

Comments on [Annex XV Restriction Report on Per- and polyfluoroalkyl substances \(PFAS\)](#)

1. Summary of this document

Introduction

First of all, Fujifilm would like to appreciate ECHA for kind contribution and activities to protect human health and the environment for many years. Our stakeholders operate around the world and are committed to protecting human health and the environment, and complying with laws and regulations for chemical substances in each countries and regions. After careful consideration of the proposed restrictions on the Annex XV report, Fujifilm would like to provide the following comments and suggestions. Especially, we would like to share the information about PFAS in photosensitive materials, silver halide (AgX) technology based photosensitive materials coating on film, applied for photographic and industrial applications.

- Request for derogation:

We would like to propose ECHA to create and add new sector as “Photosensitive Materials” for the draft opinion of RAC and SEAC. Although ECHA is requiring to specify the sectors and (sub-)uses identified in the Annex XV report (Table 9), it was difficult to categorize the photosensitive materials to the use into the existing sectors. Additionally, Dossier Submitter(DS) had proposed the Photographic Application as the sector the public consultation on Annex XV report for PFHxA. Photographic coating on film, in printing plates, and on inkjet photo media, had been specified as sub-uses. Therefore, we would like to propose to create new sector same as PFHxA discussion.

Our company has been producing “photosensitive materials” for industrial and photographic use. This comment is for silver halide (AgX) technology based photosensitive materials coated on film. Examples of the materials are microfilms, medical use films, film for conductive film for touch screen, signage films, film achieving film and photographic films (such as color negative films, color reversal films, instant photo films and black/white films). These photosensitive materials are based on silver halide (AgX) technology and coated on plastic substrate such as polyethylene terephthalate (PET) or Triacetate Cellulose (TAC), and contain small amount of PFAS.

The materials contain gelatin as its main matrix. Because of its triboelectric series property, gelatin charges positively during film manufacturing, during transport in cameras or in photofinishing equipment. If the charge has exceeded some extent, it sparks accompany with light emission, so called statics light emission. Since AgX technology based photosensitive materials are quite photosensitive, even tinny light emission caused by statics exposure create various fogging issue on the materials. Preventing charge build up is also important for its safety, potential cause of accidents at manufacturing site. Very small amount of PFAS plays an essential role to control this charge build up property.

In our experience on the case of switching from PFOS/PFOA to shorter perfluoroalkyl PFAS in the past, it took a lot of resources and approximately 10 years to find the alternative, prototyping, and introduce as the commercial products. We couldn't find the solution to get rid of PFAS surfactant completely at that moment, but with extensive RD, we could reduce amount of coated PFAS surfactant by more than 50%. Now, our challenge is to find alternative of those shorter perfluoro-alkyl PFAS. We have been searching one for more than a year, however, we have not yet find the appropriate candidate. It is still in the preliminarily phase of R&D. Considering its challenges for photosensitive materials, adjust charge build up property without any PFAS materials, and there are many kind of photosensitive materials which need to adjust substitution recipe product by product, it may take long time to replace PFASs. We would like to propose a sufficient transition period as the condition of regulation. **The current restriction proposal is not feasible. At least, we need 5 years for derogation.** For full confirmation on the safety issue, it might not be possible to replace PFAS for all the photosensitive materials. We would like to request the new system which allows extensions of

the derogation to be applied in EU-REACH as the same way on RoHS exemption.

2. Details

Please find the following comment from next page based on the consultation format.

URL:

Comments for Annex XV restriction report

Substance name

Per- and polyfluoroalkyl substances (PFAS)

EC Number

-

CAS Number

-

Scope

Restriction on the manufacture, placing on the market and use of PFASs.

Before you fill in the form, read the **Consultation Guidance** and the specific **Information Note** as they explain both the process and the proposal itself.

[Link to the Consultation Guidance](#)

[Link to the Information Note](#)

Compulsory fields/tick boxes are marked with an asterisk (*)

* ☒ I have read the Consultation Guidance and Information Note

All non-confidential comments will be made publicly available once a month during the duration of the consultation.

The Consultation is intended to provide ECHA's Committees with scientific and technical information to assist them in the development of their opinions. Although other information can be submitted, any abusive comments will not be published monthly and only published at the end of the process without any response from the Dossier Submitter or the Rapporteurs.

Where did you learn about this consultation? (please select all that apply):*

☒ **ECHA**

☐ European Commission

☐ National Authorities

☐ Social media

☒ **Industry organisation**

☐ NGOs and trade unions

☐ Press

☐ Other (please specify)

SECTION I. Personal information

We may contact you about your comment and to request additional information.

* First Name : Mitsuyuki

* Family Name : Komiya

Email: * mitsuyuki.kom

* Country :
Japan

Phone
[REDACTED]

Any personal data submitted is subject to [ECHA's data privacy rules](#)

SECTION II. Organisation

I am submitting information: *

☐ On behalf of a Member State Competent Authority

Please select country..

☐ As an Individual

☒ On behalf of an organisation or institution

Type of organisation/institution:

Company

Country where the organisation or institution is legally established:

Japan

Name of organisation / institution:

FUJIFILM Cor

Select one of the following options : *

☒ I agree to the disclosure of the name of my organisation/institution to the public

☐ I want to keep the name of my organisation/institution confidential

Note: the type and country of your organisation/institution will always be disclosed.

