Aligning policies with real-world medical needs

The bridging role of HCP organisations in the EMA-ECHA regulatory overlap

Case study: The Universal PFAS Ban

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How can healthcare professionals ensure that EU chemical and medical policies truly meet patients' needs?

Ophthalmology recently faced this issue

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January 2023

Submission of restriction proposal to ECHA

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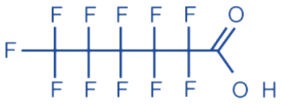
Proposal was submitted by Germany, Denmark, Sweden, Norway and Netherlands

Proposed restriction: BAN

on manufacture, use and placing on the market of poly- and perfluoroalkyl substances (PFAS)*

as substances on their own, constituent, mixture and article

Perfluorinated



Polyfluorinated

PFASs are defined as **fluorinated substances** that contain at least one fully fluorinated methyl or methylene carbon atom (without any H/Cl/Br/I atom attached to it), i.e. with a few noted exceptions, any chemical **with at least a perfluorinated methyl group (–CF3) or a perfluorinated methylene group (–CF2–)** is a PFAS.

OECD (2021) PFAS definition

*Whether all hydrogen on the fluorinated carbon chain are replaced by fluorine (i.e. **perfluoro**) or not (i.e. **polyfluoro**)

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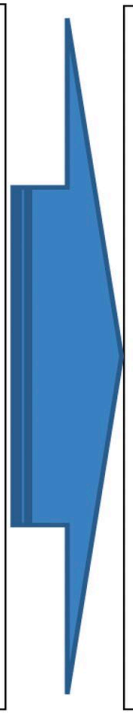
What are the concerns about PFAS?

PFAS are dangerous for enviroment and human health

Properties
Very high persistence
Long-range transport potential
Mobility
Accumulation in plants
Bioaccumulation potential
Ecotoxicity
Endocrine activity
Effects on human health



Concerns related to combinations of properties
High potential for ubiquitous, increasing and irreversible exposures of the environment and humans;
Difficulty to decontaminate intake water for drinking water production, 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.

> 10,000 PFAs available

PFAS are widely used:

- fire-fighting foams
- Water-repellant textiles
- Oil-repellant textiles
- Leather
- Food contact materials
- Cosmetics
- **Medical devices**
- **Medicines**
- **Coating**
- **Packaging**
- Semiconductors
- **Pharmaceuticals**
- Biocides, etc.

Contamination happens at any time of PFAS life

If releases are not minimised, there will be an **increasing and irreversible exposure** of the enviroment and humans with **inevitable adverse effects.**

https://echa.europa.eu/documents/10162/f605d4b5-7c17-7414-8823-b49b9fd43aea

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What would this restriction mean in OPHTHALMOLOGY?

Multiple **PFAS-containing medical devices** are currently used in Ophthalmology

- Most of the available **Ocular Endotampoandes (OEs)**
- Ocular **drug delivery systems** e.g. for cyclosporine
- Rigid Gas-Permeable (**RGP) Contact Lenses**
- Coatings and materials in **ophthalmic optics / lens coatings**
- **Rinsing agents** for other substances used in eye surgery
- Theatre equipment components (e.g. PTFE/FEP/PFA tubing and FFKM seals)

PFAS were not examined separately for ophthalmic use in the Restriction Report and not specifically mentioned among the medical devices

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In addition, **the case of PFAS in Ophthalmology represents a**

CROSS BOUNDARY REGULATORY ISSUE

between EU MDR and REACH regulation

Concerns

- **Do regulators have a full picture of PFAS use in medicine?** The 2023 ECHA Restriction Report lists ONLY **lenses** (contact & ophthalmic) and **ophthalmic solution packaging**

- **How to engage with ECHA as clinicians?** Healthcare professionals (HCPs) are not formally embedded in ECHA's processes as they are at EMA (HCPWP).

