

PFAS Restriction Proposal

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Restriction proposal - content

- REACH = Registration, Evaluation, Authorisation and **restriction** of CHemicals
- Restriction proposal:
 - ✓ Chemical identity
 - ✓ Hazards, risks, effects
 - ✓ Applications
 - ✓ Availability of alternatives
 - ✓ Socio-economic analysis – impact assessment



Preparation

May – July 2020
Call for evidence

July 2021 – Oct 2021
2nd stakeholder consultation

Oct 2021 – Jan 2023
Drafting of proposal

Stakeholder interviews, literature search, meetings



Jan 2020
First meeting

13 January 2023
Submission
of proposal

7 February 2023
Publication of
proposal

Restriction process – next steps

- **Public Consultation, 22 March – 25 September 2023**
- **ECHA's scientific committees:**
 - ✓ Committee for Risk Assessment (RAC)
 - ✓ Committee for Socio-Economic Analysis (SEAC)
- **Decision by the Commission together with the member states, expected 2025/26**

Next steps – key messages

- Dossier amendments are made on the basis of information submitted to the Public Consultation
- **Well-substantiated scientific evidence is key:**
 - ✓ Alternatives, impacts (costs and benefits), missed uses, tonnages and emissions, R&D efforts, etc.
 - ✓ If available, quantitative information is preferred
 - ✓ Information on sector level preferred over individual submissions
- Position papers and unsubstantiated claims are not useful

Next steps – key messages

- Dossier amendments are made on the basis of information submitted to the Public Consultation

- **Well-substantiated**

- ✓ Alternatives, tonnages and emissions
- ✓ If available
- ✓ Information on submissions

ECHA webinar 5 April

- Position papers and unsubstantiated claims are not useful

PFAS - basis for restriction



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

baua:
Bundesanstalt für Arbeitsschutz
und Arbeitsmedizin

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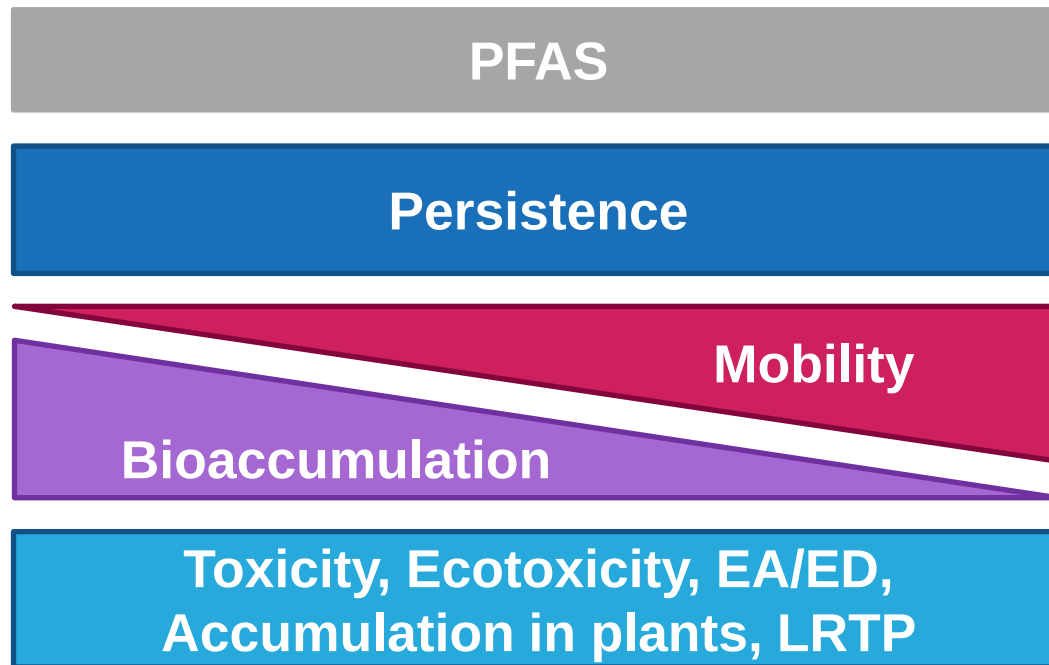
Global focus

