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SOCIO-ECONOMIC ANALYSIS

Of the impacts of a potential restriction of per-and polyfluoroalkyl substances (PFAS) for industrial test & measurement type products

SUBSTANCE: Per- and polyfluoroalkyl substances (PFAS)
FROM: Test & Measurement Coalition (TMC)
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ABBREVIATIONS

AC/DC	Alternating Current & Direct Current.
ATBC	Acetyl Tributyl Citrate
B2B	Business-to-Business
CAGR	Compound Annual Growth Rate
CMO	Contract Manufacturing Organization
COTS	Commercial Off-The-Shelf
DEHA	Bis(2-ethylhexyl) adipate
DIDP	Diisodecyl Phthalate
DINP	Diisononyl Phthalate
EBIT	Earnings Before Interest and Taxes
ECHA	European Chemicals Agency
EEA	European Economic Area
EEE	Electrical and Electronic Equipment
EPA	Danish Environmental Protection Agency
EU	European Union
EUR	Euro (currency)
EV	Electric Vehicles
GC	Gas Chromatography
IoT	Internet of Things
KEMI	Swedish Chemical Agency
LC	Liquid Chromatography
MS	Mass Spectrometry
MSCA	Member State Competent Authority
NPV	Net Present Value
PBT	Persistent, Bioaccumulative and Toxic
PCA	Printed Circuit Assembly
PCB	Printed Circuit Board
PFAS	Per-and Polyfluoroalkyl Substances
PFBS	Perfluorobutanesulfonic Acid
PFPE	Perfluoropoly Ether
PFOA	Perfluorooctanoic Acid
PFOS	Perfluorooctanesulfonic Acid
PTFE	Polytetrafluoroethylene
R&D	Research and Development
RF	Radio Frequency
RoHS	Restriction of Hazardous Substances in Electrical and Electronic Equipment
SAGA	Suitable Alternatives Generally Available
SEA	Socio-Economic Analysis
SEAC	Committee for Socio-Economic Analysis
SME	Small and Medium Enterprise
SVHC	Substances of Very High Concern
T&M	Test & Measurement
TMC	Test & Measurement Coalition

TOTM	Tris(2-ethylhexyl) benzene-1,2,4-tricarboxylate
VPS	Vapor Phase Soldering
vPvB	Very Persistent and Very Bioaccumulative
WEEE	Waste from Electrical and Electronic Equipment

1. SUMMARY OF SOCIO-ECONOMIC ANALYSIS

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, as defined within the proposal, are a group of more than 10,000 synthetic (i.e., man-made) chemical substances and polymers 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.

1 https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/72301/term

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 industrial test and measurement equipment ('industrial monitoring and control instruments' as defined by the RoHS Directive[5]). It has been prepared by EPPA[6] at the request of the Test & Measurement Coalition (hereafter TMC) 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,[7] and it is based on information and data gathered from the industrial and professional test and measurement equipment manufacturers (TMC member companies).

Major T&M manufacturers of industrial and professional test and measurement equipment have participated in the survey. The market share covered by this survey represents more than 70% of the EEA market. The assessment is, therefore, highly representative and can serve as a basis for defining the anticipated socio-economic impacts resulting from a restriction of PFAS chemicals, and test and measurement equipment products that contain PFAS substances.

The participating companies indicated that the information reported in this SEA related to the proposed restriction are relevant for a wide portfolio of products in professional, scientific, laboratory, analytical, clinical and industrial applications. PFAS substances are widely used across the companies' portfolios.

In line with the **existing official guidance from ECHA on the preparation of the Socio-Economic Analysis,[8] 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 TMC members are expected to face from the ban of PFAS.**

In particular, this SEA covers the function of PFAS in industrial T&M equipment 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.

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5 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02011L0065-20200301

6 www.eppa.com

7 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

8 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

Main findings and considerations

This SEA-Analysis of Alternatives report concludes that:

- **A broad restriction of PFAS in test and measurement equipment will have disproportionate negative impacts on the European economy and society.**

- **The Test & Measurement Coalition supports the phase out of PFAS wherever this is practicable. In test and measurement equipment, this requires the availability of technically and economically viable alternatives which are to date not readily available. Finding alternatives is not guaranteed, especially for high performance applications, 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.**

- **The expected releases of PFAS from test and measurement equipment to the environment is expected to be negligible as PFAS containing components are predominantly used in closed systems (i.e., encapsulated within the equipment enclosure) and when they finally reach end-of-life they are processed by professional recyclers.**[9] Ultimately, test and measurement manufacturers are small consumers of PFAS materials as compared to other industries such as consumer goods, and their equipment have long expected lifecycle (up to 40 years).

- **The cost effectiveness ratio is calculated to be considerable, and the restriction for test and measurement sector highly disproportionate. The high socio-economic cost would only offset a minor contribution of the total PFAS input into the environment.**

The analysis reasonably justifies a time-unlimited derogation of PFAS chemicals used in industrial monitoring and control instruments and as analytical reference materials to avoid important shortages of these critical instruments. The identified instruments are essential to environmental monitoring, the good functioning of electronic communications networks, heavy industrial processes such as steel manufacturing, the testing of vehicles for compliance with emissions standards, and the monitoring of complex and critical systems of all types. This includes nearly all of the analytical equipment that is used to study and detect PFAS in the environment.

[9] RoHS's Category 9 Industrial equipment's contribution to the Waste Electrical and Electronic Equipment stream is very small (0.2% by weight of EU WEEE) with industrial WEEE being collected through B2B systems. Consequently, the environmental impact of industrial test and measurement products is negligible compared to the total electronics sector.

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

- TMC member companies are high-mix, low volume producers, managing portfolios of thousands of highly complex instruments. Each instrument is intentionally designed for high reliability and serviceability to support long lifespans and are made available on the market for at least a decade. Key applications of T&M equipment include products in the professional, scientific, laboratory, analytical, clinical and industrial applications. These are **sophisticated Electrical and Electronic Equipment (EEE) used in a diverse range of critical & strategic applications, such as cellular communications, wireless connectivity, aerospace and defence, automotive and energy**, and analytical equipment used in Research and Quality Control Laboratories (cf. Annex I for examples of T&M equipment types which are relevant for PFAS containing components).

- Test and measurement instruments (category 9 under the RoHS Directive) are extremely complex and intentionally designed exclusively for professional and industrial use, to meet high performance requirements in critical applications, and for long useful lifespans with high reliability. Products' lifetime is typically of 10 years on average and can be extended to 40 years with regular maintenance, repair, refurbishment, and recalibration. Even though T&M products are utilized in every EU Member State, the number of products placed on the EU market every year is very low. **The contribution to the stream of waste electrical and electronic equipment (WEEE) represents only 0.12% of total EEE.**

- Thanks to the wide variety of properties offered by PFAS, these materials are used in a variety of safety, electrical performance and mechanical applications within electronics, including semiconductor and cables uses. As such, **PFAS are used ubiquitously across the entire TMC member companies' portfolios (mainly in closed systems).** Approximately **86% of the T&M equipment** are expected to be impacted by a restriction.

- It is shown that due to the unique characteristics of PFAS materials, and based on the current state of the art, **there are no known alternatives that are currently available** for most of the PFAS uses. To date, the supply chain for the T&M coalition members (suppliers and producers PFAS based components) have not been able to identify technically suitable and economically viable alternatives to PFAS. As relatively low (downstream) consumers for these parts, and generally not direct customers for the actual suppliers of PFAS based commodities, T&M manufacturers have little influence over their complex and extended supply chain and the identification and development of PFAS free alternatives. The longer the value chain, the less influence TMC member companies have over it. Moreover, because of the complex high-mix low-volume nature of their portfolio, T&M manufacturers seldom have direct influence on their upstream article manufacturers.

- **Implementing a re-design requires long timelines and high costs to convert the entire T&M portfolios.** As downstream users for PFAS based commodities, substitution timelines are highly dependent on the ability of the supply chain to offer suitable alternatives. Timelines are difficult to predict and highly subject to uncertainty. **The whole process of identifying suitable alternatives could take decades**.

- From the general availability of compliant commodities, it is anticipated that a minimum of 10 to 15 years is needed for re-designing the T&M portfolio. This extends **the timing for substitution to > 25 years (minimum) to complete transition activities (i.e., implementing the substitution of PFAS based equipment) in order to retain industrial monitoring and control instruments on the EEA market and globally for products manufactured within the EEA**. The change would involve assembling alternative components into a test product, and evaluating the new product for functionality, hardware and software performance, reliability, EMC, safety, manufacturability, and a wide range of additional technical requirements (see Section 3.4 for a list of technical requirements for cable applications). These timelines are in line with the input provided by the Test & Measurement Coalition to the various consultations related to the RoHS Directive.

- **Overall, the entire supply chains of the participating companies require a lengthy transition period in case of restriction** as they need to resource alternative materials, validate the production of components with new materials (including re-tooling), and build the critical sub-components that are used to assemble and manufacture equipment on behalf of the TMC manufacturers.

- **A potential broad restriction would have disproportionate socio-economic implications on the EEA T&M equipment sector:** the **total impact of a PFAS restriction at the level of test and measurement industrial equipment manufacturers is monetized in the range of 4.3 billion EUR to 6.2 billion EUR** (conservative estimates in net losses), consisting of social impacts from unemployment in the EEA, substitution costs and economic impacts (EBIT loss) for T&M manufacturers in the EEA.

- **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, the PFAS restriction is expected to have wider impacts on the revenues of these companies, on innovation in Europe, competitiveness of the EEA markets in comparison to the rest of the world, and on the overall EU trade balance. For instance, there would be substantial impact to 5G and 6G deployment, the electrification of the transport sector (EV deployment), and to chip producers due to the non-availability of test equipment exclusively needed for these sectors.

2. AIMS AND SCOPE OF THE SEA

2.1 Purpose, scope and methodology of SEA

On 13 January 2023, the Competent Authorities (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 (CF3-) or methylene (-CF2-) 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.

[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 (SEA) section 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. Not only covering the use of PFAS in the T&M equipment, but also the importance of PFAS used at different stages of the manufacturing process.

A survey has been conducted by providing a detailed questionnaire to gather information and data from industrial and professional test and measurement equipment manufacturers likely to be affected by a PFAS restriction in the EEA. The participating companies have provided socio-economic data in view of extrapolating (based on a large total market share) the impacts for the whole market in a conservative approach, as further detailed below. Based on the estimated total EEA market for industrial and professional test and measurement equipment, the market share covered by this survey represents more than 70% of the EEA market.

The assessment has been conducted in accordance with the existing official guidance on SEA from ECHA under REACH Restrictions.[13] ECHA has developed a solid methodology for conducting socio-economic assessments in the context of the REACH Regulation, with the support of a dedicated committee (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 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)[14, 15]. 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).

13 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

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

15 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.[16] 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 participating companies are as close to real data or perception of future changes as possible.

2.2 Overview of industrial test and measurement instruments and their value chain

2.2.1 General overview

Industrial test and measurement instruments are very different from low mix, high-volume consumer products, which are frequently re-designed to follow consumer trends and are placed on the market for a limited duration. Industrial test and measurement are high-mix, low-volume producers, managing portfolios of thousands of highly complex instruments. Each instrument is intentionally designed for high reliability and serviceability to support long useful lifespans and are made available on the market for at least a decade after introduction. These instruments are designed: exclusively for professional and industrial use; to meet high performance requirements in critical applications; with up to 40 years of service life. Redesign happens on average every seven years (as compared to every 1.5 years or less for consumer products). Once test and measurement instruments are placed onto the market, they are typically accompanied with a long-term customer support arrangement to maintain reliability, including measurement accuracy and traceability.

