

Risk management of hazardous substances

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European Chemicals Agency

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Outline

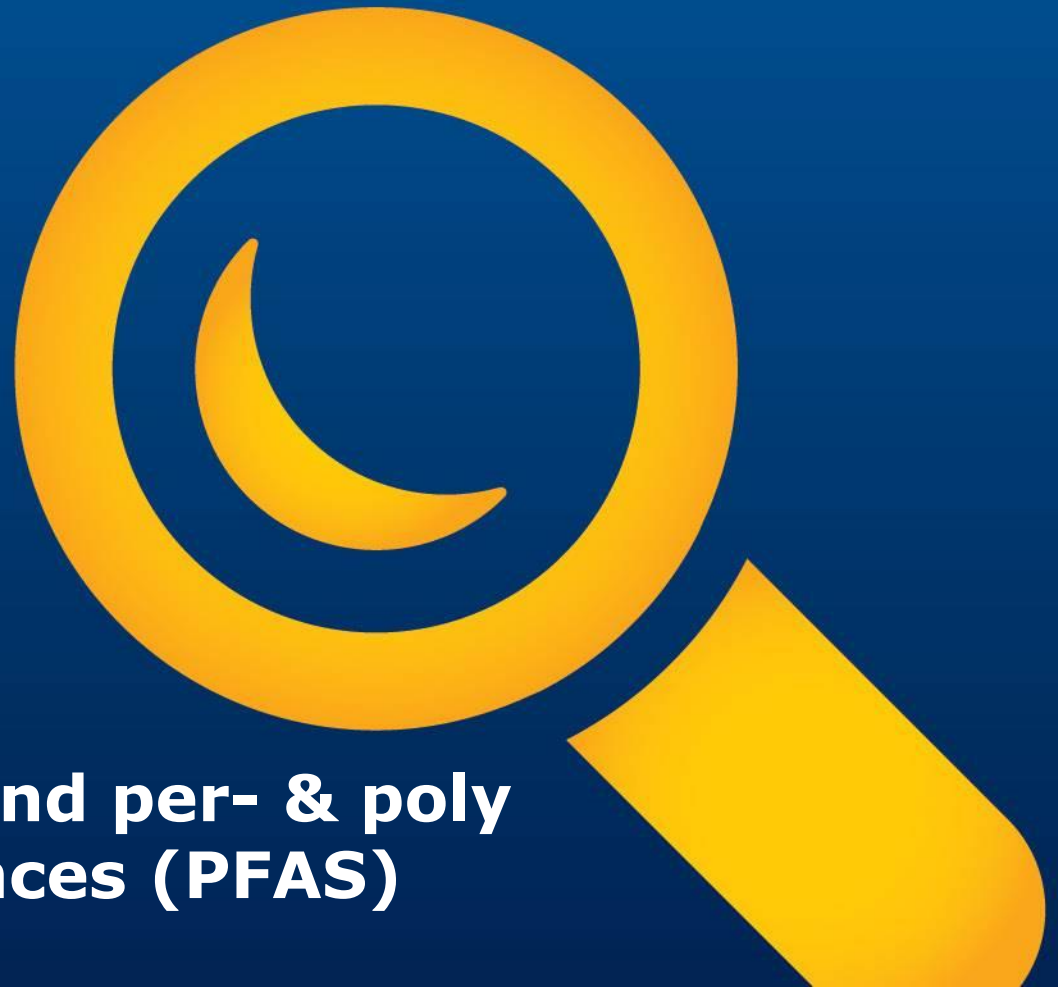
- Introduction to the European Chemicals Agency (ECHA)
- Early warnings and risk management of hazardous substances
- Substitution concepts
- Conclusions and further support

European chemicals legislation

- **REACH** – Registration, evaluation, authorisation and restriction of chemicals (2007)
- **CLP** – Classification, labelling, packaging (2009)
- **BPR** – Biocidal products (2013)
- **PIC** – Prior informed consent for import and export of chemicals (2014)
- **POPs** – Persistent organic pollutants (2019)
- **OEL** – Occupational safety limits (2019)
- **Waste** – Waste directive (2019)



Early warnings and risk management tools (REACH & CLP)



**Flame retardants and per- & poly
fluoroalkyl substances (PFAS)**

Nanomaterials are included in the scope of REACH

REACH and CLP risk management tools

- **Harmonised classification and labelling (CLH)** define the hazards of substances to ensure user safety by labelling
- **Authorisations** for substances of very high concern (SVHCs) which are included on the 'Candidate List'
 - Most are then added to the 'Authorisation List' and can only be marketed or used if authorised
 - Problem for PFAS: this does not include imported articles
- **Restrictions** are a partial or complete ban when there is an unacceptable risk to humans or the environment 'safety net'
 - Applicable to imported articles & articles in their life cycle (incl. waste)
 - Preferred approach for risk management of PFAS.

