

# Welcome

## Restriction of per- and polyfluoroalkyl substances (PFAS) under REACH

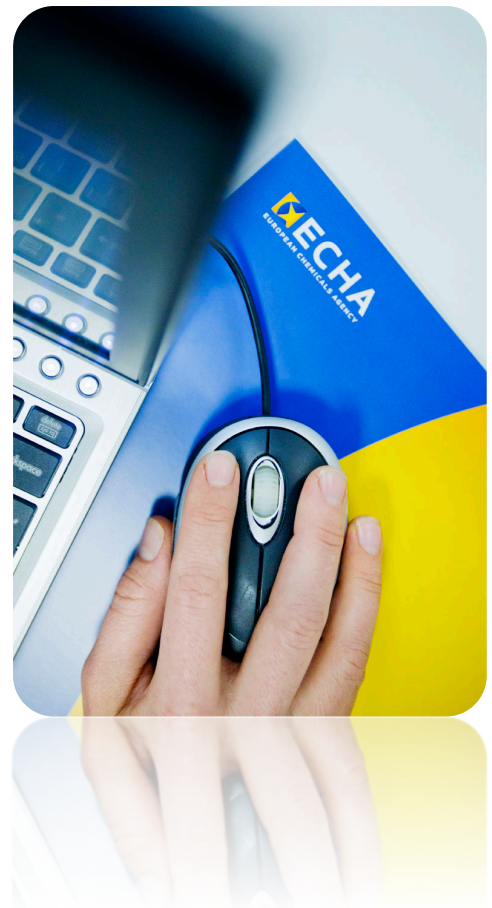
29 October 2020

Peter Simpson  
European Chemicals Agency



# What you can expect from today

- **Learn about** the REACH restriction process
- **Learn about** the work being done by Germany, The Netherlands, Denmark, Sweden and Norway on a restriction of PFAS under REACH
- Get **answers** to questions



# Questions

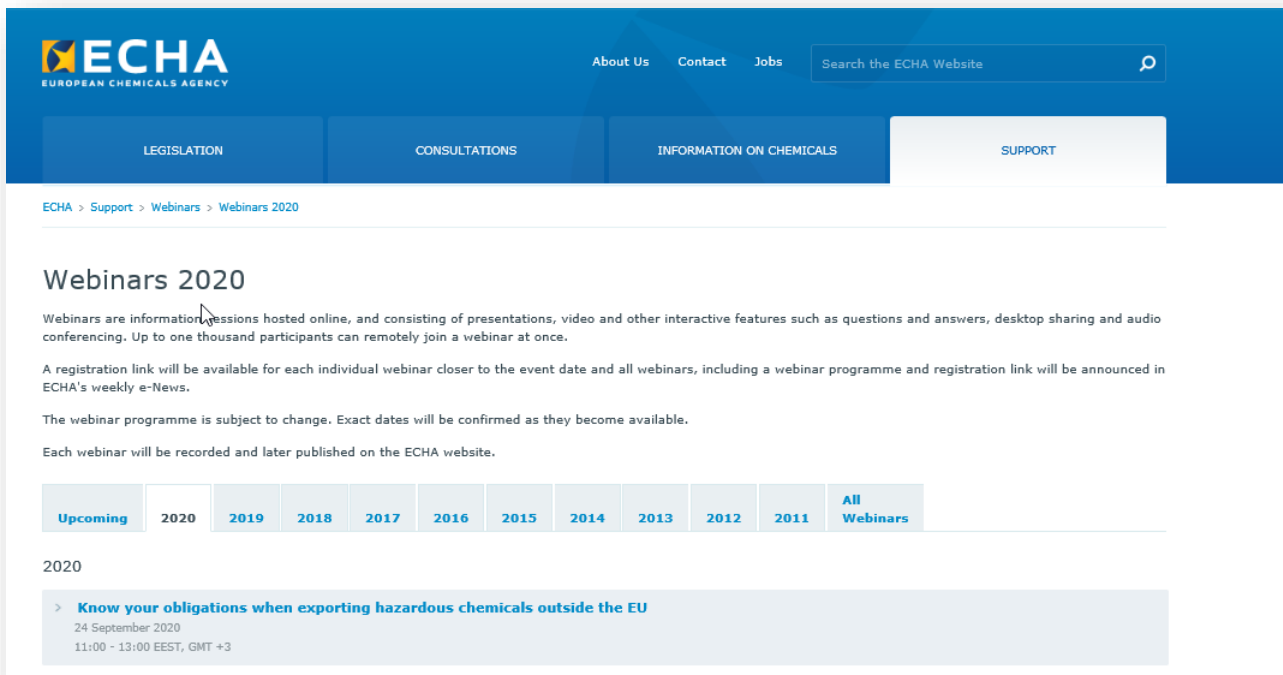
- Join Q&A at: [slido.com](https://www.slido.com)  
Event code:
- Send questions from **13:30 to 15:15 CET**
- Only questions within webinar scope
- Question not answered?  
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# PFAS restriction under REACH

