



REACH restriction PFAS

Ensure continuity and safety of chemical, pharmaceutical, bio-science production processes

BCR 28/03/2023

Federatie van de Belgische chemische industrie, life sciences en kunststoffen



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Current PFAS restriction proposal concerns

- Restriction = “**PFAS** *shall not be manufactured, used (?) or placed on the market*”
 - Derogations: use-specific and time-limited (18 months transition + possible 5 or 12 yr derogation)
- PFAS definition: description of the group of substances too broad
- The **use/placing on the market** of fluoropolymers in the chemical, pharmaceutical, life sciences sector **in process installations and equipment is not listed nor evaluated** in the Echa-report.
 - so far no derogations foreseen for this use or placing on the market
 - need derogation/exemption to continue production processes & installations
 - Process installations and equipment
 - Lab equipment
 - Spare parts ...

PFAS = wide diversity of substances with different properties

Per- and Polyfluoroalkyl Substances

- Stable bonds
- Not the same hazards



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a wide diversity of molecules with different properties

Per- and Polyfluoroalkyl Substances (PFAS)

Perfluoroalkyl acids and perfluoroalkylether acids (PFAA), e.g.

perfluoroalkyl carboxylic acids (PFCA), $C_nF_{2n+1}COOH$, e.g. PFOA

perfluoroalkane sulfonic acids (PFSA), $C_nF_{2n+1}SO_3H$, e.g. PFOS

perfluoroalkyl phosphonic acids (PFPA), $C_nF_{2n+1}PO_3H_2$

perfluoroalkyl phosphinic acids (PFPIA), $(C_nF_{2n+1})(C_mF_{2m+1})PO_2H$

perfluoroalkylether carboxylic acids (PFECA), e.g. $C_2F_5OC_2F_4OCF_2COOH$

perfluoroalkylether sulfonic acids (PFESA), e.g. $C_6F_{13}OCF_2CF_2SO_3H$

Precursors to PFAA, e.g.

perfluoroalkane sulfonyl fluorides (PASF)
perfluoroalkanoyl fluorides (PACF) and their
derivatives, $C_nF_{2n+1}SO_2R$ / $C_nF_{2n+1}CO_2R$

n:2 fluorotelomer-based substances
 $C_nF_{2n+1}CH_2CH_2R$

per- and polyfluoroalkylether-based
substances
e.g. $C_nF_{2n+1}OC_mF_{2m+1}R$

side-chain fluorinated polymers
e.g. (meth)acrylate, urethane, or
oxetane polymers with non-fluorinated
backbones and fluorinated side-chains

non-polymers
R = NH, $NHCH_2CH_2OH$, etc.

some hydrofluorocarbons (HFCs, e.g. $C_nF_{2n+1}C_mH_{2m+1}$), hydrofluoroethers (HFEs,
e.g. $C_nF_{2n+1}OC_mH_{2m+1}$) and hydrofluoroolefins (HFOs, e.g. $C_nF_{2n+1}CH=CH_2$);
perfluoroalkyl ($C_nF_{2n+1}C(O)C_mF_{2m+1}$) and semi-fluorinated ($C_nF_{2n+1}C(O)C_mH_{2m+1}$) ketones;
perfluoroalkyl alcohols ($C_nF_{2n+1}OH$)

Fluoropolymers, e.g.

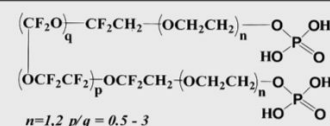
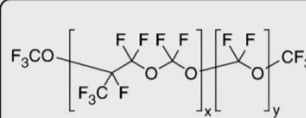
polytetrafluoroethylene (PTFE), $-(CF_2CF_2)_n-$

polychlorotrifluoroethylene (PCTFE), $-(CF_2CFCl)_n-$

polyvinylidene fluoride (PVDF), $-(CF_2CH_2)_n-$

fluorinated ethylene propylene (FEP), $-(CF_2CF_2)_n-(CF_2C(CF_3)F)_m-$

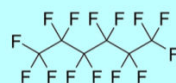
Perfluoropolyethers, e.g.



