

**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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## **Annex G Stakeholder information**

### **G.1. Introduction**

Stakeholders were regularly informed regarding the development of the broad PFASs restriction dossier by the Dossier Submitters. In addition, several stakeholder consultations, both general (CfE spring-summer 2020 and a second stakeholder consultation summer-autumn 2021) and sector-specific consultations (details below), by the Dossier Submitters or by its contracted consultants, have been conducted during the preparation of this report. These consultations aimed at covering all the relevant sectors and gather information on e.g. uses, tonnages, applied substances and alternatives. At the start of the project the following sectors, where PFASs are used or applied, were identified:

- Manufacture and import
- Textiles, upholstery, leather, apparel and carpets (TULAC)
- Food contact materials (FCM) and packaging
- Metal plating and manufacture of metal products
- Consumer mixtures
- Cosmetics
- Ski waxes
- Heating, ventilation, air conditioning, refrigeration (HVACR) and other applications of fluorinated gases
- Medical devices and medicinal products
- Transport
- Electronics, semiconductor and energy
- Construction products and lubricants
- Petroleum and mining
- Waste

## G.2. Approach

The main stakeholders consultations conducted were the following:

1. Generic stakeholders information activities
2. Generic stakeholders consultation activities
3. Sector-specific consultation activities

### G.2.1. Generic stakeholders information activities

Since the proposed PFAS restriction is expected to have an impact on many companies in various sectors, the Dossier Submitters tried to inform all stakeholders as good as possible by reaching out on several occasions. On 29 October 2020, the Dossier Submitters, together with ECHA, organised a webinar to provide information on the PFAS restriction proposal. In addition, several presentations were given at conferences organised by others (see Table G.1).

**Table G.1. General information activities on the broad PFAS restriction proposal.**

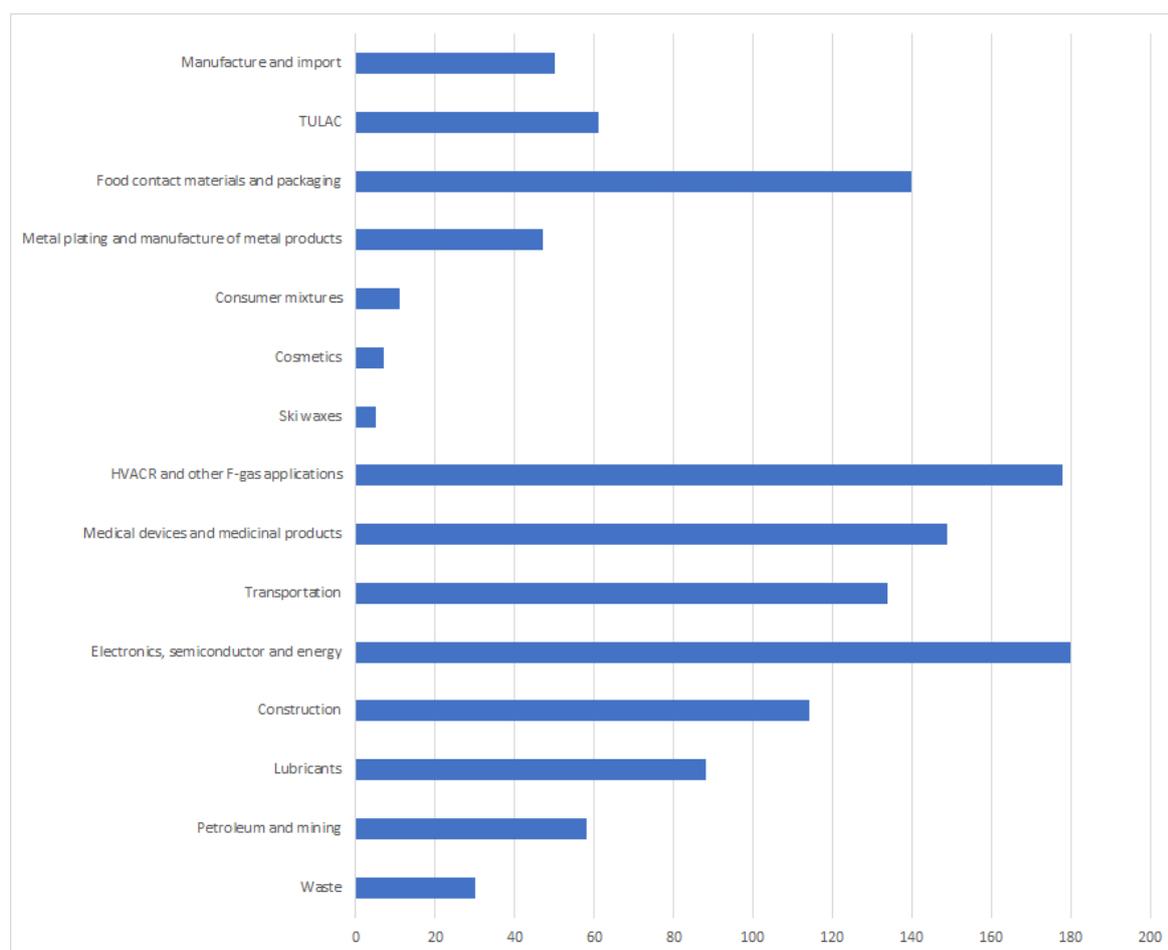
Consultation	Date	Remark
Dossier Submitter Webinar	29.10.2020	806 participants
Publication E-magazine on PFAS restriction proposal by RIVM (Netherlands)	16.12.2021	
Presentations at various international conferences	30.11.2020	International online – conference “PFAS – Dealing with contaminants of emerging concern”
	03.12.2020	Chemical Watch conference – ‘ Essential uses’ of PFASs in the EU
	23.06.2021	Chemical Watch conference – PFAS updates 2021