- **Exposure to PFAS in general has gained increasing attention**
 - ✓ EU chemicals strategy for sustainability
- **PFAS linked to pollution of the environment, including drinking water**
- **Some PFASs already restricted in the EU (PFOS, PFOA, C9-C14 PFCAs)**
 - ✓ This proposal does not affect these existing restrictions
 - ✓ Decision making for restrictions on PFHxS and PFHxA is ongoing
 - ✓ PFAS in fire-fighting foam
- **Several regulations in non-EU countries**
 - ✓ Certain US States (California, Washington, NY, etc.), Australia

«Forever chemicals»

- All PFASs in scope of this restriction proposal are either persistent themselves or degrade to other persistent PFASs
- Persistence due to strength of the carbon-fluorine bond
- PFASs remain in environment for decades to centuries

Hazard assessment



Human health effects

- **Varies with PFAS chemical structure**
- **Most common effects:**
 - ✓ Reduced immune response - increased risk of infections
 - ✓ Liver damage and disturbed metabolism
 - ✓ Developmental effects - reduced growth of fetus and offspring
 - ✓ Potentially carcinogenic

Hazard assessment

Properties

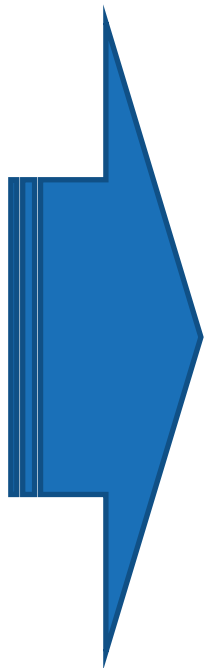
- **Very high persistence**
- Long-range transport potential
- Mobility
- Accumulation in plants
- Bioaccumulation potential
- (Eco)toxicity
- Endocrine activity

- PFASs are among the most stable organic compounds
 - Resist (bio) degradation because of the stable C-F bond
- PFASs can be transported by air, water and matrices to which they are adsorbed or absorbed
 - e.g., dust, sediments, migratory animals and polymer particles
- PFASs are found in all environmental compartments as well as in biota (e.g. mammals, birds, fish, plants, ...)
- Plants accumulate many PFASs beyond expected levels
- Exposures may be higher than observed by monitoring
- For well studied PFASs effects on behaviour, growth, reproduction, metabolism, organs & immune system observed
- Harmonised class. for some PFASs: Carc. 2, Repr. 1B, lactation effects, STOT RE 1
- *In silico*, *in vitro* and *in vivo* data provide indications of interactions of various PFASs with the endocrine system

Hazards → concerns

Properties

- **Very high persistence**
- Long-range transport potential
- Mobility
- Accumulation in plants
- Bioaccumulation potential
- (Eco)toxicity
- Endocrine activity



Concerns related to combinations of properties

- High potential for ubiquitous, increasing and irreversible exposures of the environment and humans;
- Difficulty to decontaminate raw water for drinking water, low effectiveness of end-of-pipe RMMs and difficulty to treat contaminated sites;
- High potential for human exposure via food and drinking water;
- Potential for intergenerational effects and delay of effects;
- Potential for causing serious effects although those would not be observed in standard tests;
- Estimation of future exposure levels and safe concentration limits is highly uncertain;
- Global warming potential.