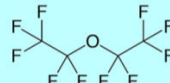
$n=1,2$ $p/q=0,5-3$

Other PFAS*, e.g.

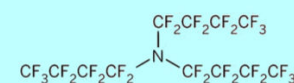
perfluoroalkanes, e.g.



perfluoroalkylethers, e.g.



perfluoroalkylamines, e.g.



* These PFAS have been less discussed in the public domain, but they meet the definition of PFAS as recommended in Buck et al. (2011) and OECD (2018). They are primarily PFAS with limited chemical reactivity.



Responsible Care

Figure 1. Examples of PFAS chemistries. *These PFAS have been less discussed in the public domain, but they meet the definition of PFAS as recommended in refs 58 and 5. They are primarily PFAS with limited chemical reactivity.

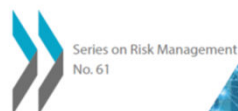
[EU Commission Chemicals Strategy for Sustainability Staff working document PFAS](#) (Oct 2020)

OECD PFAS terminology guide: not all PFAS the same



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Reconciling Terminology of the
Universe of Per- and Polyfluoroalkyl
Substances: Recommendations
and Practical Guidance



PFASs are defined as fluorinated substances that contain at least one **fully fluorinated methyl or methylene carbon atom (without any H/Cl/Br/I atom attached to it)**, i.e. with a few noted exceptions, any chemical with at least a perfluorinated methyl group ($-\text{CF}_3$) or a perfluorinated methylene group ($-\text{CF}_2-$) is a PFAS.

- “It should be noted that this general PFAS **definition is based only on chemical structure**, and the decision to broaden this definition compared to Buck et al. (2011) is not connected to decisions on how PFASs should be grouped and managed in **regulatory and voluntary actions.**” (p8)
- “As PFASs are a chemical class with diverse molecular structures and physical, chemical and biological properties, **it is highly recommended that such diversity be properly recognized and communicated in a clear, specific and descriptive manner.** The term “PFASs” is a broad, general, non-specific term, which does not inform **whether a compound is harmful or not**, but only communicates that the compounds under this term share the same trait for having a fully fluorinated methyl or methylene carbon moiety.”

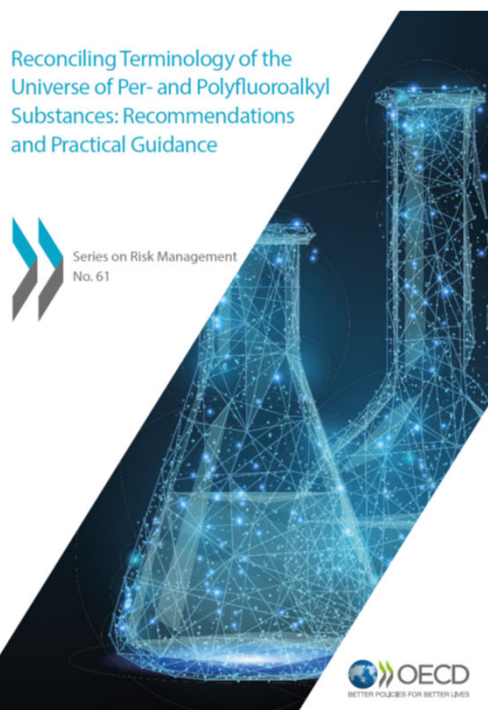
[Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance \(oecd.org\)](https://oecd.org)





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OECD PFAS terminology guide: not all PFAS the same



- Chapter 3:
- “As shown above, PFASs are a **chemical class with diverse molecular structures** (e.g. neutral, anionic, cationic or zwitterionic; with or without aromatic rings; non-polymers or polymers; low molecular weight or high molecular weight) and thus **diverse physical, chemical and biological properties** (e.g. involatile or volatile; water soluble or water insoluble; reactive vs. inert; bioaccumulative or non-bioaccumulative).
- Therefore, it **is highly recommended that such diversity be properly recognized** and communicated in a clear, specific and descriptive manner. The following sections aim to provide practical guidance to governments and other stakeholders on how to use the PFAS terminology, starting from the distinction between the general definition described here and user-specific working scopes of PFASs.”

[Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance \(oecd.org\)](https://oecd.org)





C-F stable bond

- The C-F chemical bond is one of the **most stable bonds in organic chemistry** leading to **superior chemical resistance** against acids, caustics, solvents, oxidizing materials etc.
- By definition any possible future alternative with the comparable chemical stability will carry the risk of very high persistence.
- Current draft annex XV report: **No difference** is made in approach **between**
 - structural long-lifetime **materials** (for example gaskets, mm-thick liners) and
 - **liquids/gases** (foaming agents, lubricants, anti-stick sprays,...).

Process equipment and installations

Process continuity and safety to be guaranteed

Fluoropolymer materials need to be exempted/derogated

Current use of Fluoropolymers in the chemical industry

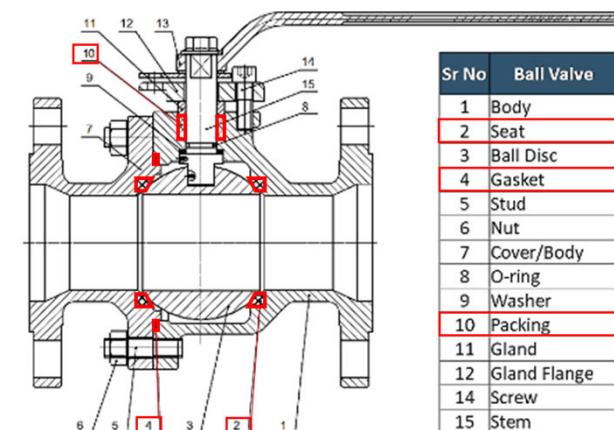
From very small and widely used...



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- Gaskets, joints, sealants, seal rings,... for example in valves
 - 44% of all valve types (>2000 valve types) are impacted
 - Detailed analysis on 2 recent world-scale plants

Number of valve <u>types</u> installed	<u>Total</u> Number of valves installed	% of Total number of installed valves Impacted by Restriction
261	52.000	70%
135	93.000	83%



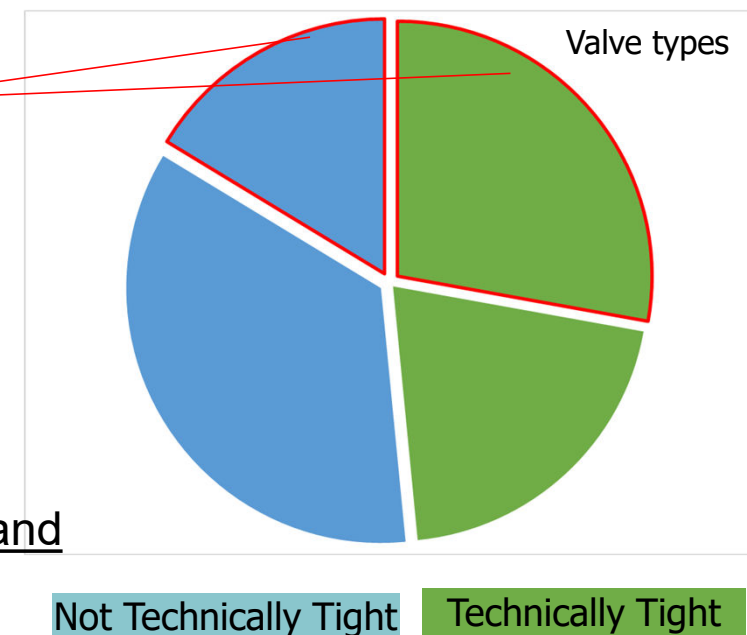
→ Small components & small volumes/tonnes, but large numbers and huge impact on industry

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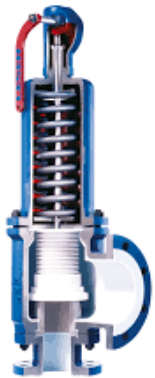
- The restriction has a more than proportional impact on the *Technically Tight* Valves
 (*Technically Tight* = TA-Luft-qualified = low fugitive emissions)