- Joined activity Denmark, Sweden, Norway Germany, Netherlands started beginning 2020
- Aim to restrict all PFAS in non-essential uses
- Close cooperation with ECHA and European Commission
- Publication of the EU Chemical Strategy for Sustainability Towards a Toxic-Free Environment on 14 October 2020, including a Staff Working Document on PFAS

# Program

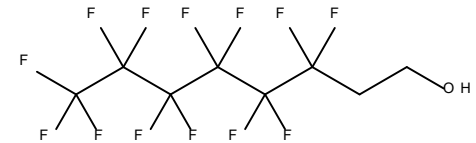
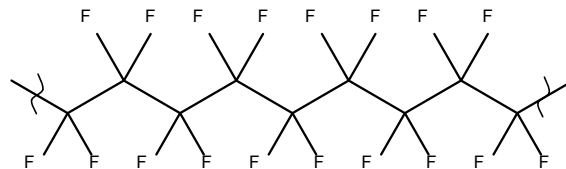
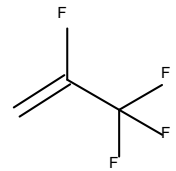
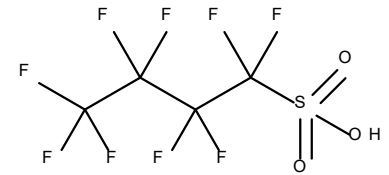
Timing	Title	Speaker
13:30	Introduction and Sli.do Q&A open for questions	Peter Simpson, ECHA Martijn Beekman MSc, NL-CA
13:36	Why is this restriction on PFAS needed?	Jenny Ivarsson, SE-CA
13:49	REACH restriction process and status of the PFAS restriction	Dr. Mandy Lokaj, DE-CA
14:07	Introduction to the panellists answering questions	Martijn Beekman MSc, NL-CA
14:14	Closing remarks	Peter Simpson, ECHA
14:15 – 15:30	Sli.do Q&A open for questions	Panel

# PFAS Restriction Proposal: Concern

*A joint activity by Denmark, Norway, Sweden,  
the Netherlands and Germany*

# Per- and polyfluoroalkyl substances, PFAS

- Synthetic compounds, manufactured since 1950's
- Very diverse group of substances
- OECD (2018): 4700 PFAS
- Unique and useful properties from technical viewpoint
- Harmful properties – common for the whole group





# Per- and polyfluoroalkyl substances, PFAS

- Main uses include:
  - Fire-fighting foam
  - Textile treatment
  - Food contact materials



- Widespread use of PFAS, including in products

# Worrying observations

# PFAS in humans

- Median for the sum of PFOS, PFOA, PFHxS, PFNA, PFDA and PFUnDA in serum or plasma - general populations (EFSA, 2020):
  - Adults: approx. 12 ng/L
  - Children: approx. 8 ng/L
- People living in areas with point sources and those who work with PFAS, have much higher plasma/serum concentrations

# PFAS in biota

- PFAS have the ability to disperse over long distances through air and water
- Are detected far from any areas of manufacture or use, e.g., in arctic environments – making PFAS very much a global problem
- Volatile variants, such as fluorotelomers, can be dispersed over large areas in the air
- Less volatile, ionised forms are largely dispersed in water and bound to particles of organic matter, soil particles for example, or through absorption into living organisms

# PFAS in water bodies

- Detected in water samples from the Arctic to the Antarctic
- Ubiquitous in the aquatic environment across Europe
- Both legacy and novel PFAS detected in drinking water in non-EU countries. Limited monitoring in the EU
- In Veneto, Italy, industrial activity contaminated drinking water with PFAS for 127.000 citizens

# PFAS – Difficult to remove

- Many PFAS are highly soluble in water and have a low sorption potential, resulting in a preferred distribution to the aqueous phase
- These are often difficult to remove with conventional purification techniques
- May apply to wastewater purification, drinking water production and removal of industrial emissions

# Health effects (1/2)


Health effects in humans that have been associated with exposure to certain PFAS are:

- Increased cholesterol levels
- Impact on infant birth weights
- Effects on the immune system
- Possible increased risk for cancer
- Thyroid hormone disruption

## Health effects (2/2)

- There is limited knowledge of the health effects of many PFAS
- Based on similarities between PFAS, there is good reason to consider all PFAS as a health hazard
- In addition, based on their similarities, combination effects of PFAS can be expected





# Substance properties responsible for the observations

# Persistence

## Concept

PFAS

Persistence

Bioaccumulation

Mobility

(Eco)toxicity

## Persistence

- Almost all PFAS are either very persistent or degrade to very persistent PFAS
- Precursors --> Arrowhead substances
- PFAS arrowheads are among the most stable organic compounds known...
- ... due to the strong C-F bond
- May survive in the environment for decades and centuries and expose future generations

