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On the UPFAS-Restriction Proposal

– Brief opinion on procedural aspects –

[TRANSLATION – original opinion in German]

Commissioned by:

BDI –	Bundesverband der Deutschen Industrie e.V.
and	
BDLI	Bundesverband der Deutschen Luft- und Raumfahrtindustrie e.V.
BDSV	Bundesverband der Deutschen Sicherheits- und Verteidigungsindustrie e.V.
Textil + Mode	Gesamtverband der deutschen Textil- und Modeindustrie e.V.
VCI	Verband der Chemischen Industrie e.V.
VDA	Verband der Automobilindustrie e.V.
VDMA	VDMA e.V. (Verband des Maschinen- und Anlagenbaus)
VHI	Verband der Holzwerkstoff- und Innentürenindustrie e.V.
WVMetalle	WirtschaftsVereinigung Metalle e.V.
ZVEI	ZVEI e. V., Verband der Elektro- und Digitalindustrie

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Results

The procedure regarding the PFAS restriction dossier submitted by DE, DK, NL, NO, and SE (dossier submitters) infringes the requirements of Title VIII of the REACH Regulation in several respects. The procedural errors—particularly when considered cumulatively—preclude the European Commission from adopting a restriction in accordance with the proposal. Should such a restriction nevertheless be adopted, it would be unlawful. It could be challenged by affected parties through an action under Article 263(4) TFEU and declared null and void by the European courts pursuant to Article 264 TFEU.

Specifically, the proposed restriction is flawed by the following legal errors:

1. The group-based approach of the proposal is incompatible with the wording, structure, and purpose of the REACH regulations. The restriction requirements under Title VIII of the REACH Regulation clearly follow a substance-by-substance approach (Section C. 1. a. aa.).

2. Furthermore, the group-based restriction proposal violates the principle of proportionality both in its entirety and in its individual aspects (Section C. 1. a. bb.).

   A restriction in the form of a general ban is neither necessary nor proportionate, as the existence of a risk has not been demonstrated for all PFAS. Also, there are significant doubts as to whether sufficient exemptions are granted for all uses where – taking into account the socio-economic impacts and available alternatives – there is no unacceptable risk to human health and the environment. With regard to the proposed time limit on the exemptions, there is also a lack of the necessary individual assessment of the substances and their uses. The SEAC shares these doubts.

   For these reasons, a comprehensive ban without a necessary exemption also unjustifiably interferes with the fundamental rights of those affected to freedom to conduct a business under Article 16 of the Charter of Fundamental Rights of the European Union (CFREU) and the right to property of those affected under Article 17 CFREU.

3. The group-based restriction proposal (initial dossier from January 2023 and background documents from August 2025) does not comply with the relevant procedural rules. The errors of procedure violate the rights of participation and the European fundamental rights of the parties concerned under Art. 69(6) in conjunction with Art. 69(4) REACH and Art. 41(1) and (2) CFREU (Section C. 1. b.):

   a. Violation of the rights to participate under Article 69(6) in conjunction with Article 69(4) REACH (Section C. 1. b. aa.).

- Due to its group-based approach, the restriction proposal leads to an impermissible reversal of the burden of proof to the detriment of those affected by the proposal. To obtain an exemption from the general ban, those affected must—beyond the requirements of Article 69(6), second sentence of REACH—provide detailed information on uses, quantities used, emissions, the absence of alternatives, etc. However, these are facts whose presentation and proof, pursuant to Articles 68(1), 69(1), and 69(6) REACH as well as Annex XV of REACH, are imposed only on the initiators of the restriction—i.e., specifically not on the affected parties.

- The consultation of affected parties on the restriction proposal was flawed because it overburdened them.

  The burden on those affected stems from the complexity of the proposal and the associated volume of information. Determining the extent to which parties are affected by the proposal requires, on the one hand, technical and human resources that SMEs in particular do not possess. The same applies to manufacturers and suppliers of products. They, too, are often overextended by the requirement to participate because they cannot identify – nor can they determine with reasonable effort and sufficient certainty – which of the precursor products supplied to them contain PFAS and for which uses an exemption might therefore be necessary.

- Against this background, the six-month consultation period under Article 69(6), second sentence, REACH was too short. To ensure the necessary effective participation of stakeholders in a procedure concerning such a complex proposal, the period should have been extended. This was legally permissible and necessary, not least in view of the (significant) exceeding of the deadlines applicable to RAC and SEAC, which was foreseeable from the outset.

b. Violation of the Union fundamental right to good administration under Article 41 CFREU (Section C. 1.b. bb.).

   The violation of the rights of participation of the parties concerned under Art. 69(6) in conjunction with Art. 69(4) REACH is also incompatible with the Union fundamental right of the parties concerned to good administration under Art. 41(1) and (2) CFREU, to which the ECHA and the European Commission are bound pursuant to Art. 51(1) CFREU in the procedure for adopting a restriction. The requirements of Art. 41 CFREU and the relevant case law of the European courts must be observed in the interpretation and implementation of the rather brief provision on participation in Art. 69(6) REACH. This is all the more true when one considers that the final decision of the European Commission on the restriction proposal under Article 73(2) REACH in conjunction with Article 133(4) REACH is made in a comitology procedure in which no further consultation of stakeholders is provided for.

4. RAC and SEAC should have notified the dossier submitters of the deficiencies in the Annex XV dossier submitted in January 2023, as outlined here, in accordance with Article 69(4), subparagraph 3, sentence 3 of REACH. The submitters would then have had to remedy the deficiencies within 60 days. However, this would not have been possible, as the deficiencies are of a structural nature. This would have automatically concluded the restriction procedure (see Article 69(4), third subparagraph, fourth sentence REACH).

   Instead, RAC and SEAC erroneously confirmed the conformity of the original dossier pursuant to Article 69(4), subparagraph 3 REACH, thereby preventing the legally required termination of the procedure. By processing the restriction proposal while repeatedly exceeding the statutory deadlines set forth in Article 70, sentence 1, and Article 71(1), sentence 1 of REACH, and by submitting or drafting an opinion to the European Commission, the RAC and SEAC have repeatedly violated the requirements of the restriction procedure (Section C. 2. a. – d.).

5. It is against the procedural requirements of Articles 68 and 69 REACH for the dossier submitters to have completely revised—and thereby replaced—the original restriction dossier based on the comments received during the public consultation. This also constitutes an encroachment on the powers of RAC and SEAC. By deliberating on the new restriction dossier nonetheless, RAC and SEAC, for their part, violated the legal requirements for the restriction procedure. The resulting violation of the affected parties' rights to participate cannot be offset by their hearing under Article 71(1), fourth sentence of REACH regarding the draft SEAC opinion. The affected parties are thus denied the required hearing at the first stage regarding the replaced restriction proposal (Section C. 3. a. – c.).

6. As a precautionary measure, disregarding the above deficiencies:

   a. By refusing to issue sector-specific opinions for the eight new sectors, the RAC and SEAC are violating the requirements of the restriction procedure. On the one hand, the approach of the dossier submitters is disregarded; on the other hand, the procedure provided for in Article 71 REACH is not followed. Furthermore, this approach potentially constitutes an error of discretion on the part of the European Commission, as the facts underlying the restriction proposal have not been fully investigated. A referral of the restriction proposal by ECHA pursuant to Article 72(1) REACH is inadmissible (Section C. 4. b. aa. – ff.).

   b. The recommendation by RAC and SEAC associated with the refusal to conduct sector-specific assessments for the eight new sectors is incompatible with the provisions and structure of Title VIII of the REACH Regulation and proposes an impermissible course of action (Section C. 4. c. aa. – cc.):

      - Adopting a restriction in the form of a comprehensive ban on the use of PFAS in the new sectors is impermissible due to the lack of legal prerequisites, even if a comprehensive exemption is to be granted at the same time. For legal reasons, SEAC must refrain from making this recommendation and could, at most, recommend exempting

the eight sectors from the general ban (or, alternatively, from the general scope of the restriction) (Section C. 4. c. bb.).

- Likewise, the proposed retroactive sector-specific assessment is not permissible. For legal reasons, the SEAC must refrain from making this recommendation. Should the SEAC maintain the recommendation, the European Commission would likely not follow it for legal reasons (Section C. 4. c. -cc.).

7. The ongoing consultation on the draft SEAC opinion is procedurally flawed in several respects. Given the scope and complexity of the restriction dossier, the 60-day deadline under Article 71(1), fourth sentence, REACH is unreasonably short. At the same time, the participation rights of stakeholders are violated by the excessively short deadline as well as by unreasonable requirements regarding the structure and scope of stakeholders' opinions.

   ECHA is obligated to facilitate a comprehensive consultation within a sufficient timeframe and under reasonable conditions. If it fails to do so and forwards the opinions of RAC and SEAC to the European Commission, the European Commission must reject the adoption of a restriction corresponding to those opinions (Section C. 5. a. – c.).

Content

A. Assignment

The Federation of German Industries (BDI) and its member associations listed on the cover page have asked us, in light of the facts set forth below, to prepare a brief legal opinion examining whether the comprehensive PFAS restriction proposal under the REACH Regulation[1] contains procedural errors. In particular, the review should examine whether the restriction proposal violates the requirements of Title VIII of the REACH Regulation and the fundamental right of the parties concerned to good administration (in particular, the right to participate in the procedure).

B. Facts

The subject matter, content, and course of the procedure regarding the proposal for a comprehensive restriction of all PFAS[2] can only be presented here in the brevity required for this brief opinion. The parties involved in the PFAS restriction procedure and those affected by it are familiar with the details of the facts.

Four EU Member States—Denmark, Germany, the Netherlands, and Sweden—as well as Norway (hereinafter: dossier submitters) submitted a dossier to ECHA in January 2023 for a general restriction of PFAS[3] following the provisions of Title VIII and Annex XV of the REACH Regulation. The dossier consisted of a general Annex XV Restriction Report of 224 pages and seven annexes, as well as four appendices in PDF and Excel format totalling approximately 2,100 pages. In substance, the dossier proposed a group approach in the form of a general ban on the manufacture, placing on the market and use of all PFAS (estimated at over 10,000 substances) in all known—as well as unknown—areas of use. At the same time, exemptions were defined for certain uses in 15 sectors, which were generally time-limited. In addition, potential exemptions were listed that were to be re-evaluated following the required consultation.

After the review of the dossier's compliance by ECHA's competent committees – RAC and SEAC – in accordance with Article 69(4), third subparagraph of REACH, a stakeholder consultation was conducted pursuant to Article 69(6) REACH. It ran from March 22, 2023, to September 25, 2023. More than 5,600 comments were submitted during this process. Since September 2023, RAC and SEAC have been reviewing the restriction proposal and the stakeholder comments.