Product portfolios are widely diversified, with TMC members each having typically 2,000 to 3,000 products currently made available on the market. These are highly complex electronic instruments such as signal generators, power analysers, oscilloscopes, spectrum analysers, digital multi-meters, electron microscopes, chemical and biological analysers, complex chromatography systems and their detectors, each having various necessary options and accessories. Each instrument can have a minimum of 2,000 and up to 40,000 parts; requiring a vast supply chain involving tens of thousands of suppliers and hundreds of thousands of unique components.

Considering the EEA added-value, test and measurement equipment is manufactured and sold in relatively small volumes (per instrument design) and placed on the global market. There is an added value in community level action, which guarantees more coherent and consistent rules across Europe. This regulatory action will disproportionally impact manufacture of products within the EEA while PFAS free components become commercially available globally. This will promote the transition of instrument manufacturing to regions outside the EEA.

The professional test and measurement products provide the tools for engineers to develop new solutions and businesses to bring them to market. These instruments are used in research, quality control and testing laboratories (including field testing) in universities, manufacturing, and clinical

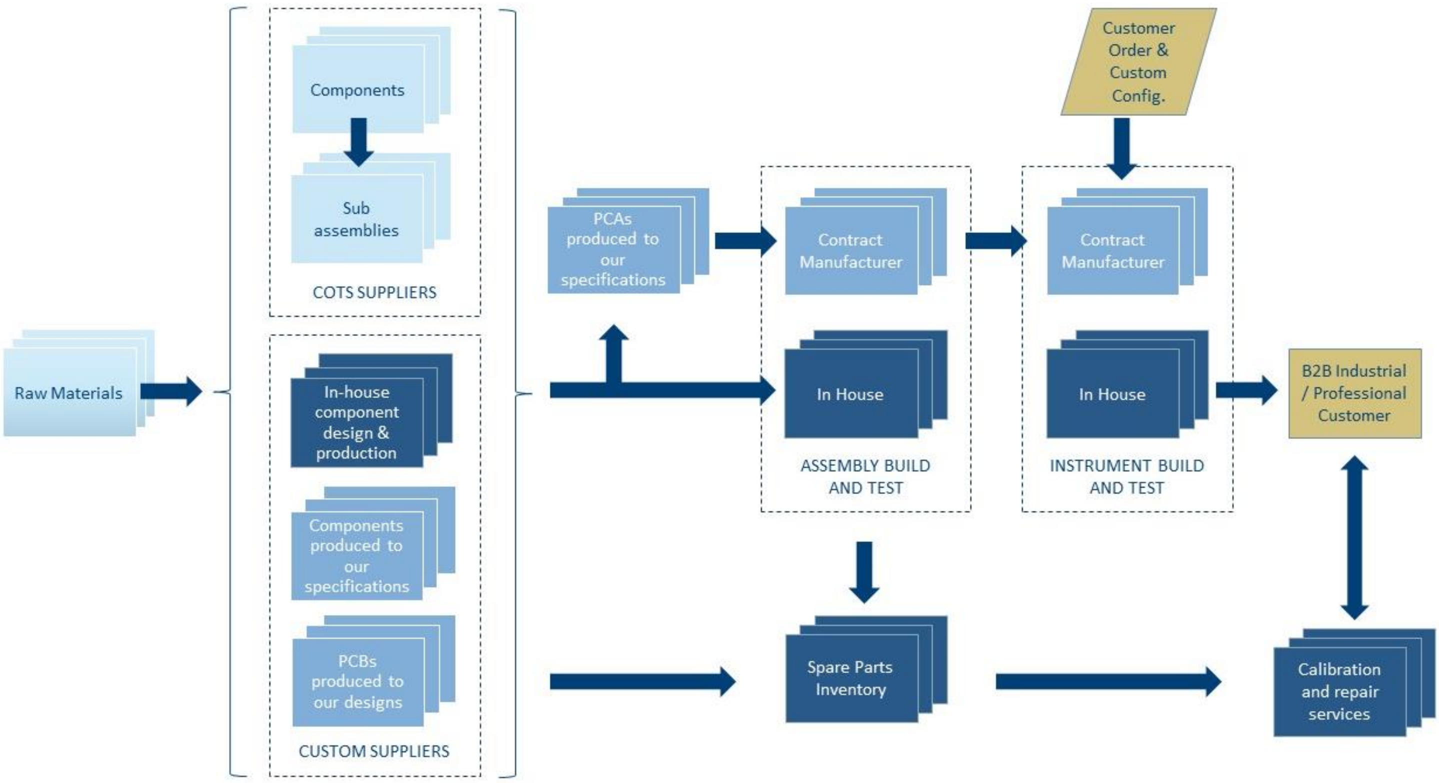
16 European Commission, 2021. Better Regulation Guidelines and Toolbox. https://commission.europa.eu/document/download/9c8d2189-8abd-4f29-84e9-abc843cc68e0_en?filename=br_toolbox-nov_2021_en.pdf

facilities and by governmental agencies for conformance verification and environmental testing. They are essential to the good functioning of electronic communications networks, heavy industrial processes such as steel manufacturing, the testing of vehicles for compliance with emissions standards, and the monitoring of complex and critical systems of all types. The nature of the tests and measurements made by these industrial products necessitates that the equipment itself is highly complex; with upwards of 40,000 components necessary to produce a single instrument. Even a relatively simple hand-held instrument incorporates significantly more components than a typical consumer product.

Historically, between 25 - 35% of the components used in test & measurement products are custom designed. The features of the TMC equipment necessitate the development and production of unique components that are not commercially made available on the open market and are typically made by sole, boutique suppliers. These components have their own development lifecycle and take years to bring into production. When these suppliers are unable to deliver compliant parts that meet current regulations in the EU (e.g., RoHS) and when alternative suppliers can't be identified or qualified, the product would be stopped from being sold into the EU.

2.2.2 Typical supply chain

The typical supply chain for test and measurement industrial type products is as follows:



- Raw materials are globally sourced for component production;

- Components, sub-assemblies, and Printed Circuit Boards (PCBs) are manufactured and sourced globally. These are either produced as Commercial Off-The-Shelf (COTS) products or custom made according to in-house Test & Measurement producers' designs and specifications;
- Printed Circuit Assemblies (PCAs) are produced and tested to Test & Measurement producers' designs and specifications;
- Assemblies are built and tested, either in-house or by contract manufacturers;
- In response to customer orders or for inventory, finished equipment is configured, built, and tested for global distribution;
- Equipment is supplied into the EU market either directly or through distributors to industrial and professional customers (B2B market);
- Spare parts are made available from the supply chain and utilised in the ongoing support (including servicing, calibration, repair, and refurbishment services) typically provided in-house by Test & Measurement producers.

More specifically, with regards to the typical supply chain related to PFAS based components, TMC member companies have several suppliers that provide components made using PFAS chemicals to be used and assembled in their products. These chemicals are expected to be found both in custom components and COTS.

Majority of suppliers for commodities (components, including cables) are based outside the EEA (e.g., Asia, North America). It is likely that in most cases, direct suppliers are also buying pre-formed fluoropolymers for assembling sub-components. For example, PTFE tape or insulated wire. It is very unlikely these direct suppliers are manufacturing fluoropolymers themselves.

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 T&M manufacturers procuring the PFAS material from the producers (upstream). In other instances, for example where PFAS materials are incorporated within an electronic component, the supply chain can be several stages long, involving PFAS materials suppliers, component manufacturers, and electronics manufacturers.

The longer the value chain, the less influence TMC member companies have over it. Moreover, because of the complex high-mix low-volume nature of their portfolio, T&M manufacturers seldom have direct influence on their upstream article manufacturers.

3. ANALYSIS OF ALTERNATIVES

This section provides a closer look at the **use, function, and requirements of PFAS chemicals used in industrial test and measurement equipment**. It covers the technical obstacles that prevent substitution via alternatives to PFAS, the typical timelines related to the re-design of T&M equipment, and the complex challenges related to a transition towards PFAS-free T&M equipment.

The analysis of alternatives concludes that **there are no appropriate chemical alternatives** that could substitute PFAS in industrial test and measurement equipment. **In the best-case scenario, substituting PFAS will easily require up to 25 years**, highly dependent on the time to find, if possible, a successful candidate (alternative) substance exists.

The following paragraphs describe the function and technological advantages of PFAS for all T&M uses. Unless clearly specified, all below information are sourced from participating companies' replies to the survey conducted in the context of this Socio-Economic Analysis.

3.1 Function and technical performance of PFAS in T&M equipment

3.1.1 Function of PFAS within T&M equipment

Per- and polyfluoroalkyl substances (PFAS) are extremely stable and non-reactive substances which are used in a wide range of consumer products and industrial applications because of their unique chemical and physical properties. Namely, the chemical and physical inertness, chemical and physical stability, low permeability to gasses, heat-resistance, low dielectric constant, surface tension reduction, flame retardancy, and low friction properties offered by PFAS materials make them excellent for industrial equipment applications, including T&M instruments.

PFAS, principally as fluoropolymer-incorporated articles, are used in the assembly of T&M equipment. Precisely, **PFAS are typically found in the final product as it is incorporated in the purchased articles used in the construction of T&M equipment and not intentionally added as part of the finished equipment manufacturing process.** PFAS may be used in non-fluoropolymer applications, but at the moment, manufacturers are not fully aware of such applications.

The most common fluoropolymer used is likely Polytetrafluoroethylene (PTFE), though other fluoropolymers are used, such as perfluoroalkoxy (PFA), fluorinated ethylene propylene (FEP), polyvinylidene fluoride (PVDF) and polychlorotrifluoroethylene (PCTFE) to name a few known examples.

These fluoropolymers can also be in different physical forms such as coatings, films, tapes, composites, solid mechanical pieces, air-infused, as further described below. Fluoropolymers are typically more expensive than other polymers and thus are generally only used when there is a substantial functional benefit over other polymers.

Based on available documentation, the main properties offered by PFAS chemicals in T&M instruments include:

- **Low dielectric constant**: PFAS-containing materials can have an extremely low dielectric absorption, which means they do not store as much electric charge per unit of volume. This property makes them useful in several electronic components used in low level/sensitive measurement instruments where low dielectric loss is important. This is critical for ensuring measurement accuracy of signals, where losses could result in signal amplitudes falling below the noise floor. Moreover, PFAS offer a stable dielectric constant. Consequently, capacitors utilizing PFAS, for example, are very time and temperature stable; cables with a PFAS dielectric have signal loss, phase and amplitude stability characteristics that are unmatched by other materials.
- **Electrical insulation**: PFAS-containing materials can provide excellent electrical insulation, which makes them useful in applications such as electrical wires and cables, circuit boards, and electronic coatings. For example, PTFE is used in safety applications due to its high insulation strength and Comparative Tracking Index (CTI). This is required in high voltage applications, where the properties are required for cable and connector insulation and physical barriers that enable T&M manufacturers to meet the requirements set out in the Low Voltage Directive (LVD) (2014/35/EU) and harmonised standards (i.e., safety standard EN 61010-1:2010+A1:2019 'Safety requirements for electrical equipment for measurement, control, and laboratory use General requirements').
- **High thermal stability**: PFAS are highly stable at high temperatures, which makes them useful in electronic components that generate heat, such as integrated circuits and power electronics.
- **Chemical resistance**: PFAS are highly resistant to a wide range of chemicals, including acids, bases, and solvents, which makes them useful in electronic components that are exposed to harsh environmental conditions, or require protection from chemical exposure.
- **Lubrication**: PFAS-containing lubricants can reduce friction and wear in moving parts of electronic devices, improving their performance and longevity.
- **Moisture resistance**. PFAS-containing coatings and films can provide low absorption of water, which is often present in PCAs wash during manufacturing, as well as moisture resistance to electronic devices, protecting them from corrosion and other forms of damage.[17]
- **Surface tension reduction**: PFAS-containing substances can reduce the surface tension of liquids, which makes them useful in cleaning process of semiconductor components allowing the liquid to penetrate and remove contaminants more effectively.
- **Anti-sticking properties**: PFAS-containing materials can prevent the adhesion of contaminants and other materials to electronic surfaces, which makes them useful in applications such as semiconductors and electronic packaging.
- **Flame retardancy**: Some PFAS-containing materials have flame retardant properties, which makes them useful in electronic devices and components that are exposed to sources of ignition.

