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English version for convenience only

The Association of Swedish Engineering Industries (Teknikföretagen) comments on the proposed restriction on the manufacture, placing on the market and use of PFASs

Introduction

The Association of Swedish Engineering Industries (Teknikföretagen) represents over 4,400 member companies that constitute one third of Sweden's exports. Our member companies comprise both major, renowned, global corporations as well as a majority of micro, small and medium-sized enterprises. A common denominator is that they develop technologically advanced products and services and that almost all sales take place in global competition. While member companies solve many of the challenges of our time, they create growth and prosperity in Sweden.

Summary

- The Association of Swedish Engineering Industries (Teknikföretagen) supports a gradual phase-out of PFAS substances and for this to be successful, sufficient time and a well-founded process are needed.
- A basic prerequisite for a general PFAS restriction is that the restriction is legally compliant and proportionate to the purpose. Operators in various industrial sectors need to be able to obtain exemptions for critical uses where environmental and health risks are controlled. The restriction must also not jeopardize critical societal functions, the green transition and established climate and environmental goals.
- A well-functioning, sustainable and competitive EU market needs to be ensured. An important aspect is a level playing field and good compliance and effective enforcement, which requires guidance, effective market surveillance and legally sound enforcement.
- The implications for industry and society are significant and extensive impact assessments are required to ensure the best environmental and societal benefits and the continued competitiveness of EU industry.

General comments

Teknikföretagen welcomes limiting the use of PFAS substances under the

REACH Regulation ("REACH")[1]. There is a real need for preventive risk reduction measures aimed at substituting or phasing out PFAS substances and uses from the value chain, thereby achieving the sustainable development goals of the UN

2030 Agenda, the EU's "Green Deal" policy agenda[2] and the European

Chemicals Strategy for Sustainability[3].

In order to achieve a successful phase-out of PFAS substances, taking into account different industrial sectors and value chains as well as the green transition, Teknikföretagen believes that there is a need for additional data to justify such a comprehensive and historically unique restriction proposal. Based on the current chemicals legislation and the legal restrictions that follow from this, we see a need for the proposal to be revised taking into account the following: (i) that the risk assessment and the restriction are consistent with the conditions of the current legislation and procedures in REACH and the fundamental legal principles of legal certainty and proportionality in EU law, and (ii) that PFAS substances and their uses in different value chains and different industrial sectors are iteratively mapped, risk assessed and put in relation to technically feasible

alternatives in order to then continuously adapt the restriction and its conditions (e.g. scope and transition periods).

In the light of the above, the restriction proposal needs to be accompanied by conditions allowing operators to obtain a general exemption for PFAS substances on their own or in mixtures or in articles if it can be demonstrated: (a) that the use is under strictly controlled conditions and under the responsibility of the producer (including emission to the environment and during the waste phase); (b) that there are no technically feasible and environmentally better alternatives for the intended use; or (c) that the intended use is necessary for safety, protection of health or the environment, or that the use is necessary for society according to guidelines developed under the European Commission's Chemicals Strategy.

[1] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18

The legal and political context

The proposals submitted by Member States to ECHA differ from previous restriction proposals under REACH. According to Article 69(4) of REACH, restriction proposals shall address substances and uses that pose an uncontrolled risk to health or the environment that needs to be addressed within the Union. The current proposal concerns a general and comprehensive restriction of all PFAS substances (a group of more than 10,000 highly fluorinated substances with different properties) and uses. To justify such a general ban as currently proposed, a comprehensive risk assessment of the uses covered by the

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December 2006 concerning the Registration, Evaluation, Authorization and Restriction of

restriction and how that risk is managed in each specific industrial sector and value chain is needed.

However, in our opinion, the documentation presented to ECHA does not meet the requirements set out in that Annex. Instead, the documentation demonstrates the shortcomings in the knowledge base that exists about PFAS substances and the individual substances' widely varying uses in materials and products used in different parts of the value chain and in different industry sectors. Nor does the proposal take into account the necessity of individual PFAS substances for society (i.e. essential uses), as there are currently no established harmonized criteria for such an assessment. Furthermore, the proposal does not consider risk management measures taken by different industrial sectors and value chains to control exposure, emission and impact on health and the environment in general.