Taking into account the comments from stakeholders, the dossier submitters presented a comprehensively revised version of the restriction proposal—referred to as the "Background Document"—in August 2025, which was published on the ECHA website. The Background Document consisted of a general document in the form of an "Annex XV Report" (see Background Document, Summary,

[1] Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of December 18, 2006, concerning the Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC, and repealing Council Regulation (EEC) No. 793/93, Commission Regulation (EC) No. 1488/94, Council Directive 76/769/EEC, and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC, and 2000/21/EC (OJ L 396, 30.12.2006, p. 1) – hereinafter referred to as the "REACH Regulation" or "REACH."

[2] Per- and polyfluoroalkyl substances (PFAS).

[3] PFAS as defined by the OECD.

p. 1) comprising 320 pages and seven annexes, as well as five appendices, for a total volume of approximately 3,600 pages. It further provided for a general ban on the manufacture, placing on the market, and use of all PFAS, as well as exemptions for certain uses, with eight additional sectors of use included, bringing the total to 23 sectors of use. Proposals for possible (yet to be reviewed) exemptions were no longer included.

In its communication of August 27, 2025, ECHA announced that RAC and SEAC would not conduct a sector-specific evaluation of the eight newly added sectors, as their inclusion in the evaluations would require a significant amount of time extending beyond 2026.

On March 26, 2026, ECHA published the draft opinion of the SEAC (819 pages) and the opinion of the RAC (856 pages). These documents comprise a total of 1,675 pages. This also marked the start of the 60-day public consultation on the draft SEAC opinion pursuant to Article 71(1), fourth sentence of REACH, which runs until May 25, 2026. According to the published draft, SEAC and RAC did not conduct detailed sector-specific evaluations for the eight new sectors. However, SEAC has addressed the eight new sectors from a general perspective (general necessity and proportionality) and confirmed that the resulting requirements are met.

After evaluating the contributions from the consultation, SEAC is expected to adopt its final opinion by the end of 2026, thereby concluding ECHA's scientific evaluation and enabling ECHA to submit the opinion to the European Commission (Article 72(1) REACH). On this basis, the European Commission may, pursuant to Article 73(1) REACH, prepare a draft amendment to Annex XVII of REACH – i.e., for a restriction – within three months. This will be decided in a comitology procedure – "regulatory procedure with scrutiny" – within the REACH Committee by a qualified majority of the Member States (Art. 73(2) in conjunction with Art. 133(4) REACH and Art. 5a of Decision 1999/468/EC).

C. Legal Assessment

The procedure for the proposed restriction on PFAS can and must be broken down into a number of individual steps regarding which legal concerns exist:

- the preparation and submission of the Annex XV dossier,
- the acceptance and lengthy review of the dossier by RAC and SEAC,
- the revision and resubmission of the dossier,
- the refusal to issue a specific opinion on the eight new sectors, as well as the related recommendations from RAC and SEAC,
- the consultation on the draft SEAC opinion.

For each of these individual steps, an examination is conducted to determine whether and to what extent they comply with or violate the requirements of the provisions in Title VIII of the REACH Regulation, as well as general principles of EU law and the fundamental rights enshrined in the Charter of Fundamental Rights of the European Union.

1. Procedural errors and restrictions on stakeholders' rights to participate in the initial consultation

The drafting and submission of the restriction proposal, as well as the subsequent public consultation on the proposal – both in the form of the original dossier from January 2023 and in the form of the background document from August 2025 – are procedurally flawed. The procedural errors stem primarily from the group approach, which is against the REACH Regulation and EU primary law. These procedural errors restrict the participation rights of those affected.

On the basis of these procedural errors alone, the adoption of a restriction corresponding to the proposal must be rejected by the European Commission. Should such a restriction be adopted, it would be unlawful and could be challenged by affected parties through an action under Article 263(4) TFEU and declared void by the European courts pursuant to Article 264 TFEU.

In detail:

a. Flawed Group Approach

The group approach underlying the proposed restriction and its implications for the restriction procedure are inconsistent with the REACH Regulation and EU primary law.

aa. Inconsistency with the REACH Regulation

The approach of the restriction proposal deviates from the substance-specific regulatory system of the REACH Regulation, which means that there is no sufficient scientific data basis to support the equal treatment of all 10,000+ substances. This is unlawful.

(1) Deviation from the substance-specific regulatory concept of the REACH Regulation

The REACH Regulation follows the basic concept of a substance-specific risk assessment. This also applies to the restriction procedure, which follows from an interpretation of the REACH Regulation based on its wording, structure, and purpose.

Even the fundamental requirement of Article 67(1), first sentence of REACH regarding compliance with the conditions of restrictions on the manufacture, placing on the market, and use of substances applies to individual substances. Article 69(1) and (4) REACH authorizes the Commission or a Member State to initiate a restriction procedure if it considers that a substance poses a risk to human health or the environment that is not adequately controlled. The wording "a substance" reflects the general structure of the REACH Regulation (e.g., registration, evaluation, and the selection of candidate substances and substances subject to authorization are conducted for individual substances) and thus requires a substance-specific approach. In line with this, Annex XV, Section II.3 of REACH requires that the restriction proposal include "the identity of the substance." The plural forms used in Article 68(1) REACH do not constitute a deviation from the substance-specific approach. This provision merely sets out the general system of restrictions, which is intended to apply abstractly to the multitude of all cases and must therefore be formulated in the plural. Even if one were to assume that this does not categorically exclude restrictions on groups of substances,

the assessment of risks, alternatives, and socio-economic impacts required under Article 68(1) and 69(4) REACH would, according to the wording and structure of Title VIII and Annex XV of REACH, be necessary for each individual substance within the group.

This interpretation is required from a systematic and teleological perspective, given the fully harmonizing effect of a restriction and the clear delineation of competences required under Article 5(3) of the TEU: Member States may not adopt stricter national measures to the extent that a substance is listed in Annex XVII of REACH (see Article 67(3) REACH, which permitted this only on a transitional basis until 2013, and Article 128(2) REACH)[4]. However, this full harmonization presupposes that the substance to be regulated is clearly identified and that the conditions for an EU restriction are also met for that substance. Only then can a Member State determine which substances are regulated at the European level and are excluded from national regulation. And only then can the requirements of the principle of subsidiarity set forth in Article 5(3) TEU be met. The principle of subsidiarity requires that, in areas not falling within its exclusive competence, the EU acts only if and to the extent that the objectives of the measure cannot be sufficiently achieved by the Member States but, by reason of their scale or effects, can be better achieved at the Union level. In the case of the PFAS group approach, however, the scope of the restriction is not determined by a list of substances but by a definition based on chemical structure. As a result, it remains unclear which specific substances are restricted and covered by full harmonization. At the same time, this creates a scope of the restriction that is incompatible with the principle of subsidiarity: it also covers substances that fall under the structural definition but for which it cannot be determined whether action at the EU level is warranted – for example, because no information on their hazards or risks is available, or because they are not yet known or not on the market.

(2) Insufficient data basis due to group assessment

The restriction proposal is incompatible with the requirements of Annex XV of the REACH Regulation for risk assessment in the context of a restriction proposal and the provisions on substance evaluation under Article 48 REACH. The data basis for the restriction proposal and the risk assessment based on it are insufficient.

For the vast majority of PFAS covered by the proposed restriction, no data on hazards and risks are available. A complete toxicological profile exists for only a small number of PFAS. Therefore, identifying and grouping PFAS based on their hazards and risks using the available data is not scientifically sound. Regardless, the dossier submitters base their hazard assessment on the general persistence of PFAS as well as generalized extrapolations of the substance properties of a few known substances (e.g., PFOA and PFOS) to thousands of different PFAS compounds.

Nor have the dossier submitters sufficiently determined the full range of uses in which PFAS are employed. The 15 sectors of use underlying the original restriction proposal, along with the individual uses addressed therein, have in any case proven to be insufficient. The dossier submitters consider it necessary to include eight additional sectors of use and to exempt a large number of other uses (including those within the original 15 sectors) from the general ban. It remains questionable,

[4] ECJ C-358/11, para. 30 et seq.

however, whether this ensures that all relevant uses and the resulting potential risks have been identified and are known.

This deficiency in the insufficient information base is legally relevant: The requirements for the restriction dossier under Annex XV of REACH demand a sufficiently robust risk assessment. This must be based on information regarding the individual substances and their hazards, as well as the uses and the resulting risks. The final decision by the European Commission then requires the determination of a risk that is not adequately controlled and must be addressed EU-wide — namely, as outlined above in (1): substance- and use-specific. This is not altered by the fact that, in making such a technical-scientific decision, the European Commission has a margin of discretion based on the established case law of the Court of Justice of the European Union (CJEU), which is subject to only limited judicial review[5]. According to this case law, the European Commission, with the support of RAC and SEAC, must take into account all relevant factors and circumstances of the situation to be regulated by this legal act when exercising its discretion, for which the burden of proof lies with it[6]. The European Commission cannot meet these requirements because the factual basis of the restriction proposal is insufficient. Nor does the SEAC opinion enable it to do so, as will be shown below in section 4.

In the event that the information required for a restriction is not available, Article 48 REACH stipulates that ECHA and the Member States must obtain the necessary information—specifically through the substance evaluation mechanism provided for that purpose. The dossier submitters are also disregarding this prescribed system.

(3) Doubts regarding the sufficient relevance of persistence

The group-based approach pursued by the dossier submitters also raises doubts because, with regard to hazards, it focuses exclusively on the persistence of PFAS[7]. In doing so, the dossier submitters ignore the fact that, according to the legal provisions of the REACH Regulation and the CLP Regulation[8], persistence alone does not constitute a sufficient hazard characteristic—and thus also does not constitute a basis for a restriction.

In the CLP Regulation, with regard to persistence, the hazard classes “persistent, bioaccumulative, and toxic” (Annex I, Section 4.3), “very persistent, very bioaccumulative” (Annex I Section 4.3), “persistent, mobile, and toxic” (Annex I Section 4.4), and “very persistent, very mobile” (Annex I Section 4.4) are foreseen – and this has only been the case since April 2024[9].

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[5] For restrictions: Judgment of the General Court in Case T-226/18, para. 74 et seq., with reference to established case law, para. 224; generally on decisions under REACH and CLP: Judgments of the ECJ in Case C-293/22 on the identification of SVHCs and in Cases C-71/23 P and C-82/23 P, C-71/23 P, C-82/23 P on the classification of titanium dioxide.

[6] Judgment of the ECJ in C-71/23 P and C-82/23 P, C-71/23 P, C-82/23 P, para. 118.

[7] Draft Dossier under 1.1.2, p. 20 et seq.; Background Document under 1.1.2, p. 33 et seq.

[8] Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of December 16, 2008, on the classification, labeling, and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No. 1907/2006.

[9] Commission Delegated Regulation (EU) 2023/707 of December 19, 2022, amending Regulation (EC) No. 1272/2008 as regards hazard classes and the criteria for the classification, labeling, and packaging of substances and mixtures.

