Annex to the

ANNEX XV RESTRICTION REPORT

PROPOSAL FOR A RESTRICTION

SUBSTANCE NAME(S): Per- and polyfluoroalkyl substances (PFASs)

IUPAC NAME(S): n.a.

EC NUMBER(S): n.a.

CAS NUMBER(S): n.a.

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1	Original version for pre-publication	February 2023
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Annex F Assumptions, uncertainties and sensitivities

F.1. Key questions for uncertainty analysis

Uncertainties can affect the final conclusions on (the need for) restrictions and appropriate derogation and transition periods. Key questions therefore are:

1. Is there a risk?
   a. Persistence of PFASs and degradation products covered by the restriction proposal
   b. Potential for health and environmental harm
2. What is the extent of the problem?
   a. Range of applications of PFASs
   b. Quantities of PFASs produced/used
   c. Quantities of PFASs emitted
   d. Fate of emissions
3. Is the proposed restriction of overall benefit to society?
   a. Proportionality of the restriction proposal in general
   b. Proportionality of specific derogations to the proposed restriction

F.2. Approach to uncertainty assessment

The methods used in this Annex have been informed by a draft paper on uncertainty appraisal by ECHA (ECHA, forthcoming). The proposed restriction affects a large number of substances in a wide variety of applications and it was assumed (and justified) that the impact of PFASs, and consequently the restriction of those PFASs, can be based on a groupwise assessment. In this Annex the uncertainties in the steps of the assessment, are addressed, focusing on those that could affect key conclusions. This dossier was developed using a large amount of data both from the literature and extensive engagement with stakeholders which was qualitatively assessed.

The uncertainty assessment includes the following steps:

- A structure (Table F.1) is defined for consideration of uncertainties in the subsequent steps of the assessment. These steps include the identification of sectors using PFASs, quantification of the amounts of PFASs used and emitted, environmental and health impact assessment, the analysis of alternatives and economic assessment and the proportionality assessment.
- A summary of uncertainties is given. This in return provides input for a conclusion regarding the importance of uncertainties for the dossier overall.

In Tables 8, 9 and 13 of the main report a summary and comparison of the assessed restriction options is provided, addressing the strength of evidence. This is provided at the sector/sub-sector level.

F.3. Structure for consideration of uncertainties

Table F.1 provides an overview of the steps in the assessment. The table also provides information on whether uncertainties relate to data, methods or both (in line with a recommendation from (ECHA, forthcoming). In most cases, uncertainties are associated with data (including the lack of data).

Table F.1. Uncertainties across the stages of the analysis.

Section of the Dossier	No	Stage	Source of uncertainty: Data	Methods
Identification of sectors and uses	1	Identification of sectors that use PFASs	X	
	2	For each sector/activity, identification of specific applications involving use of PFASs	X	
	3	Determination of the desired function/properties of PFASs for each application	X	
Baseline applied to each sector and application within each sector	4	Identification of the PFASs currently used	X	
	5	Quantity of material currently placed on the market annually, or held in stocks (2020)	X	
	6	Forecast of changes in use in Baseline (withdrawal from applications or extension to new applications)	X	
	7	Forecast change in the group of PFASs used in Baseline	X	
	8	Forecast change in the quantities of PFASs used in Baseline	X	
	9	Imports and exports	X	
Environmental impact assessment	10	Quantification of emissions in 2020	X	X
	11	Forecast change in the quantities of PFASs emitted	X	X
	12	Persistence of emissions	X	X
	13	Environmental fate of emissions	X	X
Health impact assessment	14	Exposure of sensitive receptors	X	
	15	Ecotoxicity and health effects linked to PFAS exposure	X	
Analysis of alternatives	16	Identification of alternatives	X	
	17	Performance relative to PFASs	X	
	18	Chemical hazards of alternatives		X
	19	Non-chemical hazards and other trade-offs of alternatives (flammability, etc.)	X	
	20	Costs of alternatives	X	X
	21	Availability of alternatives	X	
	22	Barriers to introduction of alternatives	X	
Economic assessment	23	Costs to industry	X	X
	24	Costs to consumers	X	X
	25	Social costs	X	X
	26	Wider economic impacts	X	X
	27	Remediation costs	X	X
	28	Proportionality to risk	X	X

F.4. Review of uncertainties

In Table F.2, the importance of the main uncertainties in each stage of the assessment to the final conclusions is provided, according to the recommendation of ECHA (forthcoming). It is noted that individual steps may have a large number of uncertainties but may not have a significant impact on the conclusions. The different levels of importance are negligible, low, moderate and high.

Table F.2. Summary of uncertainties at different stages of the assessment.