The current risk assessment is based on a simplistic assumption that all uses of PFAS substances in the manufacture of materials and articles in all industrial sectors constitute an unacceptable and uncontrolled risk requiring Community action without considering how the risks of use are controlled on a case-by-case basis in different industrial sectors and value chains (cf. conditions and information requirements in Article 69(4) and Annex XV of REACH).

Teknikföretagen therefore recognize a real need to identify which specific uses pose an unacceptable risk and which products (including materials and components) and use processes are essential uses or critical to the functions of society in the sense of the European Commission's chemicals strategy.

Chemicals (REACH), establishing a European Chemicals Agency, amending Directive

Impact of the restriction proposal on industry

Below is an overview of how the restriction proposal as currently drafted affects industry and society at large and why an in-depth and holistic analysis of the impact of the proposal on individual industry sectors and value chains is required.

Complex value chains and products with high environmental and social benefits

Teknikföretagen's member companies operate in many sectors, providing materials and products essential to society and the green transition. Each

1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission

industrial sector (such as manufacturing, life sciences, food, transport, infrastructure, defense and security, energy, IT and communication, consumer products) involves long complex and global value chains. A restriction of PFAS substances needs to be designed for specific industrial sectors with the whole value chain and the circular economy in focus.

Below are some indicative examples of how the lack of sector-specific analysis of value chains can negatively impact society at large and the green transition.

- **Electrification and the electricity system:** Power transmission - to meet the demand for increased electrification with the highest reliability, safety and minimum environmental impact - requires the use of PFAS materials

Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission

due to their unique properties. A ban would negatively affect the entire transition and expansion of the electricity system.

- **Emission control equipment:** The techniques and equipment used to reduce carbon dioxide emissions and emissions of environmentally hazardous substances such as volatile organic compounds (VOCs), PFASs, and heavy metals are highly demanding today[4]. Separation techniques and equipment used for these purposes require the use of specific chemicals and metals with extreme properties such as the substance monoethanolamine (MEA) used for the separation of carbon dioxide from gas streams. To enable the capture equipment and components (e.g. gaskets, seals, valves) to withstand the extreme

Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

chemical stresses of these processes, there are currently no technical alternatives available other than PFAS substances.

- **Electronics and digitalization:** PFAS substances are currently used in the electronics sector for their dielectric and mechanical properties. For example, teflon printed circuit boards, insulated cables and sleeves are used in some key applications in e.g. telecommunications and the aerospace and security industry to minimize interference signals, reduce energy consumption, abrasion, cracks and increase product lifetime. There are currently no technically available alternatives, which is why a future restriction would negatively affect Europe's ambitions in digitalization, expansion of high-speed networks and the transition to a fossil-free society.

- **Loss of production and increased resource consumption:** PFAS substances have multifunctional properties and replacement can lead to poorer quality materials (membranes, seals, gaskets, lubricants, etc.), increasing the risk of greater machine load. This can mean loss of production, increased maintenance, increased energy and resource consumption, and shortened service life.

There are also many other examples of materials, components and equipment containing PFAS substances for which there are no alternatives, and which are necessary to ensure reliable and safe production processes.

Product development and transformation takes time

Phasing out unwanted substances and finding alternatives while ensuring the best possible technical solutions, safety, health and environmental benefits, involves complex product development work that requires significant expertise, resources and, above all, development time. Validating, certifying and gaining global recognition of new technologies in different sectors requires a lot of time, resources and technical/scientific input (cf. OECD and ECVAM procedures for validation of test methods and technologies).

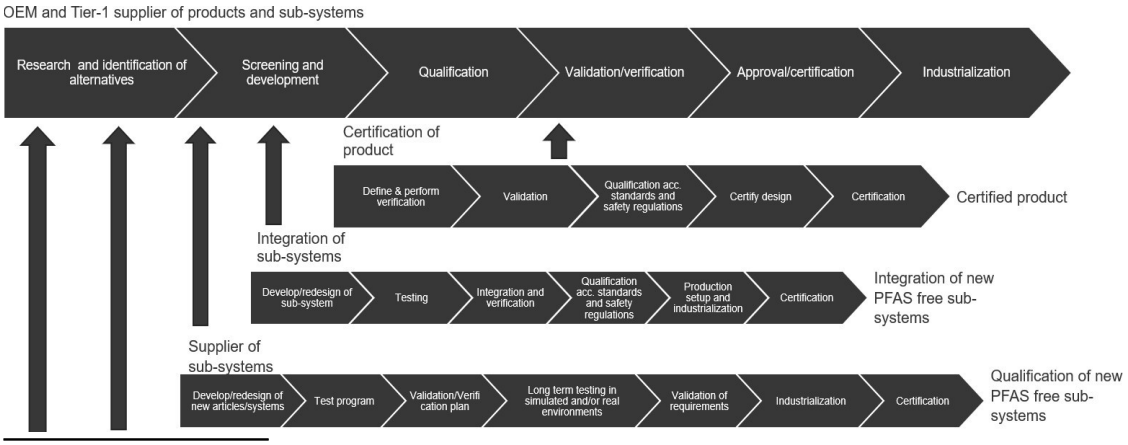
In addition, there is extensive regulation in many sectors referring to existing national, European or international standards and certifications, which themselves assume materials and components with similar technical properties