[17] High resistance and low current applications require materials with low absorption of water.

- **Optical clarity**: Some PFAS-containing materials have excellent optical clarity, which makes them useful in applications such as displays, lenses, and optical fibres.

Thanks to this wide variety of properties offered by these materials, PFAS are used in a variety of safety, electrical performance, and mechanical applications within electronics, including semiconductor and cables production applications.

The use of PFAS materials within test and measurement equipment is still being investigated as TMC member companies are currently approaching their corresponding supply chain (i.e., several thousands of vendors from whom these companies source components and assemblies containing PFAS – and an untold number of sub-suppliers who are responsible for including the PFAS into their products) and are gathering the data as to where PFAS are used intentionally (i.e., it was called out in a drawing or purchase specification).

To date, TMC member companies believe that fluoropolymers are the most common use of PFAS in T&M products. These companies are not aware of intentional use of non-fluoropolymer PFAS. However, based on literature review, there is potential for non-fluoropolymer PFAS to be present.

The following are some examples known today but are not to be considered as a complete inventory of uses.

Electronics

PFAS are used in various stages of electronic equipment production, at all stages of the value chain, from the production of electronic components to the manufacturing of finished equipment.

Electronic components include resistors, semiconductors, as well as capacitors. Different PFAS are used in the **production of electronic components** such as resistors, semiconductors, and capacitors. For example, Perfluorooctanoic acid (PFOA) is used in manufacturing of PCBs and in the cleaning of silicon wafers used in the production of microchips. Perfluorooctanesulfonic acid (PFOS) is used in the production of LCD and LED displays and in the production of fire retardants used in electronics. Perfluorobutanesulfonic acid (PFBS) is used as a substitute of PFOS in the production of LCD and LED displays.

PFAS chemicals act as a binder in the production of ceramic capacitors. The latter are used to store and release electrical charge. As such, **ceramic capacitors are ubiquitous in every electronic equipment.**

PFAS are used in the manufacturing and are an essential component in electronic devices, and they are used to connect electronic components together. It can be used in the adhesives, coatings and inks used in the production of PCBs. PFPE is used as a heat transfer fluid for the Vapor Phase Soldering (VPS) process used to mount components to printed circuit boards. VPS is used to produce Printed Circuit Assemblies (PCAs) that have temperature sensitive components, or where there is a process or quality advantage. With VPS, the board will never get above the boiling point of the liquid.

Cables

PFAS are used in the cable industry for coating or additives to enhance certain properties of cables. As a cable jacket material, fluoropolymers offer a wide range of key properties, including hard yet flexible, low friction, abrasion- and wear-resistant, chemical resistant, high thermal deflection point, low outgassing. These properties are also important for the manufacturability of cables, as well as connectors.

Known examples include:

- **Fire resistance**: PFAS are used as additives in cables to improve their fire resistance. These PFAS substances help to prevent the cables from catching fire and spreading flames, which help to improve safety in buildings.
- **Durability**: PFAS coatings (PFPE, PFAE) can be used to reduce friction in cables that help to improve the performance of the cable, reduce wear and tear on the cable and also extend its lifespan.
- **Heat resistance**: perfluorinated compounds (PFCs) are used in cables to increase their heat resistance. Examples that are used in the production of high-temperature cables and wire insulation include perfluoroalkoxy (PFA),[18] perfluoropoly ether (PFPE),[19] fluorinated ethylene propylene (FEP),[20] Ethylene tetrafluoroethylene (ETFE),[21] perfluoromethylvinylether (PMVE),[22] and PTFE.

Moreover, fluoropolymers are known to be used for wire insulation of some standard wires, especially high voltage, including insulation of power transformers.

Semiconductor

PFAS are used in various stages of the semiconductor manufacturing process.[23] For example, PFAS are used to reduce friction and prevent sticking (e.g., with lubricants).

The low surface tension and non-sticking properties of PFPE make it an ideal solution as a lubricant in all those applications where extreme temperature, pressure and chemical resistance are required. For instance, PFPE based high-performance lubricants are commonly used in vacuum applications for semiconductor manufacturing.

18 Melting point is around 305 °C.

19 Melting point is around 290 °C.

20 Melting point is around 260 °C.

21 Melting point is around 260 °C.

22 Melting point is around 210 °C.

23 See, for example, Ober, C.K., Käfer, F. and Deng, J., 2022. Review of essential use of fluorochemicals in lithographic patterning and semiconductor processing. *Journal of Micro/Nanopatterning, Materials, and Metrology*, *21*(1), 010901-010901.

Furthermore, PFAS materials have good chemical resistance and can withstand high temperatures making them ideal for cleaning equipment that is exposed to harsh chemical conditions (cleaning agents). For example, PFOA removes organic and inorganic contaminants from the surface of semiconductor wafers, PFBS is used to remove photoresist residue from the semiconductor wafers, while other PFAS (e.g., PFOS, PFHpA, PFNA, PFHxS, PFDA) are used as a surfactant and wetting agent in cleaning agents for semiconductor industry.

Dielectric Materials

PFAS have low dielectric constants, thermal and mechanical stability, making them ideal for dielectric materials in performance cables, especially Radio Frequency (RF) cables (e.g., coaxial, triaxial, and semi-rigid cables),[24] in various electronic components such as capacitors, transistors, PCB laminates, connectors, adaptors, and attenuators, especially RF.

Some known examples of PFAS types used in dielectrics are:

- ✓ PTFE in RF cables, microwave antennas, transmission lines, stripline circuits and laminate material in high performance PCBs. Air-infused PTFE is frequently used in cable dielectric materials requiring low effective permittivity. This is important in applications requiring low phase delay such as Capacitance Voltage Unit (CVU) cables and/or low loss, phase and amplitude stability in high speed / high frequency applications (phase speed of > 60% the speed of light; for mm wave signals of 30 GHz to 110 GHz).
- ✓ Perfluorooctyl methacrylate (PFOMA) is used to create thin films of fluoropolymer dielectric materials; and is used in the photolithography process, which is crucial in the semiconductor manufacturing. It serves as a protective layer on etching process, provide insulation and preventing unwanted reactions or damage to the underlying layers. PFAE is used as additives in dielectric materials. It can improve the thermal and mechanical properties of the materials and reduce the amount of water absorption.
- ✓ PFCB and PFCH (perfluorohexane) are used to create high-performance dielectric materials for microelectronics and nano-electronics. PFCB based materials have low dielectric constants and high thermal stability, making them useful in high-speed electronic devices.

Fluoropolymers are currently the industry standard material for high frequency analogue signals because they offer stable, low dielectric constant over very broadband frequency range, and homogeneous electrical properties along different axes.

Coatings

PFAS chemicals (PFOA, PFBS, PFHxA, PFOS, PFPE, PFDA) are used as coatings for semiconductor equipment such as wafer carrier and pipes. Coatings are applied in semiconductor components to provide protection against corrosion, wear, and other forms of damage.

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24 Coaxial and triaxial cables are two variations of electrical cables designed to shield the conductors from electromagnetic radiation. In other words, they are designed to transmit electromagnetic energy in the radio frequency range.

PFAS are also used for safety insulator as physical barriers within the equipment. For example, PTFE coated tubing around wiring, or coated mechanical components needing low friction and wear resistance, such as cams in handle connections and the adjustable instrument feet.

3.1.2 Function/technological advantages of PFAS in the manufacturing process of T&M equipment

Besides the uses of PFAS within T&M equipment, PFAS materials are widely used in the manufacturing environment for their specific properties as this group of substance exhibits resistance and inertness against aggressive chemicals and mechanical impact and maintain these favourable material properties over a very wide temperature range (i.e., from -30 °C up to +200 °C).

For solid mechanical components, PTFE is used for its low friction and low wear applications for improved reliability. PFAS allow for safe and reliable equipment with higher frequency, and higher voltage test and measurement capabilities. Many of these technologies are not possible without known alternatives.

As such, manufacturers who participated to the survey indicated that it is likely that most of their fixed equipment for manufacturing, validation, and R&D would include fluoropolymers in the same general uses as T&M equipment (i.e., safety, electrical performance and, especially, mechanical applications). Nevertheless, they are not in a position to quantify the importance of these applications as they are downstream users for this equipment containing PFAS chemicals. As such, they rely on their upstream supply chain to identify and come up with alternatives.

Overall, the following are the key set of properties offered by PFAS that make it the standard material for manufacturing equipment:

- **Surface modification**: PFAS can modify the surface properties of electronic and semiconductor components, improving their performance and durability. In the manufacturing process, PFAS can be used to treat surfaces of materials such as metals, polymers, silicon, glass, and ceramics, enhancing their adhesion and surface energy, and improving their resistance to wear, corrosion, and fouling.
- **Wetting and spreading**: PFAS can reduce the surface tension of liquids, making them useful in electronic manufacturing processes. For example, Fluorinated wetting agents (e.g., PFPE, PFOS) are used to reduce the surface tension of liquid used in semiconductor industry resulting in more efficient processing by improving their wetting and spreading property.
- **Etching**: PFAS can be used as an etching surfactant in the semiconductor manufacturing process to aid in selectively removing layers of materials from the substrate, creating patterns and features with high precision and accuracy, especially for complex substrate geometries.

- **Cleaning**: PFAS-containing cleaning agents can remove organic contaminants and other residues from semiconductor components and surfaces without damaging them. The high solubility of PFAS in water and other solvents makes them effective in cleaning applications. (Fluoropolymers do not contain any additive and volatile oligomers. As such, they are free from contamination by solvent extraction and out-gas generation).
- **Photolithography**: PFAS can be used as a photoresist in the photolithography process, which is a critical step in the semiconductor manufacturing process. PFAS photoresists can create high-resolution patterns and structures on the substrate, enabling the production of microprocessors and other advanced semiconductor devices.

3.2 Challenges with substitution with alternatives

The participating companies indicated that due to the unique characteristics of PFAS materials, for most of the uses specified above, there are no known alternatives that are available.

For instance, in the case of PTFE, the most widespread PFAS material in T&M equipment, the are no known alternatives that have the same electrical and mechanical properties. Other potential substitutions are being managed by T&M manufacturers' supply chain and the chemical manufacturers who are supporting the supply chain.