# Bioaccumulation

## Concept

PFAS

Persistence

Bioaccumulation

Mobility

(Eco)toxicity

## Bioaccumulation

- Certain PFAS bioaccumulate in living organisms and may then be biomagnified as they rise through the food chain
- In fish, a correlation has been shown between the quantity of PFAS the fish accumulate and the length of the carbon chain in the PFAS molecule; long-chain PFAS accumulate strongly in contrast to short-chain PFAS
- Unlike many other bioaccumulative substances, PFAS bind to proteins and are stored in other bodily organs; e.g. the liver and blood
- All PFAS have due to their extreme persistence a lot of time to distribute no matter how bioaccumulative
- PFAS can also be absorbed by plants but here the inverse applies, with short-chain PFAS accumulating to a greater extent than long-chain

# Mobility

## Concept

PFAS

Persistence

Bioaccumulation

Mobility

(Eco)toxicity

## Mobility

- Small-molecule PFAS with polar functional groups are often mobile in the aqueous environment...
- ...due to high aqueous solubility and low adsorption potential
- Continuous presence in water results in continuous bioavailability
- Volatile PFAS are mobile via air transportation
- High mobility facilitates long-range transport to even to remote areas
- In combination with extreme persistence the concerns for bioaccumulation and mobility become (to some extent) interchangeable...
- ...and may be regarded as exposure facilitators

# Toxicity/Ecotoxicity

## Concept

PFAS

Persistence

Bioaccumulation

Mobility

(Eco)toxicity

## (Eco)toxicity including ED

- Information on toxicity and ecotoxicity is increasing for PFAS, but some PFAS will stand out as example
  - (Eco)toxicological effects related to these highly persistent chemicals will continue for decades to centuries following their continues release to the environment
- Adverse effects are difficult to assess for long term cross generational exposure



# From the substance properties follow concern

# ELEMENTS OF CONCERN

## Properties

- Very high persistence
- High bioaccumulation potential
- High mobility
- Difficult removal
- Toxic effects in humans and the environment



- Continuous releases of PFAS will lead to continuously increasing levels in the environment that will last for decades and centuries (irreversible contamination)
- Increasing biota concentrations along the food-chain with highest PFAS-levels in top predators (e.g. polar bear) for the long-chain PFAS
- Potential for continuously increasing contamination of surface water, marine water and groundwater
- Societal concern for drinking water contamination
- High long-range transport potential via water and air will lead to contamination of remote regions and worldwide occurrence
- Continuous presence in water results in continuous bioavailability
- Growing probabilities of known and unknown effects, including those that would not be observed in standard tests
- Additive effects from combined exposure to multiple PFAS simultaneously
- Intergenerational effects, mother-to-offspring transfer

Thank you for your attention!





National Institute for Public Health  
and the Environment  
Ministry of Health, Welfare and Sport

b a u a :

Bundesanstalt für Arbeitsschutz  
und Arbeitsmedizin

**KEMI**

Swedish Chemicals Agency



NORWEGIAN  
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Ministry of Environment  
and Food of Denmark

Environmental  
Protection Agency

# REACH Restriction Process and Current status of PFAS restriction

*A joint activity by Denmark, Norway, Sweden,  
the Netherlands and Germany*

Webinar online information session

•29 October 2020

# Public Announcement concerning PFAS

## Five European states call for evidence on broad PFAS restriction

ECHA/NR/20/13

The national authorities of Germany, the Netherlands, Norway, Sweden and Denmark invite interested parties to send in evidence and information on the use of per- and polyfluoroalkyl substances (PFAS) by 31 July 2020.

**Helsinki, 11 May 2020** – The authorities of the five countries have agreed to prepare a joint REACH restriction proposal to limit the risks to the environment and human health from the manufacture and use of a wide range of PFAS. ....

<https://echa.europa.eu/-/five-european-states-call-for-evidence-on-broad-pfas-restriction>

# REACH Regulation and Restriction

- Aim is an EU-wide protection of human health and the environment
- Risks posed by chemicals which are not adequately controlled can be addressed via different RMMs
- Restriction is a 'safety net' where risks cannot be addressed by other REACH processes or other EU legislation
  - only few limitations to scope
  - can address non-standard hazards / risks

