Restriction proposal prepared by the authorities in Denmark, Germany, the Netherlands, Norway and Sweden

# Summary: Universal PFAS restriction

## *Introduction*

This Annex XV report addresses the risks to the environment and human health of the use of per- and polyfluoroalkyl substances (PFASs) and provides an assessment of the effectiveness, practicability, monitorability and socio-economic impacts of two restriction options (ROs) under REACH as the most suitable risk management option (RMO) to address the identified risks.

PFASs are a group of thousands of mainly man-made substances that are used in numerous applications in the EU. These applications comprise uses in textiles, (food) packaging, lubricants, refrigerants, electronics, construction and many more. The substances are used as substances on their own (either non-polymeric or polymeric) and as constituents in mixtures and (complex) articles for consumer, professional, and industrial uses.

## *Concern*

The main concern for all PFASs and/or their degradation products that are in the scope of this restriction proposal is the very high persistence, exceeding the criterion for very persistent (vP) according to Annex XIII of the REACH Regulation by far. PFASs and their degradation products may persist in the environment longer than any other man-made chemical. Further supporting concerns are their bioaccumulation, mobility, long range transport potential (LRTP), accumulation in plants, global warming potential and (eco)toxicological effects. PFASs enter the environment via emissions during manufacture, the use phase, and the waste stage.

When these substances and their degradation products continue to be released to the environment, the concentration in the environment will increase as mineralization under natural conditions does not take place for the PFASs in the scope of this restriction proposal. Once present in the environment, the removal of PFASs from surface water, groundwater, soil, sediment and biota is technically extremely difficult and very costly, if at all possible. Environmental monitoring of PFASs demonstrates ubiquitous distribution in the environment, including organisms and drinking water sources and food crop, as well as remote and pristine areas making exposure unavoidable and irreversible for now and future generations. Human biomonitoring shows the omnipresence of PFASs in humans, with highly exposed communities showing the highest levels. With the constantly increasing concentrations of PFASs in the environment due to their persistence and ongoing emissions, the exposure of humans and the environment to these substances will inevitably lead to negative effects. Also, exposure to PFASs has a high potential for intergenerational effects. Some scientists argue that the planetary boundaries for PFASs have already been exceeded, and human biomonitoring studies show that the cocktail of PFASs to which parts of the general population are exposed to through different sources (e.g. food, drinking water, products containing PFASs, dust, air) already may result in health risks.

## *Regulatory risk management options*

The irreversibility of the process of a growing environmental stock of PFASs, with associated exposure of humans and the environment, make it necessary to reduce emissions of PFASs to a minimum. Different regulatory risk management options have been considered, e.g. CLH and

authorisation, but these options follow a substance by substance approach. In contrast, a restriction offers the possibility to define a broad chemical scope, thereby avoiding regrettable substitution of one PFAS by another PFAS (which may not even be engineered yet). At the same time, it allows to tackle the problem of ongoing, uncontrollable emissions at the source, as manufacture and use can be banned, instead of an end-of-pipe solution that is not achievable, as PFASs are ubiquitously present in a wide range of products intended for industrial, professional and consumer uses. A restriction can cover a wide range of uses and can address the risks arising from the manufacture and use of the substances as such as well as in other substances, in mixtures and in articles, including imported articles from outside the EU. Hence, a restriction is the most appropriate and effective option to adequately control such a large and complex group of substances which are used in numerous applications.

### *Scope*

The chemical scope of the restriction proposal is defined as: Any substance that contains at least one fully fluorinated methyl (CF3-) or methylene (-CF2-) carbon atom (without any H/Cl/Br/I attached to it). There are however a few exceptions (see para below).

It is aligned with the OECD definition1 of PFASs that was published in 2021, and that has been scrutinized by the international scientific community and is widely accepted. This definition encompasses more than 10 000 PFASs, including a few fully degradable PFAS subgroups. As these fully degradable subgroups, which can be described by their key structural elements, do not fulfil the underlying concern of high persistence (see above), they are excluded from the scope of this restriction proposal.

