

For our Environment



Umwelt 
Bundesamt

DANISH EPA LOUS CONFERENCE

REACH regulatory activities regarding
Perfluorooctanoic acid
and other Per- and Polyfluoroalkyl Substances

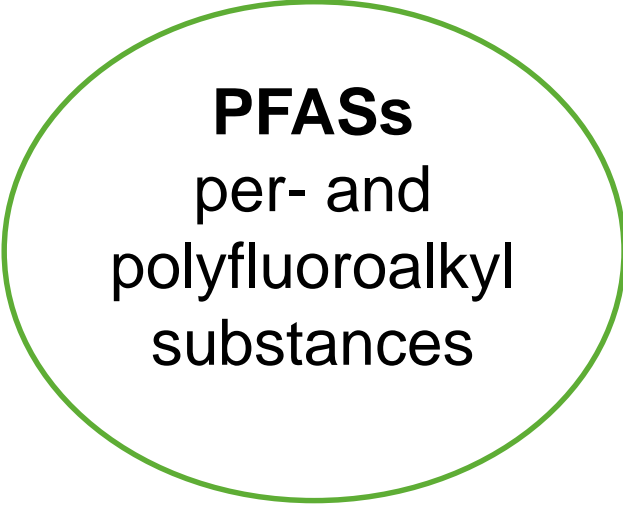
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Content

- Long-chain PFASs
 - Concerns
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 - PFOA restriction proposal
- Short-chain PFASs
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 - REACH substance evaluation
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PFASs
per- and
polyfluoroalkyl
substances

Concerns of long-chain PFASs

- Environmental persistence
- Findings and distribution in surface water
- Long-range transport and findings in remote areas
- Findings and accumulation in food webs and top predators
- Findings in food and drinking water
- Occurrence in blood samples and breast milk of the general population (and long elimination half life)
- Toxicological profile (e.g. PFOA Reprotoxic Cat. 1 B)

→ Regulatory action needed under REACH
to address these concerns

e.g. Vierke L. et al. 2012 Environmental Sciences Europe 24:16.

Regulatory approaches

- Regulatory activities must include all substances contributing to PFCAs and PFSAAs as stable degradation products
- Identify long-chain PFASs as SVHC due to PBT/vPvB properties
- Restrict manufacture, use and import of **PFOA and potential precursors**
- Restrict manufacture, use and import of **long-chain PFASs**
- Assess **short-chain PFASs** using REACH substance evaluation

REACH and CLP

Classification & Labelling

- PFOA, APFO and C₉ PFCA reprotox 1 B and STOT RE 1
- Swedish proposal: C₁₀ PFCA e.g. reprotox 1B

<http://echa.europa.eu/web/guest/harmonised-classification-and-labelling-previous-consultations>

Substances of Very High Concern

- PFOA, APFO and C₉ PFCA are persistent, bioaccumulative and toxic (PBT)
- C₁₁₋₁₄ PFCAs are very persistent and very bioaccumulative (vPvB)
- Listed on REACH Candidate List

<http://echa.europa.eu/candidate-list-table>

PFOA/ APFO

PFOA/ APFO on REACH Candidate List

- Agreement on PBT-Properties
- Signal to producers and users: Substitution
- Obligation to provide information within the supply chain, to consumers and to ECHA; if content > 0.1% in articles

In general: Authorisation process as subsequent regulatory measure following Candidate List, but imported articles and precursors (PFOA-related substances) would not be covered

→ Need for further regulatory measures to reduce human and environmental exposure



[http://www.reach-info.de/
verbraucheranfrage.htm](http://www.reach-info.de/verbraucheranfrage.htm)

PFOA human health concerns

Classification and labelling:



Repr 1B: May damage the unborn child

STOT RE 1: Causes damage to organs (liver) through prolonged or repeated exposure

Acute tox 4: Harmful if swallowed + is harmful if inhaled

Eye Dam 1: Causes serious eye damage

Carc 2: Suspected of causing cancer

C8 Science Panel:

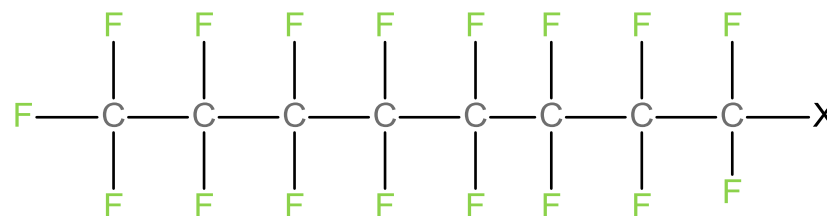
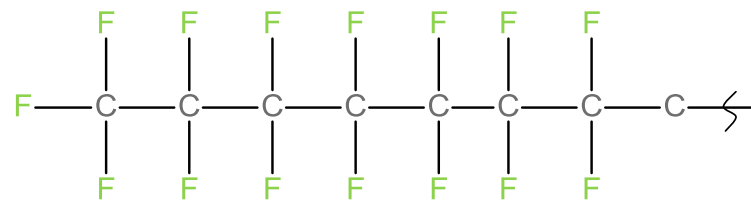


For six disease categories, the Science Panel concluded that there was a Probable Link to PFOA exposure:

1. diagnosed high cholesterol
2. ulcerative colitis
3. thyroid disease
4. testicular cancer
5. kidney cancer
6. pregnancy-induced hypertension

REACH PFOA restriction proposal

Restriction proposal for production, use and placing on the market including imported articles of PFOA, its salts and PFOA-related substances



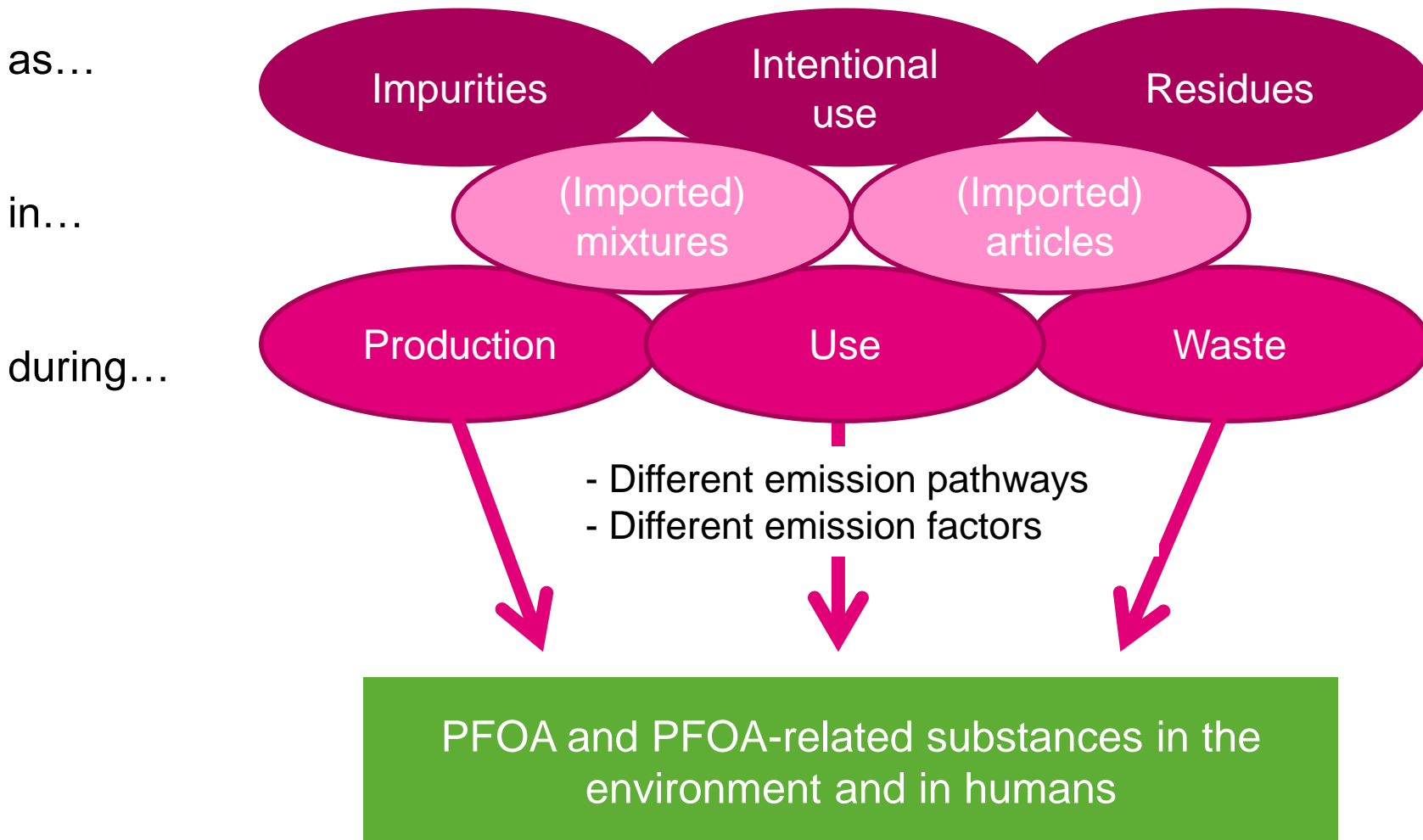
The following substances are exempted:

C8F17-X, where X= F, Cl, Br.

C8F17-C(=O)O-X' or C8F17-CF2-X' (where X'=any group, including salts).

REACH PFOA Restriction Proposal

PFOA and PFOA-related substances



Justification (that action is required on a EU-wide basis) for the opinion (on PFOA and PFOA-related substances) of RAC

“RAC supports this proposal for **substance identification**, since it effectively captures the substances considered to be of concern, but excludes those that are not.

PFOA is a highly persistent **PBT substance with a potential for environmental long-range transport**, which makes emission of PFOA and PFOA-related substances a transboundary pollution problem. Evidence from contaminated sites such as airports (where fire-fighting foams containing PFOA or PFOA-related substances have been used) shows that it is **very difficult to reduce the level of pollution once it has occurred**.

The **uses** of PFOA and PFOA-related substances are **widespread** and consumer articles and mixtures containing these substances are placed on the market in all EU Member States. In addition, emissions could potentially occur at every stage in the life cycle, i.e. during production, service life and disposal. **EU wide action is therefore necessary** to eliminate emissions of PFOA and PFOA-related substances.

Therefore, any national regulatory action cannot adequately minimise emissions of PFOA and PFOA-related substances. As a consequence, risk management action is needed on an EU wide basis.”

Justification (that action is required on a EU-wide basis) for the opinion of SEAC

The restriction proposal is based on concerns caused by the **PBT properties** of PFOA. It is also highlighted in the dossier that PFOA is ubiquitous in the environment and in humans, and that PFOA has the potential for environmental long-range transport.

Uses of PFOA and PFOA-related substances are reported to be wide-dispersive. Consumer articles and mixtures containing these substances are placed on the market in all EU Member States.

The Dossier Submitter further justifies the need for EU wide regulation by the need to **avoid market distortions** caused by action on national level, such as competitive disadvantage to enterprises concerned compared to competitors inside and outside the EU.

SEAC considers that taking into account the potential for long-range transport and also the persistence of PFOA, **global action would be more effective** in reducing environmental concentrations in the EU. However, possible future global action on PFOA is uncertain and not considered further in this opinion.

SEAC supports the conclusion of the Dossier Submitter that action is required on an EU wide basis.