The provisions governing the adoption of restrictions are linked to the classification into hazard classes under the CLP Regulation. Thus, Annex XV, Section II.3 of the REACH Regulation stipulates that the restriction dossier must present the necessary information on the adverse effects and risks of the substances covered by the proposal based on a chemical safety assessment in accordance with the relevant parts of Annex I of the REACH Regulation. Annex I of REACH requires an assessment of the adverse effects on human health and the environment, as well as of PBT and vPvB properties (see Section 0.6.1 and Sections 1 – 4 of Annex I to the REACH Regulation). This is followed by classification and labelling in accordance with the CLP Regulation (Sections 1.2, 2.2, and 3.2 of Annex I to the REACH Regulation). Although this is not yet explicitly required for PBT and vPvB properties, it is likely to become necessary following the inclusion of these hazard classes in the CLP Regulation.

Furthermore, it should be noted that, pursuant to Article 57(1)(e) and (f) REACH—which does not yet reflect the new provisions of the CLP Regulation—only substances that have either persistent, bioaccumulative, and toxic (PBT) properties or very persistent and very bioaccumulative (vPvB) properties may be identified as substances of very high concern. Even though the provision of Article 57 REACH generally does not apply to restrictions but rather to the selection of substances subject to authorization, it must be taken into account for the proposed restriction on PFAS. This is because the proposal provides not only for a restriction on the manufacture, placing on the market, or use of PFAS, but for a general ban with explicit exceptions. The proposal thus corresponds to the system for substances subject to authorization (Art. 56(1) and (2) REACH).

(4) Impermissible reversal of the burden of proof contrary to Articles 68, 69 and 73 REACH

The extrapolation methodology used by the dossier submitters is also legally problematic because, contrary to the provisions of Title VIII of the REACH Regulation, it results in a reversal of the burden of proof:

According to the provisions of Articles 68, 69, and 73 REACH, the initiators of a restriction must demonstrate and substantiate the risk for each individual substance and its uses. This evidence is examined and evaluated by the RAC in accordance with Article 70 REACH so that the European Commission can conduct its review and make its decision on this basis. In disregard of this system, the restriction proposal – as well as the RAC's opinion – assumes or presumes an unmanageable risk for all 10,000+ PFAS based on estimated emissions ("emission as a proxy for risk") and, on this basis, imposes a general ban on the manufacture, use, and placing on the market of all PFAS[10]. An exception is granted only if the parties concerned – the manufacturers, distributors, and users of PFAS – demonstrate that there is no risk associated with a specific use or that the risk is adequately controllable. This disregards the fact that, according to Articles 68, 69, and 73 REACH, the burden of proof lies with the dossier submitters and not with the affected parties. The latter have no obligation to provide further information. Under Article 69(6) REACH, they are granted the opportunity to comment on the dossiers and the proposed restrictions and, if necessary, to submit a socio-economic analysis or provide information that can be used for such an analysis, solely for the purpose of safeguarding their own interests and concerns.

[10] See Draft SEAC opinion, pp. 14, 37, 42, 109; Draft RAC opinion, pp. 14, 16, 79, 80; Background document, pp. 3, 62, 63.

This result is not precluded by the fact that the registrants of a substance must, as part of the registration dossier, identify and analyze the risks of a substance in the chemical safety assessment pursuant to Article 14(1) and (6) REACH and develop appropriate measures for adequate risk management, thereby bearing a certain burden of proof on their part. The burden of proof and presentation incumbent upon the dossier submitters exists independently of this. According to the explicit provisions of Article 69(4) in conjunction with Annex XV, Section II.3 of REACH, it is the duty of the dossier submitters to present and document the risks for the individual substances based on the information from the registration dossiers, in particular the chemical safety reports, and, building on this, to demonstrate

> *"that existing risk management measures (including those specified in the registrations pursuant to Articles 10 to 14) are insufficient." [Annex XV No. II.3, "Information on adverse effects," subparagraph 2]*

Accordingly, Article 69(4), third sentence of REACH sets out the burden of presentation and proof for a restriction proposal:

> *"If this dossier demonstrates that action is required at Community level beyond existing measures, the Member State shall submit the dossier to the Agency in the format described in Annex XV to initiate the restriction procedure."*

Those submitting dossiers are falling far short of this obligation with their group-based approach for all PFAS. They completely ignore the fact that the majority of substances (potentially) falling under the PFAS definition have not been registered at all, and that no risks have been described and no risk management measures developed in any registration dossier or chemical safety report.

This finding is not called into question by the fact that, in a judgment dated June 30, 2021[11] regarding the restriction of the siloxanes D4 (octamethylcyclotetrasiloxane) and D5 (decamethylcyclopentasiloxane)[12], the General Court did not find any manifest error of law in the fact that the dossier submitter (UK) and the RAC regarded the emissions as a "proxy for risk." This is because the case did not concern the reversal of the burden of proof for exemptions. Furthermore, no group approach was followed in the restriction of siloxanes. And finally, as far as can be seen, this is a singular decision that was not subject to review by the ECJ.

(5) Flawed analysis of alternatives

The non-specific group approach leads to an inadequate identification and assessment of alternatives to the use of PFAS, which is incompatible with Articles 68(1) and 69(4) in conjunction with Annex XV of REACH. According to these provisions, information on existing alternatives must be identified and submitted, in particular regarding the availability of such alternatives (including a timeline) and their technical and economic feasibility (Annex XV, Section II.3). This requirement can only be met on the basis of a comprehensive factual foundation, which must be determined and assessed on a substance-by-substance basis. Therefore, the possibility of alternatives must not be

[11] Case T-226/18.
[12] Annex XVII No. 79 REACH.

generally assumed until proven otherwise. This is because Art. 68(1) and 69(4) in conjunction with Annex XV of REACH are intended to ensure that the European Commission, and the SEAC in a preparatory capacity, can affirm or deny the necessary existence and availability of alternatives on a sound basis when deciding on the adoption of a restriction, thereby complying with the requirement to consider alternatives under Art. 73(1) in conjunction with Art. 68(1) REACH.

The dossier submitters' group approach does not meet these requirements. Instead of substantiating possible alternatives with facts, the existence of alternatives and the substitutability of all PFAS are merely generally assumed or rather presumed, and the burden is placed on the affected parties to provide proof of the absence of alternatives through their information and evidence regarding the lack of alternatives or their unavailability. This, too, manifests the impermissible reversal of the burden of presentation and proof already highlighted above in (3).

This is not contradicted by the fact that the dossier submitters listed information on alternatives and provided assessments regarding the existence of available alternatives in the original dossier as well as in the revised dossier (Background Document) for the individual sectors and specific uses. These are general statements that cannot replace the required substance-specific assessments.

(6) No legal justification for the group approach

The dossier submitters do not provide any legal justification for the group approach underlying their proposed restriction. They do not address the legal concerns regarding the group approach outlined above – which, in our view, are obvious – in any way, neither in the original dossier nor in the background document. They also fail to acknowledge that such concerns were raised by stakeholders, both during the consultation and in separate public statements[13]. The group approach is justified solely on the basis of the chemical similarity of all PFAS – all contain the perfluoroalkyl component – and the resulting high persistence[14].

In this context, the dossier submitters cite scientific sources in both documents using identical wording –

> *"This grouping approach is acknowledged as a basis for risk assessment also by several scientists, who consider that regulation of PFASs on the basis of persistence alone should already suffice (see e.g. Cousins et al. (2020b)[15] ; Scheringer et al. (2022)[16])."*

– this cannot serve as justification in light of the legal concerns outlined.

[13] E.g., BDI position paper of April 24, 2023, pp. 7 ff., and of October 6, 2025, p. 3; VCI position paper of August 8, 2023, p. 3.
[14] Draft Dossier under 1.1.2, p. 21; Background Document under 1.1.2, pp. 33 ff.
[15] Cousins I.T., DeWitt J.C., Gluge J., Goldenman G., Herzke D., Lohmann R., Ng C.A., Scheringer M., and Wang Z. (2020b): The high persistence of PFAS is sufficient for their management as a chemical class. Environmental Science. Processes & Impacts 22 (12), 2307–2312. DOI: 10.1039/d0em00355g.
[16] Cousins I.T., Johansson J.H., Salter M.E., Sha B., and Scheringer M. (2022): Outside the Safe Operating Space of a New Planetary Boundary for Per- and Polyfluoroalkyl Substances (PFAS). Environ Sci Technol 56 (16), 11172-11179. DOI: 10.1021/acs.est.2c02765.

Cousins et al. (2020b) do not address the legal aspects of the group approach, but refer exclusively to the chemical aspect of the perfluoroalkyl content and the high persistence generally derived from it.

The considerations and conclusions of Scheringer et al. (2022) relate solely to environmental aspects and completely disregard regulatory considerations, particularly regarding the REACH Regulation.

bb. Violation of the Principle of Proportionality

The group approach, with a blanket ban and only selective, predominantly temporary exceptions, does not satisfy the principle of proportionality which is generally applicable under EU law.

(1) Fundamentals and requirements of the principle of proportionality

The principle of proportionality is one of the fundamental general legal principles of EU law and is enshrined in Art. 5(4) TEU and Art. 52(1), second sentence of the CFREU.

As follows from Article 52(1), second sentence of the CFREU, the principle of proportionality also applies with respect to the fundamental rights of those affected by the restriction, as guaranteed by the Charter of Fundamental Rights. This means that fundamental rights may be restricted in a proportionate manner, but that those affected must also accept only proportionate restrictions. The ECJ has recognized this with regard to the fundamental rights of the affected parties relevant here – namely, the freedom to conduct a business under Article 16 CFREU and the right to property under Article 17 CFREU:

- Article 16 CFREU protects the freedom to conduct a business. The Court of Justice of the European Union has repeatedly recognized that regulatory measures may, prima facie, constitute an interference with the freedom to conduct a business. Since the freedom to conduct a business is not absolute, proportionate restrictions—and only such restrictions—are justified.[17]

- Article 17 CFREU protects the right to property, which may also include intangible assets, business assets, and acquired legal positions. Since, according to the case law of the European Court of Justice, the right to property is not absolute either, restrictions in the public interest are permissible provided that proportionality is upheld.[18]

The principle of proportionality requires that EU measures be suitable, necessary, and appropriate (proportionate in the strict sense) for achieving its objectives.

According to this principle, the following applies to EU measures:

- They must be suitable for achieving the intended objective;
- they must be necessary to achieve the intended objective;

[17] ECJ C-283/11, para. 48.
[18] ECJ C-235/17, para. 89.

- they must not impose an excessive burden on individuals in relation to the objective pursued (proportionality in the strict sense).

(2) Assessment under the principle of proportionality

There are concerns regarding the necessity and appropriateness of the proposed UPFAS restriction.