Early warning

Serious warning

Comply

Dossier Evaluation

Substance Evaluation (CoRAP)

Regulatory Management Analysis (RMOA)

PBT/ED assessment

PACT Tool

CLH
Registry of intentions (ROI)

SVHC
ROI

Restriction
ROI



ECHA processes

Harmonised classification and labelling

Candidate and Authorisation Lists

REACH restriction



COM decides

Before regulatory risk management

Regulatory risk management

1-2 years

1 year

1.5-2.5 years

ECHA's approach to risk management of PFAS

- Risks from PFAS usually **not possible to use a conventional approach** i.e. PEC/PNEC ratio because no dose-response threshold (vPvB criteria)
- Instead, REACH restrictions have been agreed on the basis of **minimising releases** and thus exposure of PFAS e.g. PFOA and C9-14 PFCAs
- **Derogations** (time-limited) added for socio-economic reasons, especially if the costs too high for industry i.e. not proportionate
- **Arrow head approach** i.e. using a representative PFAS for a group of substances, including salts and precursors (**~50-100 arrowheads; 1000s of precursors**)
- **Sector-wise approach** – now considering e.g. fire fighting foams.

Status	CLH Harmonised classification & labelling	REACH Identified as an SVHC	REACH Restricted (Annex XVII)
Completed	<5 arrowhead substances	<10 arrowhead substances	1 arrowhead substance (PFOA)
In pipeline: <ul style="list-style-type: none"> • Registry of intentions • opinion-forming/decision-making 	<5 arrowhead substances	<6 arrowhead substances	2 arrowhead substances (PFHxA, PFHxS) 6 arrowhead substance (C9-14 PFCAs)

Restriction

- **TCEP, TCPP and TDCP** (chlorine organophosphates)
- **DecaBDE** (brominated diphenylethers)

Authorisation List

- **HBCDD** (brominated flame retardant)
- **TCEP**

Substance evaluation (CoRAP)

- **Brominated flame retardants:** TBBPA-BDBPE, TBBPA, EBP, TBPH
- **Antimony based flame retardants/synergists:** antimony, diantimony trioxide, antimony sulphide

Candidate List

- **Boric acid-base substances:** disodium tetraborate, tetraboron disodium heptaoxide

Substitution concepts for hazardous substances



Why substitute and what is substitution?

- **Why substitute?**

- Due to the demonstrated or suspected hazardous properties/risk to human health / the environment