Monitoring data

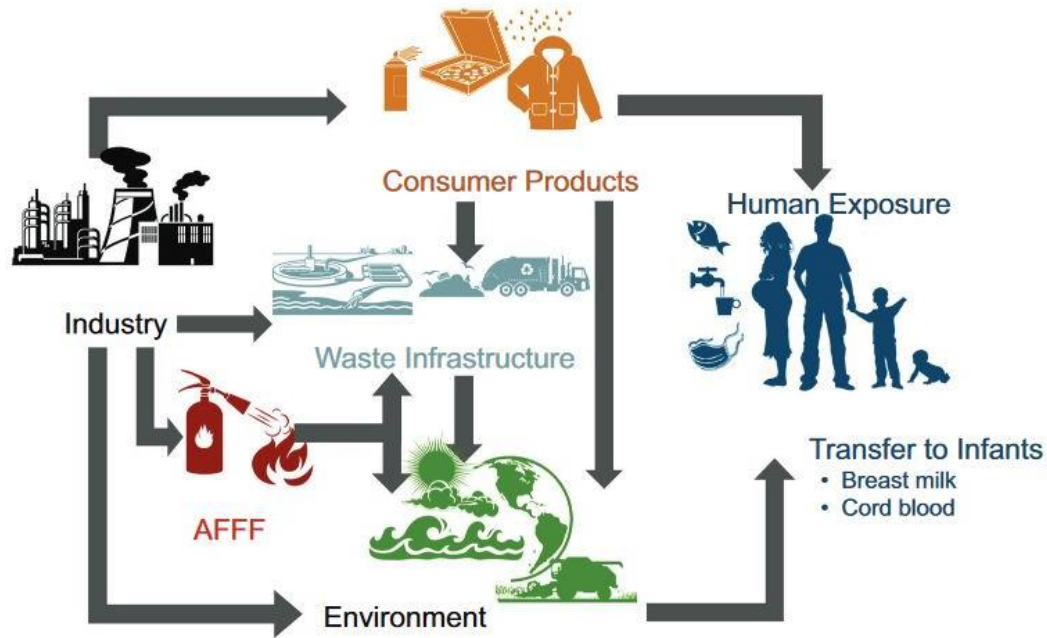


Illustration from Sunderland *et al.*, 2019, J. Exposure Sci. Environ. Epidemiol., 29, 131-147.

PFAS – uses and emissions

Function of PFASs

Combination of useful properties from technical viewpoint

- Water, oil and dirt repellency
- Durability under extreme conditions:
 - ✓ temperature, pressure, radiation, chemicals
- Electrical and thermal insulation
- Surfactants, refrigerants...