	Stage	Importance of uncertainty for final conclusions
1	Identification of sectors that use PFASs	Low: It is likely that some PFAS-using activities have not been included in the assessment, though the Dossier Submitters are confident that the main sectors

	Stage	Importance of uncertainty for final conclusions
		of use are covered, based on literature review and the response to the CfE and the second stakeholder consultation (Annex A). If additional uses and their associated emissions have to be taken into account, this will only strengthen the need for a restriction.
2	For each sector/activity, identification of specific applications involving use of PFASs	Moderate: A precise understanding of activities involving the use of PFASs is important for understanding the proportionality of the proposed restriction and targeting derogations where they are necessary. Based on current evidence it is acknowledged that some targeting of derogations is weak given a lack of detailed, disaggregated information for some (but not all) sectors. It is intended that questions identified for the Annex XV report consultation in March 2023 will improve understanding and may enable some refinement in the targeting of derogations (Annex A, Annex E).
3	Determination of the desired function/properties of PFASs for each application	Negligible: Extensive information has been collected on the functions and properties of PFASs in various applications (Annex A and E).
4	Identification of the PFASs currently used	Negligible: Dedicated PFAS analysis is possible only for a fraction of the PFASs that may be present in products. However, the broad classes of PFASs of interest have been identified (main report, Figure 1) and it is known what they are used for. For each sector a detailed list of PFASs was developed: this list may not be fully comprehensive, but this uncertainty does not affect the conclusions.
5	Quantity of material currently placed on the market annually, or held in stocks (2020)	Low: The information on amounts of non-polymeric and polymeric PFASs produced and used in the EU/EEA and additionally imported as chemical mixtures and in articles is limited, with the exception of fluorinated gases for which reporting mechanisms exist linked to the UN Framework Convention on Climate Change and the EU's F-Gas Regulation. (Illegal import might be significant). However, sufficient information is available to provide a broad indication of which activities are linked to the most substantial use of PFASs and which are minor uses (main report Tables 3 and 4).
6	Forecast of changes in use in Baseline (withdrawal from applications or extension to new applications)	Low: Based on past trends and information on the growing number of patents linked to PFAS use it is expected that usage will continue to grow in the absence of a restriction. This is reinforced by information from many stakeholders showing limited research on alternatives to PFASs in some sectors.
7	Forecast change in the group of PFASs used in Baseline	Low: The broad categories of PFASs in use are known. There will be some developments in PFASs used over time (e.g. from HFCs to HFOs) but this is expected to have little impact on the persistence of the PFASs entering circulation.
8	Forecast change in the quantities of PFASs used in the Baseline for future years	Low: Long-term forecasts of PFAS use are not available from external sources for most sectors. The approach taken here has been to extrapolate from short-medium projections up to 45 years ahead. It is acknowledged that the aggregate estimates of PFAS use become increasingly uncertain over time. However, based on past trends and information on the growing number of patents linked to PFAS use (see stage 6 above) it is logical that usage will continue to grow. This is reinforced by information from many stakeholders (though not all) showing limited research on alternatives to PFAS. Uncertainty in the precise

	Stage	Importance of uncertainty for final conclusions
		quantity of PFAS used has had little impact on the proportionality assessment: the Dossier Submitters' conclusions on proportionality would not change if use and emissions remained at current levels. The very high probability that use and emissions will continue to grow reinforces the need for the restriction (Annex E).
9	Imports and exports	Negligible: A better understanding of imports and export of PFAS across the range of applications considered would be beneficial, noting that this may explain in part why it has not been possible to close the mass balance or emissions of PFASs versus the tonnages manufactured and used. A notable omission is the lack of data from China. There are also particular concerns that the illegal import of F-gases could be significant. However, there is sufficient information available on uses and the quantities of PFAS associated with those uses in the EU for conclusions to be drawn.
10	Quantification of emissions in 2020	Moderate: A range of ±25% around the central estimate of 75 000 t/y has been calculated for use phase emissions of total PFASs in 2020. When looking at the different PFAS subgroups these ranges are ±50% for polymeric PFASs, ±60% for PFAAs and PFAA precursors, and ±10% for fluorinated gases (main report, Table 1). Emissions linked to waste management are poorly characterised. Literature studies suggest a (very low) 1 – 6 t/y EEA waste stage emission. Additional calculations based on ECHA ERCs (Annex B.9.18.2.10.) lead to EEA waste stage emissions ranging between approximately 3 700 to 7 300 t/y. It is, however, noted that the mass balance for PFASs is not closed and that there are emissions that are not accounted for. Uncertainty in this parameter could influence decisions on derogation (see Appendix to Annex F for more information on the mass balance).
11	Forecast change in the quantities of PFAS emitted	Low: Uncertainty in the forecast change in the quantities of PFAS emitted is a product of Stages [5], [8] and [10]. The extrapolation of short/medium term projections to the long-term is subject to increasing uncertainty over time. However, whilst this is indicative of potential future burdens it is less a driver for conclusions on proportionality than the more robust assessment of current emissions.
12	Persistence of PFASs emitted	Negligible: The persistence of PFASs is well recognised (Annex B.4.1.). Degradation half-lives of the arrowhead PFASs in the environment exceed the criteria for very persistent substances in Annex XIII of REACH by far. For example, if PFAAs degrade, they do it so slowly that it is not observable in standard tests.
13	Environmental fate of PFASs emitted	Negligible: Tracking of emissions across the life cycle for each use has not been attempted. However, knowledge of long-range transport potential (Annex B.4.2.8.), mobility (Annex B.1.2., B.4.2.1.), accumulation in plants (Annex B.4.4.), bioaccumulation (Annex B.4.2.9.), supported by monitoring data (Annex B.4.2.6. and B.4.2.7.) is considered sufficient by the Dossier Submitters to support the proposed restriction.
14	Exposure of sensitive receptors	Low: It is acknowledged that currently tools for reliable prediction of future exposures are in development and may not yet be available. However, there is high potential for ubiquitous, increasing and irreversible