The principle of necessity requires that the EU legislator choose, among several suitable measures, the one that imposes the least burden on those affected.[19] This is not guaranteed for all of the more than 10,000 substances covered by the proposed restriction. The group approach is based on the assumption that all PFAS are essentially equally hazardous and risky. However, this is not substantiated for a large portion of the PFAS falling under the definition due to a lack of the necessary substance-specific evidence. For this reason, the general ban on PFAS resulting from the group approach under the restriction proposal – with limited use-specific exceptions (so-called "Restriction Option 2" – RO2[20]) – cannot be regarded as necessary in light of the intended protection objectives. The general ban approach does not take into account the fact that the assumed general risk ("emission as a proxy for risk") is not relevant for certain uses, such as when a substance has low emission and exposure potential, as in cases of low usage volume or use under strictly controlled conditions. In such cases, even a ban with a temporary exemption is unnecessary and therefore impermissible. As the appropriate less restrictive measure, a restriction regarding the conditions of use (Restriction Option 3 – RO3–[21], which was considered in the Background Document but supported only in a few cases) might be permissible – for example, if emissions are limited or can be limited. In relation to the entire restriction proposal, the appropriate less restrictive measure would therefore be to specifically restrict only those uses of PFAS that are demonstrably associated with unacceptable risks to human health and the environment – and to do so in a manner that takes into account the socio-economic impacts as well as available alternatives. A comprehensive ban would therefore be necessary only if alternatives existed for every substance covered and the socio-economic impacts of the ban were reasonable for every substance covered.

The same applies with regard to the principle of appropriateness (proportionality in the strict sense). According to this principle, the measures must not impose an excessive burden on the individuals affected in relation to the intended objective.[22] This, in particular, is not guaranteed for all of the more than 10,000 substances covered by the group approach, e.g., if in individual cases the assumed risk associated with emissions is limited and/or can be controlled in other ways—such as in cases of low usage volumes or use under strictly controlled conditions. Even if no alternatives are available for a substance and the socio-economic impacts of a ban are negative, a ban would be disproportionate. The proposed restriction does not provide for the possibility of an individual, substance-specific exemption in such individual cases and thus violates the principle of proportionality.

Even if one were to consider the general ban proportionate in principle with regard to exemptions for certain uses, the principle of necessity requires that sufficient exemptions be granted for all uses where, taking into account the socio-economic impacts and available alternatives, there is no

[19] ECJ C-134/15, para. 33.
[20] See Background Document, section 2.3.2, p. 107
[21] See Background Document, p. 1
[22] ECJ C-154/04 and C-155/04, para. 126.

unacceptable risk to humans and the environment. There are considerable doubts as to whether the proposed restrictions, taken as a whole, meet this requirement.

This also applies to the time limits for the exemptions. The dossier submitters propose only blanket time limits of either five or twelve years, plus the general transition period of 18 months. Within this framework, all exemptions are treated equally[23]. There is no substance-specific or use-specific consideration of other time limits. This is questionable, particularly with regard to uses in strictly regulated products where regulatory requirements necessitate a long period for the research, development, implementation, and approval of alternatives to PFAS – a period that in many cases may extend beyond the proposed time limits (e.g., for medical devices, aircraft, and motor vehicles). For such uses, a longer deadline or even the removal of the time limit on the exemption may be necessary to ensure proportionality. Alternatively, a practical provision for extending the exemption period through a simple procedure could also be considered. The proposed restriction does not consider such a solution.

(3) SEAC shares concerns regarding proportionality

The SEAC shares these concerns regarding the proportionality of the restriction proposal. It agrees with the dossier submitters that the proposed exemptions are, in principle, necessary to ensure the proportionality of the restriction, even though it does not consider individual proposed exemptions to be necessary. At the same time, however, SEAC also emphasizes that the supported exemptions may not be sufficient, as further exemptions may be needed for certain uses to ensure proportionality[24]. Furthermore, the SEAC emphasizes that the socio-economic analysis is not quantitatively sound in many sectors and that it therefore cannot conclusively assess whether proportionality is ensured for numerous exceptions[25]. This finding by the SEAC demonstrates that the proportionality problem of the group approach is structural in nature and cannot be sufficiently resolved through selective exceptions.

cc. No justification based on the precautionary principle

The concerns raised regarding the proposed restriction cannot be remedied by invoking the precautionary principle.

Indeed, the precautionary principle (Art. 191(2) TFEU) does authorize regulatory measures in cases of uncertainty regarding risks – where the scientific evidence regarding a threat to the environment or human health is inconclusive, but failure to act could have significant consequences.

However, the precautionary principle has legal limits: According to the established case law of the ECJ, it requires that (a) the potentially adverse effects be identified with sufficient precision, (b) a comprehensive risk assessment be conducted based on available scientific data, and (c) the

[23] The SEAC itself describes these deadlines as arbitrarily chosen and accepts them only for practical reasons, Draft SEAC Opinion, p. 89.
[24] Draft SEAC Opinion, pp. 16 ff., pp. 67 ff.
[25] See comments in Draft SEAC Opinion, Table 9, p. 91 et seq.

measure be proportionate[26]. The European Commission corresponds to this in its Communication on the precautionary principle[27].

As explained in the preceding remarks, these requirements are not met.

b. Restriction of participation rights

The procedurally flawed drafting and submission of the restriction proposal by the dossier submitter—both in the form of the original dossier from January 2023 and in the form of the Background Document from August 2025 – in connection with the consultation conducted from March to September 2023 constitutes an unlawful infringement of the stakeholders' rights to participate under Article 69(6) in conjunction with Article 69(4) REACH and Article 41(1) and (2) CFREU. Consequently, the European Commission is prohibited from adopting a restriction corresponding to the proposal. Otherwise, the restriction would be unlawful and could be declared void by the Court of Justice of the European Union upon a lawsuit filed by affected parties under Article 263(4) TFEU in accordance with Article 264 TFEU.

The infringement of the affected parties' rights to participate is based primarily on the scope of the proposed restriction, which results from the unjustified group approach for more than 10,000 substances (see above under a.) and the resulting broad scope of application for uses in 23 sectors, even when considering only the identified sectors. Added to this is the shift of the burden of proof to the affected parties, which is inherent in the proposed restriction.

aa. Violation of Article 69(6) in conjunction with Article 69(4) REACH

The proposed restriction does not meet the requirements of Article 69(6) and (4) REACH and Annex XV of REACH. As a result, the parties concerned are unlawfully impeded in the exercise of their rights to participate.

(1) Inadmissible group approach

As already explained above under a. aa. (1), the REACH Regulation is based on the fundamental concept of a substance-specific risk assessment – including for the restriction procedure. Thus, Article 69(4) in conjunction with Annex XV of REACH explicitly requires that, for substances proposed for restriction, evidence be provided of a risk to human health or the environment that is not adequately controlled and must be addressed at the European level.

In the restriction proposal submitted by the dossier submitter, the risks of PFAS are not sufficiently described or documented on a substance-by-substance basis or even on a group basis. Rather, the proposal relies on emissions as evidence/presumption of a risk ("emission as proxy for risk") and explicitly acknowledges that risk actually arises from environmental deposits, but that these are unknown or cannot be determined, so that emissions are used as a "proxy"[28].

[26] See CFI T-74/00 et al.; Artegodan, C-221/10 P.
[27] Communication Com (2000) 1 final.
[28] Background Document, pp. 3, 62, 63; see also above under a. aa. (1).

(2) Inadmissible reversal of the burden of proof

This approach by the dossier submitters leads, as explained above under a. aa. (2), to a reversal of the burden of proof that contradicts Articles 68 – 73 REACH. At the same time, however, it also means that the parties concerned are not only able to comment on the dossier and the restrictions proposed therein and, where applicable, on their socio-economic impacts – as provided for in Article 69(6), second sentence of REACH. Rather, they are compelled to provide detailed information on uses, usage volumes, emissions, the lack of alternatives, etc.[29], in order to prevent the general ban or to justify a proposed exemption. Those affected must therefore expend significantly more effort when submitting comments than would be required without the reversal of the burden of proof and presentation. Furthermore, they bear the risk of failing to convince the RAC, SEAC, and the European Commission of the necessity of an exemption. This alone already undermines the right to participate granted to affected parties under Article 69(6), second sentence of REACH.

(3) Overburdening of affected parties

Furthermore, in many cases, the affected parties are overextended by the group approach and the resulting volume and complexity of the restriction proposal, which impairs their ability to exercise their participation rights. This applies in particular to SMEs, which largely lack the technical and human resources to assess the impact on their operations and to identify and provide the required information. Similarly, manufacturers and suppliers of products are often overwhelmed by the participation process because they cannot identify — nor can they determine with reasonable effort and sufficient certainty — which of the pre-products they supply contain PFAS. This is all the more true the more complex the products and, consequently, the upstream supply chains are. This, too, constitutes an infringement of the right to participation granted to affected parties under Article 69(6), second sentence of REACH.

(4) Refusal to extend the consultation period

This infringement of the rights of interested parties to participate, as guaranteed by the REACH Regulation, is exacerbated by the strict application of the six-month deadline according to Article 69(6), second sentence of REACH for the (initial) consultation on the original restriction proposal. This deadline is not mandatory. Although the legal text does not provide for an extension of the deadline, it is not precluded and would therefore have been possible; indeed, given the scope and complexity of the restriction proposal and the associated reversal of the burden of proof, it would have been appropriate. After all, the ECHA and its committees have informally exceeed the deadlines applicable to them under Art. 70 REACH – nine months for the RAC's opinion—and Article 71(1) REACH – twelve months for the SEAC's opinion – with regard to the extent and complexity of the restriction proposal as well as the comments submitted by stakeholders despite all restrictions. They have thus "extended" them, even though the deadlines, as well as the consultation period, are clearly specified and the legal text does not provide for any exceeding or extension.

[29] See the explicit requirements in the Information Note "Consultation on a proposed restriction on the manufacture, placing on the market and use of per- and polyfluoroalkyl substances (PFAS)," which the ECHA published on March 22, 2023, upon launching the consultation pursuant to Article 69(6) of REACH.

bb. Violation of the Union fundamental right to good administration, Art. 41(1) and (2) CFREU

The aforementioned violation of the stakeholders' rights to participation under Article 69(6) in conjunction with Article 69(4) REACH is against the Union fundamental right of the stakeholders to good administration under Article 41(1) and (2) CFREU, to which the ECHA and the European Commission are bound pursuant to Art. 51(1) CFREU in the procedure for adopting a restriction.