There are some applications in which fluoropolymers can be substituted by alternate polymers, but not without technical trade-offs. For example, for some applications, there might be potential alternatives, such as Polyphenylene sulphide (PPS), Polyamide-imide (PAI), polyetherimide (PEI). These substances are not PFAS yet exhibit some of the mechanical properties of PTFE. Nevertheless, these alternatives could work for a limited number of applications within T&M equipment, while most of the uses, especially the high-performance applications, would likely not be covered.

In some applications, non-fluoropolymer wire insulation may be used as an insulator (not as a dielectric) if the thickness was increased, but this would impact its flexibility and thus reliability. Since fluoropolymers are generally more expensive than other polymers, fluoropolymers would not be used unless there was a functional/technical advantage.

Without access to PFAS, it will not be possible to produce equipment reliant upon its dielectric properties in the production of high-frequency, high-speed, signal transmission applications. There is no commercial availability of new PFAS-free commodities that currently are known to be incorporated into T&M equipment.

In general, **it must be noted that industrial test and measurement equipment manufacturers are positioned downstream in the context of a global and complex supply chain that involves a large number of players distributed globally**. Particularly because of the complex high-mix low-volume nature of their portfolios, it means that they have little influence on the upstream article manufacturer to identify a technically viable alternative. Thus, T&M manufacturers will need to work with each component manufacturer to investigate if an alternative exists, and then test and validate any of these alternatives to assess product performance and long-term reliability.

According to some key suppliers of PFAS containing commodities contacted by T&M manufacturers, the proposed restriction risks to significantly undermine their ability to keep supplying these items. They highlighted, once again, that there is no known alternative material that will provide the same performance and so substitution is currently impossible.

To the best of the knowledge of T&M manufacturers, where substitution is practicable, large suppliers are already working to provide alternative items that are PFAS-free. Nevertheless, small (or unaware) suppliers are unable to influence the material and chemical manufacturers to find unique solutions for their niche intermediate products, requiring T&M manufacturers to search for and set-up alternative vendors and supply chains.

Case example: Essential Use of PFAS within Analytical Chemistry Equipment

Analytical chemistry instrumentation plays an essential role in society. Fundamentally, analytical chemistry is understanding what chemicals are within a material, be that a solid, liquid or gas. This has high impact and varied applications from drug testing in sport, environmental monitoring of air and water, forensic science and carbon dating. Without analytical chemistry, industry professionals would not be able to control the purity when manufacturing medicines or to test the water we drink.

Chromatography

Chromatography is the process of separating components within a mixture typically coupled with a detection system to identify or characterize the components. This can be done in the liquid phase – Liquid Chromatography (LC) or gas phase – Gas Chromatography (GC). The chemical analysis of the separated components can be done with a variety of detection system. In more complex setups, chromatography can be combined with Mass Spectrometry (MS) to get a highly detailed analysis of the chemical makeup of the sample. Mass Spectrometry determines an accurate mass of the molecules within a sample by ionization and then acceleration with a deflection of the molecules to separate out the masses. As an example, **Liquid Chromatography/Gas Chromatography instruments are highly effective tools for measuring the presence and quantity of PFAS within drinking water. In this context, the current PFAS restriction proposal could jeopardize its own implementability and enforceability, as described in Annex E.4 of the Annex XV report, because the tools for measuring the presence and quantity of PFAS rely themselves on PFAS.**[25]

Analytical chromatography helps scientists ensure the safety, quality, and purity of food, air, water, and pharmaceuticals; determine the composition and consistency of fuels and chemicals; and test for controlled substances in criminal investigations and sporting competitions.

25 See Annex E.4 of the Annex XV report for details: https://echa.europa.eu/documents/10162/57812f19-8c98-ee67-b70f-6e8a51fe77e5

Chromatography systems are generically comprised of complex components such as auto-samplers, pumps and flow controllers, sample-splitters, temperature controls, chromatography media, detection systems, and controllers/data loggers. Given the physico-chemical nature of the samples and mobile phases and the environmental conditions within the chromatography system (e.g., super heating within a GC), chemical compatibility with the fluid/gas handling components is critical. The criticality extends to both the analysis itself but to the safety of the instrument operation.

There is no one property of PFAS suitable for all chromatographic systems. Liquid chromatography requires the use of aggressive solvents (which depend on the customer application), gas chromatography utilises chemicals at high temperature, and mass spectrometers require high voltage parts. Currently there are no alternative materials that could replace PFAS for these components.

The required properties (many required simultaneously) of materials for these parts are:

- High chemical resistance
- High temperature resistance
- Flexibility
- Chemical stability
- High dielectric constant

Within combined LC/GC instruments, it is typically the 'wet path' that is the most critical in regards to material compatibility. This is part of the instrument where the samples and chemicals flow (both in liquid and gas phase). In the GC process, the samples flow through the chromatography resin at temperatures up to 450 °C, using highly corrosive chemicals. All of the 'wet path' components must be temperature and chemically compatible.

In Liquid Chromatography, the wet path is pressurised up to 1,300 atmospheric pressures, and sealed to the required solvents. Although this wet path often utilises stainless steel, there are requirements for seals, flexible components, gaskets which require a flexible material. PFAS are typically used in O-rings, pneumatic control systems, detector modules, valves, seals, and tubing. As an example, PFAS materials are commonly used in tubing for gas flow, as these materials are resistant to chemicals including Hydrogen Fluoride (HF), and non-PFAS materials such as PVC cannot be used.

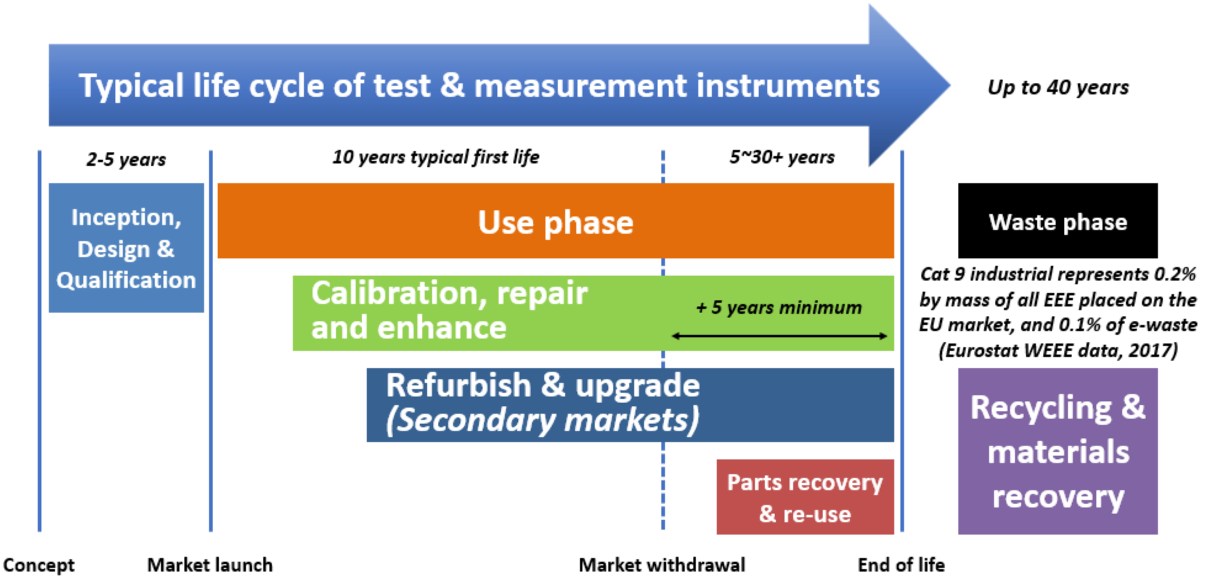
Figure 1: A typical high-performance LC/MS system for laboratory analysis. Samples and solvents are drawn from the top of the instrument, degassed, pressurized, and separated prior to analysis within the Mass Spectrometer.

LC machines that are coupled to MS instruments have further requirements for PFAS materials. The sample from the LC machine is vaporised and ionised and then passed through a capillary into the mass spectrometer. The mass spectrometer requires high voltage to accelerate the ions within the magnetic field for deflection and detection. The high voltage terminals and cables require a high dielectric constant material to avoid voltage breakdown while minimising bulk around the cables and electrodes. PFAS materials such as PTFE provide an extremely high dielectric together with their chemical and temperature resistance.

There are many other parts within these types of systems that require the use of PFAS materials. Where possible, lower specification, non-PFAS, materials are used, however PFAS remains the only option in places where a combination of unique properties are required.

3.3 Typical Industrial Test and Measurement End-to-End Life Cycle

The market sectors addressed by industrial test and measurement equipment can in some cases require that the instruments can be maintained in use for decades. The end-to-end lifecycle model below helps to illustrate how the members contribute to the circular economy by assuring the materials they consume to produce the equipment are kept in use for as long as possible.



The nature of industrial test and measurement instrument applications demand highly accurate and reproducible results throughout their life. With a typical first use of ten years and a total life of up to 40 years, great care is taken during the design and qualification phases to ensure that the stringent performance and reliability requirements are met and must incorporate design for serviceability. This provides a continuous supply chain of equipment for refurbishment with extended life through resale providing great economic and environmental benefit. Whilst the instruments are designed for long-term reliability, failures do occur during such an extended period of use requiring ability to service and replace parts. After market withdrawal, equipment is normally supported for a minimum of five years. Moreover, refurbishing and reselling on the secondary market are crucial in this sector and often account for 4–5% of producer turnover for test and measurement manufacturers.

Due to the costs, reliability, and unique applications of T&M equipment, many customers do not dispose of the equipment, but instead keep it for use at a later date or place it on the secondary market. As a result, test and measurement equipment typically enters the waste stream many decades after it is placed on the EU market. RoHS's Category 9 Industrial equipment's contribution to the Waste Electrical and Electronic Equipment stream is very small (0.12% by weight of EU WEEE) with industrial WEEE being collected through B2B systems. Consequently, the environmental impact of industrial test and measurement products is negligible compared to the total electronics sector.

3.4 Substitution timelines and costs

T&M manufacturers are heavily reliant on their suppliers to identify suitable alternatives (or combination thereof) and transition to PFAS-free alternatives (if feasible).

Participating companies highlighted the risk that component manufacturers will not undertake a costly transition for low revenue components, or in case their custom base is mainly outside the EEA. In these cases, they might decide to give up the EEA, and focus on the global market.

Given the widespread use of PFAS within test and measurement industrial and professional equipment, the economically favourable profile of PFAS compared to any other potential alternative material in the market, and the custom-made nature of the supply chain's replacement, one of the most pertinent issues in terms of substitution would appear to be that of cost and timelines.

As outlined in the previous sections, TMC member companies do not manufacture the majority of parts incorporated into test and measurement equipment but purchase most parts from the respective suppliers. **Implementing a re-design requires lengthy timelines and high costs to convert the entire portfolio.**

As mentioned previously, most products rely on various PFAS-based components. Changing out these sub-assemblies requires complex instrument re-design and a full suite of product validation and testing substantially increasing the cost and timeline of implementation, especially as there may be software implications.

Technical requirements

There are several technical requirements that components need to meet to be suitable for the T&M applications. For the sake of simplification, here we report a non-comprehensive list of technical requirements (i.e., relevant standards and regulations) that apply to cables.

When cables are incorporated into complex assemblies that become critical components in T&M equipment, the standards and regulations are specific to those sub-components.

For example, a switch mode power supplies would need to have been evaluated to EN 62368-1 ('*Audio/video, information, and communication technology equipment – Part 1: Safety requirements*') or else fully evaluated to the base standard for equipment used in T&M industry segment. The base standard for TMC equipment is EN 61010-1 '*Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements*'.

