

VCI comments on the SEAC draft opinion

## **PFAS RESTRICTION: SOCIO-ECONOMIC CONSIDERATIONS FROM AN INDUSTRY PERSPECTIVE**

The European Chemicals Agency (ECHA) has launched a public consultation on the draft opinion of the Committee for Socio-Economic Analysis (SEAC) regarding the proposed restriction of per and polyfluoroalkyl substances (PFAS) under REACH. The consultation is strictly limited to the SEAC draft opinion and therefore focuses exclusively on the socio-economic assessment of the proposed restriction, including aspects such as proportionality, practicality, enforceability, transition periods, derogations and related uncertainties. Hazard and risk assessments of PFAS are not within the scope of this consultation.

Contributions must be submitted exclusively via the ECHA EUSurvey tool, which is accessible through the dedicated consultation page on the ECHA website. Participation requires registration via an EU Login account. The consultation is time-limited and subject to the formal deadlines and procedural requirements set out by ECHA.

ECHA has structured the consultation around a complex questionnaire. The questions refer to specific sections of the SEAC draft opinion and are primarily open text fields. Responses must be entered directly into the online survey strictly adhering to the structure, formats and size-limitations; uploading separate documents is generally not foreseen. References to studies or additional information can be indicated, and ECHA may request supporting material where deemed necessary.

Against this background, the VCI is preparing a consolidated position document. This document serves internal coordination purposes, provides a structured overview of the key arguments and ensures consistency across all relevant topics addressed in the SEAC opinion. However, it does not constitute the formal consultation submission as such.

In this consultation, the VCI will limit its contribution to the General survey questions of the SEAC consultation. These questions address crosscutting, horizontal aspects of the proposed restriction, such as proportionality, practicality, enforcement, transition periods, derogations and uncertainties. The VCI will not submit sector specific responses, as the intention is to provide an overarching, cross-sectoral assessment from an industry association perspective.

## Table of contents

Table of contents .....	2
VCI Key Messages on the SEAC PFAS Opinion (Not part of the EUSurvey Questions) .....	5
VCI Contribution to the SEAC Consultation on the Proposed PFAS Restriction (EUSurvey Questions) .....	7
Question 2.17: Choose all sectors that are relevant or covered by your responses in this general survey .....	7
Question 2.18: Please provide a general description of the use(s) of PFAS (or alternatives) you are providing comments on [1921/2000 characters] .....	7
Question 2.19: Please provide your comments on section 1.2. SEAC opinion [2937/5000 characters] .....	8
Question 2.20: Please provide your comments on section 2.2 Summary of the opinion and 2.2.2 SEAC opinion summary [3827/5000 characters] .....	9
Question 2.21: Please provide your comments on section 3.2. Justification that action is required on a Union-wide level [3257/5000 characters] .....	10
Question 2.22: Please provide your comments on section 3.3.1 Availability and technical and economic feasibility of alternatives [4675/5000 characters] .....	11
Question 2.23: Please provide your comments on section 3.4.1 Regulatory risk management options other than restriction [4771/5000 characters] .....	13
Question 2.24: Please provide your comments on section 3.4.2.2.1 Socio-economic analysis: Approach [4434/5000 characters] .....	14
Question 2.25: Please provide your comments on section 3.4.2.2.2 Socio-economic analysis: Costs [3061/5000 characters] .....	16
Question 2.26: Please provide your comments on section 3.4.2.2.3 Socio-economic analysis: Benefits [2526/5000 characters] .....	17
Question 2.27: Please provide your comments on section 3.4.2.2.4 Socio-economic analysis: Other relevant impacts [3633/5000 characters] .....	18
Question 2.28: Please provide your comments on section 3.4.2.2.5 Socio-economic analysis: Proportionality [4929/5000 characters] .....	20
Question 2.29: Please provide your comments on section 3.4.2.3 Practicality, including enforceability [3805/5000 characters] .....	21
Question 2.30: Please provide your comments on section 3.4.2.4 Monitorability [3342/5000 characters] .....	23
Question 2.31: Please provide your comments on section 3.4.3.2.1 Conclusion whether the suggested restriction is the most appropriate EU-wide measure: (i) PFAS definition [782/1000 characters] .....	24

*Question 2.32: Please provide your comments on section 3.4.3.2.1 Conclusion whether the suggested restriction is the most appropriate EU-wide measure: (ii) Exclusion of PFAS from the scope [951/1000 characters]..... 25*

*Question 2.33: Please provide your comments on section 3.4.3.2.2 Conclusion whether the suggested restriction is the most appropriate EU-wide measure: Scope of the proposed restriction [904/1000 characters] ..... 25*

*Question 2.34: Please provide your comments on section 3.4.3.2.3 Conclusion whether the suggested restriction is the most appropriate EU-wide measure: Concentration limits [874/1000 characters]..... 26*

*Question 2.35: Please provide your comments on section 3.4.3.2.4 Conclusion whether the suggested restriction is the most appropriate EU-wide measure: General 18-month transition period [781/1000 characters]..... 26*

*Question 2.36: Please provide your comments on section 3.4.3.2.5 Conclusion whether the suggested restriction is the most appropriate EU-wide measure: Derogations [4240/5000 characters]..... 27*

*Question 2.37: Please provide your comments on section 3.4.3.2.6.1 Conclusion whether the suggested restriction is the most appropriate EU-wide measure: Reporting requirements [984/1000 characters]..... 28*

*Question 2.38: Please give an indication of the costs related to the reporting requirements. .... 29*

*Question 2.39: Please provide your comments on section 3.4.3.2.6.2 Conclusion whether the suggested restriction is the most appropriate EU-wide measure: Site-specific PFAS management plan [896/1000 characters]..... 29*

*Question 2.40: Please provide your comments on section 3.4.3.2.6.3 Conclusion whether the suggested restriction is the most appropriate EU-wide measure: Additional conditions considered by RAC. .... 30*

*Question 2.41: Please give an indication of the costs related to monitoring of PFAS emissions at industrial sites..... 30*

*Question 2.42: Please provide your comments on section 3.4.3.2.6.3 Conclusion whether the suggested restriction is the most appropriate EU-wide measure: Additional conditions considered by RAC [979/1000 characters]..... 31*

*Question 2.43: Please give an indication of the costs related to the additional conditions considered by RAC ..... 31*

*Question 2.44: Please provide your comments on section 3.4.3.2.7 Conclusion whether the suggested restriction is the most appropriate EU-wide measure: Interaction with other relevant legislation [990/1000 characters] ..... 32*

*Question 2.45: Please provide your comments on section 3.5.2 Uncertainties evaluated by SEAC [3840/5000 characters] ..... 32*

*Question 2.46: Please provide your comments on section 3.5.2 Uncertainties evaluated by SEAC..... 34*

## **VCI Key Messages on the SEAC PFAS Opinion (Not part of the EUSurvey Questions)**

### **1. No blanket PFAS ban**

A general PFAS ban with a short transition period would not be proportionate in light of the available socio-economic evidence and risks causing significant disruption across industrial value chains.

### **2. PFAS are essential for many industrial uses**

PFAS – in particular fluoropolymers – are indispensable high-performance materials enabling safe, reliable and efficient industrial processes, including chemicals, semiconductors, batteries and hydrogen technologies.

### **3. Suitable alternatives are often unavailable**

For many applications, technically and economically viable alternatives do not yet exist; substitution is complex, time-consuming and highly use-specific. Where alternatives with comparable resistance to chemical, physical and thermal stress may emerge in the future, their overall environmental profile, including persistence, would need to be carefully assessed.

### **4. Fluoropolymers must be clearly excluded**

Fluoropolymers appear to differ in relevant respects from other PFAS, particularly with regard to their material properties and typical use conditions. In many applications, they are chemically inert and are generally not expected to dissolve, leach or migrate under normal conditions of use.

### **5. Regulation must be risk-based and use-specific**

The decisive factor should be whether risks and emissions can be effectively controlled in a specific use, not the mere classification as PFAS.

### **6. Broad, reviewable derogations are essential**

Derogations must be realistic, value-chain coherent, reviewable and extendable; fixed and rigid expiry dates are unlikely to be appropriate for many industrial applications. This applies in particular to uses subject to sector-specific EU authorisation regimes, such as active ingredients, where inclusion in the PFAS restriction would undermine regulatory coherence and risk relocation of production without reducing global emissions.

