl. commercial and passenger vehicles) and industrial applications (stationary and mobile industrial products for hydraulics). It therefore provides sufficiently reliable data for a representative extrapolation of the EU market.

Overall, the results of the SEA show that no suitable alternatives to PFAS are commercially available for each individual application and thus a broad restriction would have disproportionate negative impacts on society.

The above statement is founded on the following:

- Thanks to the wide variety of properties offered by PFAS, these materials are used in a variety of dynamic processes within transportation and industrial applications. As such, **PFAS are used ubiquitously across the Company's product portfolio.** Approximately **[CONF.]% of product portfolio** will be impacted by a restriction, negatively impacting **[CONF.]% of the total turnover in the EEA**.

- **The Company performed several tests with potential alternative materials on a regular basis – with no suitable alternative identified thus far**. The results of these tests have shown that due to the unique characteristics of PFAS materials, and based on the current state of the art, **no PFAS-free alternative materials for PTFE, FKM and FVMQ with equal performance characteristics available today and in the foreseeable future.**

- **Implementing a re-design requires long timelines and high costs to convert the entire portfolios. It is anticipated that more than 10 years (minimum) are needed for finding a technically suitable alternative, re-designing (i.e., implementing the substitution of PFAS based products) and completing transition activities and to retain products on the EEA market**.

- **A potential broad restriction would have disproportionate socio-economic implications on the EEA manufacturers of electromagnetic valves, actuators and sensors and the relevant transportation supply chain. The total monetised socio-economic impacts of a REACH restriction of PFAS are monetised in the range of [CONF.] EUR and [CONF.] EUR**, (conservative estimates in net losses), consisting of: social impacts from unemployment in the EEA, economic impacts (EBIT loss), and substitution costs. **The estimates reported in this socio-**

economic analysis should be considered as a minimum (lower boundary) of the expected impacts.

- From an EU macroeconomic perspective, a PFAS ban in general – and especially without very long transition periods in selected cases warranted by a glimpse of hope that an alternative could be found – would cause massive damage to the EU in terms of **loss of competitiveness** and resulting **unemployment**, at least in technical/technological areas where the performance characteristics of PFAS cannot be dispensed with. This would probably not be recoverable and would only **increase the EU's dependence on other economies** like e.g., **China**. Components of essential relevance for the safety and performance of commercial vehicles and passenger vehicles as well as selected industrial specialty applications would no longer be available in the EEA, with dire consequences. Eventually, a short-term **ban on PFAS would cost the EU its technological leadership and global competitiveness**.

- **Based on the minimal estimated annual emissions (i.e., less than [CONF.] kg/year), the cost effectiveness ratio is calculated to be significantly high (> 1.8 million EUR/kg), and the restriction highly disproportionate. The high socio-economic costs would offset only a small contribution of the total PFAS input into the environment.**

Based on the above evidence-based considerations, this report concludes that a broad restriction of PFAS for electromagnetic actuators, valves, and sensors will have disproportionate negative impacts on the European economy and society.

The Company agrees to phase out the use of PFAS wherever this is possible. This requires however the availability of technically and economically viable alternatives which are to date not readily available. Finding alternatives is not guaranteed, and substitution (if possible) is a time-consuming process due to complexity of the affected products. This cannot be achieved in the proposed 18-month transition time.

This SEA-AoA report concludes that a broad restriction without derogation for the use of PFAS in electromagnetic actuators, valves, and sensors, will have disproportionate negative impacts on the European economy and society. A time-unlimited derogation for the use of critical fluoropolymers in electromagnetic valves, actuators and sensors should be foreseen.