As regards the technical requirements for high voltage or high temperature jacketed cables, insulating wraps and connectors, there are several normative standards, including but not limited to:

- ✓ IEC 60384-X. Fixed capacitors for use in electronic equipment. All applicable parts – there are 92 sections.
- ✓ IEC 62133-2. Secondary cells and batteries containing alkaline or other non-acide electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications – Part 2: Lithium systems
- ✓ IEC 60332-1-2. Tests on electric and optical fibre cables under fire conditions – Part 1-2: Test for vertical flame propagation for a single insulated wire or cable – Procedure for 1 kW premixed flame.
- ✓ IEC 60332-2-2. Tests on electric and optical fibre cables under fire conditions – Part 2-2: Test for vertical flame propagation for a single small, insulated wire or cable – Procedure for diffusion flame.

- ✓ IEC 60664-3. Insulation coordination for equipment within low-voltage systems – Part 3: Use of coating, potting, or moulding for protection against pollution.
- ✓ IEC 60664-4. Insulation coordination for equipment within low-voltage systems – Part 4: Consideration of high-frequency stress.
- ✓ IEC 60695-X. Fire hazard testing – All applicable parts for assessing the fire hazard of electrotechnical products. (There are 69 sections of this standard.)

This non-exhaustive list applies to the components and wires that T&M manufacturers purchase for use in their equipment.

T&M manufacturers must wait for these vendors to evaluate and certify their sub-components that they are relying upon for application in their equipment. Only once the revised chemistry within the wire jacket or connector material is completed and their certification has been uplifted, T&M manufacturers will be able to assess whether the alternate part would meet the product evaluation requirements.

The above referenced standards are considered type A standards, i.e., basic safety standards that can be used by a variety of type B (i.e., Group safety standards) or type C (product specific safety standards). As such, they articulate specific evaluation requirements (e.g., voltage isolation, or flame propagation) that need to be evaluated by the Group or Product safety standard requirements to determine its suitability. It is not simply a matter of component substitution once the PFAS free components has had the certification of the component itself uplifted.

The TMC members utilize a Group safety standard (EN/IEC 61010-1) and the evaluation of the end product to meet those group safety requirements will include, but are not limited to the following parameters:

- **Primary requirements based on needed ratings derived from worst case normal and single fault tests.**
  - Temperature rating (clause 10)
    - Vicat ball pressure test for plastic in direct support of live parts.
  - Voltage Isolation requirements (clause 6)
    - Re-validate the hygroscopic nature of the wire jacket for isolation in T&M application.
  - Spread of fire (clause 9)
    - Qualify the flammability of the revised plastic enclosure at the specific thickness and pigment used in T&M products.

- **Secondary requirements**
  - Moving parts (clause 7.3)
    - For any wires subject to articulation within T&M product (e.g., across a door or articulating arm), repeat the reliability study for the expected life of the product.
  - Resistance to mechanical stress (clause 8)

    - For PVC tubing that is used to contain fluidic pressure (clause 11.7) leakage and rupture at high pressure must be repeated.
  - For equipment for outdoor use
    - Repeat tests for UV durability and IP (ingress protection).

- **Other standards not linked to EN 61010-1**
  - EMC & Wireless requirements
    - For high frequency applications, as the dielectric properties change for a wire jacket repeat testing for EMC or intentional transmitters must be repeated.

The performance of test and measurement equipment is dependent upon the technical performance of cables connecting each of the printed circuit assemblies (PCAs) together in the signal path. Unlike simple AC Mains or DC secondary connections that must meet the product safety obligations outlined above but are only required to provide a galvanic contact; signal cables have a multitude of additional technical specifications covering mechanical, electrical, environment and application-specific parameters. These parameters are matched to each signal path, and tightly controlled to assure the finished equipment consistently can perform to T&M manufacturers' published specifications, over the lifetime of the product. The overall performance of the cables is dependent on both the materials and physical construction: any changes in either requires a complete recharacterization of cable's performance. Any change to the cable's published specifications will require the complete characterisation all finished equipment where that cable type is utilized.[26]

Individual instruments can have up to 50 m of signal cabling internal to the equipment, covering different signal constraints, construction, and materials (see Figure 2).

Cable suppliers provide a range of offerings for test and measurement applications that provide choices for producers to optimise design choices.[27]

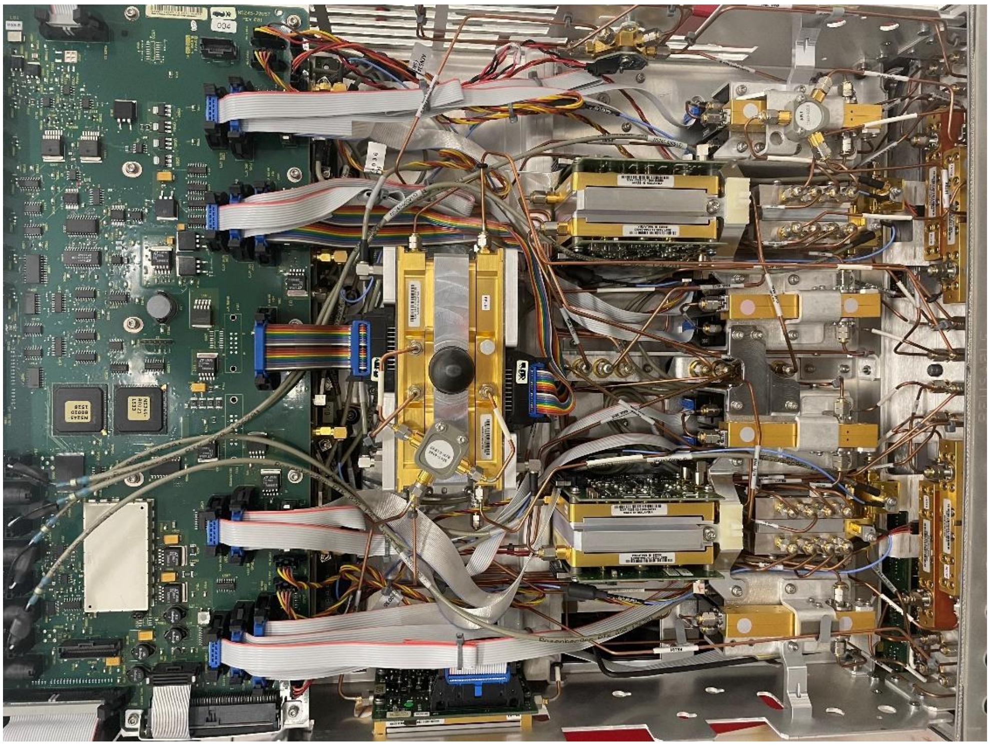
Any change in the technical performance of these signal cables must be validated against each test and measurement products original design requirements before testing and product validation can be initiated.

[26] An example of the technical nature of such cables and the complexity of the specifications under each of these four parameters is illustrated in the following datasheet: **GORE® PHASEFLEX® Microwave/RF Test Assemblies**. Datasheet: https://www.gore.com/system/files/2022-05/GORE_PHASEFLEX_Datasheet_GMCA-0025-R7-DAT-US-MAR22_web.pdf.

[27] This is illustrated by the following examples:

- GORE® Microwave/RF Assemblies, General Purpose Test & Interconnect
- GORE® PHASEFLEX® Microwave/RF Test Assemblies
- GORE® PHASEFLEX® Microwave/RF Test Assemblies, 110 GHz

Figure 2. Example of cabling internal to equipment, courtesy of Keysight Technologies, Inc.



Substitution milestones

Provided alternatives are available, substitution will take years. There are a number of activities that would need to be performed by manufacturers to substitute PFAS in T&M equipment. These activities include:

- ✓ Identifying all PFAS in T&M products and supply chain through supplier querying and testing
- ✓ Researching and testing the functional feasibility of alternatives
- ✓ Re-designing all T&M products in companies' portfolios
- ✓ Re-certifying for safety, EMC, and Environmental Compliance
- ✓ Re-qualifying for reliability, and Manufacturability
- ✓ Updating manufacturing processes before implementing design changes

<u>These substitution activities cannot be done all at once but need to be staged, and given the breadth of the portfolios, can take decades to fully adopt and commercialize. From the general availability of compliant commodities, it is anticipated that between 10 to 15 years are needed for re-designing (i.e., implementing the substitution of PFAS based equipment) and completing transition activities and to retain most products on the EEA market.</u>

These are the timelines once an alternative has been identified. The time to find alternatives is unpredictable and will vary greatly. As mentioned above, these timelines are highly dependent on the ability of chemical manufacturers to design and supply safer alternatives with equivalent performances and upon the article supply chain to adopt, requalify, re-certify their manufacturing of their raw materials to the T&M manufacturers. As downstream users, **TMC member companies will depend heavily on the capabilities of their suppliers to offer suitable alternatives**, in the context of a complex and global supply chain.

Based on previous experiences under RoHS, the importance of PFAS, and the magnitude of the substitution, the whole process of finding a suitable alternative is expected to take decades. Overall, the total timeframe for a replacement of PFAS in monitoring and control instruments could easily take more than 25 years.

These timelines are in line with the input provided by the Test & Measurement Coalition to the various consultations related to the RoHS Directive, which is a major piece of legislation impacting product design of electrical and electronic equipment. Since 2005, the Test & Measurement Coalition has been actively engaged with the European Commission and its consultants, providing data on the time required to substitute the substances restricted under RoHS as well as the exemptions needed. The TMC has authored the initial application for renewal of Annex III for category 9 industrial and has submitted in January 2023 ten exemption renewal applications, providing substantial amount of data, including socio-economic analysis.

These timelines are founded on the following findings and ex post analysis of the impacts related to RoHS compliance:

- Due to the sector's specificities, substitution is very challenging as test and measurement instruments must guarantee very high long-term reliability criteria during an extended lifetime. This is evidenced by the transition work that has been done, and is still happening, in the context of RoHS exemptions.
- TMC members estimation is that **about 86% of the product portfolio of TMC member companies would be impacted by the restriction of PFAS.** For comparison, the compliance with the RoHS Directive restriction of 6 substances required the redesign of 60% of the product portfolio. The redesign of TMC members' portfolio to comply with the initial six restricted substances took 12 years to be RoHS-compliant. In several cases, compliance had to rely upon the numerous exemptions afforded in Annex III and IV of the Directive.
- A case in point are all 6(x) type exemptions under RoHS. In January 2023, TMC member companies applied for the renewal of the Annex III exemptions 6(a) and 6(b) where T&M manufacturers developed a well-structured substitution plan (see Annex II).

  The substitution plan presumed that component manufacturers come forward with a technology that would substitute lead in all parts using these exemptions. Therefore, in the application for renewal it was highlighted that, as and when compliant parts become available, they will be designed into new equipment that is developed in a cycle of 7-10 years depending on the type of Category 9 equipment concerned.

The conclusion on the suitability and availability of alternatives was that, whilst substitution is possible, it requires time. Time that is likely to exceed the redesign cycle of equipment which as of today are already being developed without use of the exemption. Therefore, T&M manufacturers expressed the continued need for maintaining the exemption for Category 9 to allow the phasing out of the older equipment for newly designed ones which are lead-free.