### **7. An 18-month transition period is unrealistic**

A uniform 18-month transition ignores technical, regulatory and safety realities; use-specific and longer transition periods are required.

### **8. Socio-economic impacts are underestimated**

The current SEA relies to a large extent on qualitative assessments, remains incomplete for several sectors and is not fully value-chain wide, and insufficiently reflects impacts on supply security, climate objectives, innovation and industrial resilience.

### **9. Practicality and enforceability are critical concerns**

The proposed approach may give rise to considerable complexity and could prove challenging to monitor and enforce in practice, particularly with regard to imports and complex articles. In this context, e.g. a more differentiated treatment of fluoropolymers could merit consideration, as it may help to improve practicality and enforceability while maintaining environmental protection.

### **10. Focus on emission reduction instead of prohibition**

Environmental and health protection is better achieved through BAT-based emission controls, waste and end-of-life management, and existing sectoral legislations rather than broad bans.

## **VCI Contribution to the SEAC Consultation on the Proposed PFAS Restriction (EUSurvey Questions)**

### **Question 2.17: Choose all sectors that are relevant or covered by your responses in this general survey**

#### **Instructions:**

Select the sector(s) for which you will provide information. You can select PFAS manufacturing and 22 sectors. You can select as many sectors as you see fit. Information provided will apply to all selected sectors unless you specify otherwise. If your use is not covered, choose “other” and specify it in the next question.

#### **VCI response:**

*PFAS manufacturing, 22 sectors and others*

### **Question 2.18: Please provide a general description of the use(s) of PFAS (or alternatives) you are providing comments on [1967/2000 characters]**

#### **Instructions:**

Consult the SEAC draft opinion and provide your comments relevant to this specific section of the opinion.

#### **VCI response:**

*PFAS are used as high performance materials and process chemicals in many industrial sectors because their chemical and physical stability enables functions that are difficult to achieve under real operating conditions with other substances. They are used in modern high technology applications such as semiconductor manufacturing and related electronics applications and in research and development relevant to innovative and sustainable technologies.*

*In industrial plants, PFAS (especially fluoropolymers and per- and polyfluoroether compounds such as PTFE, PFA, FKM, PFPE and PVDF) are essential for reliable and efficient operation, for example in manufacturing infrastructure and process-internal applications such as linings, seals and gaskets, valves and other pressure-bearing components, coatings, membranes/diaphragms, lubricants, electrical insulators, and protective/safety clothing, often without being present in the final product. Their resistance to heat, aggressive acids and alkalis, pressure and demanding operating conditions supports durable tightness, helps prevent emissions, and ensures reliable performance in production equipment and installations.*

*For energy- and climate-relevant technologies, PFAS membranes are used in water electrolysis and chlor-alkali electrolysis, enabling highly efficient production of hydrogen and chemical*

energy carriers and having enabled the replacement of older processes using amalgam and asbestos. PFAS are also used as stable binders in lithium ion batteries.

PFAS are also used in chemical synthesis as reagents, processing aids, solvents, intermediates or catalysts, as well as in filtration and sterile filtration systems for water treatment and the manufacture of medical, pharmaceutical and biotechnological products. They are also broadly used as high-performance materials, especially fluoropolymers, in medical devices, including implantable, invasive and non-invasive devices and their packaging.

## **Question 2.19: Please provide your comments on section 1.2. SEAC opinion [3254/5000 characters]**

### **Instructions:**

Consult the SEAC draft opinion and provide your comments relevant to this specific section of the opinion.

### **VCI response:**

*From an industry perspective, section 1.2 of the SEAC draft opinion is an important step in the right direction because it indicates that a blanket PFAS ban with only an 18-month transition period would not be proportionate. For essential industrial, professional and healthcare applications, such an approach risks causing severe socio-economic and technological disruption that is not justified by the available evidence. Certain PFAS-based materials, particularly some fluoropolymer-based materials, are used in highly regulated and sensitive applications, including medical applications. This indicates that a differentiated assessment of use conditions, substitution feasibility and proportionality is necessary, especially where product performance, reliability and patient safety are critical. From an industry perspective, it is therefore crucial that regulation avoids endangering life-saving or life-sustaining applications simply because emissions cannot be fully excluded in every life-cycle stage.*

*The draft opinion makes clear that the current evidence base is still incomplete. SEAC explicitly states that justified derogations are necessary, but may not be sufficient on their own, and that uncertainties as well as unknown or unidentified uses prevent it from specifying all additional derogations that may be needed. From an industry perspective, this is highly significant. Where uses have not yet been fully assessed, where substitution is not technically or economically feasible, or where the real consequences for industrial production or the society are still uncertain, the regulatory response must be cautious, practical and based on a real-world feasibility check. The same applies even more strongly to the additional sectors that have not been subject to detailed sector-specific evaluation. In such cases, long-term derogations are not an exception, but a minimum requirement to avoid disproportionate socio-economic and technological damage. Consistent with this need for regulatory coherence and proportionality, active ingredients should be excluded from the PFAS restriction, as they are already subject to comprehensive and substance-specific risk assessments under established EU regulatory frameworks.*

*We also share SEAC's concerns regarding additional obligations for continued use. Site-specific PFAS management plans, emission monitoring, labelling, safe use and disposal instructions and expanded reporting requirements may create significant burdens for companies, especially where they are introduced without a clear demonstration of proportionality, feasibility and enforceability. Derogations must remain workable in practice. They must not be undermined by compliance obligations that are overly complex, legally uncertain or impossible to implement consistently across highly diverse industrial uses and global multi-tier supply chains. If the final restriction is to be proportionate, it must provide broad and realistic derogations for essential industrial and professional uses, sufficiently long transition periods for the development, qualification and implementation of alternatives, and a regulatory framework that avoids simply shifting production, emissions and strategic technologies outside Europe.*

**Question 2.20: Please provide your comments on section 2.2 Summary of the opinion and 2.2.2 SEAC opinion summary [3853/5000 characters]**

**Instructions:**

Consult the SEAC draft opinion and provide your comments relevant to these sections of the opinion.

**VCI response:**

*From an industry perspective, the summary of the opinion confirms an essential point: a blanket PFAS ban is not a workable solution. It is therefore welcome that SEAC concludes that a full ban with only an 18-month transition period is likely not proportionate and that a restriction can only be considered proportionate if use-specific derogations are granted where the socio-economic costs outweigh the benefits.*

*This conclusion is of fundamental importance for European industry. PFAS are essential for a broad range of industrial and professional applications, including semiconductors, batteries, fuel cells, hydrogen-related technologies, defense, water treatment, medical manufacturing and healthcare, and the safe and reliable operation of industrial equipment. In many of these uses, PFAS are critical for performance, durability, chemical resistance and process safety, and adequate alternatives are not yet available. Even if alternatives might be technically available in certain cases, these will still require several years to be broadly implemented, if feasible at all, considering the complexity of multi-tier supply chains and strict regulatory requirements in several sectors and product groups. In all of these cases, a broad restriction without realistic derogations would not drive a sustainable transition, but would instead interrupt industrial processes, weaken strategic value chains and shift production to regions outside Europe. This is particularly relevant for sectors that are central to industrial transformation and technological sovereignty and where substitution requires coordinated change across the value chain.*

*The summary should, in our view, reflect even more clearly that many important uses remain insufficiently assessed. SEAC itself states that justified derogations are necessary, but may not be sufficient on their own, and that uncertainties as well as unknown or unidentified uses*

*prevent it from specifying all additional derogations that may be required. This means that the current knowledge base creates significant socio-economic risks and is not yet robust enough to justify a restrictive approach across the full PFAS universe.*

*This concern is particularly serious for the eight additional sectors for which no detailed sector-specific SEAC evaluation was carried out. In those cases, the summary should make even clearer that no final restrictive conclusions should be drawn before a proper assessment of alternatives, technical feasibility, economic feasibility and socio-economic impacts has taken place. In line with SEAC's own reasoning, time-limited derogations are therefore an important interim safeguard until such an evaluation has been completed and an appropriate decision on proportionality can be made.*

*The same applies to additional conditions for continued use. The summary notes that SEAC in principle supports further risk management measures, but also states that the Committee lacks sufficient information to assess their proportionality and has concerns regarding enforceability. From an industry perspective, this is a critical point. Derogations must remain workable in practice and must not be undermined by compliance obligations that are overly burdensome, uncertain or impossible to implement consistently across highly diverse industrial applications.*

*Overall, the summary rightly moves away from the logic of a uniform ban and towards a more differentiated approach. This approach must be followed consistently in the final opinion and in the subsequent decision-making process. A proportionate restriction requires broad and realistic derogations for essential uses, sufficient transition periods, and a real-world feasibility check that prevents the loss of innovation, industrial capacity and supply security in Europe.*

### **Question 2.21: Please provide your comments on section 3.2. Justification that action is required on a Union-wide level [3257/5000 characters]**

#### **Instructions:**

Consult the SEAC draft opinion and provide your comments relevant to this specific section of the opinion.

