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Umwelt   
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Webinar Global PFC-Group Risk Reduction Approaches

# Per- and Polyfluorinated Chemicals – Risk Reduction Approaches in the EU

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## Objectives for managing PFASs globally

PFASs are

- manufactured worldwide
- released from fluoropolymer and fluorinated polymer manufacturing or processing facilities, wastewater treatment plants and landfill all over the world
- present as residuals or impurities in fluoropolymers and fluorinated polymers used for a variety of (imported) (consumer) products
- ubiquitously present in the environment

## PFASs - Main concerns

1. Environmental persistence
2. Findings and global distribution in the environment
3. Findings and accumulation in food webs and top predators
4. Long-range transport and findings in remote areas
5. Occurrence in blood samples and breast milk of the general population (& long elimination half lives)
6. Findings in food and (increasingly) drinking water
7. Toxicological profile (PFOS; PFOA; PFNA: Repr. Cat. 1B)

**=> Need for global management**



## REACH – Substances of Very High Concern (SVHC)

Objective is proper control and progressive replacement where economically and technically viable

### Criteria for SVHC

- CMR Cat 1A or 1B
- **persistent, bioaccumulative and toxic (PBT)**
- **very persistent and very bioaccumulative (vPvB)**
- endocrine disrupting or PBT or vPvB properties (but not fulfilling the criteria) for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern



## REACH – Regulatory instruments

### 1. Candidate List

- Substances for eventual inclusion in Annex XIV
- EU-wide agreement on SVHC-Status
- Need for EU-wide regulatory action to minimise exposure of men and environment
- motivation for producers, users, and suppliers to behave self-responsible to initiate substitution
- Give consumers the opportunity to ask for SVHC in articles (and to influence the market)



## REACH – Candidate list

ECHA > Addressing Chemicals of Concern > Authorisation > Substances of very high concern identification > Candidate List of Substances of Very High Concern for Authorisation > Candidate List table

### Candidate List of Substances of Very High Concern for Authorisation

(published in accordance with Article 59(10) of the REACH Regulation)

Substance Name	EC Number	CAS Number	Date of inclusion	Reason for inclusion	Decision number	IUCLID 5 Substance Dataset	
Ammonium pentadecafluorooctanoate (APFO)	223-320-4	3825-26-1	2013/06/20	Toxic for reproduction (Article 57 c); PBT (Article 57 d)	ED/69/2013		<a href="#">Details</a>
4-Nonylphenol, branched and linear, ethoxylated [ <i>substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof</i> ]	-	-	2013/06/20	Equivalent level of concern having probable serious effects to the environment (Article 57 f)	ED/69/2013		<a href="#">Details</a>
Pentadecafluorooctanoic acid (PFOA)	206-397-9	335-67-1	2013/06/20	Toxic for reproduction (Article 57 c); PBT (Article 57 d)	ED/69/2013		<a href="#">Details</a>

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



## REACH – Regulatory instruments

### 2. Authorization

- Substances of Very High Concern (SVHC)
- Prerequisite: Listed in Annex XIV of Regulation
- Only authorized uses are allowed
- Authorization may be granted, if

Risk is adequately controlled,

or

Socio-economic benefits outweigh the risk and  
no substitutions or alternatives are available



## REACH – Regulatory instruments

### 3. Restriction

- Substances with unacceptable risk to health or the environment
- All uses which are not specifically restricted are allowed
- Any manufacture, use or import of substance is regulated by conditions of restriction





## Activities under REACH and CLP for PFOA

- 2010:** Norway proposed to classify and label **PFOA** toxic for reproduction Cat 1B (and STOT RE 1)
- June 2013:** **PFOA** identified as CMR- and PBT substance and included in Candidate List
- October 2013** **PFOA** included in Annex VI of CLP-regulation: toxic for reproduction Cat 1B (and STOT RE 1)
- October 2014** DE and NO submitted Restriction proposal for **PFOA and precursors:**  
PFOA, its salts and PFOA-related substances shall not be manufactured, used or placed on the market as substances, as constituents or in a mixture



## Activities under REACH and CLP for long-chain PFCAs

**December 2012 C11-C14 PFCAs** are identified as vPvB,  
and included in Candidate List

**June 2013** Sweden proposed to classify and label **PFNA**  
toxic for reproduction Cat 1B

**December 2014** Sweden intends to propose to classify and label **PFDA**  
toxic for reproduction Cat 1 B

**January 2016** Sweden and Germany intend to submit proposals to  
identify **PFNA** and **PFDA** as PBT-substances,  
and inclusion in candidate list



## Activities under REACH and CLP for further PFASs

### 2013 Substance Evaluations

Ammonium salts of mono- and bis[3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl and/or poly (substituted alkene)] phosphate

Reaction mass of mixed (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) phosphates, ammonium salt

### 2015 Substance Evaluations

3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl acrylate (6:2 FTA)

3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl methacrylate (6:2 FTMA)

## UBA-strategy to assess and manage PFASs under REACH



- **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
- Information and awareness – raising
- Restrict manufacture, use and import of **PFOA and precursors**
- Restrict manufacture, use and import of **long-chain PFASs and precursors**
- Evaluate the environmental risks of **short-chain PFASs** using REACH substance evaluation

## Summary

1. The world-wide distribution of PFASs is leading to long-term and global exposure and risks for ecosystems and the population
2. Sources are complex and include precursors, degradation products and residues in articles
3. Regulatory activities must include all substances contributing to PFCAs and PFSAAs as stable degradation products
4. Production and use are increasingly expanding globally, hence risk management need to be coordinated globally as initiated by OECD, UNEP, and others (global PFC Group)
5. The scope of risk management activities needs to be expanded from long chain PFASs to include also short-chain PFASs

# Thank you for your attention!

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