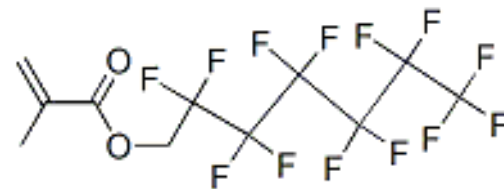
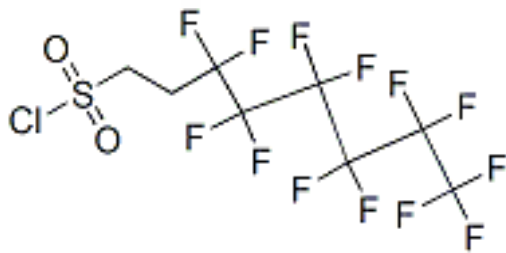
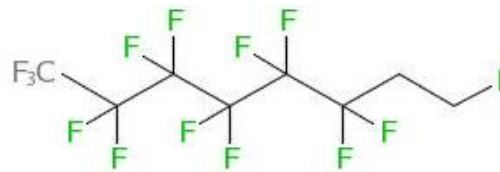
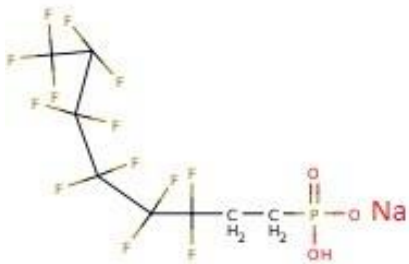
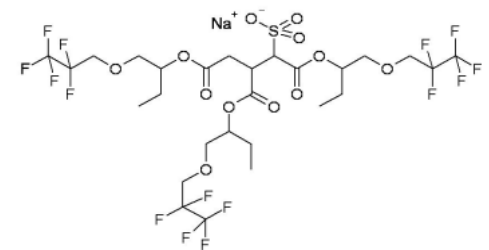
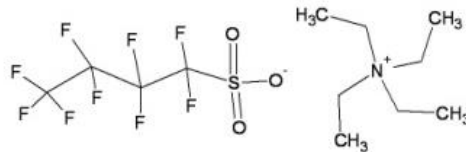
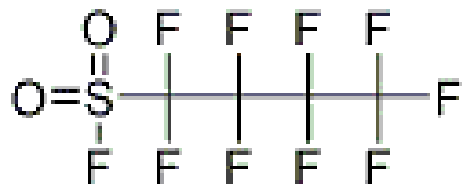
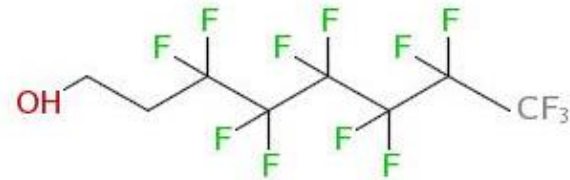
Status PFOA restriction

- ECHA forwarded their recommendation on our proposal to the EU commission in December 2015.
- Discussion in REACH Comitology committee in preparation
- Proposal is also on WTO hearing and inter-service consultation within the EU-commission
- EU commission proposal on listing PFOA and PFOA-related substances in Stockholm convention



Short-chain PFASs

Registered under REACH – Some examples



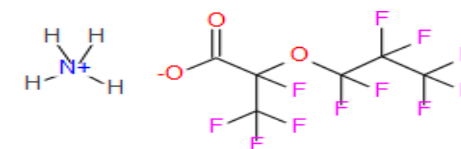
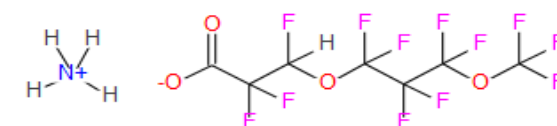
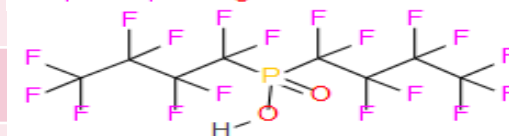
<http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances>

Concerns of short-chain PFASs

- Potential for transport over long distances
e.g. Benskin J. et al. 2012
- Potential to reach remote regions
e.g. Kirchgeorg et al. 2013
- Potential to reach drinking water
e.g. Vierke L. et al. 2014, Gellrich V. et al. 2012
- Enrichment in plants
e.g. Blaine A.C. et al. 2014
- Difficult to be removed from the environment
e.g. Eschauzier C. 2012
- Accumulation in the environment
- Potential for “man via environment” exposure
- Potential concern due to endocrine activity