	Stage	Importance of uncertainty for final conclusions
		exposure of the environment and humans based on the general knowledge on persistence, degradation pathways and, more specifically, the observations from monitoring data, model data, degradation testing (Annex B.4.1.) and information on mobility (Annex B.4.2.1.) and volatility (Annex B.4.2.4.). There is high potential for human exposure via food and drinking water (Annex B.9.21. and B.9.22.).
15	Ecotoxicity and health effects linked to PFAS exposure	Low: Ecotoxicity and endocrine activity of a subset of PFASs is described in Annex B.7. Effects on human health are documented in Annex B.5. for a range of PFAS. Increasing evidence for effects of low exposures and combined exposures , e.g. from HBM studies. Potential for intergenerational effects is recognised (Annex B.4.2.9. and B.5.1.). It is acknowledged that experimental data is limited for many PFAS, in part a consequence of the size of the group of chemicals. However, there is a substantial body of evidence available that demonstrates the risks of PFAS exposure.
16	Identification of alternatives	Moderate: Alternatives are identified and discussed for each application in Annex E. It is likely that the listing of alternatives is incomplete for the current day, and becomes more incomplete into the future as research will identify further alternatives. This biases to a more pessimistic view of the potential for substitution than may be the case.
17	Performance of alternatives relative to PFAS	Moderate: Uncertainty arises regarding the extent to which alternatives can replicate PFAS performance to the required level in specific applications (Annex E).
18	Chemical hazards of alternatives	Low: Information on the chemical hazards of alternatives is available and summarised in Annex E.
19	Non-chemical hazards and other trade-offs of alternatives	Low: A variety of non-chemical hazards (e.g. flammability) and other trade-offs (e.g. reduced performance) of alternatives is available and reviewed sector by sector in Annex E, where appropriate.
20	Costs of alternatives	Low: In cases where alternatives are currently in use, cost data have been identified or can be assumed to be lower than the costs of than PFAS use (Annex E). There is, naturally, higher uncertainty in the costs of alternatives that are not currently on the market, or those that do not currently have significant market share.
21	Availability of alternatives	High: The availability of alternatives is a key factor in determining whether to propose or consider a derogation. Responses from stakeholders on availability of alternatives were for some sectors inconsistent leading to uncertainty. In some cases this inconsistency appeared well founded, for example concerning production of goods differing in technical specification, whilst in others no rationale for inconsistency was provided. (Annex E)
22	Barriers to introduction of alternatives	High: In some cases deployment of alternatives is limited by legal or technical barriers. An example of a legal barrier concerns the existence of building standards and codes at national or city level that restrict the use of some refrigerants or foam blowing agents in (e.g.) high rise residential buildings. The lack of consistent regulation across the EU creates uncertainty in assessing how widely some alternatives can currently be used. An example of a technical barrier concerns specification of standards for PPE. For some technical barriers there is uncertainty regarding