7. Annex I – Chemical Safety Report

7.1. Identity of the substance

Table 6: Name and other identifiers of the substance

Nr.	Polymer Name	CAS	EINECS
1	FKM (Fluoroelastomers)	64706-30-5	
2	FVMQ (Fluorosilicone rubber)	n.a.	
3	PTFE	9002-84-0	618-337-2

7.2. Classification and labelling

Table 7: Classification and labelling

Nr.	Polymer Name	CAS-nr.	CLP	CLI
1	FKM (Fluoroelastomers)	64706-30-5	No classification	No classification
2	FVMQ (Fluorosilicone rubber)	n.a.	No classification	No classification
3	PTFE	9002-84-0	No classification	H315, H319, H332, H335, H372, H413 (no information given on the physical details of the polymer material)

7.3. Exposure assessment (and related risk characterisation)

7.3.1. Introduction

7.3.1.1. Overview of uses and Exposure Scenarios

Tonnage information:

The following table lists the volumes of PFAS, by market sector of the service life:

Table 8: Tonnage supplied by market sector

PFAS	Total kg/a	Commercial Vehicles	Passenger Cars	Industry	
FKM	[CONF.]	[CONF.]	[CONF.]	[CONF.]	kg/a
FVMQ	[CONF.]	[CONF.]	[CONF.]	[CONF.]	kg/a
PTFE – Bearing	[CONF.]	[CONF.]	[CONF.]	[CONF.]	kg/a
PTFE – Armature coating	[CONF.]	[CONF.]	[CONF.]	[CONF.]	kg/a
PTFE – Elastomer Coating	[CONF.]	[CONF.]	[CONF.]	[CONF.]	kg/a
PTFE – Granulate	[CONF.]	[CONF.]	[CONF.]	[CONF.]	kg/a

The following table lists all the exposure scenarios (ES) assessed in this CSR.

Table 9. Overview of exposure scenarios and contributing scenarios

Identifiers (*)	Market Sector	Titles of exposure scenarios and the related contributing scenarios	Tonnage (tonnes per year)
ES1	**IW**	**PTFE spraying**	
ECS1-1	IW	Emissions of particles during PTFE spraying	
WCS1-1	IW	Exposure during PTFE coating processes	
ES2	**IW**	**Assembly phase**	
ES3	**SL-PW**	**Use phase**	
ECS3-1	SL-C	Emissions of PTFE particles during use phase	
ES4	**EoL**	**Emissions from waste treatment**	
ECS4-1	EoL	Emissions during waste incineration	
ECS4-2	EoL	Emissions from landfills	
(*) Manufacture: M-#; Formulation: F-#; Industrial end use at site: IW-#; Professional end use: PW-#; Consumer end use: C-#; Service life (by workers in industrial site): SL-IW-#; Service life (by professional workers): SL-PW-#; Service life (by consumers): SL-C-#; End of Life: EoL			

7.3.1.2. Introduction to the assessment

Environment

Scope and type of assessment:

According to the Annex XV restriction dossier annex section B.7.6, fluoropolymers are a group of materials with different properties, and for some of the fluoropolymers, persistence is well known.[39] The bioaccumulation potential is poorly understood so far. Environmental hazards from fluoropolymers can occur due to leachate of processing aids from the polymer and due to formation of microplastic particles. No endpoint-specific PNEC have been identified for fluoropolymers.

For this assessment, we are going to focus on the total volume of fluoropolymers that can be emitted into the environment (worst-case scenario).

Man via environment

Scope and type of assessment:

Table 10. Type of risk characterisation required for man via the environment

Route of exposure and type of effects	Type of risk characterisation	Hazard conclusion (see section 5.11)
Inhalation: Systemic Long Term	n.a.	
Oral: Systemic Long Term	Oral administration (Rat)	No effect (Zapp, 1962)[40]

[39] BAuA, RIVM, KEMI, Norwegian Environment Agency, The Danish Environmental Protection Agency: Annex to the ANNEX XV RESTRICTION REPORT PROPOSAL FOR A RESTRICTION, SUBSTANCE NAME(S): Per- and polyfluoroalkyl substances (PFASs), 2023

[40] Zapp J.A., Jr., 1962. Toxic and health effects of plastics and resins. Archives of environmental health 4, 335-346. DOI: 10.1080/00039896.1962.10663162

Comments on assessment approach:

Although fluoropolymers are present in the environment and there could be uptake via inhalation or orally (drinking water, food), no hazards have been identified so far.