# REACH Regulation and Restriction

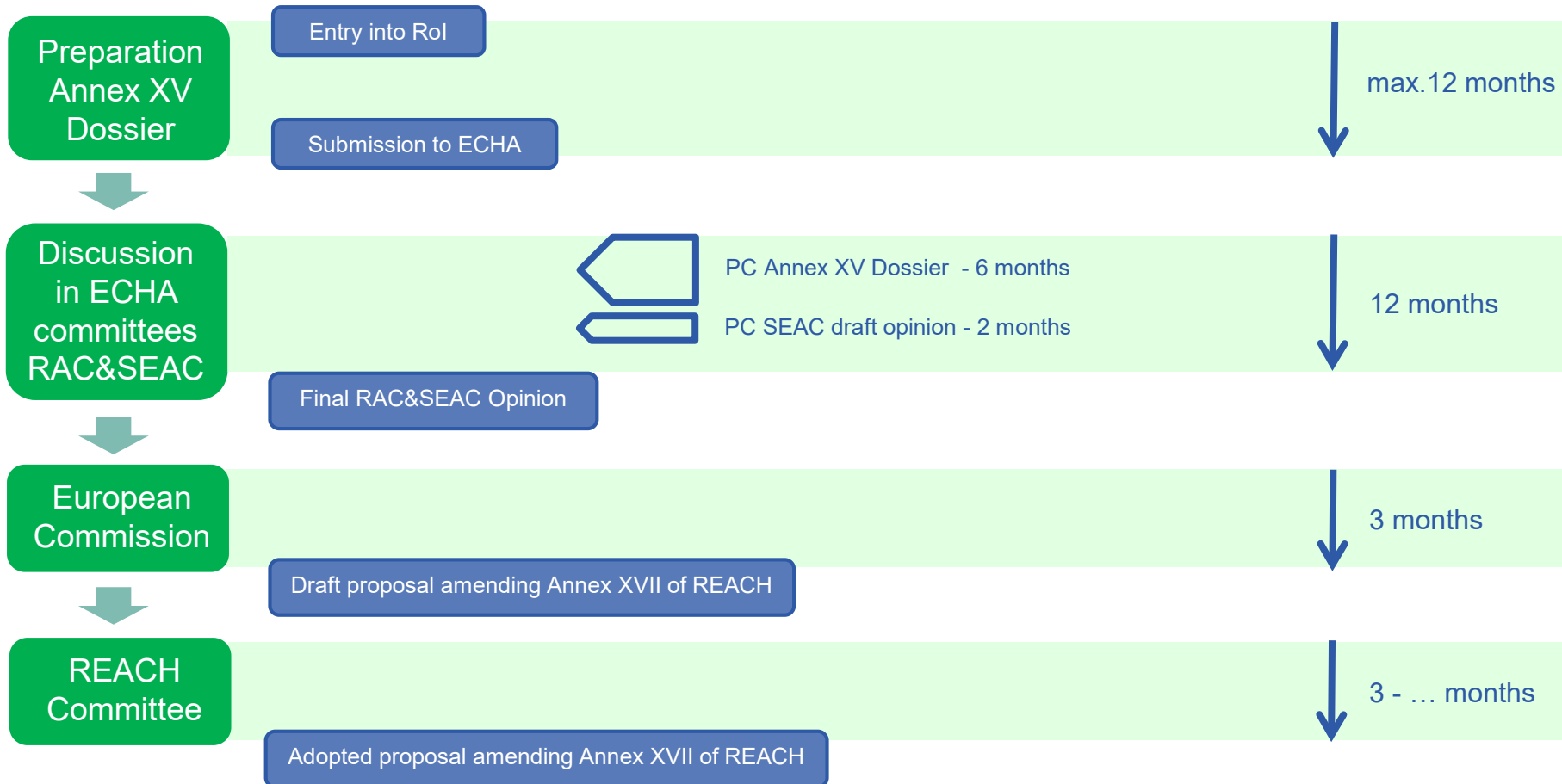
- Restrictions usually limit or ban:
  - manufacture,
  - placing on the market and/or
  - use of a substance
- Restrictions can set out specific conditions e.g. technical measures or labelling requirements
- Annex XV Dossier submitter of a restriction proposal can be ECHA (requested by Commission) or a Member State

# RoI – Registry of Intentions

- Intention to prepare a restriction proposal has to be notified into RoI
- Annex XV dossier has to be submitted within 12 months
- Indicates when a restriction proposal is planned to be submitted to ECHA for a particular substance or substance group

[echa.europa.eu/registry-of-restriction-intentions](https://echa.europa.eu/registry-of-restriction-intentions)

# REACH Restriction Process according to Art. 68(1)



# PFAS in REACH Restriction Processes

## Entered in force

PFOS: POP Regulation

PFOA: Restriction Entry Nr. 68 in Annex XVII of REACH but  
entry into force of POP Regulation

