EssilorLuxottica

EssilorLuxottica Group´s contribution to ECHA´s public consultation on the U-PFAS restriction under REACH

NON-CONFIDENTIAL VERSION

20th September 2023

EssilorLuxottica

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Introduction

EssilorLuxottica Group ("ELG"), a French-Italian multinational, is a global leader in the design, manufacture and distribution of ophthalmic and plano lenses, frames and sunglasses. ELG results from the combination of Essilor International (Compagnie Générale d'Optique) and Luxottica in 2018. Its mission is to help people around the world see more by addressing their evolving vision needs. ELG brings together the complementary expertise of two industry pioneers, one in advanced lens technology and the other in the craftsmanship of iconic eyewear, to set new industry standards for vision care. Influential eyewear brands including Ray-Ban® and Oakley®, lens technology brands including Varilux®, Transitions® and Crizal®, and world-class retail brands including Sunglass Hut, LensCrafters, Salmoiraghi & Viganò and GrandVision are part of the EssilorLuxottica Group.

Plano and ophthalmic lenses are eyeglasses lenses that provide either no vision correction (plano) or vision correction (ophthalmic). Both lens types can include applications such as sun protection and safety glasses and can be clear, photochromic and tinted. Ophthalmic lenses require a refractive prescription from an ophthalmologist or optometric physician. They correct refractive errors such as myopia, hyperopia, presbyopia, and astigmatism. Ophthalmic lenses are classified as medical devices of class 1 under the EU Medical Device Regulation (EU) 2017/745. Plano lenses overall cover lenses subject to the Personal Protective Equipment (PPE) Regulation EU/2016/425, which includes sunglasses. Ophthalmic and plano lenses are often treated with coatings either in the manufacturing process including photochromic coatings or scratch resistant coatings which give the lenses additional functionality, features and benefits which are recommended by eye care practitioners and/or desired by consumers.

Ophthalmic lenses must be surfaced with the wearer's specific lens prescription as determined by an ophthalmologist or optometrist[1]. This customization activity is performed by an optical prescription laboratory, also called an Rx Lab. An Rx lab may also apply additional coatings to clear or photochromic lenses which provide different functionality, features and benefits recommended by eyecare professionals to align with wearers of glasses' needs (e.g. antireflective coatings, hydrophobic and/or oleophobic topcoats, tints, gradients and mirror coatings). Ophthalmic lenses must be cut to the appropriate shape of the eyeglass frames selected by the wearer and then mounted into said frame, prior to being dispensed by an eyecare professional. Prescription eyeglasses are only available by interfacing with an eyecare professional. Plano lenses may also be edged and mounted into frames and sold as complete pair of eyeglasses directly to wearers by retailers.

Transitions Optical Limited ("TOL"), established in 1991 in Tuam, Ireland is a wholly owned affiliate of ELG. It was the first company to commercialize plastic photochromic lenses and is global market leader with control of design, development and contract manufacturing of photochromic molecules (dyes) and lenses. TOL or its affiliated contract manufacturers apply

[1] Except Finished Single Vision lenses, which are produced with a prescription already in them.

TOL's proprietary technology to clear and tinted lenses to make photochromic lenses. Photochromic lenses are adaptive light management lenses automatically adapting to changing light (i.e. they darken when outdoors and exposed to sunlight and return back to clear when indoors).

Essilor International (SAS) ("EI"), a wholly owned subsidiary of EssilorLuxottica, is a worldwide leader in eyeglass lens. It offers an extensive range of advanced ophthalmic lenses technologies that help address and correct visual health issues such as myopia, hyperopia, astigmatism and presbyopia. Every Essilor lens is a combination of multiple complementary technologies, including innovative brands such as Crizal®.

ELG's premium brand of antireflective coating for ophthalmic and plano lenses is **Crizal®**. As part of the antireflective coating, hydrophobic and/or oleophobic **topcoats** are required to protect the antireflective layer and reduce the strong tendency for smudge to stick on the lens. Hydrophobic and/or oleophobic topcoats protect lenses from fingerprints and smudge, and provide easiness to clean properties. These key functions of the hydrophobic and/or oleophobic topcoats are enabled through it containing PFAS substances (i.e. topcoats are typically solutions which composition comprises a silane modified polyfluoropolyether group). Hydrophobic and/or oleophobic topcoats thereby ensure clearer and safer vision while strength and durability of the lenses are improved.