#### **VCI response:**

*Action at Union-wide level is required because PFAS are produced, placed on the market, transported and used across sectors and value chains throughout the internal market. SEAC itself recognises that PFAS-related pollution is transboundary and that any action to address the identified risks should therefore be taken on a Union-wide basis. A purely national approach would not reflect the reality that uses, products and supply chains are interconnected across the EU. From an industry perspective, however, such action should be risk-based, targeted and proportionate.*

*A risk-based, targeted and proportionate Union-wide approach is also necessary to avoid problem-shifting and unintended market effects. The proposed restriction addresses the*

*manufacture, placing on the market and use of PFAS as substances on their own and as constituents in mixtures and articles, including imported articles. From an industry perspective, this also means that while PFAS-containing products could no longer be placed on the EU market, products whose manufacture depends on PFAS process uses – even where PFAS are no longer present in the final product – may no longer be manufacturable within the EU and would instead have to be imported. The result would be a shift of production rather than a real solution to the underlying problem.*

*A Union-wide framework is further needed to ensure planning security, practicability and enforceability, including with regard to imports, and to avoid a fragmented regulatory landscape that would increase complexity and administrative burden. This is particularly important for industrial applications embedded in core functions across Europe, including sealing applications, machinery applications, technical textiles and other broader industrial uses. SEAC itself notes that several sectors and uses remain insufficiently assessed and that, for the eight additional sectors without detailed sector-specific evaluation, no final conclusion on proportionality can yet be drawn.*

*Finally, realistic transition pathways require coordinated action across the entire value chain. Substitution and innovation cannot be achieved in isolated national markets, but require alignment between material suppliers, component manufacturers, system suppliers, industrial users and customers across the EU. A targeted Union-wide approach is therefore necessary not only to reduce risks effectively, but also to support the development of safe and sustainable alternatives while safeguarding strategically important industrial and high-technology applications. This is particularly relevant in sectors such as semiconductors, batteries and hydrogen-related technologies, where alternatives often require long development, qualification and implementation periods across multiple actors in the value chain.*

*At the same time, Union-wide action cannot be regarded as proportionate if standardised and validated methods for testing and enforcement are not available and if enforceability cannot be ensured in practice, especially for imported articles and complex supply chains. Otherwise, EU companies may face the double burden of substitution costs and compliance obligations, while equivalent enforcement vis-à-vis non-EU producers remains uncertain.*

### **Question 2.22: Please provide your comments on section 3.3.1 Availability and technical and economic feasibility of alternatives [4675/5000 characters]**

#### **Instructions:**

Consult the SEAC draft opinion and provide your comments relevant to this specific section of the opinion.

**VCI response:**

*Across many industrial and professional uses, adequate alternatives with comparable performance are still not available today. This is not due to a lack of effort by industry. Intensive research is ongoing across the value chain. The problem is that PFAS combine a range of high-performance characteristics that are extremely difficult to replicate at the same level with other material classes. These include resistance to heat, acids, alkalis, pressure, demanding operating conditions and long-term material stability. In many cases, replacing PFAS means accepting a loss in performance, durability, purity, efficiency or safety.*

*The SEAC draft opinion is therefore right to assess alternatives on a sector-by-sector and application-by-application basis. Any broader or generic assumption that alternatives are available would be technically unsound and economically unrealistic. PFAS are not one uniform material group, and their uses are equally diverse. Fluorinated gases, non-polymeric PFAS and polymeric PFAS serve very different technical functions. Furthermore, the feasibility of substitution depends on the exact use, the performance profile required, the surrounding system, and the consequences of failure. There is no meaningful “one-size-fits-all” answer to the question of alternatives, including at the level of broader sectoral assessment.*

*This is especially evident in industrial equipment and infrastructure. In many plant-related applications, such as seals, valves, linings, membranes, filters, diaphragms and other critical components, fluoropolymers remain very difficult or impossible to replace without creating serious technical disadvantages. These materials are often required to ensure tightness, chemical resistance and long service life under aggressive process conditions. If substitute materials cannot provide the same level of long-term reliability, the result is not simply reduced convenience. It can mean higher leakage risks, more frequent shutdowns, higher maintenance costs, compliance challenges and, in the worst case, risks for plant and operational safety.*

*From an industry perspective, the debate on alternatives must therefore go beyond the theoretical question of whether a PFAS-free material exists in principle. The relevant question is whether a substitute is technically feasible, economically viable and demonstrably suitable in the specific use and life-cycle context. A nominally PFAS-free option is not automatically the better alternative. A meaningful assessment must consider functionality, use conditions, system integration and life-cycle implications in the specific application concerned.*

*Economic feasibility is equally application-specific and must not be underestimated. Substitution in industrial settings often requires major investment, redesign of components and systems, new testing and qualification procedures, adaptation of manufacturing processes, and in some cases changes to permitted installations. Such transitions are especially difficult where equipment is highly regulated, capital-intensive and operated over long time horizons. Even where alternatives may exist in principle, implementation can take many years and require substantial financial resources. Inferior substitutes can also create permanent cost increases through shorter service life, lower efficiency, increased maintenance or reduced product quality.*

*Substitution is therefore not simply a materials question. It is a full value-chain challenge. Alternatives can only be developed and deployed through close coordination between raw material suppliers, formulators, component manufacturers, system suppliers, plant operators and customers. It also requires suitable framework conditions: long-term legal certainty, realistic transition periods, funding for research and industrial scale-up, testing and validation capacity, and a regulatory approach that allows innovation instead of forcing premature replacement in applications where no equivalent solution exists. This is also valid for use of PFAS in other sectors and products, outside industrial equipment and infrastructure, especially in those with complex multi-tier supply chains and strict product regulations. These factors can significantly reduce the availability of technically feasible alternatives in practice and extend the time needed for transition.*

*For this reason, the availability and feasibility of alternatives must be assessed with maximum care and realism. Any other approach would risk damaging essential industrial applications and strategic technologies in Europe without ensuring better overall outcomes for safety, sustainability or innovation.*

**Question 2.23: Please provide your comments on section 3.4.1 Regulatory risk management options other than restriction [4420/5000 characters]**

**Instructions:**

Consult the SEAC draft opinion and provide your comments relevant to this specific section of the opinion.

**VCI response:**

*A central weakness of the broad restriction logic is the insufficient differentiation between fundamentally different PFAS categories. Fluorinated gases, non-polymeric PFAS and fluoropolymers differ substantially in their functions, use patterns and emission profiles. Fluoropolymers merit more differentiated treatment, including broader or longer-lasting exemptions where substitution is not yet feasible and uses are controlled. In many industrial and professional applications, a more targeted regulatory approach focused on manufacturing emissions, operational controls and end-of-life management may be more proportionate and effective than a broad market restriction. Applying the same restriction logic to fluoropolymers as to all other PFAS would therefore be disproportionate and would jeopardise critical applications where these materials are indispensable.*

*Against this background, a broad REACH restriction is not an appropriate regulatory instrument for all PFAS uses. From an industry perspective, a blanket approach is neither proportionate nor practical. A more credible approach would be risk-based, targeted and use-specific. The decisive question should not be whether a substance belongs to the broad PFAS universe, but whether emissions and exposures in a specific use can be effectively prevented or controlled. In many industrial applications, the key issue is not the mere presence of PFAS, but whether releases can be minimised through operational conditions, technical controls, equipment standards and*

*appropriate end-of-life management. Where this is possible, prohibition should not be the default response, and socio-economic impacts and uncertainties must be considered. Additional information available to VCI on full-scale thermal waste treatment also indicates that, under the tested conditions, PFAS destruction rates above 99.9999 wt.-% were achieved and no significant increase in stack PFAS concentrations was observed, supporting the relevance of targeted end-of-life measures in the overall regulatory assessment.*