→ Used in high tonnages in many different sectors

Sectors/uses of PFASs



Rainwear



Non-stick coating



Cosmetics

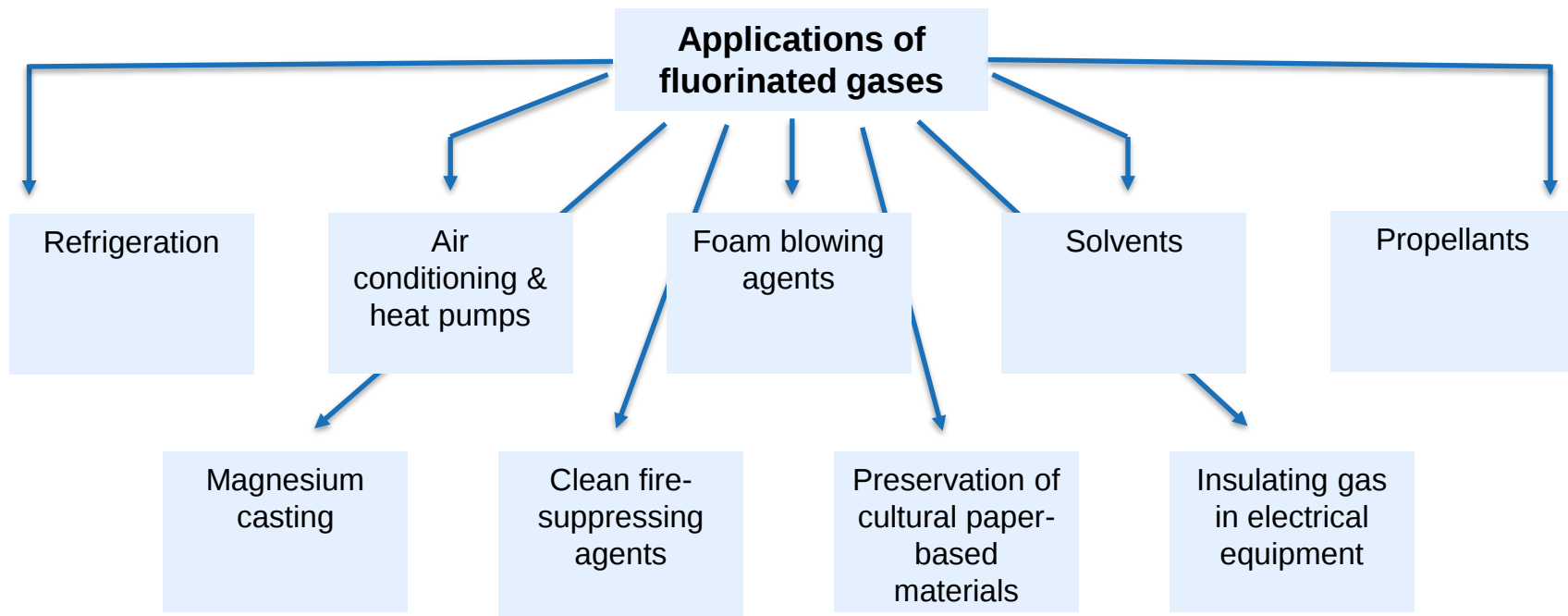


Medical equipment

- Industrial processes
- Firefighting foams
- TULAC
- Food contact materials (incl. packaging)
- Metal plating/metal products
- Consumer mixtures
- Ski wax
- Transport
- Applications of fluorinated gases
- Electronics and semiconductors
- Energy sector
- Construction products
- Lubricants
- Petroleum and mining
- Medical devices
- Cosmetics
- Other uses

Uses - subuses

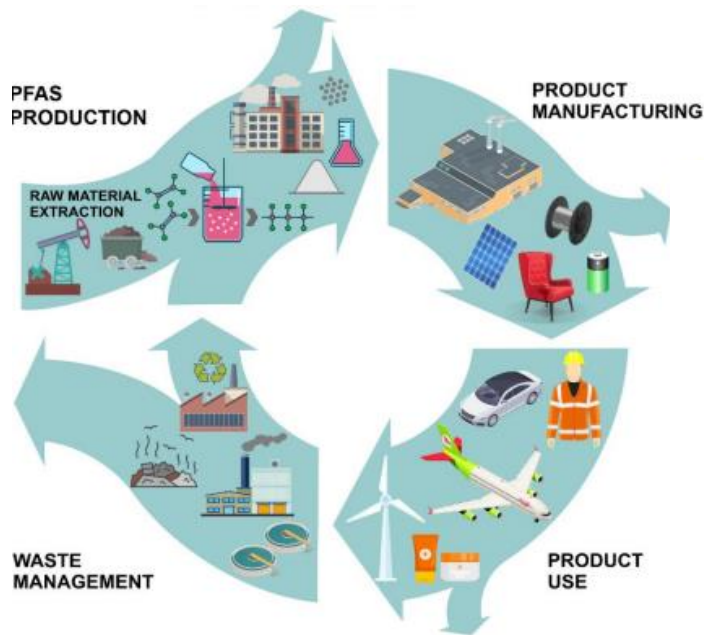
Many uses are further sub-divided



Emissions

75 000 tonnes of emissions in 2020

4.5 million tonnes of emissions over 30 years including an estimated increase of PFAS use



Source:

https://ec.europa.eu/environment/pdf/chemicals/2020/10/SWD_PFAS.pdf

Emissions estimations

- **Focus on emissions to the environment (PBT/vPvB approach)**
- **One compartment model**
- **Emissions estimated for each use and life-cycle stage**
- **Input parameters based on literature, industry information and expert judgement**