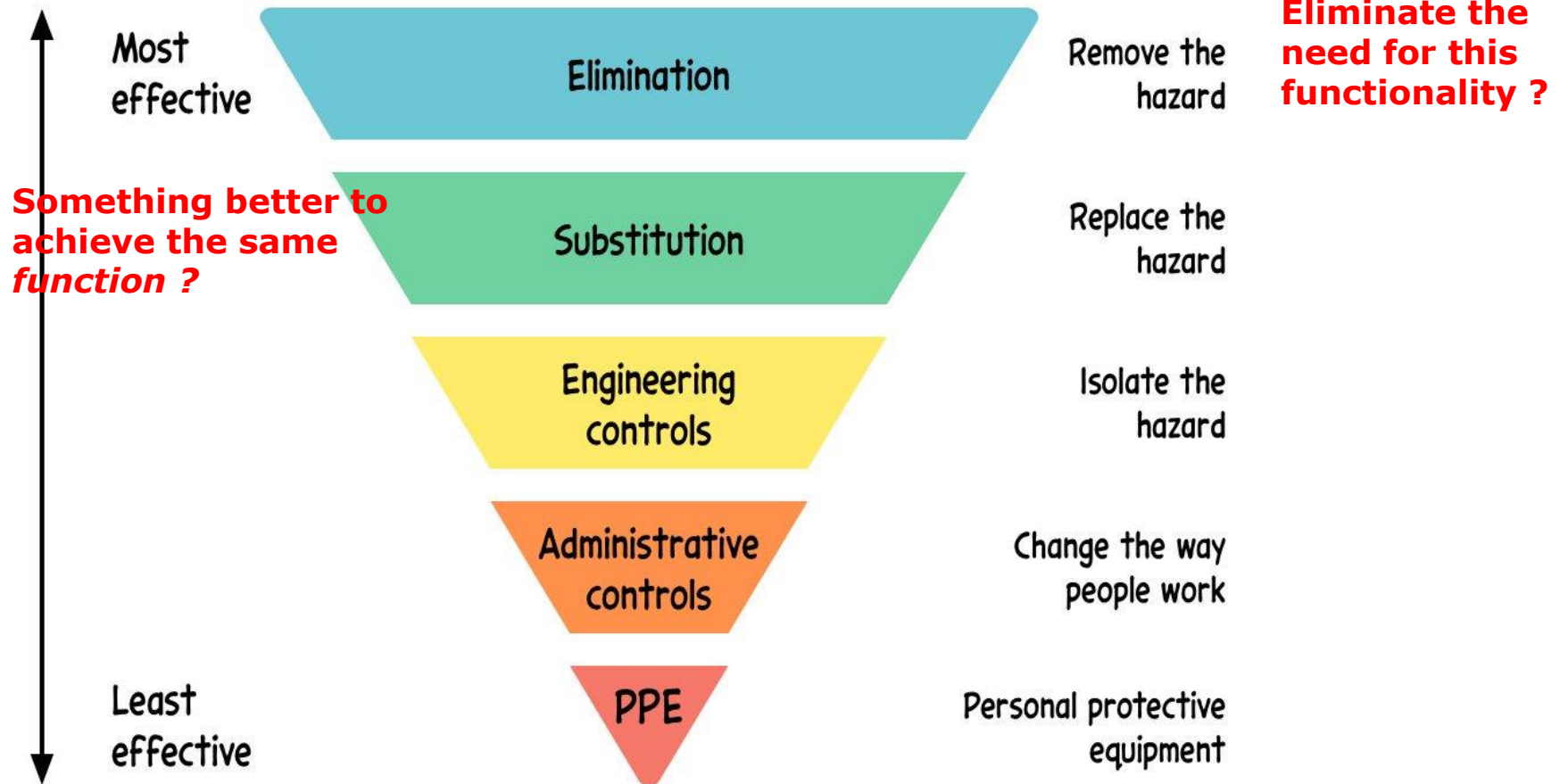
- **What is substitution?**

‘The replacement or reduction of hazardous substances in products or processes by less hazardous or non-hazardous **substances, or by achieving an equivalent functionality** via technological or organisational measures.’ (Lohse J. et al. 2003)

- **Key to substitution:** *consider the technical function (rather than a chemical switch)* - allows a wider range of substitution solutions and helps avoid regrettable substitution.

Inverted pyramid: Elimination and substitution first

HIERARCHY OF CONTROLS



The concept of 'functional Use' applied to PFAS in clothing

Most effective



Least effective

Functional substitution level	Substitution options	Innovation/Business opportunity
System change	<p>Biocidal actives need EU approval before use</p> <p>Is high performance oil and water repellence necessary for day-to-day jackets?</p> <p>If not, eliminate this function</p>	
<p>End use function</p> <p>(Product, material, process change)</p>	<p>Is there another way to achieve the same function?</p> <p>e.g. making a textile fibre or design which is intrinsically water and oil repellent.</p>	
<p>Chemical function</p> <p>(chemical change)</p>	<p>Is there a 'drop in' chemical replacement?</p> <p>Avoid regrettable substitution by switching to non-hazardous water and oil repellents.</p>	

Available resources (1 of 3)

ECHA's substitution pages

Substitution to safer chemicals

Companies in the EU are increasingly substituting away from hazardous chemicals and manufacturing processes to safer chemicals and greener technologies. This can bring substantial benefits to the companies, the environment and the health of workers and consumers. It can also have a significant positive impact on the implementation of a circular economy.

CONTACT

For general questions or suggestions on substitution related matters contact [substitution\[a\]echa.europa.eu](mailto:substitution[a]echa.europa.eu)

Supply chain workshops

Supply chain workshops are intended to advance research, evaluation and adoption of safer chemicals.

Networks

Collaborative networks play an important role in coordinating and advancing innovation and informed substitution.

Funding and technical support

Facilitating access to technical support and additional funding is critical to boosting substitution away from hazardous chemicals.

Data to prevent regrettable substitution

More effective use of REACH, CLP and BPR data in performing hazard and risk assessment of alternatives can help prevent the instances of regrettable substitution.



Why substitute?