*In this context, time-unlimited RO3-type approaches demonstrate that a more realistic middle way is available. Continued manufacture, placing on the market and use under clearly defined conditions can be more effective and proportionate than bans combined with time-limited derogations. Such approaches can build on existing compliance structures and target emissions where they occur, for example through BAT-based off-gas and wastewater treatment, controlled operating conditions, waste handling and structured substitution planning.*

*At the same time, RO3 must be understood realistically. Compared with a simple exemption, it entails additional monitoring, reporting and documentation obligations. From an industry perspective, such requirements are only justified where they demonstrably contribute to emission reduction or support substitution in practice. Reporting should therefore be proportionate and focused on relevant, actionable information. If applied pragmatically, RO3 can nevertheless be more workable than RO1 or RO2, as it avoids cliff-edge risks linked to bans or expiring derogations while linking continued use to credible emission control efforts.*

*Existing emission control and permitting frameworks should be used more consistently. Industrial emissions, product and waste legislation already provide effective tools to minimise releases and ensure high technical standards. Strengthening and coherently applying these instruments can reduce environmental releases more effectively than duplicative REACH requirements.*

*Where derogations remain necessary, they must be reviewable, extendable and responsive to technical and economic reality. Short derogation periods are incompatible with development and investment cycles that often span up to ten and more years. Regulatory coherence across REACH, industrial emissions, product and waste legislation is therefore essential to ensure effective environmental protection without undermining critical industrial uses.*

*For the transport of dangerous goods, a comprehensive and internationally harmonised risk management framework already exists (ADR/RID, IMDG, UN Model Regulations). As these systems operate outside REACH, time-unlimited or otherwise reviewable long-term derogations may be necessary to ensure a workable and legally coherent solution for safety-critical PFAS-based sealing systems.*

**Question 2.24: Please provide your comments on section 3.4.2.2.1 Socio-economic analysis: Approach [4434/5000 characters]**

**Instructions:**

Consult the SEAC draft opinion and provide your comments relevant to this specific section of the opinion.

**VCI response:**

*A socio-economic analysis (SEA) for PFAS should be designed to capture system-wide effects, not only immediate use-level effects. A careful SEA, which considers the full relevance of the use under assessment, is needed before any broad restriction, covering not only the end product but the wider production chain, because PFAS may be used as process aids, intermediates or auxiliary substances during manufacturing even where they are not present in the final product.*

*Methodologically, the SEA should therefore assess impacts along the supply and value chain, including raw materials, precursors, intermediates, auxiliary products and components and, where relevant, wider societal impacts linked to downstream availability. Exemptions limited to specific end uses, while overlooking upstream inputs and wider supply-chain dependencies, can render exemptions ineffective and may shift production out of the EU, with consequences for jobs, imports, supply security and strategic autonomy. Where such wider effects are considered, they should be clearly identified as system-wide or societal impacts rather than conflated with direct company-level impacts.*

*A key weakness of the current approach is that for most sectors there is no robust quantitative SEA and, in many cases, only a qualitative SEA is being performed. Furthermore, certain critical uses appear not to be fully reflected in the current assessment, resulting in information gaps or uncertainties in the evaluation. This significantly limits the ability to assess and compare the socio-economic consequences of the proposed restriction in a consistent way. Given that PFAS are used in many critical industrial and high-technology applications, this methodological gap can have severe consequences for society, industrial resilience and the functioning of strategic value chains. Where benefits cannot be quantified and costs are assessed only qualitatively, particular caution is needed before drawing far-reaching conclusions on proportionality. The socio-economic consequences of potential gaps in coverage and remaining uncertainties in the assessment should be carefully considered, particularly for socio-economically critical sectors and uses.*

*From an industry perspective, the SEA should also reflect that PFAS-related impacts are often indirect, cumulative and system-wide. The loss of a PFAS use may affect not only one product, but also upstream manufacturing steps, plant design, component qualification, process safety, product purity, maintenance cycles and downstream availability of essential goods. These effects can multiply across value chains and should not be underestimated simply because they are difficult to express in a standardised numerical form.*

*The consultation format itself also creates methodological limitations that should be acknowledged in the SEA. ECHA has chosen a structured questionnaire with predefined answer fields and no possibility to upload attachments. While this may simplify data collection, it risks preventing affected stakeholders from submitting relevant technical, economic and value-chain information in a complete and usable manner. In practice, a questionnaire-based approach can*

*also create significant and partly unnecessary administrative effort, especially where different actors, different uses and different steps in the value chain require separate submissions.*

*More fundamentally, the procedure to date illustrates that a restriction approach of this breadth and complexity risks becoming overloaded and difficult to implement. If the consultation format does not allow stakeholders to explain complex production chains, indirect impacts and interdependencies in sufficient depth, the resulting evidence base may remain incomplete. This should be considered when judging the appropriateness of the proposed restriction and when interpreting the socio-economic analysis.*

*Overall, the SEA approach should be broadened and strengthened. It should capture full value-chain effects, reflect indirect and upstream dependencies, recognise the limits of largely qualitative assessments, and ensure that the consultation process can collect the information needed for a robust and balanced evaluation. Otherwise, there is a serious risk that the socio-economic consequences of the proposed restriction will be underestimated, particularly for critical industrial uses and strategically important technologies in Europe.*

### **Question 2.25: Please provide your comments on section 3.4.2.2.2 Socio-economic analysis: Costs [2931/5000 characters]**

#### **Instructions:**

Consult the SEAC draft opinion and provide your comments relevant to this specific section of the opinion.

#### **VCI response:**

*Under the current PFAS restriction discussion, the socio-economic cost assessment should not be limited to substitution and transition costs alone. As reflected in section 3.4.2.2.2 of the SEAC draft opinion, no conclusion has been reached on the overall costs associated with RO1, RO2, RO3 or the proposed restriction as a whole, and the existing assessment is largely based on sector- and/or (sub-)use-level analyses and on the analysis of alternatives. While this is a relevant factor, it is not sufficient on its own to determine the magnitude of costs expected to result from the restriction.*

*From an industry perspective, this creates a risk that important cost elements are underestimated. In addition to substitution and transition costs, the cost assessment should capture the direct compliance and administrative burdens created by the regulatory design itself. The updated dossier introduces additional obligations, such as documentation and information requirements and, in some cases, further conditions linked to derogations. Where companies rely on derogations, recurring documentation and reporting duties may arise, which can translate into substantial internal workload, process changes and ongoing compliance costs.*

*Beyond pure administrative effort, further cost drivers arise from information-handling requirements. Reporting on quantities used and exemptions claimed may require extensive data collection across complex supply chains and, in sensitive areas, may create additional management and legal costs. These aspects are not systematically reflected when the cost assessment focuses primarily on the availability of alternatives.*

*In addition, time-limited derogations can create significant upstream cost effects that are not yet adequately reflected. Capital-intensive PFAS manufacturing, in particular fluoropolymer production, depends on stable demand volumes and minimum utilisation rates over long investment cycles. A progressive reduction of authorised downstream uses can fragment demand and lead to declining plant utilisation, increasing unit costs and undermining economic viability. As a result, upstream capacity may become unavailable in practice even while some downstream uses remain formally derogated, thereby undermining the practical effectiveness of such derogations.*

*Finally, the cost analysis should also reflect wider economic impacts. As SEAC itself notes that the costs associated with a full ban are likely significant, an undifferentiated restriction approach risks disrupting industrial production across multiple sectors and value chains, with knock-on effects on jobs, planning certainty and investment decisions. Where SEAC identifies a general lack of data and substantial shortcomings in the cost assessment, this should militate against drawing far-reaching conclusions on proportionality for the affected use or sector until the relevant uncertainties have been reduced.*

## **Question 2.26: Please provide your comments on section 3.4.2.2.3 Socio-economic analysis: Benefits [2497/5000 characters]**

### **Instructions:**

Consult the SEAC draft opinion and provide your comments relevant to this specific section of the opinion.