As outlined above, the restriction proposal is tailored to address the manufacture, placing on the market, as well as the use of PFASs as such and as constituents in other substances, in mixtures and in articles above a certain concentration. All uses of PFASs are covered by this restriction proposal, regardless of whether they have been specifically assessed by the Dossier Submitters and/or are mentioned in this report or not, unless a specific derogation has been formulated.

### *Socio-economic analysis*

The Dossier Submitters have identified main PFAS uses in which the largest amounts of PFASs are used and emitted. This has been done by literature research, stakeholder consultations, and a call for evidence. Fourteen sectors and/or applications – subdivided in numerous sub-uses - have been addressed in detail in this report. For the EU, this resulted in an estimated amount of 140 000 to 310 000 tonnes of PFASs introduced to the market in 2020, which – due to the expected economic growth in several sectors – is expected to increase even further under the baseline scenario. Over a 30-year period the expected mean PFAS tonnage in the EEA is 49 million tonnes, leading to emissions of about 4.4 million tonnes during the manufacture and use phase when no action is taken. The emissions during the waste phase, which may be significant, are not accounted for in that estimate as they are highly uncertain. Hence, it can be assumed that emission estimates are severely underestimated.

The overall annual health costs following from exposure to PFAS in Europe has been estimated in a Nordic Council report from 2019 to be between €52 and 84 billion.

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Two restriction options (ROs) have been assessed. A full ban with no derogations and a transition period of 18 months (RO1), and a full ban with use-specific time-limited derogations (18 month transition period plus either a five or 12 year derogation period). As specific information on costs of a ban of PFASs for the different actors associated with the addressed uses was scarce and mainly qualitative, the derogations and their duration were mainly based on the availability and applicability of alternatives to PFASs. RO2 also includes a few time-unlimited, more general derogations, e.g. for PFASs used as active substances in Plant Protection Products (PPP), Biocidal Products (BP) and human and veterinary Medicinal Products (MP), as these are addressed under their respective regulations.

Besides the proposed derogations, the Dossier Submitters also identified uses for which a derogation could be warranted, but for which the evidence base is weak. These uses are between brackets, which indicates that additional information is needed and should be provided during the third party consultation of the restriction proposal to substantiate a derogation. Only if substantial evidence is provided, the Dossier Submitters can assess this and consider whether a derogation is warranted. For the time being, uses between brackets should be read as 'no derogation'.

### *Conclusions on proportionality*

For the 14 use sectors and/or uses that have been addressed in detail in this dossier, the Dossier Submitters conclude that the extent of PFAS emissions warrants regulatory action. This need is further strengthened by the fact that additional emissions from use sectors and/or uses (as well as from the waste stage) that have not been addressed (in detail), only add to the concern and consequently to the call for regulatory risk management measures. For a large number of uses, functional alternatives are already available.

Both RO1 and RO2 are deemed proportionate to the risk, as eventually the societal cost of inaction will always surpass the costs of a ban on the use of PFASs. This has its basis in the persistence of PFASs and their degradation products in the environment. It has to be realized that once a restriction is in place, emissions will go on for many years to come due to the presence of PFASs in technical stock ((long-lived) products in use and on shelf) and waste, leading to increasing environmental stock of PFASs and consequently increasing exposure to PFASs to humans and the environment.

Although both restriction options (RO) are deemed proportionate to the risk, the Dossier Submitters propose RO2 as the most balanced option. RO2 leaves room to mitigate unwanted effects to society due to the sudden unavailability of products for which alternatives are not yet in place and allows stakeholders and industry to prepare for a smooth transition to alternatives. It should be noted, however, that a delay of banning PFASs as a result of the proposed derogations under RO2 will shift the cost burden arising from health and environmental impacts to future generations.