ELG's premium brand of photochromic lenses is **Transitions®**. **Photochromic coatings** provide the photochromic property (light sensitivity and molecular changes to light) on ophthalmic and plano lenses.

After recent investigations with suppliers of topcoats, those may not be considered polymeric PFAS but rather PFAS substances or oligomeric PFAS mixtures. Those substances seem not be covered by the proposed wording in 6k.

Therefore, ELG in line with its industry association Spectaris, EUROM1 and GIFO would like to request - instead of the proposed derogation under 6k - a derogation under paragraph 5, with a proposed new wording to ensure that hydrophobic and/or oleophobic topcoats and photochromic coatings with a different PFAS chemistry than fluoropolymers and perfluoropolyethers are also included:

ELG is pleased to provide its contribution to the public consultation on the universal PFAS restriction. **We will provide information on PFAS use in hydrophobic and/or oleophobic topcoats as well as photochromic coatings of ophthalmic and plano lenses.**

Derogation under reconsideration in the restriction dossier	Proposed change
*6. By way of derogation, paragraphs 1 and 2 shall not apply to **fluoropolymers and perfluoropolyethers** for the use in (k) [Rigid gas permeable contact lenses and **ophthalmic lenses** until 13.5 years after EiF];*	5. By way of derogation, paragraphs 1 and 2 shall not apply to: plano lenses and ophthalmic lenses until 13.5 years after EiF;
	Justification:
	Chemistry is *not limited to fluoropolymers and perfluoropolyethers*, and wording should include the additional use for *plano lenses* compared to the initial 6k to cover hydrophobic and/or oleophobic topcoats and photochromic coatings on these lenses.

We complement this public contribution with a confidential contribution.

1. Sectors and (sub-)uses

This contribution applies to the **medical sector**, with the sub-use of ophthalmic lenses as well as the **optical sector**.

In the U-PFAS restriction dossier, the sub-use is partially listed in 6k as potential derogation marked for reconsideration after the Annex XV report consultation.

*"By way of derogation, paragraphs 1 and 2 shall not apply to **fluoropolymers and perfluoropolyethers** for the use in [Rigid gas permeable contact lenses and **ophthalmic lenses** until 13.5 years after EiF];"*

This contribution supports and complements the contribution of our industry associations Spectaris, EUROM1 and GIFO.

This derogation request covers more specifically the uses of PFAS in hydrophobic and/or oleophobic topcoats and photochromic coatings detailed below.

Hydrophobic and/or oleophobic topcoats

Hydrophobic and/or oleophobic topcoats (also called antismudge coatings) for plano and ophthalmic lenses are typically solutions which composition comprises a silane modified polyfluoropolyether group.

Recent investigations with our suppliers for topcoats indicated that the chemistry used is not limited to fluoropolymers which consists of another chemistry than those covered in 6k.

Photochromic coatings

The coating technology used in Transitions photochromic lenses consists of a resin matrix working in unison with photochromic dyes and other additives (i.e. stabilizers and catalyst) to provide the photochromic functionality.

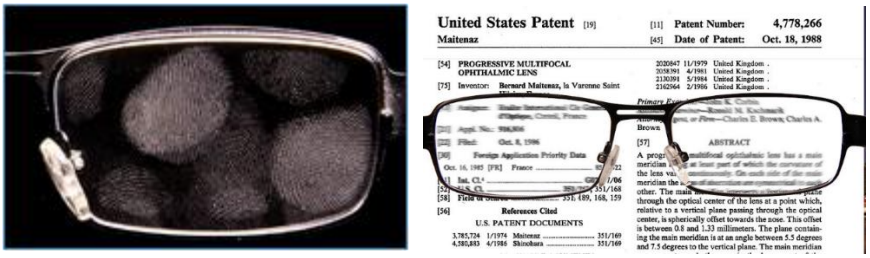
2. The key functionalities provided by PFAS for the relevant use.