### **VCI response:**

*Socio-economic benefits should be framed in terms of the benefits of effective, risk-based management that ensures safe and sustainable use across the product life cycle. As written in the SEAC draft opinion, PFAS are very persistent substances and risks to human health and the environment can arise where handling, use or disposal of certain PFAS are not adequately controlled.*

*A key socio-economic benefit therefore lies in reducing emissions through appropriate risk management measures, including safe handling, controlled operating conditions and proper end-of-life management. By keeping emissions as low as possible along the life cycle, unavoidable exposure of humans and the environment can be minimised and long-term accumulation in the environment can be avoided.*

*From an industry perspective, the socio-economic assessment should distinguish more clearly between uses where broad restrictions are likely to reduce emissions effectively and uses where the main regulatory relevance lies in manufacturing emissions or end-of-life handling rather than in the controlled use phase itself. For fluoropolymer-based applications in particular, the available evidence should be assessed carefully regarding actual release pathways, use conditions and the realistic contribution of alternative risk-management measures.*

*Available information on thermal waste treatment under real operating conditions also indicates that end-of-life management may, under certain conditions, contribute significantly to the destruction of PFAS and should therefore be considered when assessing the relative benefits of broad use restrictions versus targeted life-cycle measures. Additional information available to VCI on full-scale thermal waste treatment also indicates that, under the tested conditions, PFAS destruction rates above 99.9999 wt.-% were achieved and no significant increase in stack PFAS concentrations was observed, supporting the relevance of targeted end-of-life measures in the overall regulatory assessment.*

*Regarding particle emissions from fluoropolymers, the assessment remains predominantly qualitative and does not allow for a comprehensive quantitative or holistic evaluation. The SEAC opinion refers to similarities with micro-particles from other polymer materials, while acknowledging remaining uncertainties. From an industry perspective, these uncertainties should be reflected more clearly when drawing conclusions on the relative socio-economic benefits of broad restrictions for fluoropolymer-based applications.*

*A proportionate socio-economic assessment should therefore focus on the benefits of measures that reduce emissions where they actually arise, while considering the specific use conditions, the feasibility of alternative control measures and the wider socio-economic consequences for critical industrial and professional applications.*

**Question 2.27: Please provide your comments on section 3.4.2.2.4 Socio-economic analysis: Other relevant impacts [4042/5000 characters]**

**Instructions:**

Consult the SEAC draft opinion and provide your comments relevant to this specific section of the opinion.

**VCI response:**

*Other relevant socio-economic impacts go beyond direct compliance costs and include broader effects on strategic policy objectives, value chains and essential societal functions. These impacts are often difficult to quantify and are therefore only partially reflected in the socio-economic analysis, but they are nonetheless highly relevant when assessing the proportionality of the proposed restriction. This is particularly important where impacts arise indirectly across multiple sectors or over longer time horizons.*

*A particularly important dimension concerns climate protection and sustainability. PFAS-enabled materials and components are used in a number of technologies that are central to decarbonisation and the energy transition. This includes, in particular, semiconductors, batteries, fuel cells and hydrogen-related technologies. If such materials were no longer available in the EU before technically equivalent solutions are ready, development timelines and the scale-up of key climate technologies could be delayed. This may have knock-on effects on investment planning, industrial transformation pathways and the overall pace of achieving climate objectives.*

*A second major impact relates to the health sector and security of supply for medical and pharmaceutical products. PFAS are used in parts of pharmaceutical and medical manufacturing chains, including in process equipment and in production steps for important precursors. If access to these uses is restricted without workable derogations and realistic transition periods, this could reduce the EU's ability to manufacture essential inputs, active substances and certain medicines or medical products domestically. Such effects would increase dependency on imports and may create risks for supply security.*

*A third important consideration applies to wastewater treatment membranes that are foundational to EU water resilience ambitions, enabling wastewater reuse, drought adaptation, pollution control, and a climate-resilient infrastructure. A restriction of PFAS-based membranes would reduce treatment capacity, delay water-reuse projects, and weaken the EU's ability to manage water scarcity and extreme climate events.*

*Further relevant impacts concern technological sovereignty and industrial competitiveness. High-technology manufacturing, in particular electronics and semiconductors, relies on highly controlled processes and specialised materials. A sudden loss of key PFAS-related functionalities could weaken the EU's capacity to maintain or expand strategic production capabilities, with downstream effects on innovation, related industries and overall economic resilience.*

*Another important aspect is future innovation that is not yet captured in current use mappings or derogation lists. Where regulation relies on a fixed and static set of use-specific exemptions, new or still-developing applications cannot be proactively covered because they are not yet identified or documented. SEAC itself notes uncertainty as to whether all PFAS (sub-)uses have been identified, assessed and properly discussed. This can create a chilling effect on research and development and on the industrial scale-up of new applications in Europe, as innovators cannot rely on predictable access to necessary materials during development phases. This may have long-term negative effects on innovation, including in emerging climate, health and other strategic technologies.*

*Finally, there are cross-cutting implications for industrial operations and investment behaviour. If regulatory frameworks are perceived as unpredictable, inflexible or not practicable, companies may postpone investments, relocate parts of production or restructure supply chains outside Europe. These effects are difficult to reverse and should be considered as part of the broader socio-economic impacts of the proposed restriction. This is particularly relevant where broad restrictions are introduced despite substantial uncertainties regarding alternatives, costs and the full range of affected uses.*

**Question 2.28: Please provide your comments on section 3.4.2.2.5 Socio-economic analysis: Proportionality [4929/5000 characters]**

**Instructions:**

Consult the SEAC draft opinion and provide your comments relevant to this specific section of the opinion.

**VCI response:**

*A proportionality assessment should ensure that regulatory measures are commensurate with the demonstrated risk and workable in practice. As reflected in the SEAC draft opinion, proportionality must be assessed on a sector- and use-specific basis and cannot be ensured through a uniform approach covering very different substances and applications.*

*We support SEAC's conclusion that, based on the currently available data and the heterogeneity of the sectoral analyses, the proportionality of neither RO2 nor RO3 can be conclusively assessed at the level of the restriction. As proportionality is a core requirement of any restriction under REACH, this supports a more differentiated and cautious approach, particularly where important uncertainties remain regarding costs, benefits, alternatives and the need for additional derogations.*

*The current approach raises concerns where it applies a very broad regulatory logic despite substantial differences in use conditions, substitution feasibility, available evidence and socio-economic relevance across sectors and applications. Proportionality remains a core requirement even where precaution is invoked. A restriction that broadly captures very different PFAS categories and uses risks going beyond what is necessary to address the identified concerns.*

*In this context, it is particularly important to recognise that fluoropolymers merit more differentiated treatment within the overall PFAS framework, given their relevance in many controlled industrial applications and the practical difficulties of substitution in numerous sectors. Treating fluoropolymers under the same broad regulatory logic as all other PFAS, without appropriate differentiation, raises serious proportionality concerns.*

*Proportionality requires that procedural and evidentiary demands placed on stakeholders are realistic. The current approach raises concerns because it expects companies to provide detailed*

*information for a wide range of applications within very short timeframes. For many sectors and complex value chains, compiling comparable, application-specific data at the requested depth and speed is not feasible. ECHA and SEAC have pointed to remaining data gaps and invited further contributions during the consultation. The current consultation framework, however, also operates through structured questionnaires with character limits and without attachments, which may make it more difficult to provide complex technical and value-chain information in full. This creates a risk that relevant uses and interdependencies are not accurately represented in the assessment, while simultaneously imposing a significant administrative burden.*

*A more proportionate approach would therefore rely on targeted regulation of risk-relevant uses, provide adequate time and workable formats for data submission, and ensure that regulatory requirements reflect the practical realities of industrial supply chains as well as the availability of robust and complete evidence. It should also reflect that realistic transition pathways depend on value-chain coordination, application-specific assessment and sufficient time for development, qualification and implementation of alternatives.*

*Without adequate enforceability and sufficiently developed monitoring and analytical methods, the practical proportionality of regulatory measures is harder to demonstrate. SEAC notes that additional conditions for continued use (such as reporting obligations, site-specific PFAS management plans, monitoring or labelling requirements) may entail significant costs and raises concerns regarding their proportionality and enforceability. However, these elements are largely assessed individually rather than in their combined effect.*

*From an industry perspective, it would therefore be appropriate for SEAC to consider the cumulative compliance burden resulting from derogations together with their associated conditions. In certain low-emission and non-dispersive industrial uses, the aggregation of multiple obligations may render continued use technically or economically unfeasible, even where a derogation formally exists. This creates a risk that derogations become nominal in nature and lack practical effect.*

*A cumulative assessment could also support a more differentiated and targeted regulatory approach. Rather than assessing RO2 across the entire restriction proposal as a single, uniform option, it may be more appropriate to advance those sectors and uses where risks, emissions, alternatives and socio-economic implications are already sufficiently understood. In contrast, sectors with remaining data gaps, uncertainties or complex use patterns would benefit from further analysis before conclusions on proportionality and practicality are drawn. Such a selective approach would be more consistent with SEAC's mandate to assess feasibility, enforceability and socio-economic impacts on a case-by-case basis.*

**Question 2.29: Please provide your comments on section 3.4.2.3 Practicality, including enforceability [3805/5000 characters]**

**Instructions:**

Consult the SEAC draft opinion and provide your comments relevant to this specific section of the opinion.