	Stage	Importance of uncertainty for final conclusions
		the levels at which specifications are set – whether they reflect actual need, or whether they are based on the performance of PFAS which may exceed 'need'. The existence of such barriers has been a driver for considering a number of derogations. (Annex E)
23	Costs to industry	Moderate: In cases where alternatives are already widely available at a competitive price it can generally be assumed that costs to industry will in most cases be low: clearly some companies will experience losses through having to develop or accelerate substitution plans at a faster rate than they might otherwise have done, but losses to such companies may be compensated by increased profitability for others in the same sector. Limited data on the costs to industry was provided through the consultation, some of it contradictory: A significant number of respondents reported that delays in implementing a restriction would lead to higher costs. (Annex E)
24	Costs to consumers	Moderate: Limited data was identified to establish differences in the costs or quality of some goods produced with alternatives to PFAS. For some sectors (e.g. ski wax and cosmetics) this uncertainty is low and has negligible impact on the conclusions reached. (Annex E)
25	Social costs	Moderate: Potential for job losses via company closures has been noted for several sectors in Annex E. However, the extent to which negative impacts on companies are mitigated by positive impacts on others more advanced in the process of substituting out PFAS, is in general not known. Information provided by stakeholders was of questionable reliability, with many not distinguishing between a restriction brought in on a short time scale and one brought in on a longer timescale. (Annex E)
26	Wider economic impacts	Low: Limited scope for wider economic impacts beyond those specified above was identified. (Annex E)
27	Remediation costs	Low: Decontamination of sites that have been polluted by PFAS is recognised as extremely expensive both in terms of financial cost and the time required to achieve decontamination. Estimates for clean-up for individual sites can run to many millions of € or beyond. (main report, section 2.4.4.)
28	Proportionality to risk	The rating of evidence for proportionality to risk is further considered in Table F.3 below at a sectoral and sub-sectoral level.

To summarise, the stages are distributed across the ratings for the importance of uncertainty for final conclusions as follows:

- High
  - Availability of alternatives; Barriers to introduction of alternatives
- Moderate
  - Identification of specific applications involving use of PFASs; Quantification of emissions in 2020; Identification of alternatives; Performance of alternatives relative to PFASs; Costs to industry; Costs to consumers; Social costs
- Low
  - Quantity of material currently placed on the market annually, or held in stocks (2020); Forecast of changes in use in Baseline (withdrawal from applications or extension to new applications); Forecast change in the group of PFAS used in

Baseline; Forecast change in the quantities of PFAS used in the Baseline for future years; Forecast change in the quantities of PFAS emitted; Exposure of sensitive receptors; Ecotoxicity and health effects linked to PFAS exposure; Chemical hazards of alternatives; Non-chemical hazards and other trade-offs of alternatives; Costs of alternatives; Wider economic impacts; Remediation costs

- Negligible
  - Determination of the desired function/properties of PFASs for each application; Identification of the PFAS currently used; Imports and exports; Persistence of emissions; Environmental fate of emissions

Overall, the ratings given in Table F.2 indicate that uncertainties increase in importance for the final decision towards the latter stages. This reflects in part a higher level of knowledge and data availability in the earlier stages of analysis.

To be clear, a low or negligible rating in this section should not be interpreted as indicating that particular factors are unimportant in the development of the dossier: these ratings instead indicate that plausible levels of uncertainty in those stages of the analysis are not likely to change the conclusions reached.

F.5. Uncertainty by sector

Information in Table F.2 is not specific to individual sectors or activities. For some sectors the level of uncertainty will vary from use to use within the sector. However, it has been concluded that uncertainty in the proportionality assessment is negligible for all uses in several sectors:

- Consumer mixtures: Alternatives are already present in the market at competitive prices.
- Cosmetics: Alternatives are available at competitive prices and are already in very wide use. Reformulation costs are expected to be small.
- Ski waxes: Alternatives are available and have been accepted by sporting bodies for use in competition.

For the socio-economic analysis, The Dossier Submitters distinguish in both the main report and Annex E between the following levels of evidence:

- **Sufficiently strong evidence**: Good evidence from one or more lines of evidence, where conflicting information can be explained and reconciled;
- **Weak evidence**: Insufficient information has been identified, or received from consultation, to establish a firm conclusion;
- **Inconclusive evidence**: Conflicting evidence from one or different lines of evidence, where conflicts cannot be explained and reconciled; and
- **No evidence**.

The conclusions on the strength of evidence for each sector (and subsector where appropriate) are summarised in Table F.3.

In case of uncertainties leading to 'weak evidence', the Dossier Submitters have formulated questions for stakeholders to reply to.

Table F.3. Rating of the quality of evidence for conclusions on alternatives from the main report, Tables 8, 9 and 13. Key: Green – sufficiently strong evidence; Orange – weak evidence; Red – inconclusive evidence or weak evidence.