Regarding the costs, the main substitution costs for test and measurement equipment manufacturers would be associated with the engineering re-design and qualification efforts. Products would be prioritized for conversion by feasibility and per product EEA revenue. For those products with feasible substitution, there likely would be a portfolio cut-off where lower revenue products would not convert due to insignificant business case. Manufacturers may also decide not to convert products that are within a few years of obsolescence. Despite these practical considerations, without sufficient time to comply and naturally replace the PFAS based equipment through their product re-design cycle, T&M manufacturers estimated a major portfolio re-design effort.

TMC member companies have indicated that substitution of PFAS containing equipment would cost at least 360 to 720 million EUR (one-off costs, including labour). This also includes incremental investment necessary to characterize potential substitutes, and where practicable, tailor production processes to assure existing product's published specifications can be maintained.

By making use of the market share of about 70% covered in this SEA, we can extrapolate a **total switching cost in the range of 514 million EUR and to 1 billion EUR** for all manufacturers of test and measurement equipment industrial products in the EEA.

Unless equivalent, less harmful, alternatives are identified, the T&M equipment will be adversely affected by the solvents and chemicals used. This will lead to higher maintenance costs to replace components, shorter lifetime of components and lower reliability. Without PFAS materials, seals, gaskets etc are likely to fail prematurely, resulting in higher downtime of equipment.

3.5 Overall conclusion on suitability and availability of alternatives

Thanks to the wide variety of properties offered by PFAS, these materials are used in a variety of safety, electrical performance, and mechanical applications within electronics, including semiconductor and cables uses.

Based on available documentation and literature review, PFAS materials offer a wide range of characteristics which make them the preferred solution for T&M equipment. The list of technological advantages of PFAS is extensive and includes: non-reactive, stable, low surface tension, non-sticking, high purity, excellent dielectric performance for low signal loss, low off-gassing, ensuring vacuum environment, low dissipation factor, ultra-thin, hydrophobic and oleophobic properties, chemical resistance (compatibility and no leaching), high volume/surface resistivity, high dielectric breakdown strength, piezoelectric and pyroelectric properties, dipoles, optically clear, low loss insulation, flame resistance, thermal stability, low refractive indices, good heat conductivity, and good evaporative cooling.

The use of PFAS materials within test and measurement equipment is still being investigated as TMC member companies are currently approaching their extended supply chain and gathering the data as to where PFAS are used.

Fluoropolymers (especially PTFE) are the most common use of PFAS in T&M products. The participating companies indicated that due to the unique characteristics of PFAS materials, for most of the uses specified above, there are no known alternatives that are currently available. Other potential substitutions are being managed by T&M manufacturers' supply chain.

Until there are commercially available alternatives for the specified PFAS articles, the EEE that use PFAS-containing articles will be removed from the EEA market, potentially permanently. **TMC member companies will depend heavily on the capabilities of their suppliers to offer suitable alternatives**, in the context of a complex and global supply chain.

It is anticipated that re-designing and completing transition activities would easily require more than 25 years, including the time to find technically suitable alternatives and to retain products on the EEA market with total substitution costs estimated in the range of 514 million EUR to 1 billion EUR.

Equipment will only be released to customers once it has been proven that substitution from a PFAS substance does not negatively impact product performance to its published specifications. Precisely, TMC member companies will only incorporate alternative components (to those used today that contain PFAS) where they have been evaluated to meet their performance and reliability needs. **If substitution of components is not available, or forced within a compressed timeframe that does not allow sufficient time to complete before the restriction is enforced, T&M products will have to be removed from the EEA market but continued to be offered to the rest of the world.**

4. ANALYSIS OF IMPACTS

4.1 Human health and environmental impacts

Test and measurement manufacturers are small consumers of PFAS materials as compared to consumer industries. Overall, on the basis of the information gathered in the context of the survey, less than 8,700 kg of PFAS enter the EEA market every year within test & measurement instruments.

As stated above, fluoropolymers are the predominantly used PFAS in the T&M products. It should be noted that fluoropolymers are distinctly different from other polymeric and non-polymeric PFAS due to their thermal, chemical, photochemical, hydrolytic, oxidative and biological stability. They have very high molecular weights and are not subject to long-range transport[28]. Based on available studies, the molecules of these fluoropolymers are believed to be too large to cross cell membranes and are therefore believed to pose less risk to human and ecological health relative to non-polymer PFAS.[29]

Contrary to other PFAS, fluoropolymers are considered to be non-mobile in the environment, not bio-accumulative and unable to bioconcentrate. Stability studies reported reveal fluoropolymer stability in terms of light, hydrolysis, heat, oxidation, and biodegradation.[30]

Despite that for particular PFAS (like PFOS and PFOA) severe health consequences have been disclosed by toxicological and epidemiological studies, potential risks of polymers to human health are still under estimation, while certain studies point that polymeric PFASs are not toxic or exhibit low toxicity (Ebnesajjad 2015, Sina Ebnesajjad 2017, PlasticsEurope, Fluoropolymers Product Group (FPG) 2021, Korzeniowski, et al. 2022). (e.g., PTFE, PVDF, FEP, FKM and PFA show that their polymer composition, molecular weight, ionic character, structural similarities, ratio of residual monomers, solubility and Kow, particles size and stability meet the PLC criteria.[31, 32]

The participating companies have reported that **no releases of PFAS to the environment are likely during either T&M equipment production or use phases of the concerned products**. Under normal

[28] Henry, B.J., Carlin, J.P., Hammerschmidt, J.A., Buck, R.C., Buxton, L.W., Fiedler, H., Seed, J. and Hernandez, O., 2018. A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers. *Integrated Environmental Assessment and Management*, *14*(3), 316-334. https://doi.org/10.1002/ieam.4035

[29] Korzeniowski, S.H., Buck, R.C., Newkold, R.M., kassmi, A.E., Laganis, E., Matsuoka, Y., Dinelli, B., Beauchet, S., Adamsky, F., Weilandt, K. and Soni, V.K., 2023. A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: fluoroplastics and fluoroelastomers. *Integrated Environmental Assessment and Management*, *19*(2), 326-354. https://doi.org/10.1002/ieam.4646

[30] Korzeniowski, S.H., Buck, R.C., Newkold, R.M., kassmi, A.E., Laganis, E., Matsuoka, Y., Dinelli, B., Beauchet, S., Adamsky, F., Weilandt, K. and Soni, V.K., 2023. A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: fluoroplastics and fluoroelastomers. *Integrated Environmental Assessment and Management*, *19*(2), 326-354. https://doi.org/10.1002/ieam.4646

[31] Henry, B.J., Carlin, J.P., Hammerschmidt, J.A., Buck, R.C., Buxton, L.W., Fiedler, H., Seed, J. and Hernandez, O., 2018. A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers. *Integrated Environmental Assessment and Management*, *14*(3), 316-334. https://doi.org/10.1002/ieam.4035

[32] Korzeniowski, S.H., Buck, R.C., Newkold, R.M., kassmi, A.E., Laganis, E., Matsuoka, Y., Dinelli, B., Beauchet, S., Adamsky, F., Weilandt, K. and Soni, V.K., 2023. A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: fluoroplastics and fluoroelastomers. *Integrated Environmental Assessment and Management*, *19*(2), 326-354. https://doi.org/10.1002/ieam.4646

conditions of equipment use, PFAS are not released through the use of the product because PFAS containing components/parts are predominately encapsulated within the equipment enclosure and will neither be touched nor released to the environment. Furthermore, due to the precision nature of these high-performance instruments, their internal components are handled infrequently and with care.

Moreover, T&M products have an expected lifetime of 10+ years, with many products being used for up to 40 years. Therefore, within T&M products, a ban will have no impact on PFAS materials being released into the environment in the short term since they would not end up in the waste stream. As this equipment is sold B2B for professional and industrial use only, equipment that finally reaches end of life will be appropriately processed by professional recyclers who are obligated to have suitable controls to avoid any environmental releases.

TMC member companies have only indicated a minor risk for substances to be released to the environment during the manufacture of the components. These are not produced by TMC members. Thus, data are not available, however the estimate is expected to be bounded by the total use of the substance (i.e., release to the environment is expected to be less than the mass of substance incorporated into the components). In this way, the estimate would be a maximum of 8,700 kg/year.

Ultimately, the process of by-products generated during waste treatment of articles that contain fluoropolymers via incineration is not well understood and no clear evidence of PFAS emission has been found (Lohmann et al., 2020).[33] Furthermore, fluoropolymers at their end of life when incinerated under representative European municipal incinerators conditions do not generate any measurable levels of PFAS emissions and therefore pose no risk to human health and the environment.[34]

4.2 Economic impacts

The sections below provide a general overview of the social and economic impacts, considering business impacts (i.e., at different stages of the value chain), market impacts (i.e., on the product market), substitution costs, and broader macroeconomic consequences resulting from a potential restriction of the PFAS used in industrial test and measurement instruments.

4.2.1 Business impacts on manufacturers

[33] PlasticsEurope, Fluoropolymers Product Group (FPG), *Regulatory Management Option Analysis (RMOA) for fluoropolymers (FPs)* (2021) - https://fluoropolymers.plasticseurope.org/application/files/5416/5104/8333/20211104_FP_RMOA_Final_3.pdf

[34] Hans-Joachim Gehrmann, Andrei Bologa, Krasimir Aleksandrov, Philipp Bergdolt, Philip Taylor, Michael Schlipf, Bruno Ameduri, Priyanga Gunasekar, Deepak Kapoor, *Pilot-Scale Fluoropolymer Incineration Study: Thermal Treatment of a Mixture of Fluoropolymers under Representative European Municipal Waste Combustor Conditions*

A survey of T&M Coalition members was utilized in the preparation of this report. **Major TMC manufacturers of test and measurement industrial equipment contributed to the data**. The participating companies are among the biggest producers in the EEA test and measurement equipment market. The market share covered by this survey is more than 70% of the whole EEA test and measurement equipment market. The assessment is, therefore, highly representative. This large market share can be used to obtain reliable estimates for the EEA market via extrapolation, as detailed below for the assessment of the economic impacts.

Surveyed companies do not produce PFAS containing components, but these are, instead, procured in the context of an extended value chain, as illustrated in Section 2.2.2. Accordingly, assuming PFAS materials can be found in all T&M equipment, potentially all products manufactured by TMC member companies 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).

As mentioned above, these companies manufacture test and measurement industrial equipment instruments. They either directly manufacture T&M instruments within the EEA (e.g., in Germany, Spain, Finland) and/or rely on contract manufacturers based within the EEA to manufacture T&M instruments. These products are then supplied to more than 20,000 EU industrial customers.

Due to the very specialized nature of the industrial test and measurement equipment, sales volumes are, in orders of magnitude, lower than those of consumer products. Industrial test and measurement equipment are not subject to fast-paced changes in market patterns.

The industrial Test & Measurement sector is a driver of innovation. Key applications of T&M equipment include products in the professional, scientific, laboratory, analytical, clinical and industrial applications, as listed in Annex I. Notably, this equipment includes sophisticated Electrical & Electronics Engineering (EEE) used in a diverse range of **critical & strategic applications**, such as:

- Calibration & National standards;
- Cellular Communications;
- Wireless Connectivity;
- Aerospace and Defence;
- Component and Device-Specific;
- Forensics;
- Automotive and Energy;
- Food & Beverage;
- Pharmaceutical;
- Government and security;
- Digital Design and Interconnect;
- RF & Microwave;
- Optical & Photonic;
- Petrochemicals;
- Education;
- Bioproduction;

- Mining;
- Environmental and occupational monitoring.