C6 Siloxanes: Restriction Entry Nr. 73 in Annex XVII of REACH

## Ongoing:

PFHxS: Publication of final RAC/SEAC opinion expected soon

PFHxA: Public consultation ended

Opinion Development Phase in RAC/SEAC

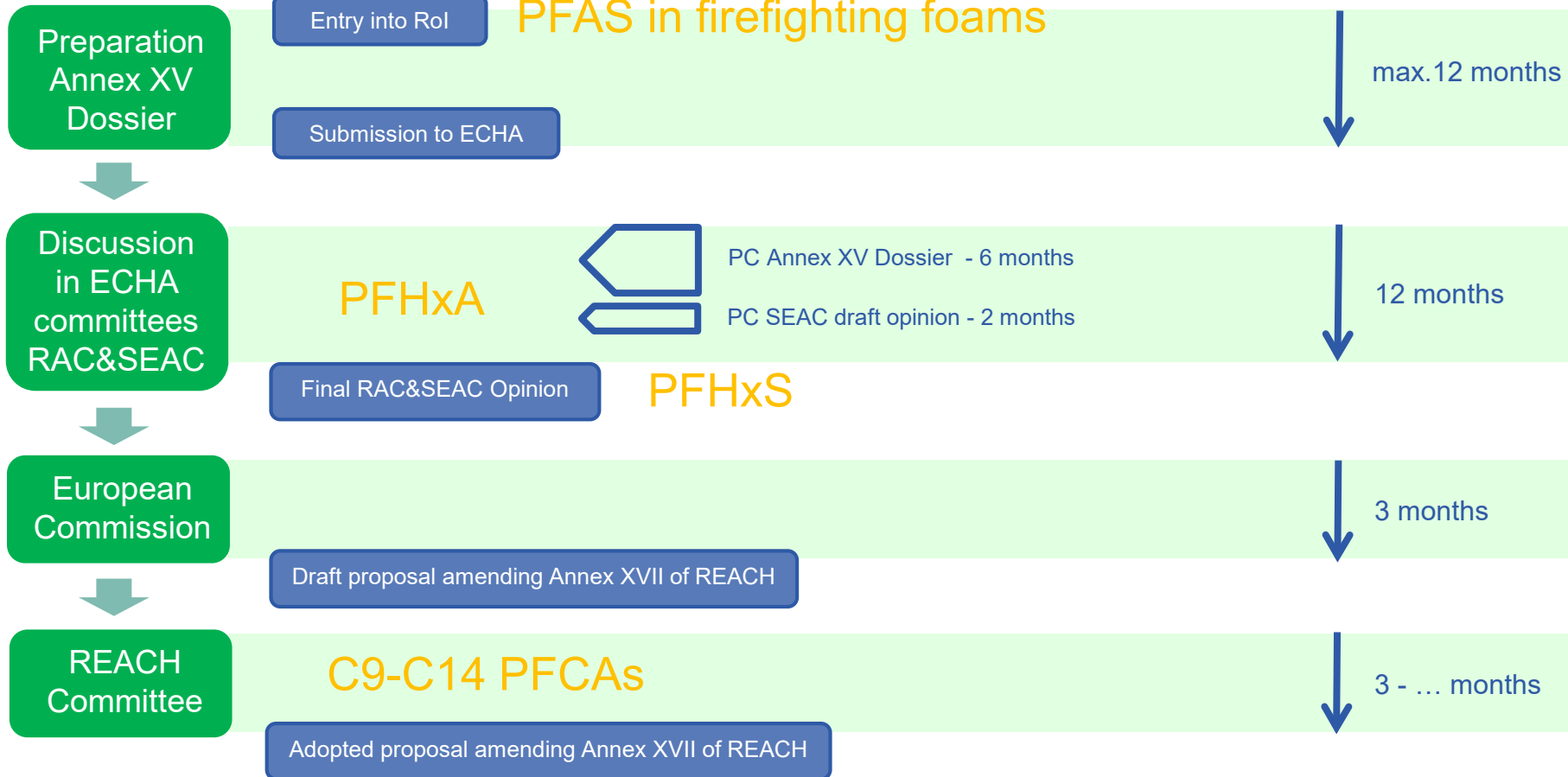
PFAS in firefighting foams: Rol

PFAS broad restriction: preparatory phase

# REACH Restriction Process according to Art. 68(1)



Currently PFAS restriction work is prior to Rol in a preparatory RMOA phase !





# Preparatory Work for Restriction

- If MS or ECHA (requested by Commission) have a concern that a substance or group of substances poses a risk to human health or the environment preparatory work takes place investigating the problem through risk regulatory management option analysis (RMOA)
- Competent authorities for REACH of the Netherlands, Germany, Denmark, Sweden and Norway are currently working on an analysis of restriction options for PFAS in the frame of an RMOA
- Notification into PACT: [echa.europa.eu/pact](https://echa.europa.eu/pact)

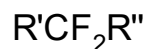
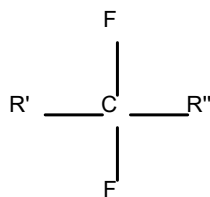
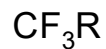
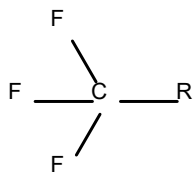
# Preparatory Phase

- Call for evidence (CfE) took place 11 May – 31 July
- Aim of CfE: a better understanding of identity, hazards and uses of PFAS that would be in scope of PFAS restriction proposal
- Ca. 560 responses were received
- Responses and information received in CfE will not be published
- Assessment of responses and planning of follow up of CfE i.e. stakeholder meetings if necessary and needed is still ongoing

# Preparatory phase – Potential Scope of PFAS Restriction - Substances

- Aim to address PFAS as a group of substance
- CfE used a broad scope as starting point:

“Substances that contain at least one aliphatic -CF<sub>2</sub>- or -CF<sub>3</sub> element”.