Sector	Alternatives
PFAS manufacturing	
Sector as a whole	
TULAC	
Home textiles	
Consumer apparel	
Professional apparel including PPE	

Sector	Alternatives
Technical textiles	
Leather	
Home fabric treatments (sprays)	
Textiles for car engine bays	
Food contact materials and packaging	
Consumer cookware	
Industrial food and feed production	
Non-stick coatings (industrial/professional)	
Paper and board packaging	
Plastic packaging	
Other packaging applications	
Metal plating and manufacture of metal products	
Hard chrome plating	
Decorative chrome plating	
Plating on plastics	
Plating with metals other than chrome	
Manufacture of metal products not addressed elsewhere	
Consumer mixtures	
Cleaning agents	
Waxes and polishes	
Rinse aid for dishwashers	
Windscreen treatments	
Guitar strings	
Use in pianos	
Cosmetics	
Sector as a whole	
Ski waxes	
Sector as a whole	
Applications of fluorinated gases	
Refrigeration	
Air conditioning and heat pumps	
Foam blowing agents	
Solvents	
Propellants	
Magnesium casting	
Fire suppressants	
Preservation of cultural materials (paper)	
Insulating gas in electrical equipment	
Medical devices	
Implantable medical devices	
Hernia meshes	
Wound treatment products	
Tubes and catheters	
Coatings of metered dose inhalers	
Other coating applications	
Cleaning and heat transfer: engineered fluids	
Sterilisation gases	
Diagnostic laboratory testing	
Rigid Gas Permable contact lenses and ophthalmic lenses	
Propellants in MDIs	
Membranes used for venting of medical devices	
Packaging of medical devices	
Transport	
PFAS applications for proper functioning and safety of vehicles not addressed elsewhere	
Hydraulic fluids	
Mobile Air Conditioning systems	
Transport refrigeration	
MAC and refrigeration systems in military applications	
Electronics and semi-conductors	
Electronics	

Sector	Alternatives
Semiconductors	
Energy	
Sector as a whole	
Construction	
Architectural coatings and paints	
Wind turbine blade coating	
Coil coating	
Architectural membranes (composite membranes with top coating)	
Architectural membranes (pure fluoropolymers)	
ETFE film/foil for greenhouses	
Windows frames (laminated with fluoropolymers)	
Bridge and building bearings	
PTFE thread sealing tape	
Polymeric PFASs used as processing aids for production of non-PFAS polymers/plastics	
Side-chain fluorinated polymers used for surface protection/sealants	
Fluorosurfactants as wetting/levelling agents in e.g. coating, paints and adhesives	
Non-polymeric PFASs as processing aids	
Window film manufacturing	
Lubricants	
Sector as a whole	
Petroleum and mining	
Non-polymeric PFAS applications	
Fluoropolymer applications	

Appendix to Annex F

The mass balance for emissions of PFASs versus the tonnages manufactured and used is not closed. A large deficit is noted between yearly tonnage and yearly emissions from manufacture, use and waste.

Part of this deficit can be attributed to the presence of PFASs in technical stock (products on shelf and in use) and part could be caused by environmental stock (i.e., PFAS still present in landfills), but this does not account for the full deficit.

Industry specific emission factors for estimating emissions were often lacking and ECHA ERCs for organic substances were applied. Applying ERCs for organic substances to a group of persistent substances might be too conservative and lead to emission underestimates in both, the use phase and the waste phase.

For many uses the PFAS load entering waste stage is significant. The fate of PFASs at end of life depends on the waste management options (see section 1.1.5.1 of the main report), but a complete picture on PFAS fate in waste management is not availabe and specific emission factors for PFASs for the different waste treatment methods are lacking. The effectiveness of removal and (full) destruction of PFASs strongly depends on the type of waste management and on conditions during the waste treatment (e.g. temperature during waste incineration). Emission estimates may be too conservative, especially since the effectiveness of waste management to destruct PFASs is unclear. Where emissions are estimated by chemical analyses, only a relatively small number of PFASs can be identified, as not all PFASs (including their PFAS degradation products) can be analysed. This means that certain PFASs may not be detected, and are, therefore, not accounted for.

On the other hand, export of PFAS-containing material (new articles, second hand articles and waste) can possibly account for part of the deficit between tonnage and emission.

Better information on PFAS tonnages and the fate of PFASs during the full lifecycle, especially the waste stage, is needed to allow for a better closed mass balance.

Further explanation and examples

Mass-balance

The difference between PFAS tonnage brought to the EEA market (as presented in Annex A) and the PFAS emissions (as presented in Annex B) is large. PFAS waste stage emissions, as presented in Annex B.9.18., are illustrated in Figure F.1.

For emissions a distinction is made between on the one hand article manufacturing emissions (no. 2 in Figure F.1) plus use phase emissions (no. 3 in Figure F.1) and waste stage emissions (no. 4 in Figure F.1). The PFAS manufacture emissions are presented as no. 1 in Figure F.1.