2.1. Key functionalities of PFAS in hydrophobic and/or oleophobic topcoats for plano and ophthalmic lenses

ELG, as the leader in the ophthalmic industry, has been innovating for more than 30 years to provide their wearers the products fitting their needs and providing key benefits for a smoother daily use of plano and ophthalmic lenses. Hydrophobic and/or oleophobic topcoat overall ensures clearer vision and contributes to vision safety. Among the benefits it provides to a lens, antismudge resistance can prove to be important. The presence of smudge on the lens would indeed impair the vision of the wearer, which could potentially lead to situations such as driving in unsafe conditions.

One can distinguish different steps in the severity of smudge effect. A thin smudge layer will have a small effect on the visible light transmission of the lens, but there will be possibly a shift of residual colour of the antireflective coating. With a thicker smudge layer, the reflection increases, and the diffusion appears. In addition smudge will alter the contrast by scattering (Figures 1 & 2).

Figure 1: Antireflection coated lens with smudge: reflection increases and diffusion appears.



United States Patent [19]
Maitenaz

[11] Patent Number: 4,778,266
[45] Date of Patent: Oct. 18, 1988

[54] PROGRESSIVE MULTIFOCAL OPHTHALMIC LENS

[75] Inventor: Bernard Maitenaz, la Varonne Saint

[57] ABSTRACT

Figure 2: Alteration of contrast by scattering due to smudge (fingerprints)

Antireflective coating, at microscopic level, provides an irregular surface in which dirt composed of aqueous or lipidic molecules can lodge. In fact, these thin layers of coating are relatively porous and greasy pollutants and impurities can become encrusted in the pores of the top layer. To overcome this, techniques borrowed from the manufacture of electronic components are used. These consist of coating the surface with an extra layer, giving it oil- and water-resistant properties.

These coatings work in 3 ways:

- They repel molecules of oily matter and reduce their adherence by creating a very weak surface force;
- They act against migration of the molecules of oily matter into the microscopic pores of the antireflective coating by closing the interstitial gaps;
- They facilitate their removal by making the lens surface very slippery.

This antismudge coating is extremely thin – in the order of only a few nanometers (10^{-9} meters). It consists of chemical components containing a silane modified polyfluoropolyether group.

It is common practice to coat ophthalmic and plano lenses, with successively, starting from the surface of the lens substrate, an impact-resistant coating (impact resistant primer), an abrasion- and/or scratch resistant coating (hard coat) and an antireflective (AR) coating. The antireflective coating is made of several mineral layers and the outermost layer is the topcoat layer, also called antismudge coating (Figure 3).

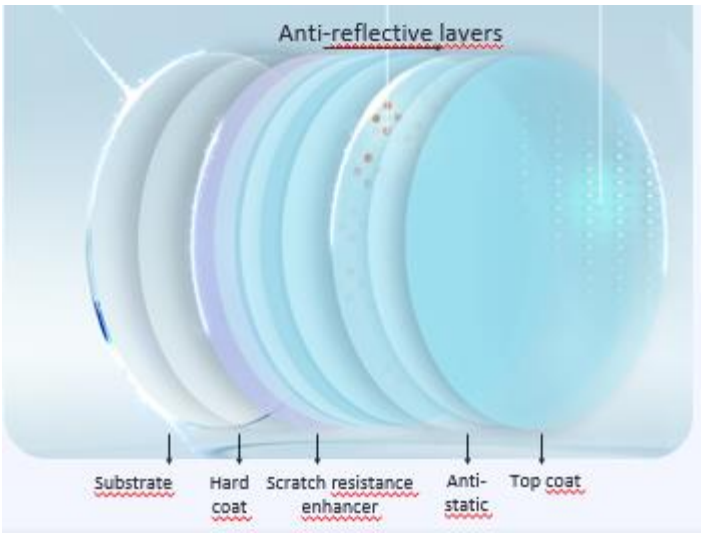


Figure 3: Typical structure of antireflective coating with topcoat

The use of hydrophobic and/or oleophobic topcoat to provide easy to clean lenses is now considered indispensable in the industry. All lenses (plano or ophthalmic) coated with antireflective coating have a topcoat layer to avoid smudge adhesion and facilitate cleaning.