### G.2.2. Generic stakeholders consultation activities

The Dossier Submitters organised two generic consultation rounds. The first consultation round (CfE) aimed to give stakeholders the opportunity to provide information on the type and amount of PFASs used by manufacturers, importers and downstream users, the hazard properties, the functionalities, their area of use, and alternatives, among others. The reactions were used inter alia for the sector-specific studies (see below, Table G.2 and Figure G.1). The second stakeholder consultation aimed at clarifying remaining questions on tonnages, emissions, use conditions, socio-economic information and alternatives. The five countries preparing the restriction proposal have informed about both consultation rounds on their websites. Additionally, companies and industry associations were made aware of the consultations via email.

**Table G.2. General consultation activities on the broad PFAS restriction proposal.**

Consultation	Date	Remark
CfE	11.05. – 31.07.2020	537 reactions on the questionnaire (see Appendix G.1)
Second stakeholder consultation	19.07. – 17.10.2021	Study summaries on 16 use sectors were provided for commenting accompanied by a questionnaire (see Appendix G.2). 1252 reactions were received in total, the number of reactions per use is included in Figure G.1 below.



**Figure G.1. Overview of reactions received during the second stakeholder consultation.**

### G.2.3. Sector-specific consultation activities

In addition to the general stakeholder activities, consultations have been held on specific PFAS uses. Table G.3 provides an overview of the studies carried out for the different identified uses. Where relevant the external consultant is mentioned. Some full study reports are publicly available.

**Table G.3. Studies on specific uses including information on the consultant.**

Use	Consultant	Link to publication (if available)
Manufacture and import	RPA / Arche	-
Textiles, upholstery, leather, apparel and carpets (TULAC)	Wood	-
Food contact materials and packaging	Exponent	-
Metal plating and manufacture of metal products	-	-
Consumer mixtures	-	-
Cosmetics	IVL – Swedish Environmental Research Institute	<a href="#">PM 9/21: PFASs in Cosmetics - Kemikalieinspektionen</a>
Ski waxes	Wood	<a href="https://www.miljodirektoratet.no/publikasjoner/2021/april-2021/pfas-in-the-treatment-of-skis">https://www.miljodirektoratet.no/publikasjoner/2021/april-2021/pfas-in-the-treatment-of-skis</a>
HVACR and other applications of fluorinated gases	Exponent	<a href="https://www.miljodirektoratet.no/publikasjoner/2021/juli-2021/application-of-fluorinated-gases-f-gases-in-the-european-economic-area/">https://www.miljodirektoratet.no/publikasjoner/2021/juli-2021/application-of-fluorinated-gases-f-gases-in-the-european-economic-area/</a>
Medical devices and medicinal products	De Milieutafel	-
Transportation	-	-
Electronics, semiconductor and energy	Royal Haskoning DHV	-
Construction products	Wood / COWI	-
Lubricants	Wood / COWI	-
Petroleum and mining	Wood	<a href="#">PFAS in mining and petroleum industry – use, emissions and alternatives – Miljødirektoratet (miljodirektoratet.no)</a>
Waste	Ramboll	-

Moreover, representatives from the five countries preparing this REACH restriction proposal held approximately 25 meetings with individual stakeholders (companies, industry associations, NGOs) in order to gather further insight into the different uses and to collect additional information on alternatives and socio-economic consequences of a potential restriction. Some stakeholders also provided additional information by email.

A short description of the sector-specific consultation activities is given below.

