



SAAB

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Comments for Annex XV restriction report – SAAB AB

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General comments

Saab appreciates the opportunity to provide comments on ECHA's Annex XV Report that proposes a restriction on per- and polyfluoroalkyl substances (PFAS) under REACH.

Saab supports a ban and phasing out of PFAS where alternatives are readily available, qualified and certified. Saab is however very concerned by both the scope and the timeline of the recommended proposal for a PFAS restriction.

Given the high importance in the industry, uses of PFAS must remain possible as long as their risks can be sufficiently managed or in case no suitable alternatives are readily available. Therefore, legislation restricting substances should not be implemented without differentiated consideration of their uses and the consequences. A differentiated regulatory approach that is risk-based according to Article 68(1) REACH and substance-based according to Article 69 REACH should be used.

A restriction on PFAS must be balanced against all relevant European policy strategies and existing regulatory and policy measures in place for the EU internal market. Specifically, the main environmental objectives laid down in the European Green Deal and its EU Circular Economy Action Plan and upcoming ESPR regulation such as longer lasting products that can be repaired, recycled and re-used, the right-to-repair energy efficiency, clean technologies globally competitive and resilient industry.

If adopted by the EU legislator, the recommendations for a regulatory text, as currently proposed, will jeopardise the fulfilment of the Green Deal (climate goals and circular economy) as many technologies are dependent on the use of PFAS and would not work at all, or work with significantly less efficiency without it. That results in reduced product durability and substantial increase in waste generation (premature scrapping). The timeline constraints would also increase the risk of regrettable substitution as unregulated alternatives are implemented without being thoroughly evaluated for ecological and human toxicity.

The impact on Saab would be significant. Saab will not anymore be able to produce, place on the market nor maintain or repair products if the recommended regulatory restrictions would be adopted by the EU legislator.

Saab support the consultation answers by European Aerospace, Security and Defence Industries (ASD), the Association of Swedish Engineering Industries and Orgalim.

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We have not given input to the consultation on applications which other sectors are experts in. In our answer to the consultation, we have focused on the A&D and civil Safety & Security specific applications.

Importance for security and society

A categoric PFAS ban would undermine the European Defence Technological and Industrial Base (EDTIB) capacity to produce and maintain critical defence materials and capabilities that Sweden and other EU Member States as well as NATO allies and the EU have ordered and are expecting the EDTIB to develop, produce and deliver. The EDTIB is facing unprecedented supply chain and production challenges to deliver the necessary critical equipment and material to support Ukraine to defend itself against Russia and to replenish stocks. A PFAS ban would undermine the ability to deliver and maintain requested equipment and material, hence jeopardizing the security situation of Member States' and the EU.

Saab also provides, services and solutions for civil safety & security. With operations on every continent, Saab continuously develops, adapts and improves new technology to meet customers' changing needs.

A total PFAS ban will hinder the development of new European technologies and capabilities, putting the EDTIB and EU Member States at a disadvantaged position compared to other global players on a competitive international market. This is highly problematic at a time when the EU seeks to reduce the reliance on third countries, boost innovation, competitiveness and growth.

PFAS identification and collection of data

The identification of PFAS is extremely challenging and Saab do not see that it will be possible to get all the necessary information within the consultation period to identify all areas of use. Internal substance identification and information exchange within the supply chains are usually done with CAS-numbers, not by molecular structures. Data/IT-tools used for information exchange are built on CAS numbers for identification and search of regulated substances. The lack of an exhaustive list with CAS numbers in the Annex XIV report gives a large uncertainty in the substance mapping of our products and within our supply chain.

Other difficulties are that many PFAS have not been classified as hazardous according to the GHS/CLP (Global Harmonised System/Classification, Labelling and Packaging) nor listed on the Candidate List of SVHC for Authorisation and has

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therefore not been obliged to be reported in Safety Data Sheets or material declarations even if the substance is present.

Moreover, if there are no obligations to report substances, many chemical and material suppliers protect their products by intellectual property rights to get return of investment. The information is then considered as proprietary information.

Around 40 PFAS substances have been identified in Saab products to date, but more are expected in the continued data gathering. Saab products contain of varied number of articles, from a couple up to 2,5 million parts in very complex products. Thousands of articles and chemical products containing PFAS are already identified.

Fluoropolymers are the most widely reported PFAS included in a wide range of articles and chemical products. Fluoropolymers meeting the criteria for “polymers of low concern”¹ and used safely in industrial applications, equipment and articles, generally do not cause relevant emissions to the environment when used as intended.

