POLICY PAPER

Restriction on the manufacture, placing on the market and use of PFASs

Key messages

The use of numerous PFAS has a positive societal contribution, e.g. in critical areas such as medical technology or semiconductor manufacturing.

The restriction PFAS should be dealt with within the Ordinary Legislative Procedure.

The collection of potential derogations and other arguments through public consultation is an is inappropriate process.

To make the restriction proposal workable, key actors across the supply chain must be involved in an appropriate and coordinated way.

Choice of legislative procedure

The restriction of per- and polyfluoroalkyl substances (PFAS) in accordance with the REACH Regulation is to be carried out within the framework of a comitology procedure. In principle, such procedures serve non-essential adaptation for legal acts. However, there are significant aspects of the PFAS restriction that argue against the fact that it is a non-essential adaptation.

With around 10,000 individual substances, the scope of substances regulated by the proposed restriction measure is unprecedented, as is the scope of regulated applications. The economic and social impact of such a measure will be massive. The acceptance or non-acceptance of such effects can only be negotiated politically, for which the EU essentially provides for the Ordinary Legislative Procedure.

Furthermore, the restriction would undermine political compromises reached under an ordinary legislative procedure. For example, by effectively undermining the timetable for the phase-down of f-gases within the framework of the EU f-gases-regulation.

The 6-month public consultation is used for the systematic collection of requests for derogations. This suggests that although it was assumed at the time of submission of the dossier that derogations are needed, it was not clear what these should be. This shows an incorrect application of the restriction procedure as described in Title VIII, which clearly places

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the burden of proof on the dossier submitter. This means that the legal text does not foresee that a restriction should be carried out to such an extent quasi-jointly with interested third parties, the dossier submitters and the ECHA committees. The dossier submitter is expected to present a robust proposal and the public consultation should help to further fine-tune this proposal.

The PFAS restriction combines the classic restriction procedure under Title VIII and the authorisation procedure under Title VII. The REACH Regulation does not foresee such a link to this extent. In fact, this creates a completely new regulatory instrument that is not provided for by law.

In view of the expected and already received data during the public consultation, one can reasonably assume that RAC and SEAC will not be able to meet the statutory deadlines given to them in the restriction procedure. In view of the complexity of the PFAS restriction, it can also be assumed that the European Commission will not be able to comply with the statutory period of 3 months for the publication of a legislative proposal to amend Anh. XVII. This assumption is even more valid based on the experience with the proposal for the much less extensive microplastic restriction, which was also very complex. This proposal was not published within the 3-months-period, but with a delay of more than a year.

The PFAS restriction takes a completely new approach to describe hazard, risks and economic impacts. In some cases, conclusions in the Annex XV dossier are based on anecdotal knowledge, individual cases or non-representative small samples. Furthermore, in some places the dossier explicitly recognises that, due to the random samples, extrapolation of the data to the entire EU or EEA is not possible or only possible to a very limited extent. In some cases, data from non-EU countries are used.

In view of the current case law, in particular Case C-144/21, such an approach must be regarded as critical. In its judgment in Case C-144/21, the ECJ states that a decision cannot be based on arbitrary uncertainties, but that there must be a sufficient basis for a decision. The ECJ also states that although such a basis for decision-making can be based on random samples, these must be representative of the situation and the EU as a whole.

With regard to the appropriate sample, the question also arises as to how appropriately the grouping of all PFAS into a group is sufficiently well-founded. Ultimately, conclusions are drawn for around 10,000 individual substances of the PFAS group on the basis of a limited number of PFAS. The grouping into a single group is carried out although the Annex XV dossier highlights that there are many different classifications for certain groups of PFAS. This means that with regard to hazard characterization and consequently risk assessment, PFAS is by no means a homogeneous group. The decision as to whether or not the very high persistence constructed specifically for the PFAS dossier is a hazard property is ultimately not a technical issue, but a political one. Such an issue should not be clarified in an ECHA assessment procedure or comitology procedure.

Public consultation

The collection of potential derogations and other arguments through public consultation is a process that is inappropriate for SMEs. The dossiers are voluminous and in technical English. This is a general problem of ECHA´s public consultations, but because of the complexity of the dossier even more for the current PFAS restriction. Considering the complexity of this assessment, the number of potential actors involved and the time needed to collect such data across the whole supply chain, industry can often not even make a full assessment nor provide relevant input.

Furthermore, we would like to highlight the findings of the EC study on "Essential Use". There it was found that in comparable processes, e.g. in the context of finding and/or find tuning derogations for the RoHS Directive, the participation of companies is in general low. The participation of SMEs is virtually zero.

Basic structure of the restriction

The restriction proposal is not functional in its current basic structure. It is based on a very simplified supply chain model. PFAS in particular have very broad and varied use patterns. In this respect, supply chains are long and branched. This makes it practically impossible for an end user or an actor in the middle of the supply chain to be able to comply with a limit value at the same time as the actor, who places a substance/material on the market for the first time. In such a model the initial distributor can take full advantage of transitional periods, place PFAS-containing products on the market and then all downstream actors have to dispose these products very quickly.

Another problem is that even natural raw materials may get contaminated by PFAS at different manufacturing stages. The concentration of PFAS in these raw materials will be measurable for some time after the ban on the first placing on the market. Examples for this are paper or aqueous products.

In order to solve this problem, supply chains would have to be divided into different levels. To each of these levels an own transitional period and/or PFAS concentrations needs to be assigned. For example, the use of a PFAS in finished products, where there is an alternative available, may be substituted in a reasonable time-frame. On the other hand, when regulating unintentional uses of PFAS, e.g. coming from a manufacturing process, a different approach is necessary and the handler of the finished product may not even be the key actor in developing a substitution strategy. In this case various actors across the supply chain would need to be involved and would need to work in a coordinated way. This requires significantly more time.

Acceptance of PFAS

The use of numerous PFAS has a positive contribution to society. Many technologies are based on these chemicals. These include critical areas such as medical technology or semiconductor manufacturing. A regression to materials of the industrial past would be irrational and irresponsible in these areas.

Therefore, careful handling of PFAS should be encouraged. Purification methods and destruction methods for PFAS should also be encouraged. Ultimately, one should assume that there will be socially relevant applications for a long time to come.

We underline that some uses may not have available suitable alternatives and this should be considered when defining related implementation timelines and full exemptions.

Brussels, 18 August 20213

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