#### Manufacture and import

To obtain data for the study, RPA carried out a systematic literature review and designed a questionnaire which was sent to a targeted list of stakeholders with an invitation to participate and provide responses. 152 stakeholders were invited by email to participate in the consultation exercise. Of these, 45 confirmed receipt of the invitation, 33 stated their intention to respond to the survey, and 27 ultimately provided responses. To clarify their responses and provide an opportunity for the stakeholders to ask questions, 14 follow-up telephone meetings were held between selected stakeholders and RPA.

Additionally, a literature review and internet search were conducted to get an overview of main PFAS producers and PFAS tonnages in the EEA. A condensed SEA was conducted to get insight into the impact of a PFAS restriction.

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### Textiles, upholstery, leather, apparel and carpets (TULAC)

The collection of data that underpins the analysis and results of the study on TULAC comprised three specific aspects: a review and collation of information from the CfE and the second stakeholder consultation, a rapid review of relevant literature and direct consultations with key stakeholders.

While the primary source of information underlying this analysis was expected to be from the CfE, there remained considerable data gaps. An additional stakeholder consultation was intended to fill key data gaps. This consultation was undertaken primarily in October 2020 to February 2021, with some complementary consultations in September and October 2021. In total, 47 companies and branch organisations were contacted, which resulted in 16 interviews and 5 written reactions.

### Food contact materials (FCM) and packaging

A thorough literature survey was carried out, information from the CfE and the second stakeholder consultation was analysed, and value chain actors and stakeholders were interviewed in depth.

The consultant completed a project for the UN/OECD PFC Group entitled 'PFASs and alternatives in food packaging (paper and paperboard): report on the commercial availability and current uses'. The scope, methodology and deliverables of the current restriction proposal were closely aligned with this OECD project.

### Metal plating and manufacture of metal products

For chrome plating, mainly information from the previous PFHxA restriction process (including the Annex XV report consultation on the submitted dossier) was used. Furthermore, information from the CfE and the second stakeholder consultation were analysed and included in the report.

### Consumer Mixtures

Stakeholder information provided during the CfE and second stakeholder consultation was used. One company supplied further written information on the use of PFASs in the coating of guitar strings after the second consultation round.

No further targeted consultation with stakeholders took place regarding the use of PFASs in consumer mixtures. However, because of potential overlap with other uses in transportation (e.g. in products used for car care), members of the group working on consumer mixtures participated in two further meetings with stakeholders that were organised by other work packages. No additional information on the use of PFASs in consumer mixtures was obtained in these meetings.

### Cosmetics

The PFASs searched for were based on a list provided by the Swedish Chemicals Agency, adapted by IVL Swedish Environmental Research Institute and forwarded to three European cosmetic databases: CosmEthics (Finish), Kemiluppen (Danish), ToxFox (German). These databases were consulted to get an overview of the identity and frequency of occurrence of PFASs i.e. compounds with at least one  $-CF_2$  group attached to it in cosmetic products.

Several chemical analyses were carried out, i.e. total fluorine (TF) content, giving an estimate for the total PFASs content. TF content was measured in 43 purchased cosmetic products listing PFAS(s) as ingredients.

### Ski waxes

The collection of data that underpins the analysis and results of this study is comprised of three specific aspects: 1) A review and collation of information from the CfE; 2) A rapid review of relevant literature; 3) Direct consultation with key stakeholders.

The survey questions provided in this consultation yielded useful information, specifically on the uses of PFASs, as well as the alternatives in ski wax products that fed directly into the assessment. An additional stakeholder consultation was intended to fill key data gaps and was undertaken primarily in October and November 2020. 17 stakeholders were contacted for wider interviews, however only four of them responded.

### Heating, ventilation, air conditioning and refrigeration (HVACR) and other applications of fluorinated gases

Information about the applications of fluorinated gases have been identified by a combination of literature research, CfE information (summer 2020), and from discussions with stakeholders. Main sources of information about use volumes and emissions for different applications are the Greenhouse Gas (GHG) Inventory (data reported to the UN climate convention) and F-gas Report (data reported under the F-gas Regulation). 178 different responses were received in the second stakeholder consultation (in 2021), and the respondents consisted of both NGOs and industry, including industry stakeholders from both fluorinated gas-based equipment as well as non-PFAS alternatives. Information about the PFAS restriction proposal with a special focus on fluorinated gas applications to the sector was presented by the Norwegian CA in March 2022.<sup>1</sup>

### Medical devices and medicinal products

A range of products and PFASs were derived from the response to the CfE. 89 companies indicated that they produce, import or distribute PFASs for medical devices and medicinal products. Moreover, information of ten trade organisations was received. However, this combined information did not fully cover the whole market of medical devices and pharmaceuticals in the European Union, as a comparison with ECHA data revealed. Reported volumes were therefore compared with estimations that were based on statistics from other sources, such as literature and databases (for instance European Medicines Agency (EMA), World Health Organization (WHO), Eurostat and ECHA). However, the ECHA database only contains information about non-polymers, hence research for polymer volumes relied on information gathered via responses from the CfE.