Therefore, surveyed companies have indicated that the PFAS restriction would have significant impacts on their business and customers. Given the broader definition of PFAS, it is estimated that the vast majority of the overall company turnover in the EEA depends on activities where PFAS-containing components are used.

PFAS are used ubiquitously across the entire TMC member companies' portfolios. More than 6,000 single T&M products are likely to be affected by the restriction. Especially Gas Chromatography, Liquid Chromatography, and Mass Spectrometry where there are components made of or containing PFAS where the properties of the PFAS materials are essential. **On aggregate, this represents around 86% of the product portfolios of TMC member companies.**

In the business-as-usual scenario (i.e., assuming no PFAS restriction), the annual sales of these products are projected to grow at a rate of 5% for the next years.

Accordingly, **the loss of income generated through the sale of these products, likely to be affected by a PFAS restriction in 2027, is estimated at approximately 1.87 billion EUR/year** (rounded).

The direct cost of a PFAS restriction is represented by the loss of the contribution to the EEA economy of the EBIT generated by manufacturers using PFAS chemicals and PFAS-based products and components, such as it is the case. The relevant economic measure to quantify this economic impact is given by EBIT. The monetization (net present value, NPV, with 3% discount rate)[35] of this economic impact (lost EBIT) is reported below.

Therefore, if the PFAS Restriction proposal would materialize,[36] it is estimated that **manufacturers of test and measurement equipment using PFAS chemicals and PFAS-based products and components would experience a net EBIT loss of approximately 460 million EUR in the first year (2027). In annualised terms, the net EBIT loss amounts 474 million EUR/year** (rounded).

Over four years (the time horizon suggested by SEAC when there is no suitable alternative available in general, as described in the AoA section), **the total impact is expected to be approximately 1.76 billion EUR for TMC companies** (NPV, 3% d.r.).[37]

35 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

36 Companies were asked to project lost sales and EBIT under the assumption that a PFAS restriction for test and measurement industrial products types were to be fully adopted as of 2027. To be conservative in the approach, where EBIT was not available, we assumed that EBIT = 20% sales.

37 Using the Excel function =PV(3%,4,-474000000,0,0).

We can use the market share of the test and measurement equipment manufactured by the participating companies to extrapolate the total economic impact in the EEA across all manufacturers. The market share covered by this survey represents more than 70% of the whole EEA test and measurement equipment market. This market share is used for the extrapolation of the impacts for the whole EEA market in a conservative approach. **The total monetised impact for the EEA industrial test and measurement equipment market segment would therefore be in the range of 1.76 billion EUR**, derived above, **and 2.51 billion EUR** (viz., the result of the extrapolation: 1.76 / 0.70).

It ought to be highlighted that the survey covers only the downstream level of the supply chain (manufacturers of T&M instruments). 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 T&M industry, the corresponding loss in value added (i.e., loss in EBIT) can be considered an EEA industry-wide impact.

Furthermore, it must be noted that what occurs in the EEA also has repercussions on other markets. This is because the CE mark is used by T&M equipment manufacturer as evidence that their products are suitable for the EU and therefore are considered of acceptable quality in a non-EEA location. Consequently, the economic consequences of a PFAS restriction would result in much larger impacts for the industry than those reported above. In these markets (e.g., China and India), non-EEA manufacturers could gain market share at the expense of EEA manufacturers. The risk is that they could leverage the benefit from the increased revenue to secure their domestic market and strengthen their global position.

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 downstream in the EEA T&M supply chain.

4.3 Social impacts: unemployment

The restriction of PFAS will have a direct impact on the headcount of the manufacturer companies. However, to what extent these impacts will be felt on the employment is difficult to be predicted for T&M manufacturers. Indeed, all participating companies highlighted that the unemployment effect of a PFAS ban on sales will likely depend on the adaption of the supply chain to non-PFAS products.

In general, it is complex to estimate the unemployment because this depends on whether the end user market can be addressed in the future with products that do not rely on PFAS and if that transition is capable of retaining the same precise product specifications and reliability performance.

However, the TMC member companies declared that a PFAS restriction would very likely lead to unemployment within the companies. If there were not specific derogations assigned to critical applications which included the ability to continue to manufacture the products with the EEA, the amount of revenue at risk could force the closure of EU based manufacturing sites and relocation to non-EU based locations where the product could be imported under derogation (in select cases), otherwise distributed globally.

With the loss of business, action would be deemed necessary to reduce workforce, especially high-skilled (e.g., scientists, engineers, microbiologists, and quality experts). It is estimated that, assuming a PFAS restriction is implemented, approximately 11,000 workers in the companies participating in the survey will face layoff in the EEA. Here we report the monetization of the likely social costs of unemployment for these workers.

The average annual salary across these European workers (including the employer's social security contributions) is approximately 100,000 EUR.

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)[38] and the paper of Dubourg (2016)[39] endorsed by ECHA. Thus:

- 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 EU is equal to 2.16 times the annual gross salary.[40]
- Table 1 presents the statistics from Eurostat (data for 2022-Q4) on the average duration of unemployment for both men and women in the age of 15-64 years in EU-27.[41]
- 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.

Table 1. Duration of unemployment in EU-27

Duration Grouping	Thousand units	Proportion (A)	Assumed duration (B)	Weighted average (A*B)
Less than 1 month	1717.6	0.132975141	0.5	0.066487570
From 1 to 2 months	2658.0	0.205780114	1.5	0.308670171
From 3 to 5 months	2013.9	0.155914436	4.5	0.701614964
From 6 to 11 months	1779.0	0.137728677	8.5	1.170693753
From 12 to 17 months	1352.4	0.104701665	14.5	1.518174147
From 18 to 23 months	602.5	0.046645041	20.5	0.956223339
From 24 to 47 months	1459.7	0.113008741	35.5	4.011810292
48 months or over	1333.6	0.103246185	48	4.955816888
Total	12916.7	1		**13.689491124**

38 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

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

40 This value is greater than one (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).

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

The social costs of unemployment would therefore be equal to:

100,000 EUR x 11,000 people x 2.16 x 13.68949112412 x 75% = 2.03 billion 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 other 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: 2.03 billion EUR x $(1 + 0.03)^{-3}$ = **1.86 billion EUR** (rounded).

We can use the market share to extrapolate the total social impact of the unemployment in the EEA across all T&M manufacturers: 1.86 billion EUR / 0.70 = **2.65 billion EUR (rounded).**

We can affirm with a high likelihood that the total social impact of a restriction of PFAS *along the whole supply chain* would be much larger than 2.65 billion EUR, once all other economic operators having business linked to test and measurement industrial equipment products are considered.

Other workers would be likely impacted, even though the TMC member companies are not in a position today to quantify the unemployment effect.

Moreover, as a progressive result and due to the expected reduction in sales**, job creation is also expected to be negatively affected**. Manufacturers anticipated that eventually they would inevitably reduce new recruitment as all R&D activities would relocate outside the EEA.

4.4 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 (increase of imported test and measurement industrial product types) and on the competitiveness of EEA market.

Impacts on the market – Competitiveness

Because REACH Restrictions apply to all producers equally when placing equipment on the EEA market, **a potential broad restriction of PFAS would disadvantage the EEA manufacturing and EEA players in their competition with the rest of the world.**

Compared to the non-EEA market, EEA industrial and professional sectors relying on T&M equipment, such as communication, defence, research & development, aerospace, and electronic manufactures would be **subject to significant hurdles as these industries would have limited access to T&M equipment, thereby hindering the EEA technology industry, and potentially leading to operational disruptions**.

It is worth noting that most of the global definitions proposed restricting or otherwise eliminating PFAS fail to include polymers within the regulatory definition of PFAS. Creating a global divergence of what can be used and placed on the market in the EU/EEA from the rest of the world.

Conversely, the impact of these sectors' limitations would have downstream effects, affecting the entire EU society. T&M instruments are extensively used across various sectors of the electronics industry for production testing and product development purposes. At present, a majority of production already takes place outside the EEA, predominantly in the United States. If the EEA were to lack access to such equipment, it would likely drive investments in the development and production of electronic equipment to other regions.

As a result, the EEA would experience a loss of competitiveness relative to the rest of the world, leading to a significant shift from EEA manufacturing to non-EEA manufacturing.

At a time when there is increasing interest in increasing investments and reducing supply chain reliance within the electronics industry, a restriction on PFAS for test and measurement equipment would only exacerbate this situation.

Impacts on the market – Quality and costs

Should PFAS containing components no longer be available for use in test and measurement equipment, industrial and professional sectors relying on these products, including the electronic, semiconductor, automotive, and chemistry industry would be particularly affected.

A restriction would likely result in a withdrawal of products from the EEA market until high-revenue products are converted, if (and when) possible. Any low revenue products that require significant re-design, or products that are within a few years of obsolescence, are likely be withdrawn from the EEA market. Meanwhile, while the PFAS polymers remain unrestricted in other markets, those countries will continue to advance technologically (albeit reliant on PFAS polymers) and take strides ahead of the EU.

The biggest impact is likely to be the availability of analytical chemistry equipment within the EEA for analytical techniques. This will likely have an impact on laboratories within the EU able to run the analysis that are needed by their customers, including the testing of and monitoring for PFAS. Where these laboratories do not need to be in a specific physical location, this will reduce the competitiveness of laboratories within the EU as they will not be able to run analysis to the same level or with the same equipment as those outside. This will affect all laboratories from universities through to contract analytical laboratories. This would likely impact investment into the high value manufacturing within the EEA as biological, pharmaceutical, and chemical manufacturing relies on being able to run analysis alongside the manufacturing process. If this analysis is not possible within the EU, then manufacturing sites outside the EEA are likely to see preferential investment.

Yet still, there will be an impact on all customers across all electronic sectors and all EEA countries, and in particular on development in EV and autonomous vehicle electronics and drivetrains, on the production of 5G Wireless communication equipment, and on the deployment of 6G wireless communication.

Additionally, the impact of reduced volumes manufactured will also have a **significant impact on the fixed costs of various supply chain actors**. Participating companies would be strained by increased costs associated with addressing new product development and resourcing components for manufacturing**. As a result, prices of final products are expected to increase.**

Impacts on suppliers and customers

As described in Section 2.2.2, the supply chain for PFAS is extensive. A wide number of actors are involved in the supply chain linked to T&M equipment, including suppliers of raw-material components, sub-assemblies, PCBs and PCAs as well as contract manufacturers, and test and certification agencies. This extensive supply chain is typically global and not limited to businesses 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.

Since T&M equipment is typically low volume, this would not impact large suppliers, especially those supplying off-the-shelf components. A reduction in business would most directly impact smaller suppliers (SMEs), especially those providing custom designed components.

The greatest direct impact would be on the component and subassembly producers whose core business is to provide such items to the electronics market. **Reduced product volumes from equipment producers would impact profitability (viz., via reduced volumes, and increased fixed costs) of contract manufacturers**. This could lead to further social and economic impacts in the EEA, as highlighted before, even though participating companies are not in a position to quantify this impact.

More broadly, the entire supply chains of the participating companies would require a lengthy transition period in case of restriction as they would need to: track through their respective supply chains where PFAS materials are used or intentionally added, resource alternative materials, validate the production of components with new materials, and build the critical sub-components that are used to assemble and manufacture equipment on behalf of the TMC manufacturers. Suppliers are generally the ones who manufacture and provide the PFAS-containing parts. **If there are no feasible alternatives found, TMC members would not be able to produce their components and consequently lose business. This would, in turn, impact all customers of T&M equipment in the EEA.**

Impacts on the market – Trade

A REACH restriction of PFAS would hamper the EEA's relative importance as an exporter and trading partner for the goods and industries mentioned above. As a result, the **overall EEA trade balance would be adversely impacted**.