(1) Content of the Union fundamental right to good administration under Article 41 CFREU

Article 41 CFREU grants persons affected by an administrative measure a fundamental right to good administration. Its scope of protection has both a participatory and a temporal dimension. Under paragraph 1, every person has the right to have their affairs handled impartially, fairly, and within a reasonable time by the institutions, bodies, offices, and agencies of the Union. According to paragraph 2, this fundamental right includes, in particular, the right of every person to be heard before any individual measure which would adversely affect them is taken

According to the case law of the ECJ, the fundamental right to be heard is a general principle of Community law with a broad scope of application. It requires and guarantees that the addressees of decisions that significantly affect their interests are given the opportunity to present their views on the elements on which the administration intends to base its decision in a relevant and effective manner. To this end, they must be granted a sufficient period of time. This is intended to allow the competent authority to take all relevant factors into account appropriately and thereby ensure effective protection of the individual or undertaking concerned. In particular, the authority should be enabled to correct errors and take into account individual circumstances that speak for or against the adoption of the decision or for or against a specific content of the decision.

The fundamental right to be heard is of particular importance in proceedings involving complex technical assessments and in which, according to the case law of the European courts, the European Commission has a margin of discretion[30].

(2) Scope of application of Art. 41 CFREU

Under Article 51(1) CFREU, Article 41 CFREU is binding on all institutions, bodies, offices, and agencies of the Union.

As a general principle of Community law with a broad scope of application, it applies in all proceedings that may result in a measure adversely affecting a person. The fundamental right must also be observed even if the applicable provision does not expressly provide for the right to be heard.[31]

(3) Applicability of Art. 41 CFREU to the restriction procedure

[30] ECJ C-269/90 Technische Universität München (1991), paras. 13–14.
[31] See, among many others, the established and consistent case law of the ECJ: ECJ C-349/07, paras. 36–38; ECJ C-277/11, paras. 85–88, with numerous references to other decisions.

Against this background, there can be no doubt that the fundamental right of the parties concerned to a fair hearing also applies in proceedings for the adoption of restrictions under Title VIII of the REACH Regulation and must be observed.

On the one hand, a restriction on the manufacture, placing on the market, and use of a substance – or even an entire group of substances – is a burdensome measure that can lead to significant adverse effects on those affected. As for the PFAS restriction sought by the dossier submitters, it is certain that it would lead to extensive and very significant adverse effects on those affected. On the other hand, decisions by the European Commission on restrictions under Title VIII of the REACH Regulation involve complex technical assessments, meaning that the European Commission and the preparatory review committees of the ECHA have a margin of discretion[32] and, consequently, the fundamental right to a fair hearing is of particular importance.

ECHA, including its committees, is a body of the Union (Art. 75(1) and Art. 76(1) REACH) and is therefore, pursuant to Art. 51(1) CFREU, bound by Art. 41 CFREU in the restriction procedure under Articles 68 – 73 REACH. Furthermore, the REACH restriction procedure concludes with a decision by the European Commission pursuant to Art. 73 REACH, i.e., one of the highest Union institutions, which is likewise required under Art. 51(1) CFREU to observe the fundamental rights set forth in Art. 41 CFREU.

This finding is not contradicted by the fact that ultimately no decision is issued by the European Commission as an administrative body against individual addressees, but rather an implementing regulation addressed to all manufacturers, distributors, and users supplementing Annex XVII of REACH. This far-reaching, non-individualized nature of the decision does not alter the fact that the restriction thereby imposed has direct and individually onerous consequences—prohibitions and requirements—for those affected.

In principle, the REACH Regulation also aligns with this finding by enshrining in Article 69(6) the right of those affected to assert their interests during the public consultation on the restriction dossier. However, this merely rudimentary provision must be interpreted and applied in light of the fundamental rights guarantees of Article 41 CFREU. If, according to case law, the fundamental right applies even when an applicable regulation does not expressly provide for the right to be heard, it must all the more apply with its requirements when the right to be heard is granted (only) in principle.

This is particularly true given that, once the consultation phase has concluded, affected companies have no further opportunity to assert their interests or influence the decision-making process during the actual decision-making procedure at the European Commission (Article 73 REACH). The European Commission decides pursuant to Article 73(2) REACH in conjunction with Article 133(4) REACH through a comitology procedure in the form of the so-called "regulatory procedure with scrutiny" (Article 5a of Decision 1999/468/EC) without further involvement of the parties concerned. Instead, representatives of the Member States are involved through the REACH Committee. The decision-making process is therefore not public and is purely technical and political in nature.

[32] General Court T-226/18, para. 74 et seq., on the restriction of siloxanes (D4, D5) in wash-off cosmetics, hereinafter ECJ C-558/21 P, para. 57; see also ECJ C-71/23 P and C-82/23 P; T-279/20, T-283/20, and T-288/20 regarding the classification of titanium dioxide.

It serves exclusively to facilitate coordination between the Commission and the Member States and does not compensate for any shortcomings in the required participation. Therefore, if the only opportunity for participation is moved to an earlier stage (Art. 69(6) REACH), particularly high standards must be applied to it in order to meet the requirements of the fundamental right of those affected under Art. 41 CFREU.

(4) Requirements of Art. 41 CFREU not met in PFAS restriction procedure

In the procedure regarding the proposal to restrict all PFAS, the requirements of the fundamental right of the parties concerned to good administration, in particular to be heard regarding their interests under Art. 41 CFREU, are not met.

As outlined above under aa., the proposal to restrict PFAS is characterized by the group approach. Consequently, the submitted dossier is of unprecedented scope and unparalleled complexity, which alone makes it extremely difficult for a large part of the affected parties to determine the nature and extent of their impact.

Added to this is the reversal of the burden of proof contained in the restriction proposal (see above). This forces the affected party, in order to protect their interests, not only to comment on the dossier and the restrictions proposed therein and, where applicable, on their socio-economic impacts. Rather, they must provide detailed information on uses, usage volumes, emissions, the lack of alternatives, etc., in order to prevent the general ban or justify a proposed exemption.

This places an excessive burden on the affected parties and impairs their ability to exercise their participation rights. This applies in particular to SMEs and manufacturers and suppliers of products, especially when these are of a complex nature. Contrary to the requirement of Article 41(2) CFREU, this often leaves them unable to present their views on the elements upon which the administration intends to base its decision in a relevant and effective manner.

A proposal that, due to its complexity, effectively precludes the submission of an informed opinion within the statutory deadline violates the procedural guarantees provided for in Articles 68 – 73 of the REACH Regulation, interpreted in light of Article 41(1) and (2) CFREU.

This is all the more true given that the parties concerned have a right to a sufficient period of time to assert their interests, which has not been respected. The scope and complexity of the restriction proposal, as well as the accompanying reversal of the burden of proof, effect that the six-month period provided for in principle in Article 69(6) of the REACH Regulation is too short for a large proportion of the affected parties to adequately assert their interests. Those affected must be able identify and understand the implications of the proposal, generate and present the required information, and articulate and convincingly present their concerns and objections. This would have required a period longer than six months. Instead, ECHA simply adhered to the general requirement of a six-month consultation period, thereby disregarding the requirements of Article 41 CFREU. The deadline set forth in Article 69(6) is not mandatory and immutable. This provision is open to interpretation and requires interpretation. In due observance of Article 41 CFREU, ECHA should have arrived at the interpretation consistent with fundamental rights that a longer consultation period can and must be set. This is all the more true given that ECHA itself unproblematically disregarded the time limits applicable to its committees under Articles 70 and 71(1) REACH—which are similarly

formulated in absolute terms—and thereby extended its own timeframe. This, too, results in an unfair and unequal burden on those affected and reinforces the violation of the requirements of Article 41 CFREU.

(5) Consideration of the principle of effet utile

The above conclusion is further reinforced when one also takes into account the principle of effet utile enshrined in Article 4(3) TEU.

The principle of effet utile (the requirement of effectiveness) requires that a provision be interpreted and applied in such a way that the objective of the Treaty can be achieved in the best and simplest (most effective) manner.

With regard to the right to participate provided for in Article 69(6) REACH and the fundamental right under Article 41 CFREU that must be taken into account in this context, the principle of effet utile implies that the consultation on the restriction proposal must not be a mere formality but must be structured in such a way that the fundamental right to participate can be exercised effectively and efficiently. The consultation on the PFAS restriction proposal does not meet these requirements because, due to its scope and complexity, the restriction proposal makes it virtually impossible to submit a well-founded opinion within the statutory deadline, yet a reasonable extension of the deadline is denied.

(6) Significance of the violation of Art. 41 CFREU

The violation of the fundamental right under Article 41 CFREU outlined above is also relevant. According to the case law of the Court of Justice of the European Union (CJEU), in cases of procedural errors, what matters is whether the error was causal to the decision and whether the rights of the parties concerned were actually infringed.

Even though the final decision is still pending, it must be assumed that the procedural errors identified will have an impact should the European Commission issue a decision confirming the proposed restriction in whole or in part. Given the said obstacles that prevent a large portion of those affected from submitting an adequate statement, it must be assumed that, to a large extent, no substantiated statements were possible. Consequently, a decision would be based largely on an incomplete factual basis and also on a lack of knowledge and consideration of the impact on and interests of manufacturers, distributors, and users of PFAS.

c. Interim conclusion on 1.

The dossier submitters have presented a restriction proposal that does not comply with the requirements of Title VIII of the REACH Regulation – including an impermissible group approach with a reversal of the burden of proof. The public consultation conducted in this regard – both in the form of the original dossier from January 2023 and in the form of the background document from August 2025 – was procedurally flawed due to the resulting scope and complexity. These procedural flaws violate the rights of participation of the parties concerned under Article 69(1) REACH and Article 41 CFREU. For this reason alone, the adoption of a restriction corresponding to the proposal must be rejected by the European Commission.

2. Procedural errors due to the acceptance of the dossier and massive delays in the proceedings

a. Flawed acceptance of the dossier

Pursuant to Article 69(4), third subparagraph of REACH, RAC and SEAC reviewed and confirmed the compliance of the original dossier submitted in January 2023 with the requirements of Annex XV of REACH. This was legally erroneous because the dossier contained the errors detailed above under B.1.a.aa. regarding the demonstration of an unacceptable, inadequately controlled risk and the presentation of available alternatives – both of which are required under Annex XV of REACH.

Instead of confirming the dossier, RAC and SEAC should have, pursuant to Article 69(4), third subparagraph, third sentence of REACH, notified the dossier submitters of the identified – and obvious – deficiencies within 45 days. The submitters would then have been required to remedy the deficiencies within 60 days. However, this would not have been possible, as the deficiencies are of a structural nature, meaning that the restriction procedure would have been automatically concluded, as provided for by Article 69(4), third subparagraph, fourth sentence of REACH. Since this did not occur, the adoption of a restriction corresponding to the proposal by the European Commission must be rejected. Should a corresponding restriction nevertheless be adopted, it would be unlawful and could be challenged in court by affected parties, as mentioned above.

b. Unlawful exceeding of the deadlines for opinions

The opinions of the RAC and the SEAC do not comply with the deadlines for opinions set forth in Article 70, sentence 1, and Article 71(1), sentence 1 of REACH.