This covers many substances of various structures:

- PFAAs, PFSAAs, PFAEs;
- side-chain and backbone fluorinated polymers
- hydrofluorocarbons,
- side-chain fluorinated aromatics etc. ...

# Preparatory phase – Potential Scope of PFAS Restriction – Concern(s)

- Despite considerable differences in structure and properties, there is an underlying concern for all members of the PFAS group
  - Persistence as main common concern
    - Persistent due to strength of C-F bond
    - PFAS remain in the environment for decades to centuries
    - Covers all PFAS directly or indirectly as precursors can be transformed/ degraded to persistent PFAS

# Preparatory phase – Potential Scope of PFAS Restriction – Concern(s)

- Despite considerable differences in structure and properties, there is an underlying concern for all members of the PFAS group
  - Persistence as main common concern

## Supporting Concerns:

- Bioaccumulation and Mobility (as exposure facilitators)
- (Eco)Toxicity

# Preparatory Phase – Potential Justification of Need for EU-wide Measures

- when adverse effects are identified it will be technically challenging, and costly, or even impossible to reverse the chemical contamination and therefore the effects → threats of irreversible damage
  - EU wide concern (unacceptable risk following Art. 69(4))
    - = **Persistence** (very long lasting presence of PFAS)
    - + **consequences** of much higher likelihood for particularly serious (widespread, long-lasting) adverse effects
- ➔ Restriction is seen as this safety net measure to address these identified non-standard hazards and risks

# Preparatory phase – Scope of potential PFAS Restriction - Uses

- Textiles, Leather, Apparel
- Cosmetics and personal care products
- Consumer mixtures
- Lubricants, greases and construction products
- Electronic devices, batteries, fuel cells, semiconductors, energy sector
- Transport (automotive, aviation etc)
- F-gases
- Oil and mining apart from firefighting foams
- Food contact material and paper and board
- etc. ....

# Preparatory Phase – Work on PFAS Uses

- Assessment of responses of CfE is taking place according to use with different Member States in lead for different uses:

**NL:** medical devices and pharmaceuticals; food contact materials;  
production of fluoropolymers; waste and recycling

→ contact: [restrictiePFAS@rivm.nl](mailto:restrictiePFAS@rivm.nl)

**DE:** chrome plating; consumer mixtures; transport

→ contact: [ChemG@baua.bund.de](mailto:ChemG@baua.bund.de)

**SE:** textiles, leather, apparel; cosmetics and personal care products

→ contact: [jenny.ivarsson@kemi.se](mailto:jenny.ivarsson@kemi.se)

**DK:** lubricants and construction products

→ contact: [towin@mst.dk](mailto:towin@mst.dk)

**NO:** F-gases; ski waxes; applications within oil, gas and mining

→ contact: [audun.heggelund@miljodir.no](mailto:audun.heggelund@miljodir.no)