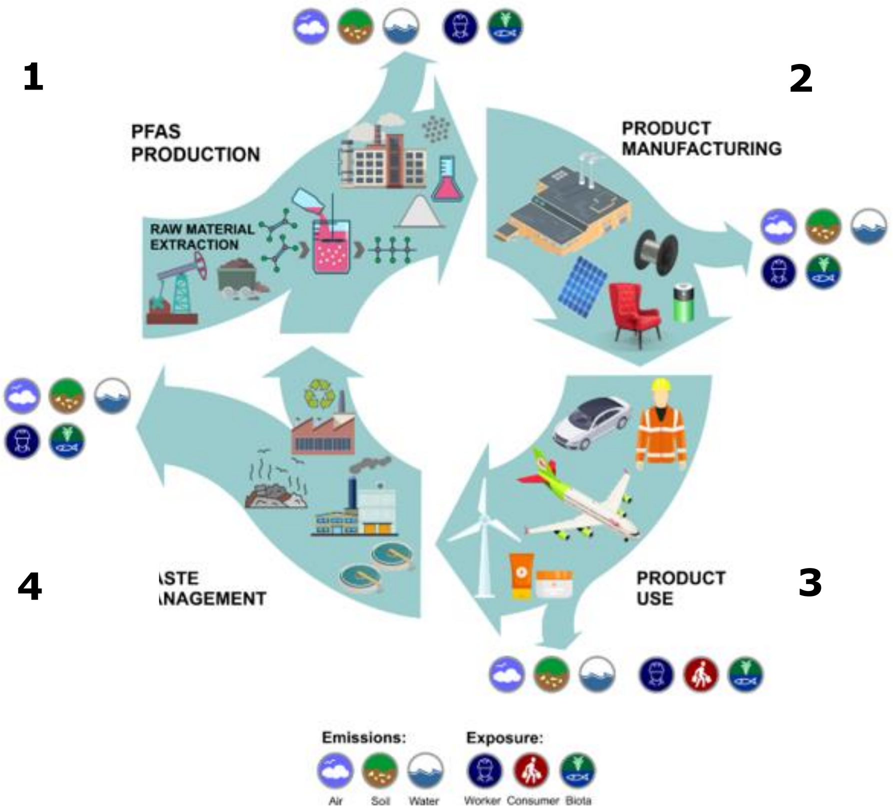

Figure F.1. The PFAS lifecycle with four main stages where PFAS are produced/applied and PFAS emissions can occur.

1) **PFAS Production:** In the beginning of the PFAS lifecycle, PFAS manufacturing emissions occur. There are around 20 PFAS manufacturers in Europe. PFAS manufacturing tonnages as well as emissions are relatively accurate for the sites and substances for which information was available (i.e. via permits and enforcement information). This information may, however, not be representative for sites and substances for which this information is lacking, and the picture can be overseen due to the relative low number of PFAS production facilities in Europe. Emissions from PFAS processors like drying facilities etc. likely occur at far more than 20 sites and are largely unclear.
2) **Product manufacturing:** After PFAS production (and PFAS processing for instance drying, making granules etc.), substance/article production starts where PFAS are applied. Manufacturing of articles like food contact material, textile, electronics, construction, etc. takes place at (an estimated) many thousand sites in Europe. In these factories emissions can occur. It is hard to get a solid overview on the number of sites and the site specific/industry specific emissions. In many cases generic ERCs for organic substances had to be applied for the broad PFAS group.
3) **Product use:** After PFAS article production about 450 million EEA consumers[1] are using PFAS containing products and again direct/indirect/point source emissions or wide dispersive use emissions take place. The emissions from the use phase are quite uncertain (emissions from washing clothes, using PTFE bike-chain spray, painting, using impregnated furniture etc.). Use phase emissions are for instance reflected in analysis of Waste Water Treatment Plants. WWTP plants still face significant PFAS concentrations if treatment plants are solely linked to citizen waste water discharge (STOWA, 2021). In many cases generic ERCs for organic substances had to be applied for the broad PFAS group introducing a lot of uncertainty.

[1] https://ec.europa.eu/eurostat/web/products-eurostat-news/-/ddn-20220711-1, date of access: 2023-01-13.

4) **Waste management**: There are a few main waste treatment methods (incineration, landfilling, recycling and wastewater treatment mainly). Emissions in waste management are highly uncertain and are not considered in the environmental impact assessment. In waste incineration it is uncertain if full mineralization to HF, H_2O and CO_2 is taking place at operational conditions. In landfilling emissions via leachate to water are of importance (but uncertain) and prolonged. Emissions to air are hardly investigated and uncertain as well. Indirect PFAS emissions via compost, biosolids, sludge as well as via industrial waste transport and bulking is reality.

   There will be delay between article production and waste stage: Products put on the market will, depending on the substance/mixture/article lifetime, enter the waste stage (far) later. Applications with longer lifetimes i.e., passenger cars or construction material might have highly deviating waste quantities compared to production volumes in the same year because of market dynamics (I.e. strong market growth).