Tonnages and emissions

Application	Tonnage range	Emission range % emitted in manufacturing and use phase	Emission contribution Contribution to total emission [%]
Applications of fluorinated gases	> 10 000	5 – 25	> 50
Textiles, upholstery, leather, apparel & carpets	> 10 000	5 – 25	10 – 50
Medical devices	> 10 000	5 – 25	5 – 10
Manufacture	> 10 000	0 – 5	1 – 5
Food contact materials and packaging	> 10 000	0 – 5	0 – 1
Transport	> 10 000	0 – 5	0 – 1
Construction products	1 000 – 10 000	25 – 75	1 – 5
Electronics and semiconductors	1 000 – 10 000	5 – 25	0 – 1
Lubricants	1 000 – 10 000	5 – 25	0 – 1
Petroleum and mining	1 000 – 10 000	0 – 5	0 – 1
Energy sector	1 000 – 10 000	0 – 5	0 – 1
Metal plating and manufacture of metal products	100 – 1 000	0 – 5	0 – 1
Cosmetics	10 – 100	> 95	0 – 1
Consumer mixtures	10 – 100	75 – 95	0 – 1
Ski wax	0 – 10	25 – 75	0 – 1

PFAS – risk-related considerations

Substance scope

- A concern-based scope using the OECD (2021) PFAS definition as a starting point, but only including persistent substances
- Substances that contain at least one $\text{-CF}_2\text{-}$ or one -CF_3 group, without any H/Cl/Br/I attached to it
- With some exceptions

Grouping approach

- **Grouping based on two properties:**
 - ✓ chemical structure, i.e. in line with OECD 2021 PFAS definition
 - ✓ persistence
- **Acknowledged as a basis for risk reduction measures by several research groups: e.g. Cousins et al. (2020), Scheringer et al. (2022)**
- **Justified to avoid regrettable substitution**
- **Prevention of future exposures of PFAS which are not currently in use**

Risk characterisation

- **Risks are not adequately controlled, and emissions should be minimised...**
- **... because of accumulation over time which leads to levels likely to cause effects for humans and environment**
- **Risks of PFASs are considered as non-threshold**
- **Emissions are used as a proxy for risk**
- **Effectiveness of the proposed restriction is based on the effectiveness of emission reduction**

Analysis of alternatives

- Alternatives already adopted in many sectors/uses
- For some sectors alternatives already identified but time needed to implement or alternatives not available in sufficient quantities (e.g. industrial food and feed production)
- In other sectors research and development still needed (e.g. medical devices)

Justification for EU wide measures

- **Manufacture, import and uses in EU**
- **Global market with growing volumes**
- **Large variety of emission sources**
- **Ubiquitous presence and increasing levels in environmental media**
- **PFASs are mobile and cross borders**
- **EU internal market: level playing field**

EU-wide risk reduction measures: Implement control efficiently and uniformly

PFAS – some specifics of the restriction proposal



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Proposed restriction: Ban

Ban on manufacture, use and placing on the market



- As substances on their own
 - As a constituent
 - A mixture
 - An article
- } ≥ 25 ppb for any PFASs
} ≥ 250 ppb for sum of PFASs
} ≥ 50 ppm* for PFASs

* If total fluorine exceeds 50 mg F/kg the manufacturer, importer or downstream user shall upon request provide to the enforcement authorities a proof for the fluorine measured as content of either PFASs or non-PFASs.

