

General Comments:

Select the relevant boxes that cover the content of your comments and provide your non-confidential comments below, (maximum 63 999 characters)

- ✓ **Scope or restriction option analysis**
- **Hazard or exposure**
- **Environmental emissions**
- **Baseline**
- **Description of analytical methods**
- ✓ **Information on alternatives**
- ✓ **Information on benefits**
- ✓ **Other socio economic analysis (SEA) issues**
- ✓ **Transitional period**
- ✓ **Request for exemption**

Corden BioChem GmbH and Corden BioChem International GmbH are an industrial production partner for biotechnologically manufactured products in the sector of food, feed additives, enzymes and for technical applications. The company operates large fermentation plants in the Höchst Industrial Park in Frankfurt. Our production plants uses seals, gaskets and liners made of Fluoropolymers. Without this equipment a high quality, safe and compliant production is not possible, because there are not adequate alternatives available.

1. Sectors and (sub-)uses: Please specify the sectors and (sub-)uses to which your comment applies according to the sectors and (sub-)uses identified in the Annex XV restriction report (Table 9). If your comment applies to several sectors and (sub-)uses, please make sure to specify all of them.

Answer to specific info request 1:

Biochemical, chemical, food and feed industries use PTFE and other Fluoropolymers as liners, seals, gaskets, moldings, cabling and sensors, lubricants etc.

Biochemical industry is not listed in table 9 in Annex XV

2. Emissions in the end-of-life phase: The environmental impact assessment does not cover emissions resulting from the end-of-life phase. To get a better understanding of the extent of the resulting underestimation, (sub-)use-specific information is requested on emissions across the different stages of the lifecycle of products, i.e. the manufacture phase, the use phase and the end-of-life phase. Please provide justifications for the representativeness of the provided information. In particular:

- **Please provide, at the (sub-)use level, an indication of the share of emissions (as percentages) attributable to these three different stages. An indication of annual emission volumes in the end-of-life phase at sector or sub-sector level would also be appreciated.**
- **If possible, please provide for each (sub-)use what share of the waste (as percentages) is treated through incineration, landfilling and recycling. Please provide information to justify the estimates as well as information on the form of recycling referred to.**

Answer to specific info request 2:

Liners, seals, gaskets, moldings, etc. based on fluoropolymers do not cause any emissions during use.

For Food industry Fluoropolymers (f.e. PTFE) are highly recommended. The use of plastic materials is regulated in the EU by EU legislation Regulation (EC) No 1935/2004 and EU legislation Commission regulation (EU) No 10/2011. Those regulations cover among other things the migration limits of materials with contact into food.

Furthermore they are classified by OECD. Their safety are reviewed in the context of specific applications (e.g. as food contact materials or for use in a medical context) by the US EPA, the US FDA, and the US Consumer Product Safety Commission, and similarly in the EU.

3. Emissions in the end-of-life phase: With respect to waste management options, additional information is requested on the effectiveness of incineration under normal operational conditions (for different waste types, e.g. hazardous, municipal) with respect to the destruction of PFAS and the prevention of PFAS emissions.

Answer to specific info request 3:

Currently the liners, seals, gaskets, moldings, cabling and sensors, lubricants etc. at the end of life -phase will be send to an incineration plant.

4. Impacts on the recycling industry: To get an understanding of the impacts of the proposed restriction on the recycling industry, information is requested on:

- The impacts that the concentration limits proposed in paragraph 2 of the proposed restriction entry text (see table starting on page 4 of the summary of the Annex XV restriction report) have on the technical and economic feasibility of recycling processes (together with a clear indication on the waste streams to which the described impacts relate).
- The measures that recyclers would need to take to achieve the proposed concentration limits.
- The costs associated with these measures.

Answer to specific info request 4:

I don't have information on this topic.

5. Proposed derogations – Tonnage and emissions: Paragraphs 5 and 6 of the proposed restriction entry text (see table starting on page 4 of the summary of the Annex XV restriction report) include several proposed derogations. For these proposed derogations, information is requested on the tonnage of PFAS used per year and the resulting emissions to the environment for the relevant use. Please provide justifications for the representativeness of the provided information.

Answer to specific info request 5:

I don't have information on this topic.

6. Missing uses – Analysis of alternatives and socio-economic analysis:

Several PFAS uses have not been covered in detail in the Annex XV restriction report (see uses highlighted in blue and orange in Table A.1 of Annex A of the Annex XV restriction report). In addition, some relevant uses may not have been identified yet. For such uses, specific information is requested on alternatives and socio-economic impacts, covering the following elements:

- a. The annual tonnage and emissions (at sub-sector level) and type of PFAS associated with the relevant use.
- b. The key functionalities provided by PFAS for the relevant use.
- c. The number of companies in the sector estimated to be affected by the restriction.
- d. The availability, technical and economic feasibility, hazards and risks of alternatives for the relevant use, including information on the extent (in terms of market shares) to which alternative-based products are already offered on the EU market and whether any shortages in the supply of relevant alternatives are expected.
- e. For cases in which alternatives are not yet available, information on the status of R&D processes for finding suitable alternatives, including the extent of R&D initiatives in terms of time and/or financial investments, the likelihood of successful completion, the time expected to be required for substitution (including any relevant certification or regulatory approvals) and the major challenges encountered with alternatives which were considered but subsequently disregarded.
- f. For cases in which substitution is technically and economically feasible but more time is required to substitute:
- g. the type and magnitude of costs (at company level and, if available, at sector level) associated with substitution (e.g. costs for new equipment or changes in operating costs);
- h. the time required for completing the substitution process (including any relevant certification or regulatory approvals);
- i. information on possible differences in functionality and the consequences for downstream users and consumers (e.g. estimations of expected early replacement needs or expected additional energy consumption);
- j. information on the benefits for alternative providers.
- k. For cases in which substitution is not technically or economically feasible, information on what the socio-economic impacts would be for companies, consumers, and other affected actors. If available, please provide the annual value of EU sales and profits of the relevant sector, and employment numbers for the sector.

Answer to specific info request 6:

Corden BioChem GmbH and Corden BioChem International GmbH run a biotechnological production facility with fermentation volumes of 3000m³ and similar downstream capacity with roughly 100 employees.

If fluoropolymers like PTFE will be banned this will cause a shutdown of its fermentation and downstream processes due to the lack of alternatives, high investments and long plant downtimes. Replacing all the seals and linings in a plant - if

the appropriate replacement materials would be available - would require a shutdown of more than 12 months. This results in a fatal loss of business and customers.

The socio-economic impact will be the loss of many workplaces as well as the loss of one of EUs biggest CDMO partner for biotechnologically manufactured products. Especially large fermentation capacity is very limited in Europe and Northern America due to the high demand of sustainable products generated by Industrial Biotechnology. Corden possesses key know-how and capacity to facilitate the quick upscaling of these alternatives to fossil-based products.

Substitute materials were considered. Currently, there is no equivalent alternative.

7. Potential derogations marked for reconsideration – Analysis of alternatives and socio-economic analysis: Paragraphs 5 and 6 of the proposed restriction entry text (see table starting on page 4 of the summary of the Annex XV restriction report) include several potential derogations for reconsideration after the consultation (in [square brackets]). These are uses of PFAS where the evidence underlying the assessment of the substitution potential was weak. The substitution potential is determined on the basis of i) whether technically and economically feasible alternatives have already been identified or alternative-based products are available on the market at the assumed entry into force of the proposed restriction, ii) whether known alternatives can be implemented before the transition period ends (taking into account time requirements for substitution and certification or regulatory approval), and iii) whether known alternatives are available in sufficient quantities on the market at the assumed entry into force to allow affected companies to substitute.

- **A summary of the available evidence as well as the key aspects based on which a derogation is potentially warranted are presented in Table 8 in the Annex XV restriction report, with further details being provided in the respective sections in Annex E.**
- **To strengthen the justifications for a derogation for these uses, additional specific information is requested on alternatives and socio-economic impacts covering the elements described in points a) to g) in question 6 above.**

Answer to specific info request 7:

We will monitor the market for the development of new materials for Liners, seals, gaskets, mouldings and other equipment. If new materials are available on the market in the future that can meet the high requirements, we will reassess the situation. From today's perspective, however, this will only be the case in about 15-20 years.

8. Other identified uses – Analysis of alternatives and socio-economic analysis: Table 8 in the Annex XV restriction report provides a summary of the identified sectors and (sub-)uses of PFAS, their alternatives and the costs expected from a ban of PFAS. More details on the available evidence are provided in the respective sections in Annex E.

For many of the (sub-)uses, the information on alternatives and socio-economic impacts was generic and mainly qualitative. In particular, evidence on alternatives was inconclusive for some applications falling under the following (sub-)uses: technical textiles, electronics, the energy sector, PTFE thread sealing tape, non-polymeric PFAS processing aids for production of acrylic foam tape, window film manufacturing, and lubricants not used under harsh conditions.

More information is needed on alternatives and socio-economic impacts to conclude on substitution potential, proportionality, and the need for specific time-limited derogations. Therefore, specific information (if not already included in the Annex XV restriction report or covered in the questions above) is requested on alternatives and socio-economic impacts covering the elements listed in points a) to g) in question 6 above.

Answer to specific info request 8:

I don't have information on this topic.

9. Degradation potential of specific PFAS sub-groups: A few specific PFAS sub-groups are excluded from the scope of the restriction proposal because of a combination of key structural elements for which it can be expected that they will ultimately mineralize in the environment. RAC would appreciate to receive any further information that may be available regarding the potential degradation pathways, kinetics or produced metabolites in relevant environmental conditions and compartments for trifluoromethoxy, trifluoromethylamino- and difluoromethanedioxy-derivatives.

Answer to specific info request 9:

I don't have information on this topic.

10. Analytical methods: Annex E of the Annex XV restriction report contains an assessment of the availability of analytical methods for PFAS. Analytical methods are rapidly evolving. Please provide any new or additional information on new developments in analytics not yet considered in the Annex XV restriction report.

Answer to specific info request 10:

I don't have information on this topic.