EUROM I

Brussels, 31. August 2023

EUROM 1 Comment on Proposed Restriction of PFAS

Dear Sir/Madam,

We appreciate the opportunity to provide comments on an Annex XV Report that proposes a restriction on per- and polyfluoroalkyl substances (PFAS) under REACH. European Federation of Precision Mechanical and Optical Industries (EUROM) supports the information submitted by SPECTARIS and confirms that the technical requirements outlined within their report are reflective of the entire industry. The part of EUROM representing Optical Industries is EUROM I.

As such, EUROM I also request that the following derogation is permitted under point 5:

'By way of derogation, paragraphs 1 and 2 shall not apply to plano lenses and ophthalmic lenses until 13.5 years after EiF'.

EUROM I Membership and Importance to Society
EUROM I is the European Federation gathering 8 national associations of manufacturers of optical lenses, frames, and equipment for opticians[1]. Members of EUROM I are:

- AEO-Asociación Española de Fabricantes de Optica (Spain)
- ANFAO-Associazione Nazionale Fabbricanti Articoli Ottici (Italy)
- OSA-Federation of Manufacturing Opticians (UK)
- GIFO- Groupement des Industriels et Fabricants de l'Optique (France)
- Optics Swiss Suppliers Association (Switzerland)
- SPECTARIS-Deutscher Industrieverband für optische, medizinische und mechatronische Technologien e.V. (Germany)
- VisionPAC-The Vision Council (USA) as an associate member.

The members represent 85 % of the European industry and employing about 60.000 people in the EU.

Visual health is critical to the welfare of EU citizens, with 3 out of 4 adults having visual problems and an expected 5 billion people experiencing short sight in the world in 2050.[2] The products in the sector include Medical Devices (prescription frames and ophthalmic lenses) and plano lenses which provide no vision correction but provide critical functionality for safety. Examples of plano lenses include sunglasses, goggles for motorcycles, personal protective equipment for occupational (i.e. impact resistance eyeglasses, laser protection system, liquid, gas, dust protection mask) and sport (i.e. cycling, skiing, running), blue light blocking glasses for computer, mobile devices, and any

[1] Eurom | European Federation of Precision Mechanical and Optical Industries
[2] The optical industry in France - GIFO

activity requiring prolonged observation of digital screens. All of which require the same technical performance as ophthalmic lenses, and without which pose a safety hazard.

The sector is characterised by its investment in research and development in sophisticated of lenses. Manufacturers have developed tailor-made industrial processes to be able to offer highly elaborate products manufactured, according to the specific needs of the end user. This results in countless correction formulas and comfort requirements of each manufacturer, all of which will need sufficient time to identify and qualify PFAS-free alternatives where possible.

Technical Requirements

PFAS are used in lens anti-smudge coatings (also called hydrophobic and/or oleophobic topcoats) to contribute to vision safety by reducing reflection and protecting against UV radiation and high-energy visible light. The hydrophobic layer is particularly of importance for use in traffic during rain. Traffic safety (cyclist/pedestrians) can be impacted as sight is impaired by rain. The coating also ensures the long-term durability of the lens by protecting against scratches and soiling. This also reduces the need for chemicals used for in-service cleaning and improves the environmental footprint of the devices due to their increased longevity. PFAS-free alternatives do not offer the necessary technical performance as outlined in the SPECTARIS technical report. In extreme cases alternatives may significantly disturb/worsen vision, such as in changing and difficult light conditions. In addition the forced use of PFAS-free alternatives would result in significantly increased waste as the lifetime of the lens would be significantly shorter compared to lenses using PFAS coatings.

Alternatives must be researched and tested to determine whether they can be used in a functionally equivalent manner. In addition, they must be assessed and permitted for their use in light of existing regulations (e.g. Medical Device Regulation, Personal Protective Equipment Regulation, and safety standards) in order to prevent conflicting regulation.

It is estimated that once an alternative is identified a period of at least 13.5 years is required as outlined by the following Table of qualification requirements.

Qualification Stage	Estimated time
Identification of technically viable alternative	Unknown (>10 years)
Testing of alternative of materials	6+ months
Pre-study testing by research institutes and material/technology suppliers to identify suitable characteristics	2+ years
Reliability testing	1+ year
Redesign of product for alternative solution	6+ months
Testing of in-situ performance	1+ year
Product specific requirements (e.g., documentation for conformity)	3 months
Global approvals	6+ months
Roll-out of alternative solution to the specific factory conditions in each location, potentially changing processing parameters to minimise and standardise remaining rest reflection on the lens and check quality standards. The review of the processes requires specific technical resources and personnel which are finite, so this is unable to be undertaken in parallel. Labelling and packaging adaptations to meet specific market and product requirements.	2+ years
Total time to develop	**>13.5 years**

PFAS coatings on lenses are applied via vacuum deposition, the waste of which is collected and disposed of according to local legislation.

The use of PFAS is fundamental in order to:

- Improve vision.
- Increase safety, especially in critical situations like bad lighting conditions, driving, and occupational safety.
- Ensure the long-term durability of the lens by protecting against scratches and soiling.
- Reduce the need for chemicals used for in-service cleaning and improves the environmental footprint of the devices due to their increased longevity.
- Reduce waste as the lifetime of the lens would be significantly longer compared to lenses without PFAS coatings.

Derogation under point 5 of the restriction

Currently the potential derogation k is listed under section 6 of the restriction, but this is limited to 'fluoropolymers and perfluoropolyethers'. Due to the use of non-polymeric forms of PFAS in the manufacturing process, it is recommended that the derogation is moved under section 5 of the restriction.

Key Requests

In order to meet environmental and climate protection goals of the EU Green Deal and maintain the proper safety and performance level it is critical that:

- A derogation is permitted for 'plano lens and ophthalmic lenses' for 13.5 years.
- The derogation to be permitted under point 5 of the restriction.
- The PFAS restriction proposal must provide for a quick and straightforward procedure to extend the validity period of derogations if technical alternatives are not able to be developed in the envisaged timeline.

On behalf of EUROM 1