For this assessment, hazard and risk of man via environment exposure will not be evaluated.

Workers

Scope and type of assessment:

Table 11. Type of risk characterisation required for workers

Route	Type of effect	Type of risk characterisation	Hazard conclusion (see section 5.11)
Inhalation	Systemic Long Term	n.a.	
	Systemic Acute	n.a.	
	Local Long Term	Study on workers Lee et al., 2018a)[41]	Granulomatous lung lesions by PTFE particles
	Local Acute	Study on workers (Lee et al., 1997)[42]	Pulmonary oedema and polymer fume fever
Dermal	Systemic Long Term	n.a.	
	Systemic Acute	n.a.	
	Local Long Term	n.a.	
	Local Acute	n.a.	
Eye	Local	n.a.	

Comments on assessment approach related to toxicological hazard:

According to the Annex XV restriction dossier annex section B 5.4, health hazards have been identified for the inhalation of PTFE particles and the inhalation of polymer fumes.

For this assessment, the workers exposure to fluoropolymer particles, especially PTFE will be evaluated.

General information on risk management related to toxicological hazard:

As described below, processes which include spraying of PTFE are taking place in fully enclosed production lines with filtering of the extracted air, in order to minimize worker exposure and also protect the parts from quality deficits caused by dusts and particles.

[41] Lee N., Baek K., Park S., Hwang I., Chung I., Choi W., Jung H., Lee M., and Yang S., 2018a. Pneumoconiosis in a polytetrafluoroethylene (PTFE) spray worker: a case report with an occupational hygiene study. Annals of Occupational and Environmental Medicine 30, 7. DOI: 10.1186/s40557-018-0248-6

[42] Lee C.H., Guo Y.L., Tsai P.J., Chang H.Y., Chen C.R., Chen C.W., and Hsiue T.R., 1997. Fatal acute pulmonary oedema after inhalation of fumes from polytetrafluoroethylene (PTFE). The European respiratory journal 10 (6), 1408-1411. DOI: 10.1183/09031936.97.10061408

7.3.2. Exposure Scenario 1: PTFE Spraying

Market sector: Industry **Sector of use:** SU17 General manufacturing, e.g., machinery, equipment, vehicles, other transport equipment **Article categories:** AC1 Vehicles, AC2 Machinery **Environment contributing scenario(s):** ECS1-1 **Worker contributing scenario(s):** WCS1-1 **Subsequent service life exposure scenario(s):** ES2 **Exposure scenario(s) of the uses leading to the inclusion of the substance into the article(s):** WCS1

Description of the activities and technical processes covered in the exposure scenario:

Tier -1 Coating Armatures with PTFE, coating O-Rings with PTFE (suppliers of the Company).

The process is based on a lacquer containing PTFE ([CONF.]%), avoiding exposure with or emissions of PTFE dust.
There are two different processes:

- Coating of armatures: Spraying of PTFE lacquer on part in a dedicated, fully automated installation with full enclosure and local exhaust ventilation. Extracted volumes are filtered before emission.
- Coating of O-rings: PTFE application in a coating drum, inside a dedicated, fully automated installation with full enclosure and local exhaust ventilation. Extracted volumes are filtered before emission.

Curing of applied coat is taking place in a dedicated oven with local exhaust. Controlled heat dissipation is taking place in a dedicated place with local exhaust ventilation.
Maintenance activities are carried out by trained personnel only.
Liquid and dry wastes are disposed of by certified service providers according to local regulations.

Explanation on the approach taken for the ES:

Based on the process, the exposure was modelled with ART1.5. The emissions into the environment were assessed based on the SPERC filter efficiency.