### Transport

Stakeholder information came from the CfE and the second stakeholder consultation as well as direct consultations with key stakeholders. The questionnaires and additional documents received during the CfE and the second stakeholder consultation provided a good overview over this specific sector. However, useful information on tonnages and alternatives was scarce. In order to fill these gaps, industry stakeholders were consulted directly and in addition, targeted research in public literature was performed. However, some specific aspects on used tonnages and availability of alternatives remain open.

### Electronics, semiconductor and energy

The research was based on literature and website searches, statistics databases and an extensive stakeholder survey, using an electronic made-to-measure questionnaire. For the electronics and semiconductor sector, around 30 stakeholders were contacted. A similar

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<sup>1</sup> <https://www.environmentagency.no/news/2022/the-universal-pfas-restriction-proposal-and-f-gases/>, date of access: 2022-12-02.

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number of stakeholders related to the energy sector were contacted. Some preliminary stakeholder interviews were performed mainly to provide insight on polymeric PFASs.

The information from the CfE as well as the information from the ECHA database was analyzed. Sector organisation websites were searched for PFASs and polymeric PFASs, and in Google Scholar a search was performed using combinations of keywords (non-limiting) such as PFASs, function of PFASs, sector names, PFASs in electronic equipment, PFASs in batteries, production volume, etc.

Statistic databases like Eurostat, Statista, Retail-Index, Urban mine platform and SPIN database were used as well.

### Construction products and lubricants

The collection of data comprised three main aspects: 1) A review and collation of information from a CfE launched in summer 2020; 2) The information from the CfE was complemented with a review of key information from grey and scientific literature. A systematic web search was carried out with the use of search tools like Google and Google scholar; 3) Direct consultations with key stakeholders. Based on the assessment of the data gathered from the CfE and literature, a short list of key stakeholders and two sets of questions were developed (one for lubricants and one for construction products) to address the remaining data gaps.

For lubricants, 14 stakeholders were contacted (or pro-actively contacted by the project team to offer participation in the consultation). Interviews were conducted with eight stakeholders. For construction products, 18 stakeholders were contacted (or pro-actively contacted by the project team to offer participation in the consultation). Interviews were conducted with five stakeholders. For stakeholders that did not provide input or explicitly denied the request, at least one attempt by phone (where a number was available) and at least one attempt by email was made to follow up on the initial consultation request.

### Petroleum and mining

The primary source of information underlying this analysis was from the CfE, but there were considerable data gaps. An additional stakeholder consultation was performed to fill key data gaps, and this consultation was undertaken primarily in October and November 2020. Wood did a systematic literature review and prepared a questionnaire with input from MSCA. Wider interviews and data collection were carried out with 21 stakeholders.

### Waste

The goal was to derive mass flows which cover a high PFAS freight likely related to significant emission risks during recycling or waste treatment. The most relevant waste streams were selected based on a set of criteria. These included, but were not limited to:

- Waste streams with high volumes in the EU/EEA;
- Waste streams with high average PFAS concentration or freight;
- Waste streams for which high recycling rates occur/are assumed;
- Waste streams for which high releases into the environment occur/are assumed (landfill, land application, recycling).

The information needed to assess the proposed criteria was derived from information from other work packages (WPs), Eurostat and a targeted literature research.

Furthermore, PFASs emissions from main waste treatment methods (incineration and landfill) were estimated for the EEA based on an extensive literature review.

### **G.3. Outcome and conclusions**

As explained in the previous paragraphs, the Dossier Submitters made considerable attempts to reach out to all relevant stakeholders regarding the use of PFASs and possible alternatives. The information included in this report is an abstract of the information available to the Dossier Submitters, as can be seen in the publicly available detailed consultation reports on some specific uses. Given the enormous amount of PFAS applications and large variety of PFASs, the Dossier Submitters acknowledge that certain information was not possible to obtain, or not with a sufficient level of accuracy or representativeness at EU level. Therefore, several assumptions have been taken by the Dossier Submitters to alleviate the data gaps and perform this assessment (see Annex F).

## **Appendix to Annex G**

### **Appendix G.1**



Appendix G1  
questionnaire call for

### **Appendix G.2**



Appendix G2  
questionnaire seconc