[2] https://eur-lex.europa.eu/legal-content/SV/TXT/?uri=CELEX:52019DC0640.

to PFAS. Thus, replacing PFAS substances with alternative substances will require revisions to standards and certification processes. There are examples in many different sectors where replacement of substances, components or equipment in processes and products may require extensive safety assessments and re-certification. This may increase the complexity of implementing new options, especially if there is no global consensus to revise standards across the value chain. In summary, different sectors and industries have different conditions for phasing out PFAS substances from the value chain, considering internal innovation processes throughout the value chain and the development of information needed to scientifically/technically demonstrate the protection of safety, health and the environment, and to qualify and validate (including certification) the new alternatives.

The figure below shows the different phases of the development process for developing PFAS-free alternatives in the value chain. It is important to note that each stage of the process can take several years to complete and that additional time may be needed to get the change accepted by the industry, regulatory bodies and authorities and the market in general.

[3] https://eur-lex.europa.eu/legal-content/SV/TXT/?uri=CELEX:52020DC0667.


OEM and Tier-1 supplier of products and sub-systems
Research and identification of alternatives
Screening and development
Qualification
Validation/verification
Approval/certification
Industrialization
Certification of product
Define & perform verification
Validation
Qualification acc. standards and safety regulations
Certify design
Certification
Certified product
Integration of sub-systems
Develop/redesign of sub-system
Testing
Integration and verification
Qualification acc. standards and safety regulations
Production setup and industrialization
Certification
Integration of new PFAS free sub-systems
Supplier of sub-systems
Develop/redesign of new articles/systems
Test program
Validation/Verification plan
Long term testing in simulated and/or real environments
Validation of requirements
Industrialization
Certification
Qualification of new PFAS free sub-systems

Standardization is a key tool for promoting a well-functioning economy characterized by safety, performance, quality, sustainability, and efficient use of resources. The basic idea behind standardization is to establish requirement levels for goods, services, and processes in a socio-economically beneficial way to ensure good performance, high safety and contribute to economically, ecologically and socially sustainable development.

A blanket ban on all uses of PFAS substances without a careful assessment of the impact on existing standards and certification processes may give rise to technical challenges that affect both the protection guarantees offered by these standards and the development of society as a whole.

[4] See e.g. BAT conclusions for different industrial emissions under IED Directive 2010/75/

It is therefore important that time and resources are allocated to carefully review and audit existing standards to ensure that safety and quality requirements are met and that the proposed restriction does not conflict with regulatory requirements or compromise the level of protection set by the market and legislation. The safety risks that arise must be considered on a case-by-case basis to avoid injuries and unwanted risks to persons and property.

Holistic approach to ensure the circular economy and the protection of health and environment along the entire value chain.

Many companies are involved in the production of advanced technology and high-quality products. A holistic approach is essential when designing the

restriction, as many of these products contribute to resource efficiency, reduced environmental impact and a safer working environment. It is critical to ensure circularity and protection of health and the environment throughout the value chain to achieve maximum environmental and climate benefits. The current proposal risks leading to a shorter lifetime and reduced performance of many products, which in turn can result in increased energy and resource consumption and increased waste.

Unless the potential impacts on each specific industry are carefully considered, there is a real risk of shortages of raw materials and inputs across industrial and business sectors, which could delay the transition to more sustainable technologies and negatively affect the achievement of environmental and climate

EU, https://eippcb.jrc.ec.europa.eu/reference.

objectives. This is because it may be economically and practically unsustainable to continue manufacturing products that will be banned in the future. It is also not guaranteed that it is even possible to produce alternative products with the same or better performance from an environmental perspective. A direct consequence of this is the risk of shortages of necessary raw materials and inputs for critical uses and sectors with high safety requirements, such as aerospace and energy supply.