<u>PFAS tonnage brought to EEA market versus PFAS EEA emissions</u>

There is a very large gap between PFAS tonnage put on the European market (Annex A) and PFAS EEA emissions (Annex B). Despite all uncertainties in both tonnage as emission estimates, the gap is striking.

In Figure F.2 below the PFAS tonnage (blue) is plotted as well as manufacture/use phase emissions (orange) and waste stage emissions (yellow). The difference is plotted in grey and is large. In Figure F.3 and Figure F.4 the differences are plotted in more detail per PFAS use sector.

Figure F.2. Tonnage, manufacturing, use phase emissions and waste stage emissions (Annex A, Annex B and Annex B.9.18., respectively). Gap between tonnage and emission plotted in grey.

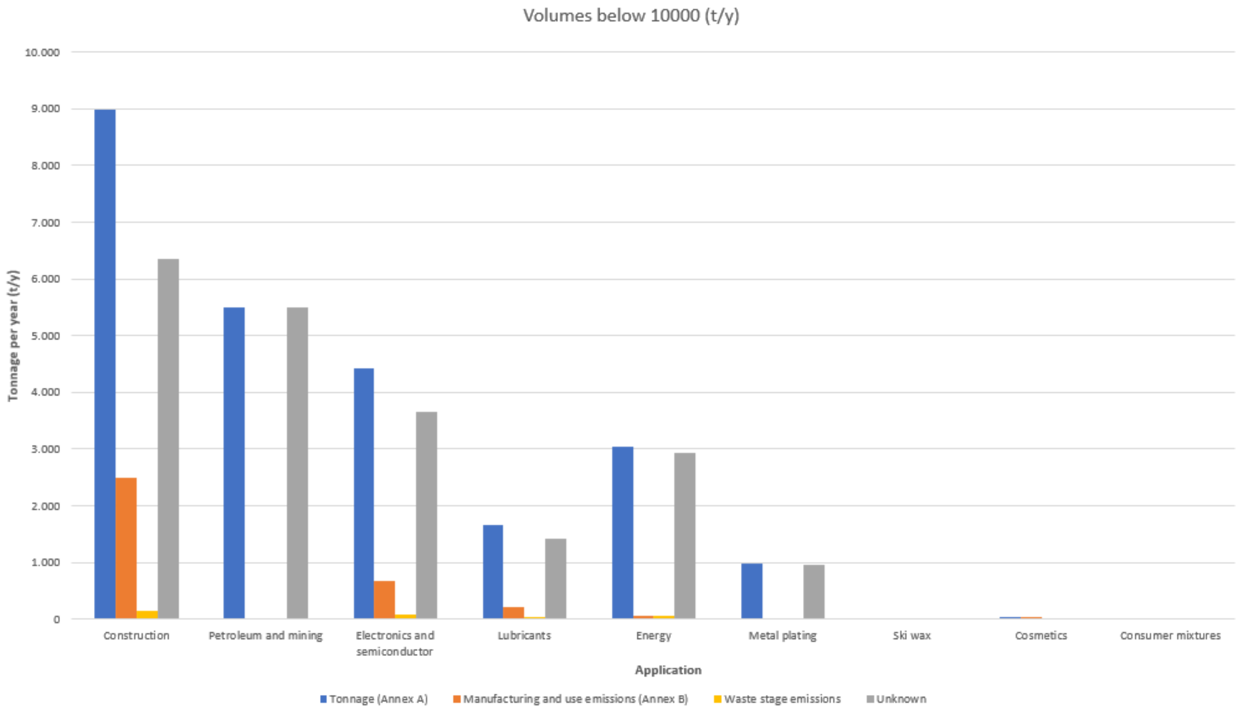

Figure F.3. Gap between tonnage and emissions (volumes below 10 000 t/y).