**VCI response:**

*Practicality and enforceability are central concerns because the proposed restriction approach has an extremely broad scope and covers a very large number of diverse uses, mixtures and articles across many sectors, including PFAS as constituents, impurities or additives. Under such a wide scope, a strictly sector-specific implementation becomes difficult to operationalise. It is not realistic to identify, classify and control every relevant use case in complex, multi-stage supply chains without creating an unmanageable regulatory system.*

*Consequently, the approach requires a constantly growing number of exemptions and derogations. This creates a highly complex legal and administrative structure that is difficult for companies to apply correctly and difficult for authorities to monitor and enforce consistently. In practice, enforceability becomes uncertain when the applicable rules depend on numerous narrowly defined exemptions with different conditions, timelines, documentation duties and follow-up requirements. Furthermore, some of the exemptions proposed by the dossier submitters and reflected in the SEAC assessment rely on terms that may lack sufficient clarity or may be difficult to interpret consistently across sectors, which may create uncertainty regarding their practical application and could risk unintended short-term impacts on socio-economically important uses.*

*Enforceability is particularly challenging with regard to imports. Effective control would require reliable information on whether imported articles contain PFAS and, if so, which PFAS and at what levels. In many cases, enforcement faces structural obstacles, including limited availability of sufficiently developed analytical methods for a wide range of PFAS in complex matrices and incomplete or inconsistent information flows along global supply chains. This makes it difficult to verify compliance at the border or through market surveillance. For complex end products, such as vehicles or other assembled goods, it is often unclear how authorities could practically determine whether specific components contain PFAS. Broad labelling or documentation obligations for PFAS in complex products would be extremely difficult to implement and enforce consistently unless they are linked to clear scope definitions, practical thresholds, harmonised calculation approaches and sufficiently developed analytical methods.*

*In addition, legal certainty and enforceability suffer where definitions, scope descriptions and derogation wording are not sufficiently precise or are difficult to interpret consistently across sectors. This increases the risk of uneven implementation, legal disputes and enforcement gaps, while at the same time raising compliance costs and uncertainty for economic operators.*

*Overall, the breadth of the restriction approach, the reliance on numerous use-specific derogations, limited traceability and testability in global supply chains, and the difficulty of controlling PFAS content in imported complex articles all point to a high risk that the measure would be difficult to implement and enforce in a predictable, consistent and effective manner.*

*SEAC itself considers the proposed restriction monitorable, but only while noting considerable challenges associated with enforceability.*

*This is particularly relevant for cross-sectorial applications such as sealing, machinery and other complex industrial uses, where PFAS-containing components are embedded in larger systems and where use categories do not always map neatly onto enforceable product categories. In such cases, practicality depends not only on legal wording, but also on whether authorities and companies can realistically identify the relevant use, verify compliance and apply derogation conditions in a consistent manner.*

### **Question 2.30: Please provide your comments on section 3.4.2.4 Monitorability [3342/5000 characters]**

#### **Instructions:**

Consult the SEAC draft opinion and provide your comments relevant to this specific section of the opinion.

#### **VCI response:**

*Monitorability is a key challenge because effective oversight depends on clear and measurable parameters, sufficiently developed and, where possible, standardised analytical methods, and reliable information flows along supply chains. Across the full PFAS universe, all of these elements are only partially available, which significantly limits consistent and comparable monitoring in practice.*

*For some narrowly defined monitoring concepts, measurement is feasible, for example where a defined list of PFAS is monitored using validated and harmonised analytical methods. However, for broader concepts such as the proposed total fluorine/“total PFAS” screening approach, or for identifying PFAS in complex matrices and articles, monitorability remains limited. Analytical methods are not consistently standardised or harmonised, and for many approaches the range of matrices that can be covered remains incomplete. This reduces the ability of authorities and companies to verify compliance in a consistent and comparable manner across Member States.*

*In addition, methods intended to determine “total PFAS”, such as total organic fluorine (TOF), are not PFAS-specific. They may also detect other fluorinated substances that do not fall under the PFAS definition used in this restriction proposal, which can lead to misinterpretation of results and inconsistent communication between authorities and economic operators. SEAC itself notes that there are currently no standard methods for total fluorine and that proof of origin for fluorine content may be difficult to provide in complex supply chains.*

*Monitorability is further constrained for products and complex articles, including imported goods. Even where legal thresholds exist, it is often unclear how to trace, document and verify whether specific components in complex end products contain PFAS. Limited transparency in global supply chains, combined with the lack of broadly applicable analytical standards and*

*practical documentation and communication mechanisms, makes systematic monitoring difficult and increases the risk of selective, inconsistent or unenforceable implementation.*

*Overall, the current situation indicates that monitorability is highly dependent on the specific use case. While it can be workable for clearly defined parameters and specific substances, it remains a major limitation for broad PFAS group concepts and for complex products, particularly where sufficiently developed analytical tools and reliable supply-chain information are lacking. RAC and SEAC consider the proposed restriction monitorable, but both acknowledge practical limitations: RAC notes that observable decreases may take time because of persistence, derogations and the large number of emission sources, while SEAC points to considerable challenges linked to enforceability and recommends continued support for the development of analytical methods, especially for total fluorine methods.*

*From an industry perspective, monitorability should therefore be assessed more explicitly in relation to specific use patterns, product types and supply-chain structures. A broad restriction may be monitorable in principle, but this does not mean that all of its elements can be monitored with the same reliability, comparability and practical enforceability across all sectors and product categories.*

**Question 2.31: Please provide your comments on section 3.4.3.2.1 Conclusion whether the suggested restriction is the most appropriate EU-wide measure: (i) PFAS definition [782/1000 characters]**

**Instructions:**

Consult the SEAC draft opinion and provide your comments relevant to this specific aspect of the opinion.

**VCI response:**

*While the OECD-based PFAS definition provides structural clarity, it covers more than 10,000 substances with very different properties, use patterns and exposure scenarios, including non-polymeric PFAS, fluorinated gases and polymeric PFAS such as fluoropolymers. The definition is based on structural features rather than hazard or risk, and its breadth therefore increases the need for numerous derogations and scope clarifications in practice.*

*From an industry perspective, this raises practical and proportionality concerns, especially where substances and uses with clearly different profiles are addressed under one scope.*

*Greater differentiation, including subgrouping where appropriate, would better reflect technical realities and improve legal certainty and enforceability.*

**Question 2.32: Please provide your comments on section 3.4.3.2.1 Conclusion whether the suggested restriction is the most appropriate EU-wide measure: (ii) Exclusion of PFAS from the scope [951/1000 characters]**

**Instructions:**

Consult the SEAC draft opinion and provide your comments relevant to this specific aspect of the opinion.

**VCI response:**

*To assess whether the proposed restriction is the most appropriate EU-wide measure, the scope should contain clear and workable exclusions or derogations for uses where a broad restriction would create disproportionate socio-economic impacts. For fluoropolymers, a more differentiated approach is warranted, given their different emission profile compared with other PFAS groups and generally low service-life emissions, while manufacturing and waste stages remain relevant.*

*At minimum, any exclusion or derogation should clearly cover continued use in existing installations, necessary spare parts and maintenance, as well as the necessary upstream manufacturing steps and inputs. Otherwise, formally excluded uses could still become unavailable in practice, creating supply-chain disruption, regulatory uncertainty and greater import dependence. A clearer treatment of fluoropolymers would therefore improve legal certainty and practical workability.*

**Question 2.33: Please provide your comments on section 3.4.3.2.2 Conclusion whether the suggested restriction is the most appropriate EU-wide measure: Scope of the proposed restriction [910/1000 characters]**

**Instructions:**

Consult the SEAC draft opinion and provide your comments relevant to this specific section of the opinion.