Instead of finalizing their opinions within nine or twelve months, respectively, the RAC took approximately 36 months to issue its opinion, and the SEAC has so far only been able to submit its draft opinion during this time. According to current announcements, the final submission of the SEAC opinion will take approximately 45 months! Not only that, but according to the draft opinion, SEAC does not currently even consider itself capable of providing the comprehensive assessment required within this extended timeframe. Rather, with regard to numerous exemptions proposed by the dossier submitters, SEAC makes no conclusive statement on whether proportionality is ensured rightly pointing out that the socio-economic analysis in many sectors lacks a quantitative basis[33]. Furthermore, with regard to the eight new sectors addressed by the dossier submitters in the Background Document, SEAC limits itself to a general assessment and refuses to provide detailed sector-specific assessments[34] (a detailed assessment of this follows below under 4.).

The massive delays resulting from the legally flawed scope and complexity of the proposed restrictions are unreasonable for the affected manufacturers, distributors, and users of PFAS. They create significant long-term uncertainty as to whether – and if so, which – of the restrictions, which

[33] See comments in Draft SEAC Opinion, Table 9, p. 91 ff.
[34] Draft SEAC Opinion, pp. 15, 16, 91 ff., Table 9

for many affected parties could potentially threaten their very existence, will be enacted, thereby preventing economically necessary planning and investments.

Against this background, the massive delay in the proceedings constitutes a procedural error and is therefore unlawful. While the deadlines set forth in Articles 70 and 71(1) REACH are not strict deadlines, however, they also cannot be extended at will. This is because they are clearly intended to ensure that the ECHA committees decide on restriction proposals promptly and within a reasonable timeframe. This serves, not least, to protect those affected from proceedings of unmanageable length and the resulting planning uncertainties. Accordingly, exceeding the deadlines by more than three times must, in any case, be regarded as impermissible for legal reasons. This also means that the adoption of a restriction corresponding to the proposal by the European Commission would be unlawful and must therefore be rejected.

c. Necessary rejection of the restriction proposal

Given the impossibility of submitting the substantiated opinion required of them regarding the restriction proposal within the deadlines specified in Articles 70 and 71(1) REACH, or at least within a reasonable time, the RAC and SEAC could and must have refused to submit an opinion once they recognized this impossibility. Consequently, in the absence of a basis for decision-making that meets the requirements of Article 73 REACH, the European Commission would have had to reject the restriction proposal as inadmissible and unreasonably extensive and complex. However, even if ECHA were to subsequently forward the emerging opinions of RAC and SEAC to the European Commission, the Commission would still have the option and the duty to reject the restriction proposal due to the excessive length of the proceedings and the other procedural errors identified, given the many gaps that would in all likelihood remain in the opinions. Consequently, the adoption of a restriction corresponding to the proposal by the European Commission must also be rejected for this reason.

d. Interim conclusion on 2.

As RAC and SEAC unjustifiably confirmed the conformity of the original dossier submitted in January 2023 pursuant to Art. 69(4) subpara. 3 of REACH and, furthermore, issued or drafted an opinion while repeatedly exceeding the statutory deadlines set forth in Art. 70, sentence 1, and Art. 71(1), sentence 1 of REACH, the requirements of the restriction procedure have been violated on multiple occasions.

Against this background, the adoption of a restriction corresponding to the proposal by the European Commission is impermissible.

3. Procedural error due to the replacement of the dossier

a. Supplement to the facts

Following the consultation, the dossier submitters extensively revised their original restriction dossier in light of the comments submitted there. A large number of new proposals for exemptions from the general PFAS ban were included, while previously considered exemptions were dropped. In addition, proposals and considerations regarding eight newly identified sectors that were not included in the initial dossier were incorporated. Furthermore, restrictions were discussed as an additional regulatory option (RO3) and proposed for a few uses[35], which provide for requirements for emission-reducing measures throughout the entire life cycle but do not prohibit the use itself[36].

The revised and significantly expanded dossier was submitted as a "Background Document" in the context of the RAC and SEAC's review of the restriction proposal.

RAC and SEAC took the changes into account – except for the individual proposals and considerations regarding the eight new sectors[37] .

b. Procedural error resulting from the submission and handling of the background document

The complete revision of the restriction dossier undertaken by the dossier submitters and its review by RAC and SEAC is incompatible with the legal requirements for the restriction procedure and constitutes an encroachment on the competencies of RAC and SEAC. This is all the more true, given that it amounts to a replacement of the restriction proposal. Also, due to these procedural errors, the adoption of a restriction corresponding to the proposal must be rejected by the European Commission.

aa. Revision of the dossier not provided for

Art. 69 et seq. REACH do not provide for the rectification of any deficiencies in a dossier that has already been submitted and accepted by the dossier submitter, nor do they provide for any involvement of the dossier submitter in the deliberations of RAC and SEAC. According to the clear structure of the system, the assessment of a dossier and, above all, of the contributions from the public consultation under Article 69(6) REACH is the sole responsibility of RAC and SEAC (Article 70 and Article 71(1) REACH). An iterative process for developing the restriction proposal, as practiced by the dossier submitters, is precisely not in line with the structure of Title VIII of the REACH Regulation. This framework clearly delineates the competences and spheres of responsibility of the Member States (including their authorities) from those of the EU (including ECHA and its committees). Once a Member State has submitted a restriction proposal to ECHA through its authority and this has been duly

[35] Manufacture of PFASs; Transport; Electronics and semiconductors; Energy; Sealing applications; Machinery applications; Some technical textiles.
[36] Background Document, pp. 1, 107.
[37] See above under A.; detailed assessment under 4.

adopted by RAC and SEAC, it falls exclusively within the sphere of the EU, specifically under the purview of ECHA and its committees. It is neither provided for nor, due to the clear differentiation of spheres of competence, permissible for the Member State that submitted the dossier through its authority pursuant to Article 69(4) REACH to influence the proposal again by revising it or remedying deficiencies. At most, the Member State could withdraw the proposal and, if necessary, submit a new (in its view, better) restriction proposal in the form of a dossier under Annex XV of REACH, which would then restart the restriction procedure, in particular the public consultation under Article 69(6) REACH.

The submission of the background document by the dossier submitter, as well as its consideration by RAC and SEAC, must therefore be regarded as inadmissible. The fact that, in other restriction procedures as well, dossiers were modified and improved by the dossier submitter in connection with the referral to RAC and SEAC without objection does not affect this conclusion. A practice cannot alter the legal requirements and must not ignore them.

bb. Errors due to the complete replacement of the dossier

Furthermore, the Background Document is more than just a contribution by the dossier submitters to the discussions of the RAC and SEAC regarding the restriction proposal. The designation "Background Document" is misleading. The dossier submitters do not merely provide the committees with "background" information. In it, they neither answer the committees' questions nor explain or specify individual aspects of their dossier. Rather, there is (as far as can be seen: unsolicited) a complete revision and replacement of the original Annex XV-dossier. From a legal perspective, this approach can be classified as follows: The dossier submitters withdraw their dossier and submit a completely new dossier which, in their view, meets the requirements of Art. 68(1) and Article 69(4) REACH. In this form, the restriction proposal, with all its exceptions, is regarded as justified, and in particular as proportionate. At the same time, the dossier submitters thereby acknowledge that the original restriction proposal, in its entirety, does not meet the legal requirements, and in particular is not proportionate.

However, by submitting the new restriction proposal only informally as a background document – and with ECHA (RAC and SEAC) accepting this – the procedure provided for in Article 69(4) and (6) REACH for the new dossier is circumvented. Contrary to Art. 69(4) and (3) REACH, no initial review by RAC and SEAC is conducted to verify compliance with the requirements of Annex XV. In particular, however, the consultation of the parties concerned required by Art. 69(6) REACH is denied. This should have been carried out upon submission of a new dossier. The fact that it was omitted constitutes an infringement of the stakeholders' rights to participation – which, as outlined above under 1. b., are protected by fundamental rights under EU law. This alone must result in the rejection of the adoption of a restriction based on the new dossier as inadmissible.

The consultation on the draft SEAC opinion pursuant to Art. 71(1), third sentence of REACH cannot compensate for this deficiency from the outset[38]. According to the legal framework, the consultation relates solely to the SEAC opinion. The short deadline of only 60 days is based on this. If a completely revised dossier is now on the table, the scope of the consultation is too narrow and the deadline too short.

[38] Any shortcomings of the consultation on the Draft SEAC Opinion are addressed in 5.

cc. Interference with the competence of RAC and SEAC

At the same time, the dossier submitters' actions also constitute an impermissible interference with the independence of the experts on the RAC and SEAC, which is expressly guaranteed by Article 85(7) REACH. According to the system of the provisions in Title VIII of the REACH Regulation, these experts must independently examine the original dossier in accordance with Annex XV of the REACH Regulation and assess it themselves, taking into account only the information and objections raised by stakeholders. The result of this review may (and must then) be the rejection of an immature, inappropriate, and disproportionate restriction proposal. This independent role and authority of the RAC and SEAC is violated by the new dossier. The fact that this interference in the RAC's and SEAC's authority and powers is ultimately accepted does not alter this. The committees' competence and powers are not at their own disposal. They are not an end in themselves, but serve a specific purpose within the framework of the restriction procedure. They are intended to ensure that a restriction proposal is assessed by independent experts with regard to legal requirements, thereby establishing an expert basis for the European Commission's decision.

c. Interim conclusion on 3.

The dossier submitters have completely revised and thereby replaced the original restriction dossier based on the comments from the public consultation. This is incompatible with the procedural requirements of Articles 68 and 69 REACH and constitutes an encroachment on the competencies of RAC and SEAC. The review of the new dossier by RAC and SEAC is equally incompatible with the legal requirements for the restriction procedure. Due to these procedural errors and the associated violation of the rights of affected parties, the EU Commission must reject the adoption of a restriction corresponding to the proposal.

4. Procedural errors due to the lack of sector-specific consideration of the eight new sectors

a. Supplement to the facts

First, it should be noted that the dossier submitters, and with them SEAC and RAC, view the proposals for restrictions and exemptions regarding PFAS use in the eight new sectors as an integral part of the restriction proposal.

This stems from the fact that the dossier submitters drafted the so-called "Background Document" in the form of an Annex XV dossier and based their comprehensive justification and assessment of the proposal on all sectors covered therein. Following this approach, SEAC and RAC (unjustifiably[39]) based their opinions on all 23 sectors and addressed all sectors, including the eight new sectors, in terms of general aspects (general necessity and proportionality), affirming these two general aspects.

[39] See above under 3.