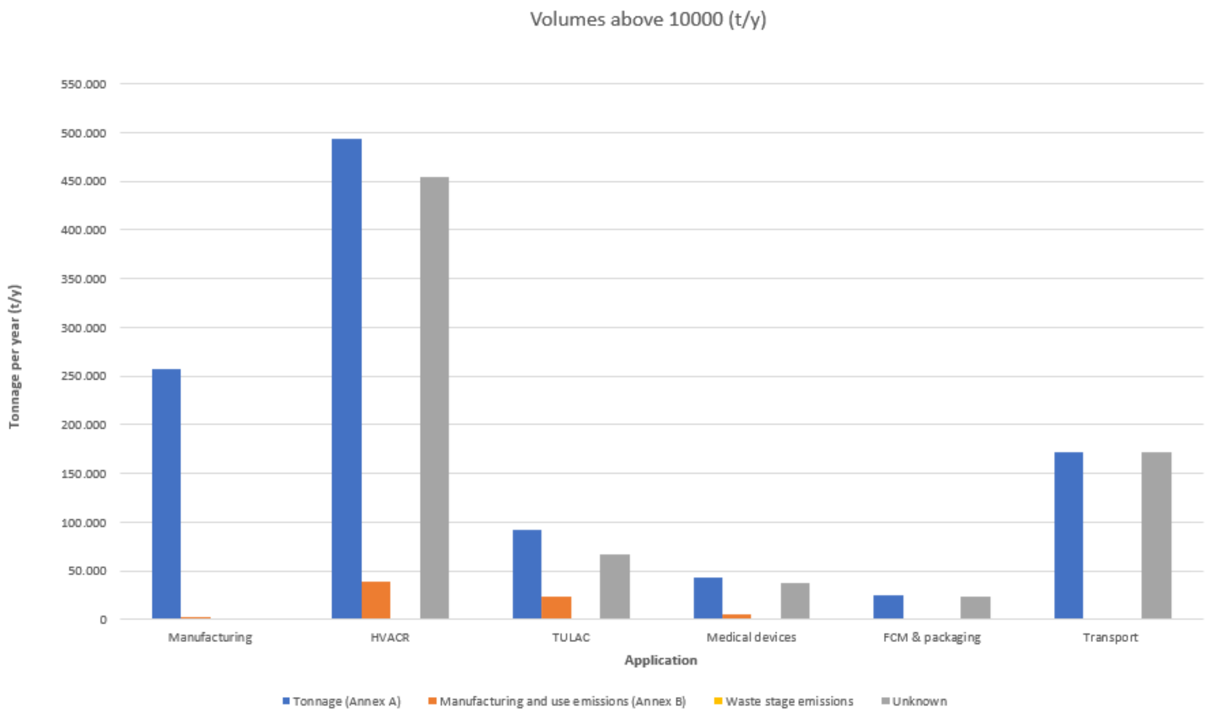

Figure F.4. Gap between tonnage and emissions (volumes above 10 000 t/y) (including PFAS manufacturing).

The plotting of tonnage and emissions can be considered 'a picture', a moment in time. Reality is a 'movie': PFAS are continuously being put on the market and PFAS emissions are taken place continuously as well. ERCs however represent lifetime (i.e. 20 years) emissions.

Some PFAS have immediate emission, e.g. the use of fluorinated-gases in inhalers. These substances are emitted to environment relatively soon after their production. Many PFAS have delayed emission because of a long period between production and waste stage. Significant amounts of PFAS are therefore in "societal stock": For instance, in (durable) substances/mixtures/articles or closed systems. Examples are painted/coated articles, construction materials, consumers articles, electronics, solar panels, cookware, furniture, refrigerators, etc. In the long term PFASs in these articles will enter the environment unless recycled or fully destroyed i.e. via high temperature, high residence time, waste incineration.

Additionally in landfill, 'building up' of PFAS may occur, as even if landfills are closed, PFAS emissions to air and water (leachate) will continue for decades to come. As a result, environmental stocks built up in both use phase (society) and waste stage.

In case 2nd hand articles and/or waste is exported outside EEA, waste stage emissions occur outside EEA but might 'return' to EEA for instance via waterflows.

Notwithstanding the environmental PFAS 'stock' in use phase and waste stage (landfill sequestration) and the potential leak via waste export, there likely still are additional reasons to explain the very large PFAS imbalance in the mass balance:

- Emission calculations are too conservative:
  - i.e. because not all PFAS can be measured and/or
  - Applied ERCs for organic substances applied to a group of persistent substances might be too conservative and lead to emission underestimates in both article manufacturing phase, use phase and waste phase. This could for instance be caused by the fact that the ERC article/substance/mixture lifetime for organic substances is too short for persistent substances like PFAS.
  - Waste stage emissions for fluorinated gas are unknown and therefore not taken into account
  - Etc.
- And/or PFAS tonnage estimates are too high:
  - i.e. because of double counting of tonnages
  - Because of underestimation of (product and/or waste) export outside EEA
  - Etc.

Despite (high) uncertainties in tonnages and emissions, the Dossier Submitters consider the building of environmental stocks in (accumulated) substances, mixtures and articles and PFAS accumulation in (some) waste stages realistic.

Because of societal stock and continuous PFAS emissions from landfills, biosolids, sludge application, compost etc, PFAS emissions will continue to occur into the future even after a restriction is in place.

References

ECHA (forthcoming): Guidance on Uncertainty Analysis in Annex XV Reports and corresponding opinions. European Chemicals Agency

STOWA (2021): PFAS in influent, effluent and sewage sludge results of a monitoring campaign at eight WWTPS. STOWA 2021-46E. STOWA Foundation for Applied Water Research.
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