How to substitute?



Real-life cases



Find substitution partners



News and activities

<https://echa.europa.eu/substitution-to-safer-chemicals>

Available resources (2 of 3)

- **ECHA's webpages :**

- ECHA guidance on REACH and CLP e.g. applications for authorisation (analysis of alternatives)
- Information on substances: tiered approach to detail
- Subscribe to ECHA's [mailing list](#) to be kept informed about substitution-related topics and activities

- **Biocidal actives substances contact:**

Hugues.KENIGSWALD@echa.europa.eu

- Social media channels:



International substitution resources (3 of 3)

- OECD substitution and alternatives toolbox – recommended!
- Others: OECD eChem portal and QSAR toolbox, Column model, GreenScreen, SUBSPORT, ChemSec tools

Conclusions

- Pay attention to early warnings (PACT, CoRAP, RMOA, RoI...) and be proactive with substitution
- Consider substitution in a broad sense: from elimination to functional substitution ('functional use')
- Avoid regrettable substitution i.e. by switching to alternatives that are sustainable
- Substitution should be seen as a business opportunity that has health and environmental benefits.

Thank you!

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Key facts

- Started in 2007
- Based in Helsinki, Finland
- 650 staff from 28 countries
- Funding both from companies (fees) and from the EU



Our mission:

We, together with our partners, work
for the safe use of chemicals

Our vision:

To be the centre of knowledge on the sustainable management of chemicals, serving a wide range of EU policies and global initiatives, for the benefit of citizens and the environment

Our strategic aims 2019-2023

- Identification and risk management of substances of concern
- Safe and sustainable use of chemicals by industry
- Sustainable management of chemicals through the implementation of EU legislation



Analysis and adoption of alternatives

- Analysis of alternatives is a step-defined, action-oriented process
- Focus on function, not the particular chemical
 - ‘Intrinsic impact reduction’
 - Considers the ‘necessity’ of a chemical
- Finding a safer alternative and getting industry to adopt the use of it are not the same thing.
- In some cases, safer, feasible alternatives may not exist and need to be developed

Source: Joel Tickner and Molly Jacobs - Lowell Center for Sustainable Production - 2017

Applying the pyramid to PFAS

- Technically challenging to develop high performance water and oil repellent PFAS in textiles
- For many applications in textiles high water & oil repellence can be seen as not absolutely necessary.
- The pyramid approach should be applied:
- Is the function necessary?
 - Yes: time-limited derogation for PFAS
 - No: eliminate, substitute etc.

Opportunity to innovate: create business opportunity, not a response to regulatory pressure.



Capacity building

Supply chain workshops

Share substitution challenges

- Substance users and suppliers
- Providers of alternatives, end-users, retailers, R&D and financial support