7.3.2.1. Environmental contributing scenario 1-1: Emissions of particles during PTFE spraying

Conditions of use

Product (article) characteristics
▪ Lacquer, containing up to [CONF.]% of PTFE
Amount used, frequency and duration of use (or from service life)
▪ Process 1: [CONF.] kg of lacquer per year, equivalent to [CONF.] kg of PTFE, daily use, 8 h per day, 200 days per year ▪ Process 2: [CONF.] kg of lacquer per year, equivalent to [CONF.] kg of PTFE, daily use, 8 h per day, 200 days

per year	
Technical and organisational conditions and measures	
▪ Fully automated installation with full enclosure and local exhaust ventilation. Extracted volumes are filtered before emission. [CONF.]% of the PTFE are found on the filter.	
Conditions and measures related to sewage treatment plant	
▪ No processes that are generating wastewater	
Conditions and measures related to treatment of waste (including article waste)	
▪ Waste treatment with Isodry® process and Hydrosolve process®	
Other conditions affecting environmental exposure	
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	

Releases

Table 12. Local releases to the environment

Release	Release factor estimation method	Explanation / Justification
Water	n.a.	**Initial release factor:** ...% **Final release factor:** ...% **Local release rate:** ... kg/day **Explanation / Justification:** no wastewater from process
Air	CEPE SPERC 5.1a.v2: Typical filter efficiency 95%	**Initial release factor:** .%. **Final release factor:** **Local release rate:** [CONF.] kg PTFE/day **Explanation / Justification:** Worst case assumption based on SPERC filter efficiency data
Soil	n.a.	**Final release factor:** ...% **Explanation / Justification:** Waste stage assessed in ES4

Releases to waste

Release factor to waste from the process: [CONF.] kg/year wet/liquid waste; [CONF.] kg/year dry waste
Release factor to waste from on-site treatment: n.a.

Exposure and risks for the environment and man via the environment

The emission of PTFE from the process has been assessed by a worst-case assumption, using the SPERC filter efficiency factor of 95%. Based on this factor, the emissions would be [CONF.] gram per day (200 days per year). The actual efficiency of the filter is not known; however, we assume that the actual emissions from the process are lower.

7.3.2.2. Worker contributing scenario 1-1

Conditions of use

	Method
Product characteristics	
▪ Lacquer with [CONF.]% of PTFE content, medium viscosity	
Amount used (or contained in articles), frequency and duration of use/exposure	
▪ Process 1: [CONF.] kg of lacquer per year, equivalent to [CONF.] kg of PTFE, daily use, 8 h per day, 200 days per year ▪ Process 2: [CONF.] kg of lacquer per year, equivalent to [CONF.] kg of PTFE, daily use, 8 h per day, 200 days per year	
Technical and organisational conditions and measures	
▪ Activity class: Surface spraying of liquids ▪ Situation: Very low application rate (< 0.03 l/minute) ▪ Spray direction: Only horizontal or downward ▪ Spray technique: Spraying with no or low compressed air use ▪ Process fully enclosed: yes ▪ Work area: indoors ▪ Room size: any size workroom ▪ Localised controls primary: fume cupboard (99% reduction) ▪ Localised controls secondary: none ▪ Room ventilation rate: only natural ventilation	ART1.5
Conditions and measures related to personal protection, hygiene and health evaluation	
▪ Standard industrial hygiene concept in place	
Other conditions affecting workers exposure	
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	

Exposure and risks for workers

Table 13. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, local, long-term	0.0063 mg/m³ (95% percentile)	

Remarks on exposure data:

The exposure data has been modelled with the use of ART1.5. The input parameters for ART1.5 were chosen based on the actual workers situation. No measured data are available at the moment.

Conclusion on risk characterisation:

Considering that PTFE is inert in the human body, the risk from inhalation can be compared to the risk of inhalation of mineral dust. The German occupational limit value for mineral dust is 10 mg/m³ for inhalable dust and 1.25 mg/m³ for respirable dust.