However, SEAC and RAC did not conduct detailed sector-specific assessments for the eight new sectors. The reason given is that the dossier submitters' assessments for these sectors were not available until a later stage in the process of drafting the opinion, and the time required for a detailed assessment of the eight new sectors could not be reconciled with the time constraints for addressing the restriction proposal[40]. SEAC therefore includes a proposal for the next steps[41]:

> *"For the eight additional sectors [...], SEAC cannot conclude whether the derogations proposed by the Dossier Submitter for specific uses/applications within the scope of these sectors are justified, nor whether additional exemptions for other uses/applications within these sectors would be justified. SEAC recommends that an evaluation of all uses/applications assessed by the Dossier Submitter within these specific sectors is performed as soon as possible. In the interim, SEAC recommends a time-limited derogartion for all uses/applications within the scope of theses specific sectors until such an evaluation has been performed and an appropriate decision can be made on proportionality."*

b. Procedural error due to refusal to issue sector-specific opinions

The refusal to provide sector-specific opinions for the eight new sectors constitutes a violation of the procedure set forth in Article 71 REACH. Without an opinion on these parts of the restriction proposal, submitting the restriction proposal pursuant to Article 72(1) REACH is impermissible, and the European Commission is barred from imposing a restriction on PFAS based on the proposal of the dossier submitters. Any restriction that is nevertheless adopted would be unlawful. It could be declared null and void by the European courts following a lawsuit filed by affected parties.

This conclusion is based on the following considerations:

aa. Precautionary considerations

It is not considered here that the replacement of the dossier using the "Background Documents" is already impermissible and constitutes a procedural error, as set forth above under 3. Therefore, these are purely precautionary considerations, which are presented without prejudice to the objections of systematic priority.

bb. Disregard for the dossier submitters' approach

By refusing to issue specific opinions on the measures proposed for the eight new sectors, the SEAC disregards the dossier submitters' approach. This is incompatible with Article 71(1) REACH. According to this provision, the SEAC must comment on the restriction proposal as submitted by the dossier submitters, not merely on selected parts or aspects.

Under the dossier submitter concept, the eight new sectors are an integral part of their restriction proposal. If the SEAC and RAC systematically and intentionally exclude these parts, they are,

[40] Draft SEAC Opinion, p. 15; RAC Opinion, p. 15.
[41] Draft SEAC Opinion, p. 16.

contrary to Article 71(1) REACH – and contrary to their own statement – failing to provide an opinion on the proposed restrictions as a whole, but only on a part thereof.

Furthermore, according to the dossier submitters' concept, the eight new sectors collectively ensure the proportionality of the restriction proposal. By limiting the sector-specific opinion to the 15 sectors originally included in the Annex XV dossier, the RAC and SEAC fail to do justice to this approach. Consequently, their general finding that the dossier as a whole – including the eight new sectors – is necessary and proportionate[42] is also untenable.

cc. Violation of the wording and system of Articles 71 – 73 REACH

At the same time, by refusing to issue specific opinions on the measures proposed for the eight new sectors, SEAC is in violation of the requirements arising from the wording and system of Articles 71 – 73 REACH.

Article 71(1) REACH contains a binding obligation: the SEAC "shall issue an opinion on the proposed restrictions." The only exception is set forth in Article 72(1), second sentence of REACH: pursuant to this provision, ECHA shall inform the Commission, stating the reasons, if only one committee or no committee issues an opinion within the twelve-month period specified in Article 71(1) REACH. Following on from this, Article 73(2) REACH specifies the timeframe within which the Commission must make its decision if the SEAC does not issue an opinion. Conversely, this implies that the absence of an opinion is not the rule, but at most a strictly limited exception.

Under this system, the SEAC is obligated to issue an opinion on the proposed restrictions unless there are compelling reasons not to do so. In any case, however, neither the SEAC nor the RAC may issue an opinion on only a portion of the restriction proposal that they themselves have defined.

The time pressure cited by SEAC and RAC with regard to the original 15 sectors cannot be regarded as a compelling reason. First, due to the procedural errors outlined above: (i) the substitution of the dossier and (ii) the impossibility of issuing a sufficiently substantiated opinion within the prescribed deadlines or, at any rate, without excessively exceeding the deadlines, RAC and SEAC could and should have refused to accept the dossier or, at least, to issue an opinion[43]. However, if the committees accept these procedural errors without objection and even tolerate a delay of more than three times the deadline for their opinions on the original dossier, then, according to the logic of RAC and SEAC, a further delay in issuing sector-specific opinions for the eight new sectors should also have been acceptable.

dd. Violation of the Requirement for an Opinion

Furthermore, SEAC's refusal to issue specific opinions on the measures proposed for the eight new sectors constitutes a violation of the rule set forth in Art. 68(1), second sentence, in conjunction with Art. 72(1) and Art. 73(1) REACH, which requires the SEAC to issue an opinion and thereby lay the foundation for an appropriate and proportionate decision by the European Commission.

In making its decision, the Commission must, in accordance with the provisions of Article 68(1), second sentence of REACH, take into account the socio-economic impacts of the proposed

[42] Draft SEAC Opinion, p. 16; RAC Opinion, p. 15 ff.
[43] See above under 2.

restriction. To this end, pursuant to Articles 72(1) and 73(1) REACH, it must rely on the opinion of the SEAC as the expert body for assessing socio-economic impacts. The Commission cannot fulfill this obligation if there is simply no sector-specific SEAC opinion for the eight new sectors.

The requirement for an opinion under Article 68(1) in conjunction with Articles 72(1) and 73(1) REACH is not an end in itself. The procedure set out in Title VIII of the REACH Regulation, in particular the issuance of opinions by SEAC and RAC, is intended to provide the European Commission with the necessary scientific information so that it can decide, with full knowledge of the facts, whether – as required under Article 68(1) REACH – there is an unacceptable risk to health and the environment and whether restrictions are necessary to address such a risk[44]. It also serves to enable the European Commission to adopt a decision that takes sufficient account of the socio-economic consequences and is therefore proportionate.

According to the established case law of the Court of Justice of the European Union, the general principle of proportionality (Article 5(4) TEU) is a general principle of Union law that must be observed in every EU measure. The absence of a SEAC assessment for the eight new sectors ultimately makes it structurally impossible for the European Commission to reach a proportionate decision. This applies to the individual proposals of the dossier submitters regarding the eight new sectors, but also to the entire restriction proposal, which, according to the dossier submitters' concept, includes the proposed measures for the eight new sectors as an integral part.

ee. Potential Error of Discretion

The EU Commission also cannot, in accordance with the SEAC's proposal, refrain from making a sector-specific and conclusive assessment of the eight new sectors and thus of essential parts of the restriction proposal. If it were to do so, this would constitute an error of discretion. As already explained above, the EU Commission has discretion when deciding on the adoption of restrictions[45]. However, the ECJ has consistently emphasized in its case law[46] that the discretion of the competent EU authorities in technical-scientific decisions is not discretion regarding the question of whether they perform their statutory duties, but only regarding the question of how they do so methodologically.

These legal requirements also apply to SEAC and RAC. This is because, in the Title VIII procedure, they are assigned a key role in determining the technical and scientific discretion of the European Commission. The EU Commission is not required to conduct its own technical and scientific review or its own socio-economic analysis; rather, it may rely on the reviews and opinions of the ECHA committees[47] and, on this basis, make the decision incumbent upon it under Article 73(1) REACH.

ff. Shift in the institutional framework contrary to the system

The SEAC's refusal to issue sector-specific opinions also results in a shift of responsibilities within the institutional framework provided for by the REACH Regulation that is contrary to the system. As outlined, RAC and SEAC are the authoritative technical and scientific expert committees. This is

[44] General Court in T-226/18, para. 217.
[45] See above under 1.b.bb. (2).
[46] See, in particular, the judgments of the ECJ in C-293/22, C-71/23 P, and C-82/23 P.
[47] General Court in T-226/18, para. 217.

supported not least by the fact that, pursuant to Article 85(7) REACH, their members are explicitly independent of the Member States. The European Commission, on the other hand, is a political body of the EU. This institutional architecture is non-negotiable. If the European Commission were to assess the socio-economic impacts itself in the absence of a SEAC opinion, this structure would be disregarded. The necessary independent technical-scientific preliminary review, which the REACH system specifically provides as a procedural safeguard, would be lacking.

c. Procedural error due to an impermissible recommendation

The recommendation made by RAC and SEAC regarding the refusal to conduct sector-specific assessments for the eight new sectors also constitutes a procedural error, as it recommends a course of action that is against the provisions and framework of Title VIII of the REACH Regulation and is therefore impermissible. For legal reasons, SEAC must refrain from making this recommendation and could, at most, recommend exempting the eight sectors from the general ban. Should SEAC maintain the recommendation, the European Commission could not follow it for legal reasons.

aa. Recommendation by RAC and SEAC

SEAC recommends that the EU Commission issue the general ban on the manufacture, placing on the market, and use of all PFAS with regard to the eight new sectors as well, but that this be combined with a time-limited – i.e., provisional – exemption for all uses/applications within the sectors. The exemption is to apply until a specific assessment of all uses and applications evaluated by the dossier submitters has been carried out and an appropriate decision on proportionality can be made. This apparently means that RAC and SEAC will make up for the reviews and evaluations required of them under Articles 70 and 71(1) REACH later and that the European Commission will then, on this basis, make a (final) decision regarding the exemptions from the general ban on use in the eight new sectors – however, when, on what basis, and within what framework this is to take place remains open.

bb. No restriction permissible

Even the recommended first step – a general ban on PFAS in the eight new sectors by the European Commission – would be impermissible because it would not be in accordance with Articles 68(1) and 69(4) REACH. Instead, the SEAC could, at most, recommend that any restriction – i.e., a ban – be avoided with regard to the eight new sectors.

(1) Conditions for a recommended restriction are not met

Under the provisions of Title VIII of the REACH Regulation, a restriction on substances shall only be imposed if it is demonstrated that the specific substance (or, in any case, the substance group) poses an unacceptable risk that is not adequately controlled and must be addressed at the EU level (Art. 68(1) and Art. 69(4) REACH). In addition, the restriction must take into account the availability of alternatives and the socio-economic consequences (Art. 68(1) REACH) and be proportionate overall (Art. 5(4) TEU)[48]. RAC and SEAC do not conclude that these conditions are met for the uses in the eight new sectors. Rather, they explicitly leave this open. Therefore, in the RAC and SEAC's

[48] On these requirements, see above under 1a.aa. (4) and bb.

own view, the legal requirements for imposing a restriction are not met. According to the recommendation, this shortcoming should not be replaced by a separate review and assessment by the European Commission; rather, the review and assessment should take place only afterward. Thus, fully aware of the absence of the legal requirements, RAC and SEAC recommend the adoption of a restriction – even a comprehensive ban. This is clearly unlawful. Without all requirements being fulfilled, however, the restriction would constitute an impermissible interference with the fundamental rights of those affected[49].

(2) Suspension of the restriction is irrelevant

This finding is not contradicted by the fact that RAC and SEAC provide for a comprehensive exemption for all uses in the new eight sectors – in effect, a temporary suspension of the ban – for the interim period until the sector-specific tests and evaluations are available, and thus the suspended ban constitutes a provisional restriction. On the one hand, this does not alter the fact that a ban is to be imposed without the legal prerequisites being met – and is thus unlawful. On the other hand, it ignores the fact that the provisions of Title VIII of the REACH Regulation do not provide for a provisional restriction.