# Preparatory Phase – Work on PFAS Uses

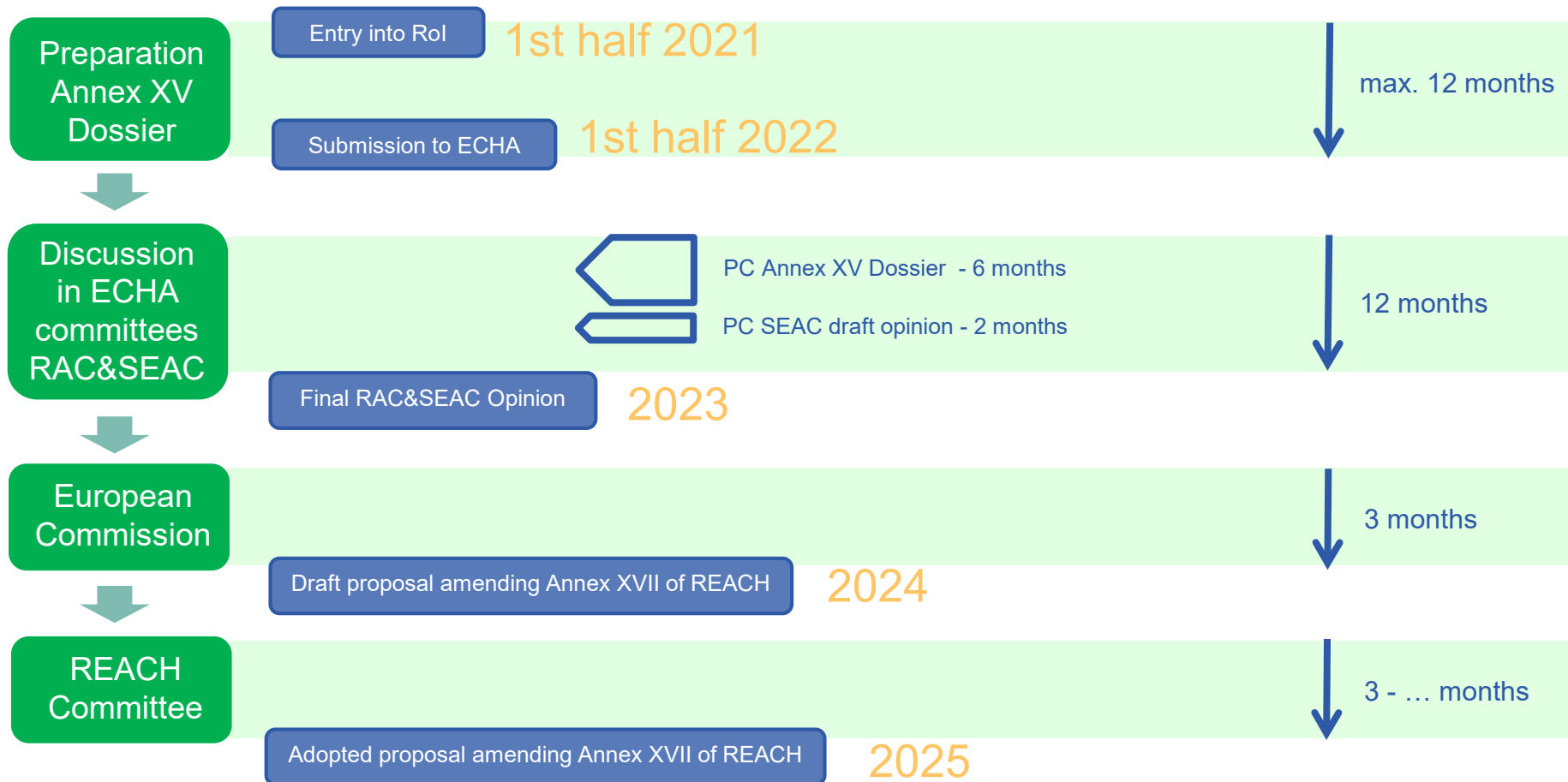
- The assessment of uses and applications not listed here are planned to be started at a later stage
- Study reports will be prepared including information on emissions and alternatives
- For PFAS in firefighting foams ECHA intention to prepare a separate restriction proposal

<https://echa.europa.eu/de/registry-of-restriction-intentions/-/dislist/details/0b0236e1856e8ce6>

# Preparatory Phase - Timing

- Outcome and information of preparatory phase will form part of a RMOA conclusion document in order:
  - to describe different risk management options and
  - to transparently demonstrate how the initial scope of PFAS restriction upon entry into RoI was considered
- Publication of conclusion document in PACT planned first half 2021
- RMOA conclusion document will not be discussed separately and form part of Annex XV dossier
- Entry into RoI planned following publication of conclusion document for first half 2021

# Potential Timing PFAS Restriction



# List of Abbreviations

PFAS	per- and polyfluoroalkyl substances
REACH	Registration Evaluation and Authorisation of Chemicals Regulation (EC) No 1907/2006
ECHA	European Chemicals Agency
MS	Member State
Rol	Registry of Intentions
POP	Persistent Organic Pollutants; Regulation (EC) No. 2019/1021
PFOS	perfluorooctansulfonic acid
PFOA	perfluorooctanoic acid
PFHxS	perfluorohexasulfonic acid
PFHxA	perfluorohexanoic acid
PC	Public Consultation
RAC	Risk Assessment Committee
SEAC	Socio-Economic Analysis Committee
RMOA	Regulatory Management Option Analyses
PACT	Public Activities Coordination Tool
PFAAs	per- and polyfluoralkyl acids
PFSA	per- and polyfluoralkyl sulphonic acids
PFAEs	per- and polyfluoralkyl ether based substances

Thank you very much for your attention!

# Expert panel



Norway  
Dr. Audun Heggelund



Sweden  
Jenny Ivarsson



Denmark  
Toke Winther



ECHA  
Peter Simpson



Germany  
Dr. Mandy Lokaj



The Netherlands  
Martijn Beekman MSc

# Prioritized questions: green deal, innovation

Q. The EU Green Deal relies on access to substances with high performance such as PFAS. [For instance...]. How can you ensure that PFAS will be allowed for Green Deal objectives?