Such antismudge coating is a hydrophobic and/or oleophobic topcoat, which reduces the surface energy of the lens to avoid the adhesion of fatty stains, which are thus easier to remove. The higher the increase in contact angle, the higher is the possibility to get the lowest smudge adhesion and lowest sliding angle possible, thereby achieving good cleanability.

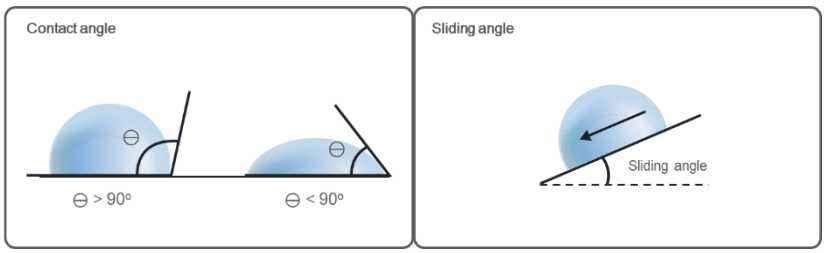


Figure 4: representation of contact angle and sliding angle methodology of measurement

Edging antireflective lenses, especially polycarbonate lenses, requires more effort. The hydrophobic and/or oleophobic topcoat also improves the edging results on the antireflective lenses and thus reduces the loss of lenses and production waste.

The following chart shows wearers' key expectations from an ophthalmic lens. Clarity of vision, scratch resistance, anti-glare, easiness to clean, UV protection and smudge resistance properties provided by topcoat are considered especially important by wearers.

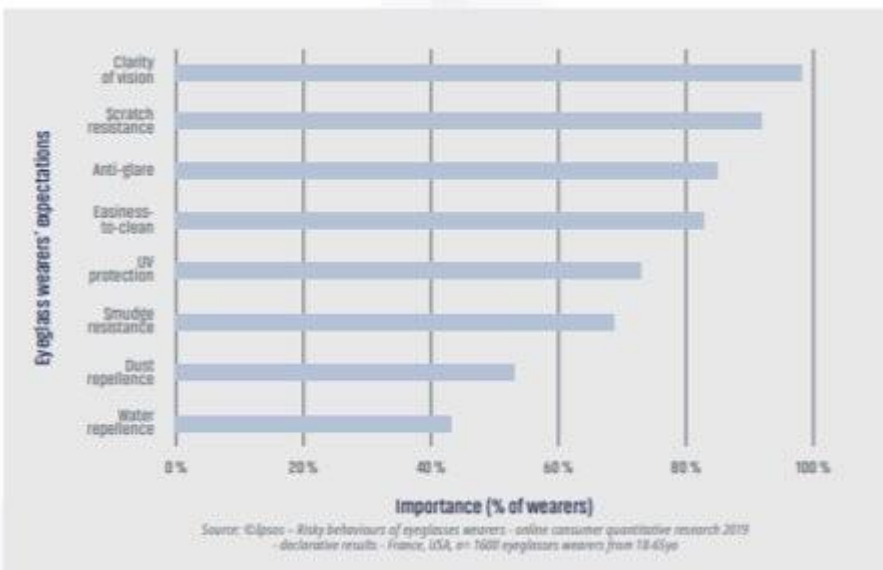


Chart 1. Eyeglass wearers' expectations from an ophthalmic lens

2.2. Key functionalities of PFAS in photochromic coatings for plano and ophthalmic lenses

Photochromic coatings enable the ophthalmic and plano lenses to automatically react to changing light. Transitions lenses darken to category 3 darkness in the presence of UV/visible light when outdoors and return back to clear when indoors. Transitions' PFAS **photochromic dye** molecules make light, dark and every shade in between possible.