Timeline for qualification and certification requirements

Saab is highly concerned about the transition time and the lack of derogations for our complex products and production equipment. Substitution in our sector is very complex, due to the requirement to use certified and qualified materials to ensure safety in the use phase of the products.

The extremely large number of PFAS containing articles and materials that needs to be replaced in combination with strict qualification and certification requirements requires a sufficiently long timeframe, not only for older product designs but also for new, on-going design and production projects.

The combination of lack of derogations, the proposed transition times and the complex verification and certification processes for our sector makes it impossible to comply with the proposed regulatory text if becomes final.

Before the qualification process can start, a PFAS-free alternative need to be identified or developed. PFAS-free materials/articles need to be tested and validated not only individually but also in sub-systems and finally qualified/certified for the final product before it can be used and placed upon the market. A redesign of an existing article (such as spare part) and sub-system that eliminates the use of PFAS needs also to go through the qualification process.

1. Korzeniowski SH, Buck RC, Newkold RM, Kassmi AE, Laganis E, Matsuoka Y, Dinelli B, Beauchet S, Adamsky F, Weilandt K, Soni VK, Kapoor D, Gunasekar P, Malvasi M, Brinati G, Musio S. A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers. Integr Environ Assess Manag. 2023 Mar;19(2):326-354. doi: 10.1002/ieam.4646. epub 2022 Aug 9. PMID: 35678199.

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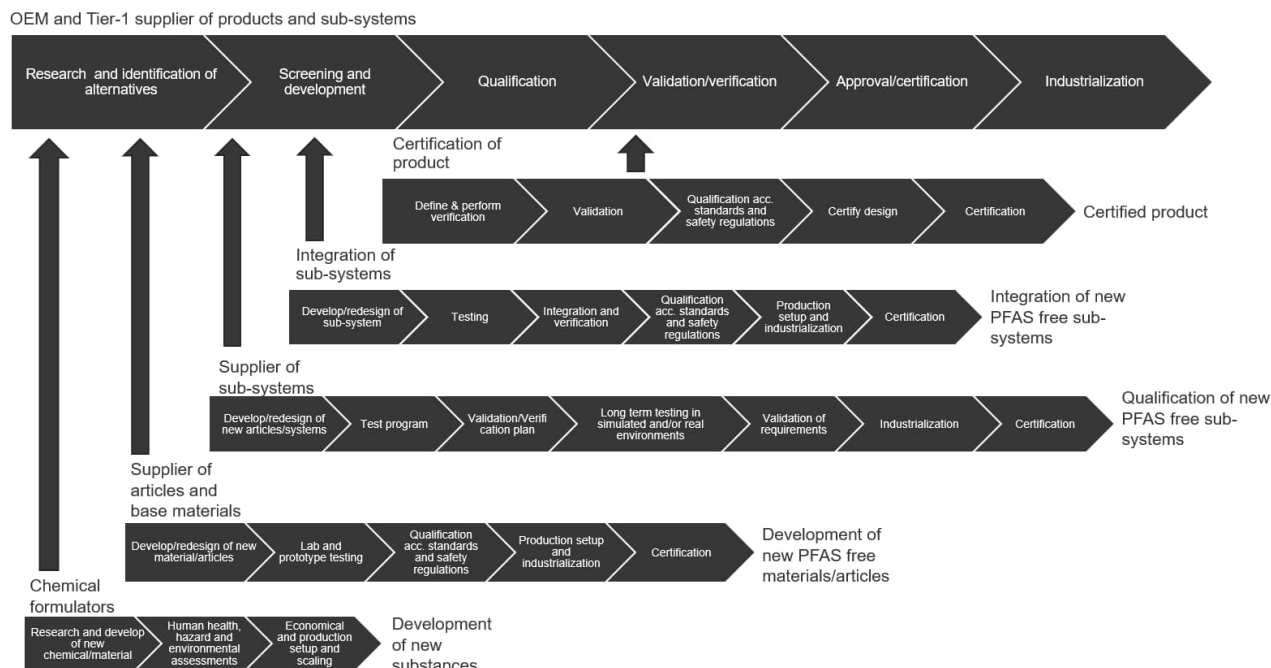


Figure 1 Qualification of products

There are numerous tests that needs to be done to pass the qualification and certification process such as:

- Mechanical
- Vibration
- Humidity
- Thermal cycling
- Corrosion tests/salt fog testing
- Chemical compatibility and stress fracture testing
- Field test

Saab products need to follow strict qualification and certification processes to secure all safety aspects globally and to comply to environmental robustness requirements. A **high number of global and industry specific standards** need to be used and followed for our sector for example Military Standards (MIL-STD), Military Detail Specifications (MIL-DTL), Military Handbooks (MIL-HDBK),

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Aerospace Quality Management AS/EN9100. Examples of two standards are MIL-STD-516, “Airworthiness Certification Criteria” and aviation safety standard ARP4761 “Guidelines and Methods for Conducting The Safety Assessment Process on Civil Airborne Systems and Equipment.”

Proposed time limited derogations are not sufficient since alternatives can only be used once they have successfully passed the qualification and certification stages. This means that substitution is a lengthy process. More than 13.5 years is required including a review clause to integrate PFAS-free alternatives in most applications.

Additional time is needed to develop, verify and certify reliable, durable and safe alternatives and/or to redesign products. Therefore must a timely and gradual implementation of a PFAS restriction be especially secured in relation to the European defence and technological base (EDTIB) but also for the European industry.

Spare parts, repairs, remanufacturing and refurbishment

As described earlier, Saab products have a long service life with lifespans of up to 40 years and need to be serviced, and maintained. Many products are also updated, remanufactured/refurbished and given an extended life span. For many applications there will not be a drop-in replacement for the PFAS on a 1:1 basis due to their specific properties. Those products already on the market will therefore need to be redesigned to permit the use of PFAS-free alternatives. Timely redesign of very complex articles already on the market is not realistic due the high number of replacements needed, see chapter Qualification and certification requirements.

Therefore, without a general exemption to permit the use of PFAS for spare parts, legacy spare parts, repairs, maintenance, operation, remanufacturing/refurbish, **this will lead to that Saab products used for aerospace, defence and civil safety & security already on the market cannot remain operational** and will have a premature end-of-life and need to be dismantled and scrapped. Nor will Saab be able to fulfil maintenance contracts with our customers. Equipment used for production and test is also dependent on spare parts, legacy spare parts, maintenance and refill of articles and chemical products.

Service, maintenance, refurbishment and repairs are **crucial for the aerospace, defence and civil safety & security** but also for the success of the European Green Deal and Ecodesign for Sustainable Products Regulation when it comes to better resource efficiency, right to repair and long-lasting products.

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NOT CLASSIFIED**General derogations are needed for:**

- **Spare parts and legacy spare parts**
- **Products for maintenance and operation of products already on the market**
- **Second life/remanufactured/refurbished products.**

Missing uses and derogation extension process

There is a need to recognise the dependence on upstream supply chains on precursor chemicals and substances, mixtures and articles used by multiple industry sectors for other, cross-sectorial derogations, for example for lubricants, fire suppressants, transport vehicles, electronics, batteries and semiconductors.

Saab is still gathering information from suppliers on the uses of PFAS in articles and products and not all uses have been identified.

Saab identifies the need of a process to add missing uses

As our complex products are reliant on a large amount of chemicals and articles containing PFAS in a wide variety of applications we are highly dependent on others sectors derogations. In case of a sectorial A&D derogation it is not economically viable for our suppliers to only supply for A&D applications.

The combination of the proposed derogations, the transition times, lack of certified alternatives and the complex verification and certification processes for our sector proves that an extension derogation process is needed.

Saab identifies the need for a clearly defined and formal procedure for the application, review and extension of derogations.

Saab refers to missing uses identified by ASD to date, Reference number: 9639d9a5-5f72-43ee-a9f8-6a8e23a3e149.

Detailed technical information for certain unique Saab uses is attached as a confidential document.

Monitoring and conformity

Saab is concerned about compliance verification process needed to secure that the thresholds are met in the restriction proposal. Firstly, compliance with the proposed



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restriction cannot be verified for all uses with currently available analytical methods and with the absence of a complete substance list.

Secondly, existing laboratory capacity and the lack of available/usable analytical methods will be a time-consuming process. Sometimes are testing needed after specific manufacturing steps which will further increase the cost for production, test equipment or external testing services.

Thirdly, nor will enforcement be possible with lack of capacity and analytical methods and the absence of a complete substance list. It is also questionable if the inspection bodies have the ability and resources to secure a level playing field on the European market.

Only enforceable restrictions should be established.