**VCI response:**

*If a restriction is pursued with the proposed broad scope, it must be accompanied by clear and workable conditions to ensure proportionality, legal certainty and continuity of critical uses where alternatives are not yet confirmed to be available. A mandatory and transparent review mechanism should therefore be anchored in the final regulation to allow exemptions to be reviewed, extended or re-applied for well before expiry.*

*Especially for safety-critical and high-performance applications, transition periods should remain use-specific and realistic, reflecting qualification, validation, supply-chain complexity and, where relevant, regulatory approvals.*

*In addition, longer-term derogations may be needed for fluoropolymers and other controlled industrial uses, and these should be framed so that necessary spare parts, maintenance and relevant upstream steps are not unintentionally blocked in practice.*

**Question 2.34: Please provide your comments on section 3.4.3.2.3 Conclusion whether the suggested restriction is the most appropriate EU-wide measure: Concentration limits [874/1000 characters]**

**Instructions:**

Consult the SEAC draft opinion and provide your comments relevant to this specific section of the opinion.

**VCI response:**

*Concentration limits can only be an appropriate element of an EU-wide restriction if they are analytically workable, practicable and enforceable across relevant matrices. Targeted limits for defined PFAS may be workable in principle, but targeted analysis covers only a limited subset of PFAS. Group-based parameters such as “total PFAS” rely on non-PFAS-specific analytical approaches that may also capture other fluorinated substances, leading to misinterpretation, inconsistent enforcement and reduced legal certainty.*

*From an industry perspective, this supports focusing on clearly defined analytical targets and ensuring that implementation remains practicable for complex articles and products. The legal text should word the threshold values clear to avoid any ambiguity as to whether the three concentration limits are intended to apply cumulatively or alternatively.*

**Question 2.35: Please provide your comments on section 3.4.3.2.4 Conclusion whether the suggested restriction is the most appropriate EU-wide measure: General 18-month transition period [781/1000 characters]**

**Instructions:**

Consult the SEAC draft opinion and provide your comments relevant to this specific section of the opinion.

**VCI response:**

A general transition period of 18 months is not appropriate across the full scope of the proposed restriction. While administratively simple, a uniform timeline does not reflect the diversity of PFAS uses, substance classes and application contexts. For many professional and industrial uses, substitution requires redesign, testing, validation, qualification and, in some cases, regulatory or customer approval. In safety-critical and high-performance applications, these steps can take several years. Transition periods should therefore be use-specific and reflect technical realities, supply-chain complexity and, where relevant, approval requirements. Longer derogation periods, and reviewable derogations where justified, may be necessary to avoid disruption of critical uses.

**Question 2.36: Please provide your comments on section 3.4.3.2.5 Conclusion whether the suggested restriction is the most appropriate EU-wide measure: Derogations [4365/5000 characters]**

**Instructions:**

Consult the SEAC draft opinion and provide your comments relevant to this specific section of the opinion.

**VCI response:**

*As recognised in the SEAC draft opinion, derogations are necessary to ensure proportionality and practicality, particularly in light of remaining data gaps and the limited and uneven information available for many uses and sectors. SEAC also notes that use specific derogations alone are not sufficient to ensure proportionality and that, under the current circumstances, no conclusion can be drawn on the proportionality of the proposed restriction as a whole. In such a situation, proportionality cannot be ensured through fixed sunset periods alone.*

*Where robust and comprehensive evidence on the availability, technical feasibility and socio-economic implications of alternatives is lacking, derogations should therefore not be treated as narrow or exceptional deviations, but as an integral and reviewable element of the regulatory framework. Time limited derogations should be understood as applying until a thorough, use specific evaluation has been completed, rather than as rigid or inflexible deadlines. In this context, stakeholder requests for a review clause or mechanism are understandable where suitable alternatives are not found during the proposed derogation periods.*

*From an industry perspective, derogations must be designed in a way that provides sufficient legal certainty and operational continuity for critical uses. This requires clear eligibility criteria, transparent review procedures and the possibility to extend or adapt derogations where justified by updated assessments. Derogations should be aligned with realistic transition and*

*review timelines and should avoid forcing premature substitution decisions that could negatively affect safety, performance or sustainability. This is particularly relevant where substitution requires application-specific qualification, system redesign and coordination across the value chain.*

*The practical effectiveness of derogations is also closely linked to the continued availability of upstream production and supply. Time limited derogations may become ineffective in practice if the necessary upstream supply chain for derogated uses is not maintained. In addition, derogations must be coherent across the entire value chain. An exemption granted for a specific use or application risks becoming ineffective if upstream inputs, intermediates or essential production steps required to supply that use remain prohibited. To avoid unintended supply disruptions and production shifts, derogations should therefore explicitly cover all indispensable elements necessary to maintain the derogated use.*

*Further clarification is also needed regarding the treatment of consumables such as processing aids, catalysts and lubricants in industrial manufacturing. The current approach addresses certain consumables inconsistently across sectors, despite their comparable functional relevance. Consumables should therefore be clearly defined and treated consistently, particularly where they are essential for the safe and continuous operation of machinery, chemical installations and infrastructure. Similarly, the proposed derogation approach for spare parts may not be appropriate for installations with very long operational lifetimes, such as chemical plants or wastewater treatment facilities. In such cases, replacements of critical components should be possible for the full operational lifetime of the installation to ensure safety and environmental protection. SEAC itself notes that it cannot conclude on the exact timeframe required and that service lives may vary substantially.*

*Overall, a restriction that relies on derogations without providing sufficient flexibility, reviewability and value chain coherence risks undermining its own objectives. Well designed, reviewable and evidence based derogations are therefore essential.*

*Against this background, exempting active ingredients (AIs) used in medicinal and plant protection products from the PFAS restriction is consistent with proportionality and regulatory coherence. AIs are already subject to comprehensive, substance-specific assessment under established EU sectoral frameworks, making a PFAS group-based restriction redundant. SEAC recognises the essential role of AIs and the potentially significant consequences of restricting them. An EU-only manufacturing ban would risk production shifts without corresponding environmental benefits.*

**Question 2.37: Please provide your comments on section 3.4.3.2.6.1 Conclusion whether the suggested restriction is the most appropriate EU-wide measure: Reporting requirements [991/1000 characters]**

**Instructions:**

Consult the SEAC draft opinion and provide your comments relevant to this specific section of the opinion.

**VCI response:**

*To qualify as an appropriate EU-wide measure, the final restriction must ensure proportionality, workability and enforceability.*

*The updated dossier introduces additional administrative requirements, including documentation, labelling, reporting and, in some cases, certification. These obligations may create recurring burdens, particularly where derogations trigger periodic reporting and record keeping, and should therefore be limited to what is necessary for enforcement and review.*

*SEAC cannot conclude on the costs or proportionality of the reporting requirement. These should be proportionate, avoid duplication and excessive frequency, protect sensitive information and avoid double counting along the value chain. Flexible measures should be preferred over physical labelling, especially for complex products and sectors already subject to other EU legislation. Proposals to include estimated downstream emissions raise concerns regarding effort, data robustness and confidentiality.*

**Question 2.38: Please give an indication of the costs related to the reporting requirements.**

**Instructions:**

Provide an estimate of the magnitude of the costs for the implementation of the reporting requirements, from very low when the impacts are estimated to be insignificant to very high when they may result in a decision to discontinue your business activities.

**VCI response:**

*Very High*

**Question 2.39: Please provide your comments on section 3.4.3.2.6.2 Conclusion whether the suggested restriction is the most appropriate EU-wide measure: Site-specific PFAS management plan [984/1000 characters]**

**Instructions:**

Consult the SEAC draft opinion and provide your comments relevant to this specific section of the opinion.

**VCI response:**

*Site-specific PFAS management plans can be a practical, risk-based tool to control emissions at industrial sites where PFAS are used or handled, by focusing on identifiable and controllable*

*emission sources. However, such plans inevitably increase administrative requirements. Each element should therefore demonstrably contribute to emission minimisation and the protection of human health or the environment, and the scope should remain proportionate and focused on industrial uses with relevant emission potential. Update and review obligations should be limited to cases where conditions of use, emissions or risk profiles change in a significant way. Management plans should not require documentation of fluoropolymer components embedded in equipment where emissions are expected to be low. Existing regulation (e.g. F-gases) should prevail, avoiding double efforts under REACH. Clear definitions and guidance are essential to ensure proportionate application and enforceability.*

**Question 2.40: Please provide your comments on section 3.4.3.2.6.3 Conclusion whether the suggested restriction is the most appropriate EU-wide measure: Additional conditions considered by RAC.**

**Instructions:**

Consult the SEAC draft opinion, section 3.4.3.2.6.2. Conclusion whether the suggested restriction is the most appropriate EU-wide measure: Site-specific PFAS management plan.