When photochromic lenses are exposed to UV light, the photochromic molecules in the lens begin to change structure. This reaction is what causes the lenses to darken.

For the **photochromic** lenses, no PFAS emissions to the environment or the consumer during use are expected as the finished goods article containing the photochromic coating (which contain the PFAS substance) are held within a "sandwich" of other layers.

3. Identification of Alternatives

3.1. Hydrophobic and/or oleophobic Topcoats in plano and ophthalmic lenses

Unlike what is stated in the restriction dossier, no non-PFAS alternatives meeting the technical performance requirements for topcoats have been identified at present. We are referring to the clarifications of our industry associations Spectaris, EUROM1 and GIFO on this.

Plano and ophthalmic lenses have to comply with the following standards:

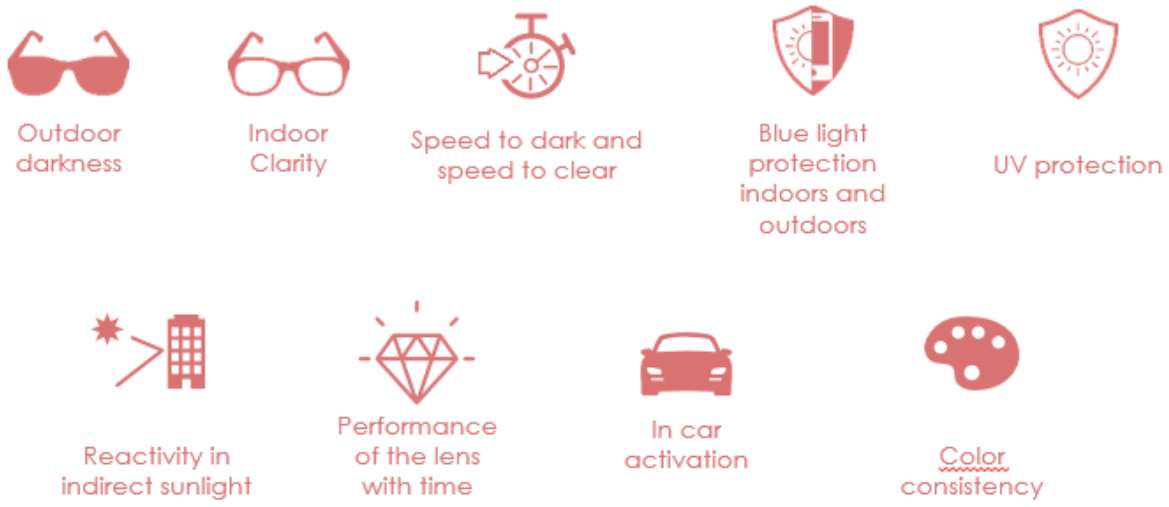
- ISO 8980-1,2,3,4,5
- ISO 14889
- ISO 10993-1, 5,10

- ISO 12312-1
- EN 14139
- ISO 16034
- ISO 21987
- ISO 10322-1, 2
- ANSI Z80.31
- ANSI Z80.1
- ANSI Z80.3
- ANSI Z87.1
- EN166
- New ISO 16321-1
- QB/T 2506
- GB 10810-1, 2, 3, 4, 5
- AS/NZ 1067-1
- AS/NZ 1337-1 & 6
- CSA Z94.3

3.2. Photochromic coatings in plano and ophthalmic lenses

When photochromic lenses are exposed to UV light, the photochromic molecules which contain one CF3 group begin to change structure. This reaction is what causes the lenses to darken.

Research done by Transitions Optical has identified the following attributes of photochromic performance as important to eyeglass wearers.