REACH Substance Evaluations 2016/2017

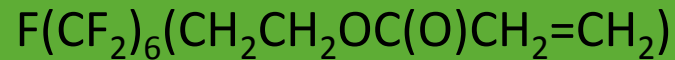
Name	EC-Nummer
3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl acrylate	241-527-8
3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl methacrylate	218-407-9
2-[methyl[(nonafluorobutyl)sulphonyl]amino]ethyl acrylate	266-733-5
bis(nonafluorobutyl)phosphinic acid	700-183-3
(WÄSSRIGE LOESUNG DES MV31-KALIUMSALZ)	444-340-1
ammonium 2,2,3-trifluoro-3-(1,1,2,2,3,3-hexafluoro-3-trifluoromethoxypropoxy)propionate	480-310-4
Ammonium 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propanoate	700-242-3
ammonium difluoro[1,1,2,2-tetrafluoro-2-(pentafluoroethoxy)ethoxy]acetate	700-323-3
Polyfluoro-5,8,11,14-tetrakis(polyfluoralkyl)-polyoxaalkane	



<http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table>
<http://echa.europa.eu/information-on-chemicals/registered-substances>

Short-chain PFASs

6:2 FTA



6:2 FTMA



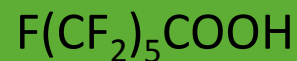
Metabolism/
(bio)degradation

6:2 FTOH

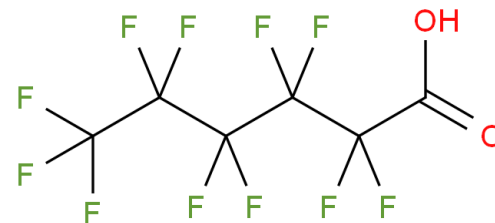


Metabolism/
(bio)degradation

PFHxA



Perfluorohexanoic acid - Monitoring



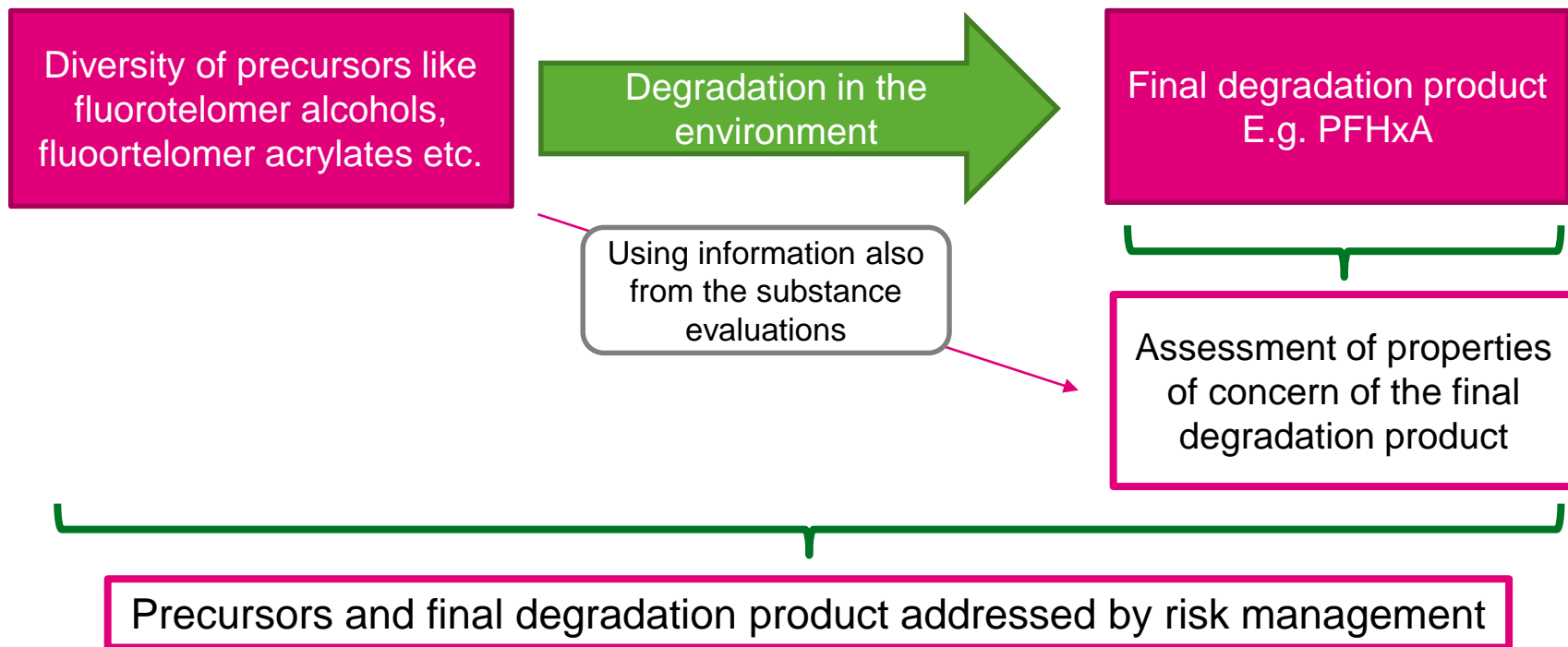
Findings in environmental samples

- oceans (Ahrens et al., 2010)
- rivers (Takemine et al., 2014)
- lakes (Sun et al., 2011)
- effluent/sludge of WWTPs (Ahrens et al., 2009)
- landfill leachates (Busch et al., 2010)
- groundwater (Eschauzier et al., 2013)
- soil and sediment (Klif, 2010)
- tap water and raw water (Llorca et al., 2012)
- snow of remote regions (Kirchgeorg et al., 2013)
- atmosphere (Jahnke et al., 2007)
- house dust and air (Shoeib et al., 2011)

Occurrence in drinking water

- 18 % of 85 Spanish tap water samples (Gellrich et al., 2013)
- 23 % of 26 German tap water samples (Llorca et al. 2012)