The modelled exposure of 0.0063 mg/m³ is a factor of 200 below the OEL for respirable dust. Therefore, we can conclude that the risk of local long-term health effects from the inhalation of such concentrations will be very low.

7.3.3. Exposure Scenario 2: Assembly phase

Market sector: Industry **Article categories:** AC1 Vehicles, AC2 Machinery **Environment contributing scenario(s):** see explanation **Worker/Consumer contributing scenario(s):** see explanation **Subsequent service life exposure scenario(s):** ES3 **Exposure scenario(s) of the uses leading to the inclusion of the substance into the article(s):** ES1

Explanation on the activities and technical processes covered in the exposure scenario:

Tier 0: Assembly by the Company

The Company is mostly using automated assembly lines with full enclosure and local exhaust ventilation. Extracted volumes are filtered with a multi-level filter (class W3). For the mounting of FMK/FVMQ O-rings, no enclosure is possible. Particles can fall off occasionally and are cleaned away with a vacuum cleaner with deduster (class A) to avoid emissions.
The parts are placed on trays and are shipped to the client.
Dry wastes are disposed of by certified service providers according to local regulations.
Maintenance activities are carried out by trained personnel only.
During quality testing of PTFE-coated parts, PTFE particles are generated at a small volume. Particles are cleaned away with a vacuum cleaner with deduster (class A) to avoid emissions.

Tier 1, Tier 2: Production of Parts and Products, containing the Company's subassemblies

In the following tiers of the supply chain, the subassemblies are taken from the tray and fed into specific production lines, depending on the product. The degree of automation can vary, depending on the product. The outcome is an assembly or product (commercial vehicle, passenger car, etc.).

The article consisting of FMK or FVMQ or PTFE typically is inside a subassembly and not manipulated during production. Manipulation of the articles can occur during quality assurance testing to a limited extent.

Explanation on the approach taken for the ES:

During production at the Company, exposure with or emissions of fluoropolymer particles from the articles can occur at a very low-level during assembly. Such particles will be cleaned from the ground and separated by the deduster or will be adsorbed by the multi-level filters. Collected dust is disposed of according to local regulations. Therefore, we assume that there will be no relevant emissions into the environment.

Emissions from waste will be assessed in ES4.

We also assume that the concentration of PTFE particles in the air of the production facilities is significantly below the level of ES1, as no spraying occurs. Therefore, we assume that no health risks do result from the PTFE particles.

At the following levels of the supply chain, the amount of fluoropolymer particles will be significantly lower, as the articles are already included in sub-assemblies and are less subject to manipulation compared to the assembly process at the Company.

Therefore, we assume that no risks from emissions into the environment and no risks to human health have to be taken into account during these stages of the product assembly.

7.3.4. Exposure Scenario 3: Service life

Market sector: Industry
Article categories: AC1 Vehicles, AC2 Machinery
Environment contributing scenario(s): ECS3-1
Worker/Consumer contributing scenario(s): see explanation
Subsequent service life exposure scenario(s): ES3
Exposure scenario(s) of the uses leading to the inclusion of the substance into the article(s): ES1

Explanation on the activities and technical processes covered in the exposure scenario:

The products are used in commercial vehicles and passenger cars (brakes, gearboxes) and industrial installations. Exposure and emissions during service life are typically very limited.

Parts with static duress (e.g., O-rings) do not have any or very low emissions during the phase of functioning. When a defect occurs, the part is exchanged and disposed of.

Parts with dynamic duress (e.g., armatures with PTFE coating) have wear and abrasion during the use phase, typically less than [CONF.]% of PTFE in 15 years.

From closed assemblies like gearboxes, there is no emission during operation. During maintenance, particles are extracted, e.g., when changing the lubricant or opening the gearbox for repair.

