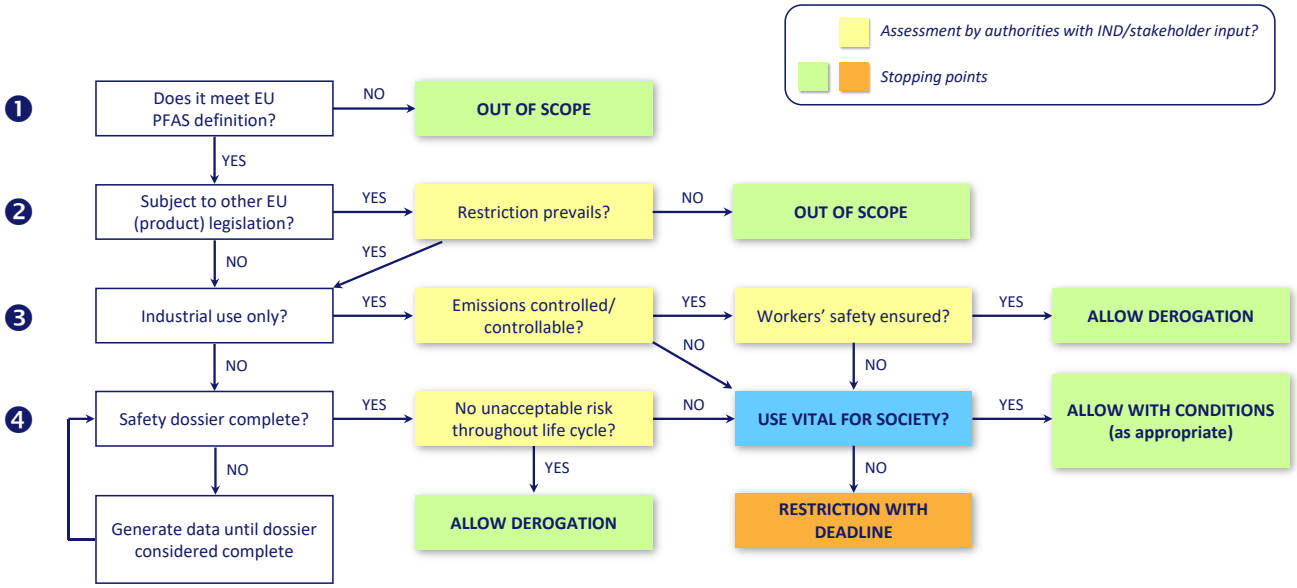
FPP4EU
FluoroProducts and PFAS for Europe

A decision tree for PFAS: Our potential solution to how this broad category of substances could be assessed in view of a REACH restriction

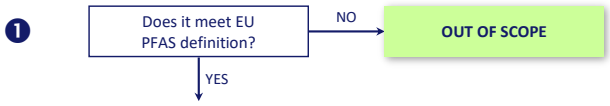
Some of the main concerns regulators have around PFAS is their ubiquitous presence in the environment, combined with their potential persistence. PFAS are a large group of molecules and not all have the same properties, yet as a group, PFAS are facing a restriction in the EU under REACH. A proposal by the competent authorities of Germany, Norway, the Netherlands, Denmark and Sweden ("the dossier submitters") is expected in January 2023. The proposal will then be assessed by the relevant scientific committees of the European Chemical Agency (ECHA), where stakeholders have the opportunity to provide input via two public consultations. Then the European Commission will draft a proposal, before it undergoes scrutiny by the co-legislators the European Member States and the European Parliament.

When we tried to find our way through the restriction, and what it could look like, we were challenged by the complexity created by the combination of such a large amount of substances with different hazard properties and some very diverse usages. FPP4EU designed a decision tree which offers a potential solution to how this broad category of PFAS substances could be assessed in view of a REACH restriction and help identify where derogations/exemptions may be allowed.

The version of the decision tree shared here, is the one approved by the FPP4EU Management Committee. We are eager to find the best approach. Therefore, our decision tree is continuously evolving, based on views shared by relevant stakeholders.

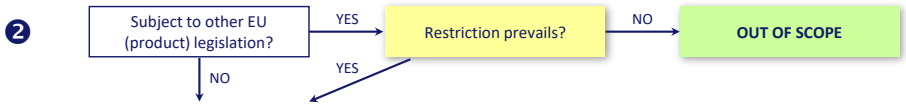


Line 1: Does the substance/breakdown product meet the PFAS definition?



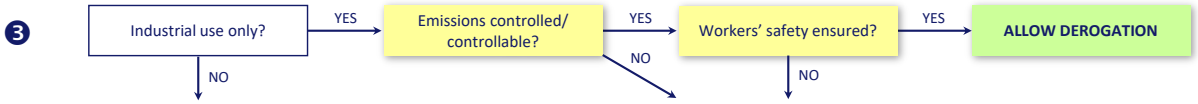
- We apply the definition of PFAS used in the EU REACH restriction process. This includes breakdown products - i.e. chemicals derived from a PFAS molecule that has been altered, e.g., by heat, light, or enzymes. Typical breakdown products of concern may be Trifluoroacetic acid (TFA), Perfluoroalkyl carboxylic acids (PFCAs), perfluoroalkyl ether carboxylic acid (PFECA) and perfluorosulfonic acid (PFSA).
- Definition of "PFAS" as proposed in February 2022 by the dossier submitters: "PFAS are defined as substances that contain at least one fully fluorinated methyl (CF_3-) or methylene (-CF_2-) carbon atom (without any H/Cl/Br/I atom attached to it)."