- 86 % of 7 tap water samples from six EU Countries (Ullah et al. 2011)
- 49 % of 26 waterworks along the river Rhine (Wilhelm et al. 2010)

Perfluorohexanoic acid - PFHxA



- Analysis of risk management options (RMOA) planned
<http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/pact/-/substance-rev/12934/term>
- Public consultation in preparation of RMOA (01.03 - 01.05.2016)
<https://www.webropolsurveys.com/Answer/SurveyParticipation.aspx?SDID=Ger1080526&SID=71338012-f4d4-4259-b4a2-5237b93aa967&dy=229525508>

Summary

Long-chain PFASs

- Human and environmental exposure needs to be minimized due to PBT-/vPvB-properties
- Regulatory measures are already in force or underway

PFOA and PFOA-related substances

- First PFASs Restriction under REACH
- Substances identified by using structural formula and not CAS numbers
- PBT concern justifies restriction
- EU-commission discusses proposal and suggests listing on Stockholm convention

Short-chain PFASs

- Market is shifting to short-chain PFASs
- Human and environmental exposure are of concern due to high persistence and high mobility in the environment, especially with regard to water resources
- Assessment and regulation in preparation

→ Alternatives without properties of concern are needed



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Thank you for your attention!

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www.uba.de/themen/chemikalien/chemikalien-reach/stoffgruppen/per-polyfluorierte-chemikalien-pfc

www.reach-info.de/pfc.htm

[http://www.umweltbundesamt.de/publikationen/understanding-the-exposure-pathways-of-per-and-polyfluoralkyl-substances-\(PFASs\)](http://www.umweltbundesamt.de/publikationen/understanding-the-exposure-pathways-of-per-and-polyfluoralkyl-substances-(PFASs))