Valves and armatures in brake systems of commercial vehicles can emit PTFE particles during operation. The air pressurized brake systems have a synthetic fabric on the inside that also acts as a filter. Remaining PTFE particles and failed parts are extracted during maintenance and repair.

Maintenance activities are carried out by trained personnel only.
Liquid and dry wastes are typically disposed of by certified service providers according to local regulations.

Explanation on the approach taken for the ES:

The emission of PTFE particles into the environment cannot be excluded during the operation of PTFE-coated armatures in brake systems. For assessment and quantification, the following approach is taken:

Environment:
Based on the Company's annual production of armatures, PTFE content per armature and maximum wear per year, a total emission rate of PTFE particles into the environment per year is calculated. Waste

from maintenance is considered in ES4.

Worker:
During maintenance of commercial vehicles, passenger cars and industrial installations, e.g., for exchanging valves or seals that are damaged, workers can come into contact with the fluoropolymer articles or particles. Per maintenance activity, the amount of airborne PTFE particles is considered to be very low, as the total content of PTFE in the article is very low itself (e.g., [CONF.] g per armature), only a small portion (max. [CONF.]%) of the PTFE is present in particulate form and the fraction of airborne, respirable particles is even lower. Additionally, the duration of work with the risk for presence of PTFE in particulate form is rather short, per maintenance activity.

Therefore, we assume that the exposure with PTFE particles is well below the occupational exposure limit for respirable dusts of 1.25 mg/m³ and that hence no health hazard exists for the workers.

7.3.4.1. Environmental Contributing Scenario 3-1

In 2022, the Company produced [CONF.] PTFE-coated armatures for valves. The amount of PTFE per armature is [CONF.] g. The wear of the PTFE-coating over the service lifetime of 15 years does not exceed [CONF.]% of PTFE. So, a total PTFE-wear of [CONF.] g can be calculated for 15 years. Per year, this will be [CONF.] g, considering the entire annual production of the Company.

[CONF.]% of the armatures are used in gearboxes, which are hermetically closed and thus no source of emission during operation. [CONF.]% of the armatures are used in brake systems which are not hermetically closed but contain a synthetic fabric on the inside that also acts as a filter. No filtering factor has been determined for the fabric, so a factor of [CONF.]% filtering efficiency has been assumed. Therefore, we assume that the annual PTFE-emissions into the environment of the Company’s armatures in brake systems will typically be lower than [CONF.] g in the regional scale.

Conclusion on risk characterisation (minimisation of emission/exposure):

The annual emission of PTFE particles into the environment on the regional scale will be below [CONF.] g per year for this ES.

7.3.5. Exposure Scenario 4: Waste treatment

Market sector: Waste treatment
Environment contributing scenario(s): ECS4-1, ECS4-2
Worker contributing scenario(s): See discussion
Exposure scenario(s) of the uses leading to the inclusion of the substance into the article(s): WCS1

Description of the activities and technical processes covered in the exposure scenario:

General aspects of waste disposal and treatment and the respective regulations in Germany:
Waste disposal and treatment is subject to detailed regulations (EU: Waste Framework Directive 2008/98/EC; Germany: Kreislaufwirtschaftsgesetz, Abfallverzeichnisverordnung, Gewerbeabfallverordnung, Deponieverordnung and also local statutes). The treatment is specific to the type of waste and the process where it is generated. Waste fractions have to be sorted and kept separate after collecting. Waste that is intended for disposal is subject to strict control by the authorities.

The disposal of passenger cars is subject to the Directive 2000/53/EC on end-of life vehicles (ELV), which regulates the management of ELV in the EU. Member States are required to establish collection systems and ensure that ELV are transferred to authorized treatment facilities.

Coating Process
Liquid wastes from the PTFE coating process (ES1) are treated with the Isodry® process, where solvents are extracted, and the solid phase is subject to material recycling as far as possible. A detailed description of the Isodry® process is included in the publication of the German environmental agency 100/2017.[43]

Liquid wastes with a low content of solid phase (e.g., from flushing the installation before change of material) are treated with the Hydrosolve® process to extract the solvents. The remaining part is treated with the Isodry® process to recover the solid phase.