Thus, it is of utmost importance to ensure a continuous availability of raw materials and inputs (including spare parts) to allow for the repair, upgrade and reuse of products. In most cases, PFAS-free alternatives cannot be used without redesigning the product, as the overall characteristics of the product in general and the component in particular change. Imposing a restriction without the

possibility of an appropriate exemption for raw materials and inputs (including spare parts) would result in products that have already been used or placed on the market before the restriction can no longer be maintained, repaired or reused (cf. the experience with RoHS[5] regarding legacy spare parts). This would counteract the Union's stated objectives of promoting greater circularity and waste minimization.

Trade and competitiveness

Teknikföretagen sees a risk that innovation and technology development will have better conditions outside Europe, leading to new investments moving

outside Europe. European industry thus risks being left behind in terms of technological development for certain products and important applications that will be available in the rest of the world.

The EU has been a pioneer in many technologies that are crucial to the green transition. If the performance and reliability of these deteriorate, this would not only have a negative impact on European growth and jobs but would also have negative consequences for the global green transition.

Supervision and market surveillance

Effective market surveillance is essential to ensure that laws are applied correctly and legally, and to maintain a level playing field and compliance. Market surveillance needs to be strengthened, particularly at the external borders but

also within the EU. The supervision of the restriction needs to be considered early in the process of designing the restriction. It is important that ECHA and national enforcement authorities have the competence and resources, as well as harmonized and validated methods and standards for analysis and testing of materials and articles. The test methods and measuring instruments to be applied must be legally sound, validated and have an adequate level of specificity, performance and repeatability to reduce the risk of regulatory discretion.

[5] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32011L0065

Conclusions and key recommendations

In summary, Teknikföretagen states the following:

Teknikföretagen supports a gradual phase-out of PFAS and for this to be successful, sufficient time and a well-founded process are needed.

- Reasonable transition times for substitution, product development and in many cases, innovation are required for a successful phase-out.
- We welcome a gradual phase-out to phase out PFAS substances as quickly as possible where technically feasible alternatives already exist, combined with a requirement to actively work towards phase-out in other sectors.

A legally compliant and proportionate PFAS restriction taking into account the purpose

- To achieve a successful phase-out of PFAS substances, the restriction needs to be accompanied by conditions (e.g. scope and transition periods) that allow operators to obtain a general exemption for PFAS substances as such or in mixtures if it can be demonstrated that scope and transition periods) that allow operators to obtain a general exemption for PFAS substances on their own or in mixtures if it can be demonstrated:

a) that the use is under strictly controlled conditions and under the responsibility of the producer (including emissions to the environment and during the waste phase),
(b) that there are no technically feasible and environmentally better alternatives for the intended use, or
(c) that the intended use is necessary for safety, health or environmental protection, or that the use is necessary for society according to guidelines developed under the European Commission's chemicals strategy.

- Ensure that all critical uses subject to bans or restrictions have been objectively and objectively screened throughout the value chain according to established harmonized assessment criteria (cf. the "essential use" concept). The use of PFAS substances in manufacturing must remain

possible as long as technically and environmentally better alternatives are not fully available.

The impact on society and industry is significant and requires a comprehensive review of each industrial sector and value chain to ensure critical societal functions and the green transition.

- The restriction of PFAS substances and their unique properties must be carefully balanced with the need to maintain critical societal functions and promote the green transition. Promoting a circular economy is crucial to achieving our environmental and climate goals and needs to be considered when designing a restriction.

- The restriction proposal must also consider national, European or global safety requirements and standards. It also needs to be weighed against the risks involved if products (including materials and components) do not meet the same quality and performance requirements.

A well-functioning, sustainable and competitive EU market needs to be ensured.

- The test methods and measurement instruments to be applied must be legally sound, validated and have an adequate level of specificity, performance and repeatability to reduce the risk of supervisory discretion.

- Ensuring a level playing field, good compliance and effective enforcement requires well-functioning market surveillance and legal certainty.
- Teknikföretagen sees a risk that innovation and technology development will move outside Europe, which would have negative consequences for the global green transition.