Restriction Options (RO's) assessed

RO1

Full ban of all uses

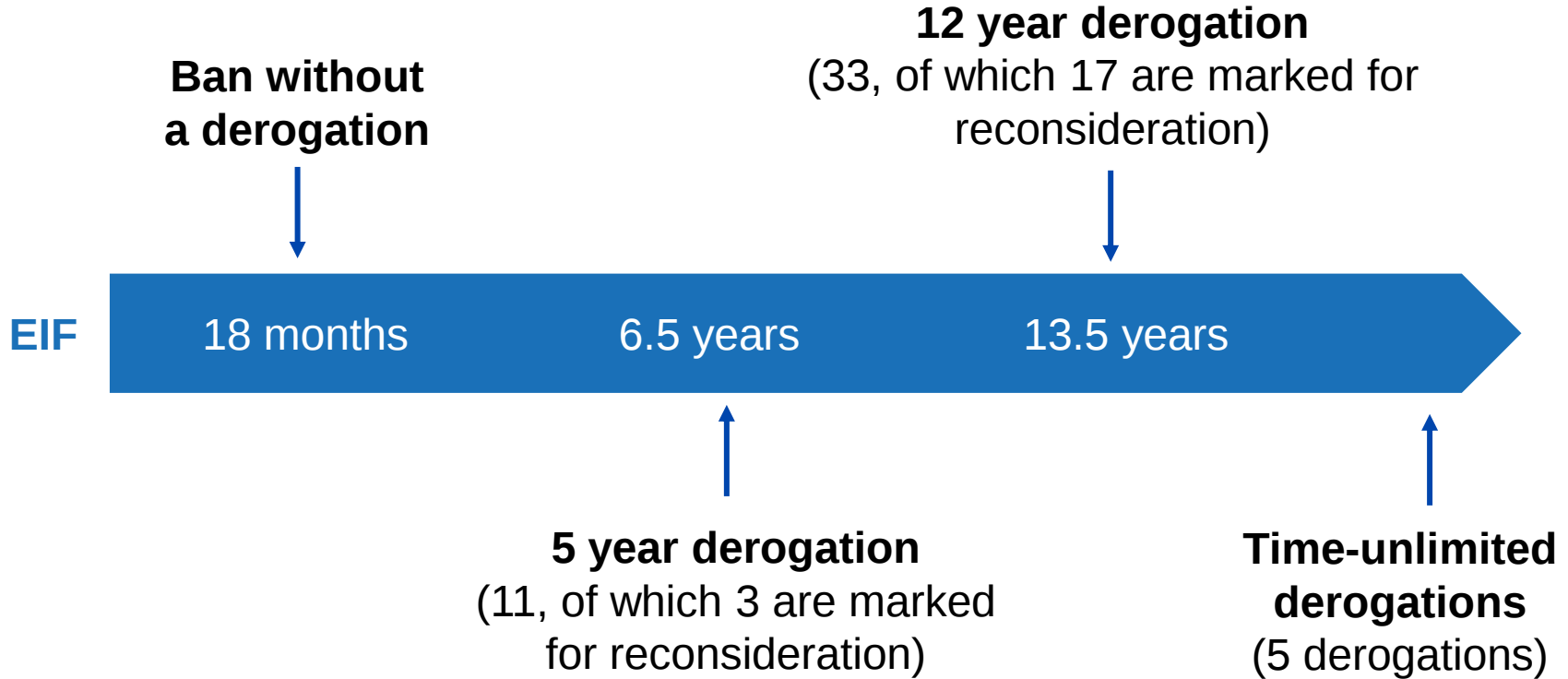
- Transition period: 18 months

RO2

Ban with use-specific derogations

- Transition period: 18 months
- Duration of derogation:
 - 5 years (based on set criteria relating to alternatives)
 - 12 years (based on set criteria relating to alternatives)
 - Time-unlimited derogations (specifically justified)

Phase-out timelines



Proposed restriction: Reporting

Mandatory reporting in relation to majority of derogations

Who

- Active substances: Manufacturers, importers
- Uses of fluorinated gases & uses with 12 year derogation period:
 - Substance & articles: Manufacturers, importers
 - Mixtures: Formulators

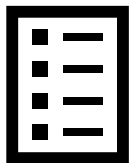
What

- Information on the use (which derogation)
- Identity and quantity of substance placed on market



Proposed restriction: Management plan

Requirement for a site-specific management plan in relation to fluoropolymers and perfluoropolyethers when making use of derogations



Who

- Importers and downstream users

What

- Identity of the substances and the products they are used in
- Justification for the use
- Conditions of use
- Safe disposal

PFAS – key take home messages

Summary

- PFASs, both unrestricted and restricted, are widely present in humans and the environment
- Broad group restriction for PFAS – time-limited derogations (RO2)
- Based on very high persistence and supporting concerns
- Need for regulatory measures on an EU wide level
- 4.5 million tonnes of PFAS emissions over next 30 years without a restriction (96% reduction with RO1, somewhat less with RO2)

Next steps – key messages

- **Public Consultation 22 March – 25 September 2023**
- **Well-substantiated scientific evidence as input is key**