Solid wastes (loaded filter materials, sweepings, etc.) typically are treated by incineration. Depending on local structures, in some cases deposition of waste in authorized landfills can occur, as long as the limits for hazardous components according to the German Deponieverordnung (landfill regulation) are not exceeded.

Assembly Process
Solid wastes (dust from vacuum cleaner and filters, damaged parts, etc.) are typically treated by incineration. Depending on local structures, in some cases deposition of waste in authorized landfills

[43] Umweltbundesamt TEXTE 100/2017 „Potenziale und Maßnahmen zur Vermeidung und insbesondere zur hochwertigen Verwertung gefährlicher Abfälle – Anhang“ („Potential and measures to avoid and in particular to recycle hazardous waste in a high-quality manner“ – Appendix) Page 158, https://www.umweltbundesamt.de/publikationen/potenziale-massnahmen-zur-vermeidung-insbesondere

can occur, as long as the limits for hazardous components according to the German Deponieverordnung (landfill regulation) are not exceeded.

Service Life

When damaged parts like O-rings are exchanged, these are typically disposed of in the plastic waste fraction and are typically treated by incineration. Depending on local structures, in some cases deposition of waste in authorized landfills can occur, as long as the limits for hazardous components according to the German Deponieverordnung (landfill regulation) are not exceeded.

When an entire vehicle (commercial vehicle, passenger car) is disposed of, it is dismantled and depolluted. Typically, the fluoropolymer parts like O-rings are not separated during dismantling as they are very small. They are shredded with the remaining vehicle bodies. The treatment of automotive shredder residues (ASR) is one of the most important processes in ELV management. According to the Annual report on end-of-life vehicle recycling rates in Germany in 2020, the plastic material of the ASR makes up for 33-49% of the non-metal part of the ASR over the last ten years and is treated in an incinerator or as substitute fuel (e.g., in cement kiln).[44]

A scientific research report from Alexandrov et al. has shown that PTFE waste can be treated efficiently by incineration and no significant levels of PFAS are found in the emissions.[45]

Depending on national regulations, there is also some deposition of waste in landfills. However, according to the amendment to the EU POP Regulation No 1342/2014, landfilling of the shredder light fraction will not be allowed any more in the EU.

<u>Explanation on the approach taken for the ES:</u>

Environment:

The treatment of liquid wastes from the coating process will be assessed in one ECS and the treatment of solid wastes from the assembly process and service life will be assessed in a second ECS, as the treatment processes are entirely different.

Worker:

During waste treatment, workers could be exposed to PTFE particles, especially when handling dry waste. No data was available on worker exposure with PTFE particles. Considering that PTFE particles make up only for a small fraction of solid waste when being sorted and treated at a facility, we assume that the exposure with PTFE particles likely is below the occupational exposure limit for respirable dusts of 1.25 mg/m³ and that hence no health hazard exists for the workers.

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44 German Ministry for Environment and Consumer Protection: Annual report on end-of-life vehicle recycling rates in Germany in 2020 in accordance with Art. 7 Para. 2 of the End-of-Life Vehicle Directive 2000/53/EC, https://www.bmuv.de/download/jahresberichte-ueber-die-altfahrzeug-verwertungsquoten-in-deutschland

45 Krasimir Aleksandrov et al.: Waste incineration of Polytetrafluoroethylene (PTFE) to evaluate potential formation of per- and Poly-Fluorinated Alkyl Substances (PFAS) in flue gas, Chemosphere 226 (2019) 898 – 906.

7.3.5.1. Environmental contributing scenario 4-1: Liquid waste from the coating process

We have a total of [CONF.] kg/a of PTFE in liquid wastes from the coating processes.