A. We are aware of the unique and useful properties of PFAS from a technical point a view. However there is common concern: persistency in the environment. In our view, it is important to consider all PFAS in one proposal to reassure a coherent approach and avoid regrettable substitution. The proposal aims to restrict the non-essential use of PFAS.

## Prioritized questions: relation to other PFAS restrictions

Q. Several PFAS are already subject to restrictions or on their way to being restricted. This is for instance the case for PFHxA, its salts and related substances. How will already restricted PFAS be handled under the future restriction on all PFAS?

A. As mentioned in the presentation by Dr. Lokaj we are aware of the different on-going discussion for groups of PFAS substance. In our view, it is important to consider all PFAS in one proposal to reassure a coherent approach and avoid regrettable substitution.



# Prioritized questions: relation to other legislation

Q. F-gases are already regulated under the F-gas regulation and should not fall under the PFAS group of chemicals. How will you avoid double regulation?

A. The broad PFAS restriction will have potential overlaps not only with the F-gas regulation. We are aware of these overlaps and it is in our interest to avoid double regulation but we consider it important as part of the preparatory work to assess these kind of overlaps in order to decide if there is a need for further regulations and/or exemptions/derogations.

# Prioritized questions: possible derogations

Q. If you were to receive data demonstrating that a group or particular PFAS molecule has no environmental and/or exposure concerns, will you exempt that group or particular PFAS molecule from the restriction proposal? By what date would you need to receive such data?

A. In our view, it is important to consider all PFAS in one proposal to reassure a coherent approach and avoid regrettable substitution. Emissions of PFAS during production, use and waste stage will be carefully considered in the restriction proposal. Information on emissions from specific processes or uses is highly appreciated (the sooner the better). The need for possible exemptions and derogations will be assessed in the process.

# Close of the meeting

Restriction of per- and  
polyfluoroalkyl substances (PFAS)  
under REACH

29 October 2020

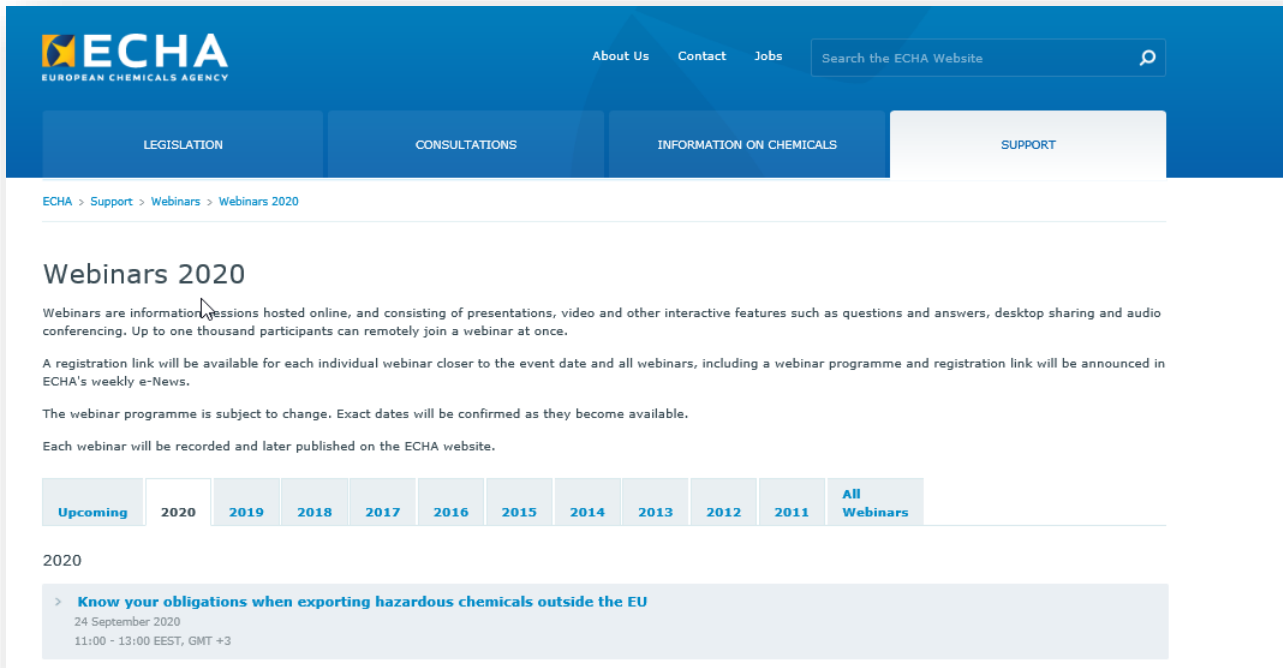
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2020

> **Know your obligations when exporting hazardous chemicals outside the EU**  
24 September 2020  
11:00 - 13:00 EEST, GMT +3

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