SECTION III. Non-confidential comments

It is possible to provide both general comments on the Annex XV restriction report subject to this Consultation and answers to the specific questions posed. In both cases, it is necessary to provide supporting evidence to allow ECHA's Committees to take your comments into account. It is important not to leave the submission of any socio-economic information until the consultation on SEACs opinion but already submit relevant comments at this stage.

General Comments

Select the relevant boxes that cover the content of your comments and provide your non-confidential comments below, (maximum 9 000 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**

* ☐ I understand that it is my responsibility not to include confidential information in responses to general comments and in any responses to requests for specific information (e.g. company name, email addresses, phone numbers, signatures etc.). ECHA will not be held liable for any damages caused by making non confidential responses publicly available.

Please provide your general comments in the box below

Introduction

First of all, Fujifilm would like to appreciate ECHA for kind contribution and activities to protect human health and the environment for many years. Our stakeholders operate around the world and are committed to protecting human health and the environment, and complying with laws and regulations for chemical substances in each countries and regions. After careful consideration of the proposed restrictions on the Annex XV report, Fujifilm would like to provide the following comments and suggestions. Especially, we would like to share the information about PFAS in silver halide (AgX) technology based photosensitive materials coated on films, applied to the photographic and industrial applications.

Specific Information Requests

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.

* Compulsory Fields

- ☒ I have information on this topic
- ☐ I don't have information on this topic

Since it was difficult to categorize the photosensitive materials to the use into the sectors and (sub)uses in Table 9 in Annex XV report, we would like to request to create an appropriate new category such as “photosensitive materials”

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:

- a. 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.
- b. 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.

* Compulsory Fields

- ☐ I have information on this topic
- ☒ I don't have information on this topic

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.

* Compulsory Fields

- ☐ I have information on this topic
- ☒ I don't have information on this topic

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:

- a. 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).
- b. The measures that recyclers would need to take to achieve the proposed concentration limits.
- c. The costs associated with these measures.

* Compulsory Fields

- ☐ I have information on this topic
- ☒ **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.

* Compulsory Fields

- ☒ **I have information on this topic**
- ☐ I don't have information on this topic

Please see confidential attachment in Section V.

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:
 - i. 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);
 - ii. the time required for completing the substitution process (including any relevant certification or regulatory approvals);
 - iii. 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);
 - iv. information on the benefits for alternative providers.
- g. 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.

* Compulsory Fields

- ☒ **I have information on this topic**
- ☐ I don't have information on this topic

Please see confidential attachment in Section V.

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.

* Compulsory Fields

- ☐ I have information on this topic
- ☒ I don't have information on this topic

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.

* Compulsory Fields

- ☐ I have information on this topic
- ☒ 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.

* Compulsory Fields

- ☐ I have information on this topic
- ☒ 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.

* Compulsory Fields

- ☐ I have information on this topic
- ☒ I don't have information on this topic

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SECTION IV. Non-confidential attachment

If needed, attach additional non-confidential information (data available in excel format, reports, etc.) below. Do not attach the same information already provided in section III here. If part of the information is confidential, please use section V to share it

Add attachment

If you would like to submit more than one document, please create a compressed archive where you include all files and upload the compressed file as attachment. Maximum file size is 20 MB.

* ☐ ***I have removed/blanked the information I wish to keep/I have claimed confidential from all the attachments in section IV (e.g.: company name, company logo, personal names, email, signatures, other confidential business data).*** I understand that ECHA will not be held liable for any damages caused by making the attachments publicly available.

SECTION V. Confidential Attachment

If needed, attach confidential information below (for example: studies, laboratory tests, additional contact details, business data, etc.). Do not add the same information already provided in the previous sections here. Confidential information will only be used by ECHA, including its Committees, by the Member State competent authorities and by the European Commission.

If you upload a confidential attachment, please justify the reasons for confidentiality of the information in the field below. This will facilitate ECHA's work if it receives requests for access to documents.

Upload Confidential Attachment:

Add attachment

If you would like to submit more than one document, please create a compressed archive where you include all files and upload the compressed file as attachment. Maximum file size is 20 MB.

* ☒ I have the following reasons enumerated in Article 4(1) or 4(2) of [Regulation \(EC\) No 1049/2001](#) regarding public access to documents why the information submitted as confidential cannot be disclosed to persons requesting access to documents (please explain below in the commenting field those reasons; a reason could be that the protection of your commercial interests, including intellectual property, would be undermined).

No confidential information of any kind should be included:

Since this input contains the information regarding formulations of chemical materials, and amount of the materials use which suggest production volume, which relate on intellectual property and confidential business information, the content should be protected as confidential.

1. After the interested party would submit the information he/she would get an automatic reply that the information was successfully submitted.
2. If the user has not filled in the mandatory fields indicated above the IT system displays the user an error message stating 'Please fill in ALL mandatory fields in 'Identification of the party submitting information'. Your submission could not be retrieved due to data lacking from these fields'.
3. If all comment fields are empty and no file is attached, submission should not be possible and there should be an error message: "One comment or one attachment should be provided as a minimum."