Waste streams that have a very low solid content are treated with the Hydrosolve® process. This process is carried out in Germany by the company Rematec, a division of Chemische Werke Kluthe GmbH. The solid part is separated by filtering and then treated with the other liquid waste in the Isodry® process.

Waste streams that have a high solid content are treated with the Isodry® process. This process is also carried out in Germany by the company Rematec. The Isodry® process consists of the main process stages of paint sludge drying (vacuum paddle dryer and disc dryer, each with cooler and distillate receivers), bubble distillation, sieving station, conditioning device, pelletizing and powder processing system. At the end of the process, the dry material is a free-flowing material. The dried product, consisting of the energy-rich binder (approx. 25,000 kJ/kg), the fillers, the pigments or, in our case PTFE particles, is ground to defined grain sizes, pelletized and can be re-used.

No detailed information is available on the emissions of PTFE in dried product during the recycling process. As the material is pelletized as a last processing step, which results in very low dustiness, we assume [CONF.]% of loss, which would result in [CONF.] kg/a of emissions.

7.3.5.2. Environmental contributing scenario 4-2: Solid waste

We have solid waste at all stages of the process:

- Coating process: [CONF.] kg/a
- Assembly process: [CONF.]% of rejected parts + less than [CONF.]% of fluoropolymer filter residue, sweep, etc. = [CONF.] kg/a
- Service life: During or after the service life, all parts will become waste = [CONF.] kg/a

Most of the solid waste will be treated in an incinerator. The behaviour of PTFE in an incinerator was evaluated in a scientific research report from Alexandrov et al.[46] Here, PTFE was added to wood pellets at a rate of 0.3% (w/w) – a factor 10 more than typically found in a German municipal waste incinerator installation. The process was carried out at partial load (870 °C, residence time 4 seconds) and at full load (1020 °C, residence time 2.7 seconds). The flue gas was evaluated for 31 species of PFAS. The conclusion reads:

Of the 31 PFAS species studied only 11 were detected. When comparing the PFAS measurements, for the few compounds detected, no difference from baseline/control levels using paired t-testing for significance could be distinguished. Based on the PFAS levels detected and the randomness of the occurrence throughout the study, it is likely that the source of these signals is due to contamination of

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[46] Krasimir Aleksandrov et al.: Waste incineration of Polytetrafluoroethylene (PTFE) to evaluate potential formation of per- and Poly-Fluorinated Alkyl Substances (PFAS) in flue gas, Chemosphere 226 (2019) 898 – 906.

the samples from the environment. With procedural quantitation limits between 0.3 and 24 mg/Nm³ depending on compound and volume captured, these results give no significant evidence that the PFAS studied were created during the incineration of PTFE could be found. Therefore, it can be expected that municipal incineration of PTFE using BAT is not a significant source of studied PFAS and should be considered an acceptable form of waste treatment.

Some of the solid waste might also be disposed of in landfills. As fluoropolymer parts and particles like PTFE are very stable and resistant to degradation, we can expect them to remain in the landfill. Decomposition and leaching of PFAS from the landfills will, if at all, happen at a very low rate.

Conclusion on risk characterisation (minimisation of emission/exposure):

With waste treatment facilities being highly regulated and controlled in the EU, we can assume that emissions of PFAS from incinerators or landfills will be very low.

7.4. Risk characterisation related to combined exposure

Worker:
For all exposure scenarios, the exposure of workers can be assumed to be below the occupational limit for inhalable dusts. Therefore, we do not see a health risk for workers.

Environment:
The annual emissions of fluoropolymers into the environment were assessed as follows:

- **ES1 PTFE Spraying**: [CONF.] kg/year
- **ES2 Assembly Phase**: No relevant emissions into the environment
- **ES3 Service Life**: [CONF.] kg/year
- **ES4 Waste treatment**: [CONF.] kg/year

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interfacing government & business society

2 Place du Luxembourg | be-1050 Brussels
+32 2 735 82 30

[redacted]@eppa.com
www.eppa.com