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PFAS restriction

By email 05-01-2021

Dear Mr 5.1.2e and Mr 5.1.2e

Thank you for e-mail dated 1 December 2020 indicating your interest in our work on the PFAS restriction dossier. In this letter I would like to inform you on the process and steps we are currently undertaking.

As you are aware five countries (Norway, Sweden, Denmark, Germany and The Netherlands) have launched the initiative to develop a REACH Annex XV dossier restricting the use of (all) PFAS in non-essential applications. We intend to submit the restriction dossier during the first half of 2022.

In preparing this dossier, the five countries launched a call for evidence on 11 May 2020[1], giving stakeholders around 2,5 months to provide information on the use of PFAS and possible alternatives in their applications. As follow-up on this call for evidence, we started preparing study reports on various applications of PFAS, partly assisted by different consultants[2]. On request of several stakeholders, the deadline for reacting on the questionnaires of the consultants have been prolonged until the end of January 2021. To be able for us to proceed in our process after January 2021, we cannot extend the deadline further. Information from these study reports will be used in preparing several parts of the restriction dossier, including a socio-economic assessment.

[1] https://www.reach-clp-biozid-helpdesk.de/SharedDocs/Meldungen/DE/REACH/2020-05-08-RMOA-PFAS.html

[2] WP4.B (SE) textiles, WP4.C (NL) FCM, food processing equipment and packaging material, WP4.D (DE) consumer mixtures, WP4.E (DK) lubricants and construction, WP4.F (SE) cosmetics, WP4.G (NL) PFAS production, WP4.H (DE) chrome plating, WP4.J (NO) ski wax, WP4.L (DE) transportation (car's, planes, boats), WP4.M (NO) petroleum and mining, WP4.N (NL) medical devices incl. pharmaceuticals, WP4.P (NO) F-gases, WP4.R (DK) electronics and energy sector and WP4.T (NL) waste / end of life stage

In response to your letter I will reflect on the four aspects you are specifically mentioning: overview, harmonization and general purpose, realistic timelines and confidentiality.

1. **Overview**
   Due to confidentiality reasons we cannot provide an overview of companies or associations contacted by one of the five countries or by the consultants. ECHA has sent the announcement of the call for evidence to all companies using PFAS according to their registration dossier or C&L notification. Further the announcement has been widely published on several websites and news letters. Many companies responded in the call for evidence, if needed they were contacted with follow-up questions.

2. **Harmonisation and general purpose**
   In the Annex to this note, you can find the information requests which have been used as basis for the ongoing studies (both by the consultants and by the countries). I hope this is helpful in getting the general purpose.

3. **Realistic timelines**
   As indicated above, we will have to proceed with our assessment in February 2021. However, additional information after the deadline of the end of January will be appreciated and preferably at your earliest convenience.
   Please note that our work will continu and we might identify data gaps, unclear information, etcetera and therefor there might be a need for additional interaction between us and several companies, stakeholders organisations. In fact, WP4.R (electric and electronic equipment) was added recently to the working program and an additional study on this specific topic will start soon.

4. **Confidentiality**
   Confidentiality is guaranteed. The REACH regulation stipulates that specific information is to be treated as confidential business information (CBI) either in all cases or by request (Article 118 and 119 REACH). The involved countries are bound to treat these data as CBI and we will not disclose them to third parties. Note that we all are used to work with confidential data in other REACH dossiers.

   All consultants have signed a Non-Disclosure Agreement[3].

[3] For WP4.N (medical devices incl. pharmaceuticals), RIVM contracted 'de Milieutafel' (Anja Verschoor). Anja Verschoor signed a confidentiality declaration (based on ECHA's standard). RIVM will not send confidential information to Anja Verschoor via mail. However, Anja Verschoor has a temporary access to the specific PFAS restriction folder in the RIVM-IT system.

As you might realize adapting procedures as requested is hardly possible as the restriction process is bound to formal deadlines and the processing of information requires serious time and attention. We however appreciate your involvement and welcome your input.

For futher information, please contact 5.1.2e or 5.1.2e

Yours Sincerely,

5.1.2e

Annex 1. Basic information targets per use in WP4, for all sub-uses of PFAS and alternatives for these uses (key information targets set in bold)

Information used in dossier for:	**Information targets**
1) Substance identification	• Identity/characterization/grouping of PFASs manufactured and used • Function of PFASs within the use • Physico-chemical property of the substance/group and PFAS degradation products • Alternatives for PFASs per use
2) Market analysis (Baseline scenario)	**For all uses** of PFASs and for identified alternatives for relevant uses, respectively: • Concentration PFAS per use/ quantities per unit (kg) use • Concentration alternative substance(s) per use/ quantities per unit (kg) use, *if relevant* • Market share per use category, of uses with PFAS included • Market share of alternatives based products • **Annual EEA production tonnage volumes (last 15-20 years)** • **Annual EEA import, export volumes (last 15-20 years)** • Future trends regarding production, import, export and use (volume/year) • Market price per use and/or product / article (preferably per year) • Current no. of producers/ importers/users • What products are being imported? What are the concentrations in these products? • Current no. and location of industrial sites in EEA • No. of formulations • **Profits and turnover per (sub-)use (per sector)** • Supply chain of PFASs per use and supply chain of alternatives • Identification of obstacles and incentives for use of alternatives • Description of methodology for data gathering
3) Environmental impact assessment	Emissions: • **Total annual emissions per use** • **Total annual emission per alternative substance** • **Release fractions per use to different media, emission entries** • Past emissions and expected future emissions per use (30 years) • **Description of method(s) used to assess emissions**
4) Economic impact assessment	Economic impacts in case of a ban: • **Substitution costs per use: affected market actors in the supply chain, cost difference to the end product consumers (what factors are the cost driver for end-products based on alternatives?)**

	• **Technical costs per use (e.g. for additional testing, technical installations etc.)** • **Organizational costs per use (e.g. training of workers, occupational safety measures, regulator costs)** • **What are the impacts of a loss in functional use?** • **Strategic consequences of PFAS ban (i.e. more dependent on suppliers outside EU, changes for business etc.)**
5) Human/social impact assessment	• Hazard profile of PFAS, relevant hazards for qualitative evaluation • Hazard profile of alternative • No of users (consumers, medical staff etc.) • No of workers exposed or total employed in the supply chain (?) • Human (consumer, worker and man via the environment) exposure per use *(if relevant)* • Potential employment effects due to substitution (i.e. skills, qualification, job quality)