- Approx. half of the (>2000) valve types is qualified as **Technically Tight** and these are specifically used on critical products
- Possible risk/impact of implementation on fugitive emissions is currently unclear

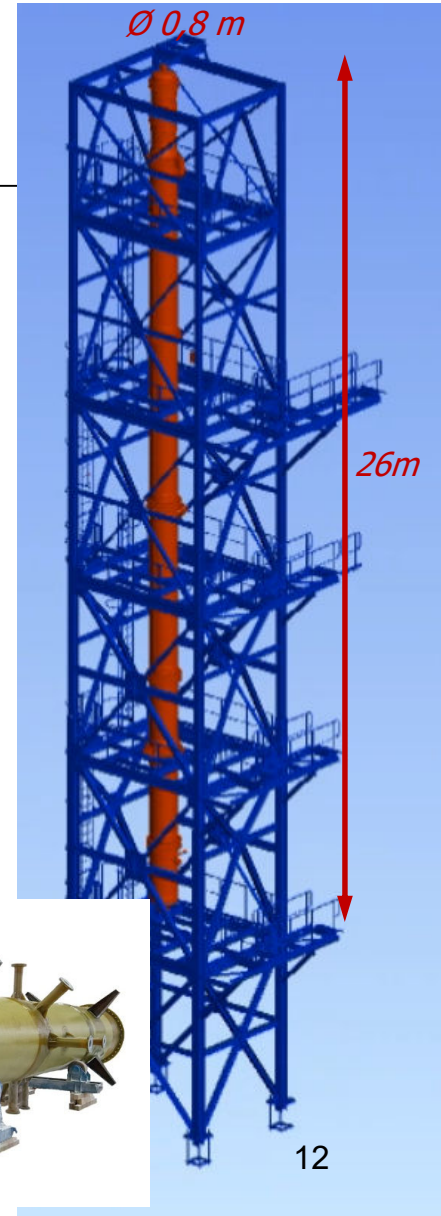
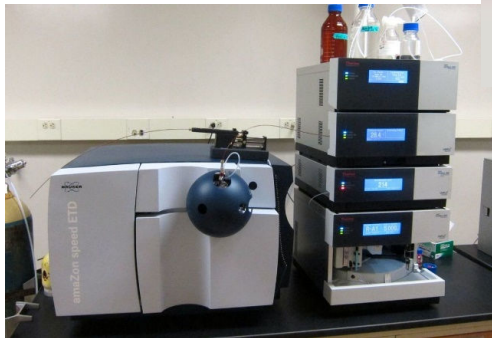
Current use of Fluoropolymers in the chemical industry

...to very large & specific applications

- Linings (mm-thickness) in pipes, valves, pumps, measurement devices,... up to vessels, columns and complete plant sections to protect from corrosion (eg HCl, H₂SO₄, HNO₃, caustic service,...).
- Widely used in analytical equipment as gasket or tubing.
- **Under these severe corrosive conditions currently no alternatives are available.**



Responsible Care



Alternatives possible?

- For some applications in theory alternatives are possible, however feasibility of implementation needs further investigation.
- For other applications alternative materials are not resistant at all or have only limited lifetime, resulting in increased safety and reliability risks.
- For some applications, glass lined piping and equipment could be an alternative, however glass lined material has to be flanged and is much more brittle, requiring
 - Soft gaskets (only fluoropolymers possible)
 - Flexible expansion bellows on the main connections (only fluoropolymers possible)
- Currently no superior materials are available (compared to fluoropolymers) fulfilling the necessary functionalities.
- **By definition any possible future alternative with comparable chemical stability will carry the risk of very high persistence.**



conclusion



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conclusion

- Restriction should be risk based and enforceable
 - Understandable scope
 - Analytical methods
- Avoid double regulations (F-gases, medical products, PPPR, BPR, ...)
- **Secure industrial uses of fluoropolymers** in the chemical, pharmaceutical, life sciences sector **in process installations and equipment** via a **derogation/exemption**.



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and Life Sciences Industries**

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