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We engaged in a coordinated effort

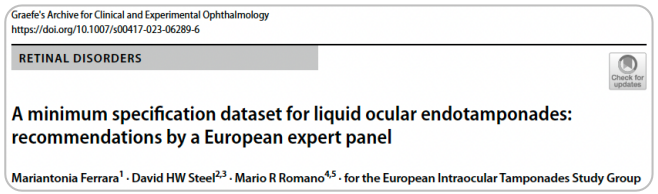
EU EYE

- **Dual-regulation issue** reported to the EMA's HCP Policy Officers Group
- **Application filed for derogation** from PFAS restriction for use in ophthalmology, based on the available literature and epidemiologic data

EURETINA

(EU EYE's member)

- a European expert panel developed **minimum specification datasets** on Ocular Endotampoandes


Graefe's Archive for Clinical and Experimental Ophthalmology
https://doi.org/10.1007/s00417-023-06289-6

RETINAL DISORDERS

Check for updates

A minimum specification dataset for liquid ocular endotamponades: recommendations by a European expert panel

Mariantonia Ferrara[1] · David HW Steel[2,3] · Mario R Romano[4,5] · for the European Intraocular Tamponades Study Group

- a **Special Focus Group** developed recommendations to minimise the emission/use of PFAS-containing OEs and move toward a more **environmentally friendly practice**

During the public consultation period **> 5600 comments** were sent to ECHA regarding the restriction proposal

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EU EYE's and EURETINA's comments

Aim: to highlight the baseline situation and the **potential impact** of a restriction on PFAS used as tamponade agents in vitreoretinal surgery (VR)

Unmet clinical need

The ban will lead to:

- **compromised quality of care**
- significant increase of **severely sight-impaired/blind people**
- **job loss** in working-aged population

Irreplaceability

Irreplaceable role as

- **long-terms OE** (C2F6, C3F8, HSO)
- **intraoperative tool** (PFD, PFO)
- **SO rinsing solution** (F6H8, F4H5)

Absence of alternatives

- There is **no available alternative** for PFD, PFO, HSO, F6H8, F4H5
- Air, SF6 and SO **presents significant limitations** as alternative to C2F6/C3F8

Specific contribution

The **contribution of PFAS for ophthalmic use** to the global production is **minimal.**

What did we ask for?

Exemption from the restriction or **time-unlimited derogation** due to their **essential use** in VR surgery

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Keep in mind!

The **domino effect** of PFAS restriction **does not stop within ophthalmology** practice

Keep in mind!

Ophthalmology practice level

- **compromised quality of care**
- significant increase in severe **vision impairment/blindness**
- significant increase of **direct medical cost and indirect costs** per patient
- **productivity loss** due to the involvement of working-aged population

EMA level

- increasing **vulnerability of supply chains** and supply chain disruptions
- increasing **risk for shortages** with impact on the Union List of Critical Medicines
- **increased workload** within the transition period (regulatory re-approval of end product).

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Outcomes to date

- **Vision applications** have been introduced in Section A.3.10.2.2.Invasive Medical Devices **in the updated background ECHA document** (PFAS-based rinsing agent as example of PFAS-containing MD)
- **Waiting for decision** of European Commission about the proposed recommendation for a derogation for PFAS-contaning medical devices

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Learning points in regulatory science for EU EYE

Effective engagement requires:

- Mindset shift from **'do no harm' on individual level** (medical needs/diseases) to **collective responsibility at system level** (emissions & waste management)

- Understanding the varying, and sometimes conflicting, demands of different regulatory bodies in target audience and type of **evidence required** (e.g. medical specialties vs industry sectors for medical devices)

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HCPs have the potential to act as a bridge between regulatory science and clinical practice

Why is this important in the context of EMA / ECHA regulatory regimens?

They can contribute to

- Strengthen **inter-agency cooperation** (e.g. Joint opinion or Coordination)
- **Tailor REACH and EU MDR processes to clinical reality** (potentially including the classification, labelling and packaging (CLP) regulation)
- **Enriching policies** with **pragmatism** and **alignment** with real-world medical needs
- **Achieve meaningful and evidence-based derogations** leading to reduced workloads and improved monitoring of supply-chain risk
- **Ensuring bidirectional information** between frontline practitioners and regulators

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Although it may be out of EMA's scope, the PFAS case (still ongoing) demostrates the critical role of HCPs in:

- **shaping meaningful regulatory decisions** through input of cross-domain expertise (clinical practice needs + exposures)
- **translating regulatory decisions into clinical practice**: e.g. communicating risk-mitigation for chemicals in products used in clinical practice

Thank you for listening