By proposing an unrestricted suspension of the ban, RAC and SEAC are themselves indicating that a restriction is not warranted in this matter. Therefore, following their own logic, it would be only consistent for them – and legally permissible – to reject the issuance of the ban for the eight new sectors from the outset, i.e., to recommend that the eight new sectors be excluded entirely from the scope of a restriction on the use of PFAS.

Notwithstanding this, the recommendation leaves completely open the question of the legal basis and framework within which the sector-specific assessment to be conducted should take place. Furthermore, there are substantial legal concerns regarding the recommended sector-specific assessment (see below). This lack of clarity also precludes the assumption that the provisional restriction could be considered permissible.

cc. Making up of sector-specific assessment inadmissible

RAC and SEAC leave it unclear which body is to conduct the recommended making up of the sector-specific assessments. However, according to the recommendation, only assessments conducted by RAC and SEAC themselves are likely to be seriously considered. For the purposes of further consideration, it should therefore be assumed that the proposed follow up assessment is to be carried out by RAC and SEAC themselves.

(1) No procedure for making up in the REACH Regulation

Title VIII of the REACH Regulation does not contain a procedure for the timely sector-specific review of the exemptions proposed by dossier submitters in the new eight sectors, as recommended by RAC and SEAC. A regulated, rule-of-law procedure with deadlines and opportunities for participation would, however, be necessary, not least in view of the constitutionally protected right of those affected to good administration.

[49] See above under 1.a.cc.

Under Articles 70 and 71 REACH, the reviews of a dossier by RAC and SEAC in the restriction procedure are intended to take place only once – namely, prior to their submission of an opinion to the Commission, and within a set timeframe. Thereafter, pursuant to Article 73 REACH, the European Commission must decide on the restriction based on the opinions submitted. There is no provision for the RAC and SEAC to be consulted again after their opinions have been submitted to the EU Commission. This must also be considered impossible in light of the overall system of the restriction procedure already discussed.

Furthermore, the recommendation by RAC and SEAC does not provide for a subsequent review to take place during the ongoing restriction procedure prior to a decision by the EU Commission. Rather, the EU Commission is first to adopt the restriction with a ban but also a comprehensive exemption for the eight new sectors, and only then is the sector-specific assessment to be carried out. Such an approach must certainly be regarded as inadmissible. This is because the recommended adoption of the restriction would conclude and terminate the restriction procedure in its entirety. A referral to RAC and SEAC could not take place again under the provisions of Title VIII of the REACH Regulation. Rather, at most, a new regular restriction procedure could be initiated, which would then allow for the preparation of a new dossier, its publication, a public consultation, and only thereafter a referral to RAC and SEAC. But this is clearly not recommended by RAC and SEAC.

(2) No making up permitted on other grounds

Even on other grounds, the recommended referral to RAC and SEAC would not be possible.

In principle, both committees have only the powers conferred upon them explicitly under the REACH Regulation (Art. 77(3)(a) REACH). As explained above, this basis of authority precludes the RAC and SEAC from being consulted retroactively.

At most, a mandate by the Director pursuant to Art. 77(3)(c) REACH could be considered. Under this provision, the Director may request committees to prepare opinions on all other aspects of the safety of substances on their own, in mixtures, or in articles. However, invoking this provision is out of the question because the review of the restriction proposals or exemptions for the eight new sectors does not constitute “other aspects of the safety of substances,” but rather restriction measures, over which the RAC and SEAC have explicit but limited competence. Furthermore, such a request by the Director would not be feasible because an opinion from RAC and SEAC on this matter would not allow the restriction procedure for PFAS to be reopened, let alone provide a basis for the supplementary decision by the European Commission intended by the recommendation.

d. Interim conclusion on 4.

By refusing to issue sector-specific opinions for the eight new sectors, RAC and SEAC not only disregard the approach of the dossier submitters but also violate the procedure provided for in Article 71 REACH. Furthermore, forwarding the restriction proposal pursuant to Article 72(1) REACH is impermissible. Moreover, this potentially constitutes an error of discretion on the part of the European Commission in adopting a restriction.

The recommendation associated with the refusal to conduct sector-specific assessments for the eight new sectors also constitutes a procedural error, as it recommends a course of action that is incompatible with the provisions and structure of Title VIII of the REACH Regulation and is therefore

impermissible. For legal reasons, the SEAC must refrain from making this recommendation and could, at most, recommend exempting the eight sectors from the general ban. Should the SEAC adhere to the recommendation, the EU Commission could not follow it for legal reasons.

In light of the above, the EU Commission is prohibited from adopting a restriction on PFAS in accordance with the recommendations of RAC and SEAC based on the dossier submitters' proposal. Any restriction adopted on this basis would be unlawful.

5. Procedural errors regarding consultation on the draft SEAC opinion

The consultation on the draft SEAC opinion pursuant to Article 71(1), fourth sentence of REACH is procedurally flawed in several respects. First, the 60-day deadline is unreasonably short. Second, the participation rights of interested parties are restricted by an unreasonably short deadline as well as by inappropriate requirements regarding structure and scope. To avoid these errors, ECHA would be required to facilitate a comprehensive consultation within a sufficient timeframe. If it fails to do so and forwards the opinions of RAC and SEAC to the European Commission, the European Commission must reject the adoption of a restriction corresponding to the opinions.

a. Too short deadline

ECHA has set the consultation period at 60 days, ending on May 25, 2026, thereby strictly adhering to the wording of Article 71(1), fourth sentence of REACH. In doing so, ECHA disregards several relevant aspects and thereby violates the constitutionally protected participation rights of the affected parties under Article 41 CFREU.

aa. Complexity of the SEAC opinion

As has been mentioned on several occasions, the restriction proposal submitted by the dossier submitters is extremely extensive and complex. This was not sufficiently taken into account during the initial consultation on the original restriction dossier, particularly with regard to the procedural rights of the affected parties, which are protected under fundamental rights. Rather, an appropriate extension of the consultation period would have been warranted. In this regard, we refer to the detailed explanations under 1.b.

This complexity is also evident in the draft SEAC opinion. It consists of a 133-page general opinion as well as individual evaluations of the 15 use sectors that were already the subject of the original restriction dossier. This alone would have required an appropriate extension of the consultation period – which, like the other deadlines in Title VIII of the REACH Regulation, cannot be regarded as mandatory – in order to safeguard the participation rights of the parties concerned, which are protected by fundamental rights[50].

[50] See above under 1b.aa. (4) and bb.

The burden on stakeholders is exacerbated by the reversal of the burden of proof associated with the restriction proposal[51]. This requires stakeholders to provide substantiated information on the uses of PFAS (type, quantities, emissions, lack of alternatives and their availability, socio-economic concerns and impacts, etc.) with regard to the entire life cycle. ECHA expressly calls for the submission of relevant information on all possible uses, whether or not they are being addressed by SEAC[52]. Precisely for this reason, the strict 60-day deadline is too short.

bb. Initial statement on the replaced restriction dossier

This is all the more true, given that the violation of the stakeholders' participation rights throughout the entire procedure has not been remedied. On the contrary. By replaceing the restriction dossier by the dossier submitters and the approval of this procedure by RAC and SEAC, the infringement of the stakeholders' participation rights was not only perpetuated but substantially intensified (see above under 3.b.bb.).

Against this background, the parties concerned can now, for the first time ever, present their concerns and interests regarding the current restriction proposal as part of the consultation on the draft SEAC opinion pursuant to Article 71(1), fourth sentence of REACH, thereby asserting their participation rights protected under fundamental rights. ECHA also indirectly acknowledges this in practice. For example, it expressly invites the submission of information on uses not evaluated by SEAC – including uses in the eight new sectors – within the framework of the General Survey – [53].

For this reason alone, the current consultation cannot, for legal reasons, be limited to a consultation on the draft SEAC opinion. Rather, it is imperative to provide stakeholders with a comprehensive opportunity to comment. The very short comment period of only 60 days is incompatible with this. Effective protection of the fundamental rights of those affected, to which ECHA is obligated under Article 41(1) and (2) in conjunction with Article 51(1) CFREU, requires that an appropriate extension of the deadline be granted.

b. Unreasonable requirements

ECHA's requirements for comments on the draft SEAC opinion make it unreasonably difficult for the parties concerned to assert their concerns and interests. This exacerbates the infringement of the parties' fundamental rights to participation under Article 41(1) and (2) CFREU.

ECHA has stipulated (apparently for the first time in restriction procedures) that, for the consultation on the draft SEAC opinion, stakeholder contributions may only be submitted in a structured format via a designated consultation platform (EUSurvey)[54]. This means that comments can only be made on predefined questions and only to a limited extent (multiple choice or free text with limited input). This results in unreasonable restrictions. For example, socio-economic impacts beyond one's own business cannot be captured at all. To justify the lack of alternatives, only multiple-choice answers are available, none of which provide for the possibility that alternatives are technically unavailable. Attachments cannot be included.

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[51] See above under 1.a.aa. (3).
[52] ECHA document – Guidance for respondents, March 2026, at 2.3.2 and 2.4.
[53] ECHA document – Guidance for respondents, March 2026, under 2.4, p. 5.
[54] ECHA document – Guidance for respondents, March 2026.

In addition, ECHA prescribes a complex use-mapping system[55] into which stakeholders must classify specific information regarding the use of PFAS. In the stakeholders' view, this often makes it difficult to categorize the various uses, e.g., due to missing or unclear definitions and deviations from definitions in other legal areas (e.g., medical devices). The use mapping is particularly difficult to apply and implement it from the perspective of suppliers and subcontractors. Furthermore, the use mapping does not include finished devices or products, which manufacturers of complex articles consider inappropriate.

c. Interim conclusion on 5.

The consultation on the draft SEAC opinion, which has since been initiated, is procedurally flawed in several respects. Given the scope and complexity of the restriction dossier, the 60-day deadline under Article 71(1), fourth sentence of REACH is unreasonably short. At the same time, the participation rights of the parties concerned are violated by the unreasonably short deadline as well as by inappropriate requirements regarding the structure and scope of the opinions. Instead, ECHA is obligated to facilitate a comprehensive consultation within a sufficient timeframe. If it fails to do so and forwards the opinions of RAC and SEAC to the European Commission, the European Commission must refuse to adopt a restriction corresponding to those opinions.

6. Conclusion

The multitude of procedural errors identified – particularly when considered cumulatively – preclude the EU Commission from adopting a restriction in line with the proposal. Should the European Commission nevertheless adopt such a restriction, it would be unlawful and could be challenged by affected parties through an action under Article 263(4) TFEU and declared void by the European courts pursuant to Article 264 TFEU.

Berlin, May 18, 2026

[55] ECHA document – PFAS Use Mapping, March 2026.