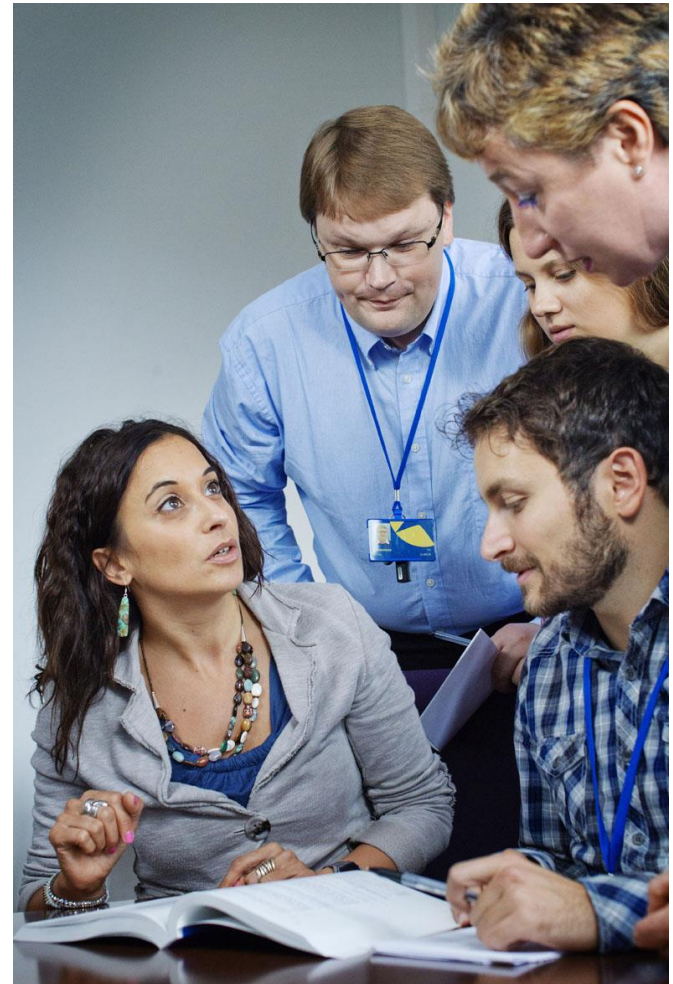




Capacity building

Supply chain workshops

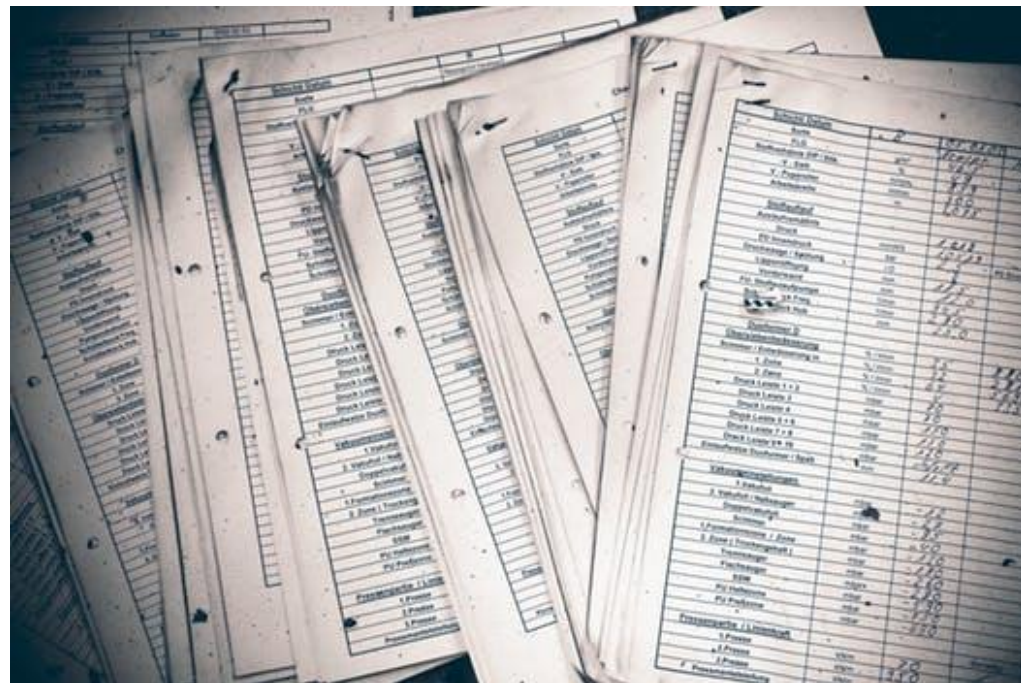
- Learn from others
- New ideas
- Identify gaps & training or research needs



Facilitating use of ECHA data for sustainable substitution

- Make use of ECHA's data (e.g. hazard) for substitution
- Avoid regrettable substitution

✓ **ECHA's role central**



Methodologies, tools, support to substitution

OECD Substitution and Alternatives Assessment Toolbox

Welcome to the OECD Substitution and Alternatives Assessment Toolbox (SAAT) – a compilation of resources relevant to chemical substitution and alternatives assessments. Visit the four resource areas below to learn more about chemical substitution and alternatives assessments and get practical guidance on conducting them.


What's an Alternatives Assessment?

A process for identifying, comparing and selecting safer alternatives to replace hazardous chemicals with the objective of promoting sustainable production and consumption. [Read more definitions...](#)



Alternatives Assessment Tool Selector

A filterable inventory of chemical hazard assessment tools and data sources to help you identify tools most relevant to your substitution and alternatives assessment goals. A listing of non-hazard assessment tools is also available.

[Learn more](#) 

Alternatives Assessment Frameworks

A summary of the current frameworks that can be used to assess alternatives. Guides and other resources for conducting a chemical substitution or alternatives assessment are included.

[Learn more](#) 

Case Studies and Other Resources

Links to case studies, toolkits, and product rating systems that provide examples, insights, and lessons learned on substitution and alternatives assessment approaches.

[Learn more](#) 

Regulations and Restrictions

A list of regulations and restrictions throughout OECD member countries that are driving the increased need for chemical substitution and alternatives assessment approaches.

[Learn more](#) 