Provide an estimate of the costs for monitoring of emissions at industrial sites. Use the scale from very low (minimal impact) to very high (may result in a decision to discontinue business activities).

**VCI response:**

*Very High*

**Question 2.41: Please give an indication of the costs related to monitoring of PFAS emissions at industrial sites.**

**Instructions:**

Consult the SEAC draft opinion, section 3.4.3.2.6.2. Conclusion whether the suggested restriction is the most appropriate EU-wide measure: Site-specific PFAS management plan.

Provide an estimate of the costs for monitoring of emissions at industrial sites. Use the scale from very low (minimal impact) to very high (may result in a decision to discontinue business activities).

**VCI response:**

*Very High*

**Question 2.42: Please provide your comments on section 3.4.3.2.6.3 Conclusion whether the suggested restriction is the most appropriate EU-wide measure: Additional conditions considered by RAC [979/1000 characters]**

**Instructions:**

Consult the SEAC draft opinion and provide your comments relevant to this specific section of the opinion.

**VCI response:**

Additional conditions considered by RAC may in principle contribute to reducing PFAS emissions where uses continue under derogations. However, such conditions should only be applied where they demonstrably improve risk management and can be implemented and enforced in a proportionate manner. As noted in the SEAC draft opinion, the additional requirements proposed by RAC, in particular expanded site-specific PFAS management plans and associated monitoring and reporting obligations, would entail even higher costs and raise concerns regarding practical enforceability.

In the absence of robust evidence on their effectiveness and socio-economic impacts, SEAC cannot conclude whether these additional conditions are proportionate. Additional conditions should therefore be targeted, risk-based and limited to situations with a clear link to meaningful emission reduction. They should not accumulate into an obligation framework that undermines practicality and legal certainty.

**Question 2.43: Please give an indication of the costs related to the additional conditions considered by RAC**

**Instructions:**

Consult the SEAC draft opinion, section 3.4.3.2.6.3. Conclusion whether the suggested restriction is the most appropriate EU-wide measure: Additional conditions considered by RAC.

Provide an estimate of the costs for implementing these conditions. Use the scale from very low (minimal impact) to very high (may result in a decision to discontinue business activities).

**VCI response:**

*Very High*

**Question 2.44: Please provide your comments on section 3.4.3.2.7 Conclusion whether the suggested restriction is the most appropriate EU-wide measure: Interaction with other relevant legislation [990/1000 characters]**

**Instructions:**

Consult the SEAC draft opinion and provide your comments relevant to this specific section of the opinion.

**VCI response:**

*The restriction will apply alongside other EU frameworks, including existing REACH restrictions, the POPs Regulation and sector-specific product, safety and environmental legislation. To be effective and proportionate, it must therefore be coherent with these instruments and avoid overlapping or conflicting obligations.*

*Where PFAS-related risks are already addressed through established sectoral requirements, such as emission control, occupational safety, product standards or waste legislation, the added value of additional horizontal restrictions should be clearly demonstrated. A lack of regulatory coherence risks increasing administrative burden, reducing legal certainty and complicating compliance and enforcement.*

*This is e.g. relevant for active substances regulated under specialised EU authorisation regimes, such as the Biocidal Products Regulation and the Plant Protection Products Regulation, where the interaction with a horizontal PFAS restriction requires clarification.*

**Question 2.45: Please provide your comments on section 3.5.2 Uncertainties evaluated by SEAC [4547/5000 characters]**

**Instructions:**

Consult the SEAC draft opinion and provide your comments relevant to this specific section of the opinion.

**VCI response:**

*A central uncertainty identified by SEAC is that the overall picture of PFAS uses is still evolving. Even after updates to the dossier, SEAC notes that, given the breadth and complexity of the proposed restriction, it is difficult to cover all specific substances and actual applications, and that providing a comprehensive inventory of uses/applications, related tonnages and emission estimates is difficult up to impossible. In addition, eight new sectors were added in the updated Annex XV report but were not specifically evaluated by SEAC. This means that the regulatory design risks being based on an incomplete use map, and that the set of derogations may need to*

*expand further. As a result, there is uncertainty as to whether all technically necessary uses are adequately covered, in particular those for which no suitable alternatives exist.*

*Closely linked to this is the uncertainty regarding alternatives. The availability and suitability of substitutes differ significantly by sector and application, and in many cases it remains unclear whether technically equivalent options can be developed, validated and scaled up within the transition periods currently discussed. These uncertainties hamper a thorough assessment of the availability and technical and economic feasibility of alternatives. Qualification, certification and redesign steps can dominate timelines, creating uncertainty as to whether predefined derogation or transition periods are sufficient across all uses.*

*There are also substantial uncertainties in the quantification of socio-economic impacts. A general lack of cost-relevant data, unclear representativeness for several sectors, and important differences in the detail and quality of the sector assessments. Many companies are unable to provide consistent and comparable data across complex and global supply chains on substitution costs, requalification requirements, downtime risks and downstream effects. Where such data is missing, SEAC must rely on assumptions or proxies, increasing uncertainty regarding both the magnitude and distribution of impacts.*

*In particular, uncertainties related to end-of-life emissions led RAC to apply precautionary assumptions in its assessment. However, new quantitative evidence now available indicates that emissions from fluoropolymer incineration under regulated conditions are substantially lower than previously assumed (GKS study, FPG EoL report, 2026), with comparable findings also reported for other polymeric and non-polymeric PFAS. These data significantly reduce the level of uncertainty in this area. In light of this, SEAC should take account of the updated end-of-life emission evidence when assessing proportionality, for example by applying sensitivity or scenario analyses, before finalising its conclusions.*

*A further uncertainty concerns the completeness and practicality of an exemption-driven regulatory system. Where a very broad restriction requires a large number of narrowly defined derogations, the system can become complex and dynamic. This increases the risk that relevant uses are overlooked or that derogation terminology or conditions do not adequately reflect operational realities, particularly where newly identified sectors have not been assessed with the same level of granularity as the originally evaluated sectors. Unknown or unidentified uses contribute to the uncertainty and prevent conclusions on proportionality overall.*

*Finally, there is uncertainty regarding future innovation. Uses that are not yet known, not yet mapped or still under development cannot be specifically exempted. This may constrain research and development activities and the emergence of new applications that are not represented in current exemption lists, thereby increasing uncertainty about longer-term impacts on innovation and on the development of strategic technologies. Uncertainties regarding SR&D and PPORD, including whether certain research-related uses are fully covered and which exact use-specific derogations could be necessary.*

*Overall, we agree with SEAC's assessment that the level of uncertainty associated with the proposed restriction remains substantial. As noted by SEAC, these uncertainties affect key elements of the proposal, including scope, costs, benefits and proportionality. A structured sensitivity analysis is necessary to allow robust conclusions on alternatives and socio-economic impacts. This supports the need to address and reduce the identified uncertainties before finalising a restriction of the proposed breadth.*

### **Question 2.46: Indicate each section for which your response contains confidential information.**

#### **Instructions:**

Select all the questions for which you consider your responses confidential. The options below include all questions in the survey.

#### **VCI response:**

N/A

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- ▶ Identification no. in the EU Transparency Register: 15423437054-40
- ▶ The VCI is registered with registration no. R000476 in the Lobbying Register for the Representation of Special Interests vis-à-vis the German Bundestag and the Federal Government.

*Verband der Chemischen Industrie e. V. (VCI) is Europe's largest association for chemicals and pharmaceuticals. Together with its 22 sector and regional organisations, the VCI represents the interests of around 2,000 member companies –from global players to highly specialised small and medium-sized enterprises. With sales of 230 billion euros in 2025 and round about 545,000 staff in Germany, the sector ranks among the major drivers of innovation, prosperity and future. The VCI works in Germany, Europe and worldwide for a strong chemical-pharmaceutical industry of today and tomorrow.*