Line 2: Subject to other EU product-specific legislation (F-Gas Regulation, Plant Protection Products Regulation etc.)?



The European Green Deal aims to move towards a 'one substance, one assessment' process for chemical safety assessments. Our decision tree applies this mechanism. If the substance/breakdown is subject to other EU legislation, and is not "overruled" by the upcoming restriction, then it is out of scope. If the restriction "tops" the existing legislation, the next line of questioning in our tree applies.

Line 3: Clear separation between 'industrial use only' and 'consumer uses'.



We distinguish consumer from industrial uses:

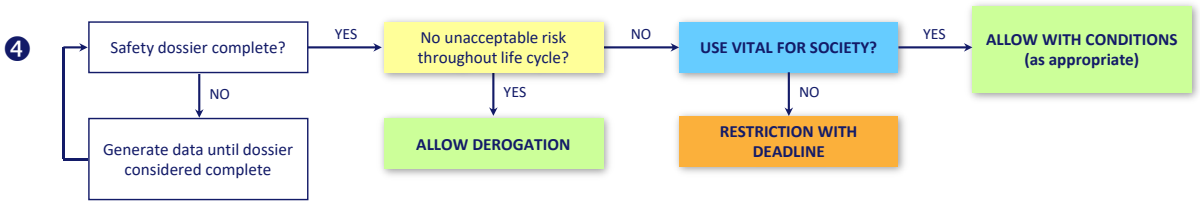
- Industrial uses:
    - Human health of workers is regulated via the EU Occupational Safety and Health legislation
    - Industrial emissions are regulated and controlled via the Industrial Emissions Directive
    - Examples of industrial use (non-exhaustive list) may include:
        - intermediates only,
        - processing aids,
        - PFAS used in equipment (pipes/gaskets/membranes etc.)

Such industrial use PFAS are not intended to end up in consumer products/ articles.

- Consumer uses:
    - Industry needs to show that there is no unacceptable risk to the consumer during use
    - Debate to be held with multiple players on emission reduction during and after use of PFAS-containing consumer products

Consumer uses will only be derogated if human exposure data are available: information throughout the value chain on which PFAS are used in which applications, will be key.

Line 4: Assessing safety and how vital the PFAS-containing application is for society



4.1. WHEN IS A SAFETY DOSSIER CONSIDERED TO BE 'COMPLETE'?

- The company/ consortium prepares the dossier according to EU REACH requirements (including data, data waivers, read-across proposals, testing proposals etc.).
- In case of mixtures, the properties of the mixture may be defined by the properties of the components and potential synergetic/ additive effects.
- The loop under point 5 is not endless but may be impacted by new guidance/ decisions from authorities as they become available.
- 'Completeness' will be confirmed/ rejected by authorities during their compliance checks.

4.2. RISK ASSESSMENT, with focus on 'safety throughout life cycle' with three important elements to consider:

- As per the EU REACH legal text, it must be assessed whether the substance poses any unacceptable risk to human health or the environment.
- Companies may decide which substances are 'grouped' for detailed risk assessment. This will typically be linked to function/ property/ use/ exposure pattern. Life-cycle assessments will count for specific cases and may be key for obtaining derogations.
- As part of the assessment consideration should be made of:
    - Physico-chemical properties (incl. size/molecular weight, physical state, K_{ow})
    - Presence in the environment (different media)
    - Official status of PBT, CMR , ED, …
    - Human data
    - New Approach Methodologies (NAMs) for risk assessment
    - Read-across proposals
    - Potential emissions throughout life cycle (involving DUs)
    - Circularity and end-of-life considerations; appropriate disposal

- At present, the socio-economic value of the substance in its use and the costs of substitution, are evaluated ECHA's Committee for Socio-Economic Assessment, well-informed by the downstream user community. This is, however, not an assessment of 'essentiality for society'.
- It is highly probable that the concept of 'essential uses' will be included in the REACH restriction process. How this will be done in practice and to which extent it will impact the PFAS restriction, is unknown.

4.4. CONDITIONS FOR DEROGATIONS (i.e. EXEMPTIONS)

- Companies / downstream users can include assessments of (absence of) alternatives. Potential practical implementation timelines will also need to be considered.
- Societal debates will guide on how to deal, case by case, with (groups of) substances that may pose a health/ environmental risk, but remain vital/ essential/ critical for society.

FluoroProducts and PFAS for Europe (FPP4EU)
Rue Belliard 40, Box 15, B-1040 Brussels
[redacted]@cefic.be
fpp4eu.eu
A sector group of Cefic
European Chemical Industry Council - Cefic aisbl
EU Transparency Register n° 64879142323-90