Indeed, just as the production of T&M instruments would turn to non-EEA markets in the long term, exports of these products would decrease considerably, while imports are projected to grow in importance (when and if an alternative is developed for the components used in these instruments).

Impacts on the market – Innovation and R&D

The PFAS restriction is expected to have wider impacts on innovation in Europe. R&D investments are generally made taking into account the new market technology opportunities and the business' financial health. **If the restriction leads to a loss in sales in the EEA market, under the assumption that the percentage of R&D spending in terms of revenue spending remains the same, then this will also lead to reduced investments in R&D.**

One of the major uses of the T&M instruments is in essential research and development processes, both within private companies and for state sponsored research. The limited access to test and measurement equipment in the EEA will constrict investment in both innovation and commercialization of new technologies in a wide variety of sectors, from life science to chemical and from engineering to material science.

T&M instruments are used across these sectors to both test their production and develop new products. **Instead of working on new product design and innovations, the current R&D efforts and resources would inevitably be redirected towards re-engineering, re-qualifying and recertifying their entire portfolio in these sectors**. This will require the R&D staff to support that effort, stalling innovation, and new product development.

Additionally, the limited access to test and measurement equipment in the EEA will be the main driver for investment in both the development and production of all electronic equipment to other non-EEA regions. This will have a market impact on the innovation and the know-how in the EEA. The removal of products from the market will therefore have a **direct negative impact on the research and innovation output within the EEA – in particular in Romania, Hungary, France, Belgium, and Germany, in which participating countries indicated their R&D activities took place.**

5. CONCLUSION

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 test and measurement equipment industry, with market share coverage of approximately 70% of the EU market. 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:

- **The expected releases of PFAS to the environment are expected to be relatively negligible as PFAS containing components are predominantly used in closed systems (i.e., encapsulated within the equipment enclosure) and** when they **finally reach end-of-life they are processed by professional recyclers**.[42] Ultimately, test and measurement manufacturers are small consumers of PFAS materials as compared to other industries, and equipment have long expected lifecycle (up to 40 years). In addition, fluoropolymers are widely used PFAS in the T&M products. Based on their intrinsic physical, chemical and biological properties and behaviour, fluoropolymers differ from other "high concern" PFAS,[43] and are considered to pose less risk for the human health and the environment since they appear to be PLC, persistent, insusceptible to degradation and insoluble (Henry et al. and Korzeniowski, et al.).

- **The cost effectiveness ratio for test and measurement sector is expected to be highly disproportionate because of the high mix, low volume nature of the segment, the re-qualification and re-certification costs versus the minor contribution of the total PFAS input in the environment.**

- Thanks to the wide variety of properties offered by PFAS, these materials are used in a variety of safety, electrical performance, and mechanical applications within electronics, including semiconductor and cables uses. As such, **PFAS are used ubiquitously across the entire TMC member companies' portfolios.** Approximately **86% of the T&M equipment** will be impacted by a restriction.

[42] RoHS's Category 9 Industrial equipment's contribution to the Waste Electrical and Electronic Equipment stream is very small (0.12% by weight of EU WEEE) with industrial WEEE being collected through B2B systems. Consequently, the environmental impact of industrial test and measurement products is negligible compared to the total electronics sector.

[43] ITRC, *PFAS - Per- and Polyfluoroalkyl Substances: 3 Firefighting Foams. Interstate Technology and Regulatory Council*. (2021), https://pfas-1.itrcweb.org/3-firefighting-foams/

- It is shown that due to the unique characteristics of PFAS materials, and based on the current state of the art, **there are no known alternatives that are currently available** for most of the PFAS uses.

- **Implementing a re-design requires long timelines and high costs to convert the entire T&M portfolios. It is anticipated that more than 25 years (minimum) are needed for finding a technically suitable alternative, re-designing (i.e., implementing the substitution of PFAS based equipment) and completing transition activities and to retain products on the EEA market**. As downstream users for PFAS based commodities, these timelines are highly dependent on the ability of the supply chain to supply adequate information and their capabilities to offer suitable alternatives.

- **The total monetized impact of a restriction is estimated in the range of 4.3 billion EUR and 6.2 billion EUR** (conservative estimates in net losses), consisting of: social impacts from unemployment in the EEA, substitution costs and economic impacts (EBIT loss) for T&M manufacturers in the EEA. **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, the PFAS restriction is expected to have wider impacts on the revenues of these companies, on innovation in Europe, competitiveness of the EEA markets in comparison to the rest of the world, and on the overall EU trade balance. For instance, there would be substantial impact to 5G and 6G deployment, the electrification of the transport sector (EV deployment), and to chip producers due to the non-availability of test equipment exclusively needed for these sectors.

Based on the above evidence-based considerations, this report concludes that a broad restriction of PFAS for industrial test and measurement equipment will have disproportionate negative impacts on the European economy and society.

The Test & Measurement Coalition agrees to phase out the use of PFAS wherever this is practicable. 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.

Based on the evidence-based considerations below, this SEA-AoA report conclude that a broad restriction without derogation for the use of PFAS in industrial monitoring and control instruments, as defined by the RoHS Directive, will have disproportionate negative impacts on the European economy and society. <u>A time-unlimited derogation for the use of critical fluoropolymers in industrial monitoring and control instruments should be foreseen.</u>

ANNEX I – Product groupings

Non-exhaustive list of product groupings with example of equipment types for each category relevant to PFAS containing components

Product Grouping	Equipment Types
Environmental Monitoring	5G NR Base Station Test
	XRF Analyzers
	Gas Chromatographs
	Liquid Chromatograph
	(AAS) Atomic Absorption Spectrometry
	(ICP-MS) Inductively coupled plasma mass spectrometry
	(ICP-OES) Inductively coupled plasma optical emission spectromtry
	Gas Analyzers
	Radiation Detectors
	Gamma Density Gauges
	PHS/ORP/ Conductivity Meters
	Handheld Raman Spectrometer
	Flow Monitors
	FTIR Spectrometer
	Elemental Analyzers
	Photometric & Electro-chemcial Analyzers
Communications	Wireless Network Emulation
	Waveform Generators
	Telecom Test Sets
	Signal Generators
	Enterprise Network test, emulation and security
	Vector Signal Generators
	Optical Modulation Analyzers
	Network Cable testers
	Wireless Channel Emulators
	Network Analyzers
	Bit Error Rate Tester
	Function Generators
	Network Health Analyzers
	Wireless Test Solutions
	Bit Error Rate Test Solutions
	Spectrum Analyzer
	Vector Network Analyzer
	Spectrum Analyzer
	Noise Figure Analysis
	In-circuit test solutions
Medical Device, Diagnostic, and Pharmaceutical Testing	Pharmaceutical Analytics PCR system
	Pharmaceutical Metal Detector
	K6460S Clinical TQ LC/MS System

Product Grouping	Equipment Types
	Automated Microbial Detection System
	Blood Bank Centrifuge
	IVF Incubator
	Magnis Next Generation Sequencing
	Capillary electrophoresis
	Blood bank refrigerators
Automotive and Energy	Airbag Test Systems
	Battery Simulators
	Power Meters and Sensors
	Parametric Curve Tracers
	Parametric Test System
	Automotive Energy emulation and test
	Parametric Test Solutions
	E8718A Radar Target Simulator
	Device Current Waveform Analyzers
COVID-19 Response	Krios Microscope
	QuantStudio
	PCR Testing Instruments
	Tecnai Microscope
	SeqStudio
	Bioreactors
Hospitals & Clinics	Centrifuge
	Chromatographs
	C02 Incubators
	Real-Time Cell Analyzers
	Capillary Electrophoresis
	Thermocyclers
	Cold Storage/Freezers
	Biosafety Cabinets
	IVD Instruments
Semiconductor Testing	Semiconductor Switching Systems
	ICP-MS (ICP-QQQ) for measuring trace & ultra-trace level contaminants in Silicon substrate
	GC/MS to detect organic impurities in air during µ-Processor manufacturer
	Scanning Electron Microscope for localization of transistor and metallization faults
	Atomic force probe based nanoprober for electrical fault localization in transistors and interconnects
	Static optical fault isolation for identifying process, design or integration issues
Industrial and Utilities	Power Suppliers
	Oscilloscopes
	Digital Multimeters
	Insulation Testers
	Power Analyzers
	Multi-phase Power Quality Standards

Product Grouping	Equipment Types
	Data Acquisition DMM
	Compact RIO Programmable Automation Controller
	Power Quality Monitors / Analyzers
	Parameter Analyzers
	Compact Vision systems
	Electronic Loads
	Current Sources
Academics (Research) / Forensic	Rapid Hit ID System
	Forensic DNA Extraction System
	X-Ray Inspection Systems
	Visual & Fluorescent microscopes
	Mass Spectrometers
	Ion & Liquid Chromatographs
	Particle Monitoring
	Flow Cytometers
	Scanning & Transmission Electron Microscopes
	Neuron Flux Monitors
	UV-Vis
	UV-Vis Spectrophotometers
Clean Energy	ICP-OES Impurity Testing of Raw Materials used in Production of Li-ion Batteries
	LC to characterize fuel composition for Biofuel
	Gas Chromatographs for the ASTM D6584 analysis of biodiesel
	Cary 630 FTIR Spectrometer for fuel quality & purity
	1260 Infinity II SFC System to determine olefins in denatured ethanol to ASTM D7347-07
	990 Micro GC system for rapid analysis of high-purity hydrogen

ANNEX II – Substitution plan of lead containing components using RoHS Exemption 6(a)

In January 2023, TMC member companies applied for the renewal of the Annex III exemptions 6(a) and 6(b).

Similarly to the case of PFAS, TMC members are not component manufacturers, and they need to rely on component manufacturer supplies of parts for 75%+ of the components in their instruments. In the application for renewal of Annex III exemptions 6(a) and 6(b), T&M manufacturers acknowledged that alternatives to lead for all 6(x) type exemptions were in development, and component manufacturers will gradually make available workable alternatives to the lead containing parts currently on the market.

In this context, T&M manufacturers developed a well-structured substitution plan. The substitution of lead containing components using exemption 6(a) can be managed along the following milestones:

1) Component manufacturer & Category 9 OEM collaborate for the development of the discrete components required in the equipment;
    a. Communication of equipment specification requirements to component manufacturer;
    b. Alignment on technology with component manufacturer;
    c. Component manufacturer develops new component without lead;
    d. Trial deliveries of components commences;
2) Testing and viability of component design for specific Category 9 equipment family;
    a. Testing of single component starts (outside of application in equipment);
    b. Lifetime stability and longevity testing (7x time compression);
    c. Redesign phase for failed components;
    d. Scale up manufacturing by component maker;
3) Design in components to Category 9 equipment families;
    a. Three stages of 500 equipment families (cannot be done concurrently);
    b. Testing for unexpected equipment interference;
    c. Lifetime testing in equipment setting;
4) Roll out of compliant equipment.

Although the timeline that follows from above may look long, it should be considered that many component manufacturers are not even aware exactly how many of their components use the exemption. This correlates with the Category 9 OEMs who are equally unaware of the full extent of the use of this very common exemption. The amounts of lead are so small and close to the RoHS legal limit of 0.1% that in some cases the component manufacture render it difficult to decide whether the limits are exceeded at homogenous material level.