Photochromic lenses with photochromic coatings have to comply with the following international industry **standards** of lens and photochromic lens performance:

- ISO 8980.3 2013 (6.2.2; 6.3; 6.3.2; 6.3.5; 6.4.1.2; 6.5)
- ISO 14889 2013 (4.3.1; 4.3.2; 4.4)
- ANSI Z80.3 2018 (4.10; 4.10.3; 4.10.1; 4.10.2.3; 4.11.4; 4.14; 4.10.2.2; 4.3; 4.2; 4.8)
- AS/NZS 1067 2016 (5.2; 5.3; 5.3.4.1; 5.3.1; 8.0; 9.0; 5.3.2.3))
- ISO 12311 2013
- ISO 12312 2013 (5.2; 5.3; 5.3.2.2; 5.3.4.1; 5.3.1; 8.0; 7.2; 5.3.2.3)
- CNIS 13.340.99 (5.2.1.1)

For more detailed information please refer to the confidential contribution.

4. Socioeconomic analysis

4.1. Socio-economic impact for Topcoats

Socio-economic impact on ELG customers & wearers for hydrophobic and/or oleophobic topcoats

Without a topcoat, the cleanability of the eyeglasses will be very poor, which would further have a negative impact on vision clarity for eyeglass wearers. The smudge will stick on the eyeglasses, making the lenses become translucent and no longer transparent. Thus, eyeglasses would have to be cleaned several times a day and this could lead to unsafe situations such as during driving, or when doing sports. In rainy conditions topcoats further ensure avoidance of water staying on the lenses. Without the topcoat, wearers for instance in micro mobility (e.g. cycling, kick-scooters) would be impacted by a degraded vision.

Antireflective coatings are first and foremost meant to reduce light reflections and manage the light around the wearers. An absence of topcoat will make the light scatter and significantly impede light management in conditions such as driving at night. Indeed, under such a condition, antireflective coatings help to reduce light reflections surrounding the driver and reduce the halo of light around the headlights of the car.

Difficulties to clean the antireflective coated lenses would certainly bring about a change in consumer behaviour, with a shift back to hardcoats. This would worsen vision clarity and durability of the lenses. Indeed, lenses with only hardcoat layers have lower scratch resistance and the clarity of vision would be greatly affected. The transparency of the lenses with antireflective coating is almost 7% higher than without.

We have run sensory analysis with trained consumers to assess the difference between lenses with only a hardcoat and lenses with antireflective coating in simulated night driving conditions. The criteria to assess the difference were sharpness of vision, contrast, luminosity of the headlights, luminosity of the halo of light around the headlights and intensity of glitter.

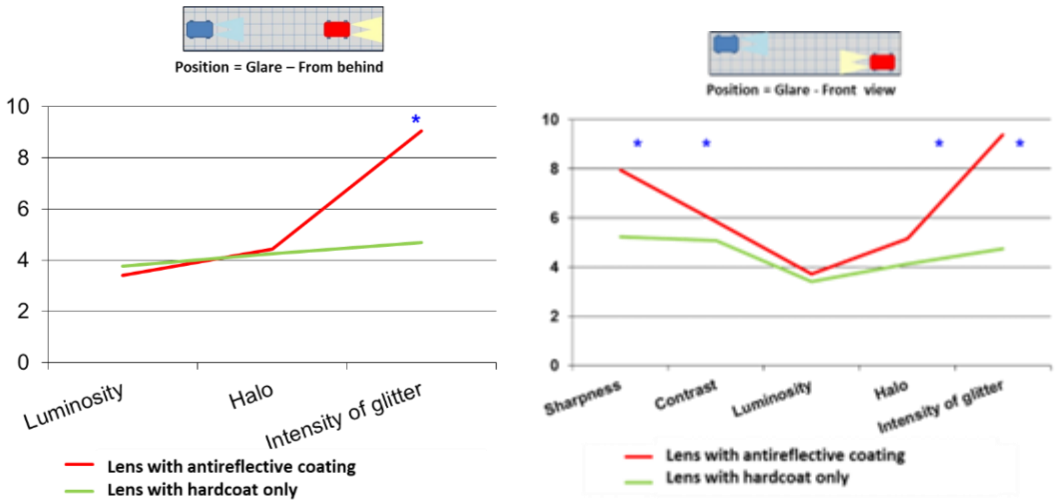


Figure 5: sensory analysis realized with trained consumers with an external lab in simulated night driving conditions testing the benefits of antireflective coating versus hardcoat only lenses.

When driving, lenses with antireflective coatings was perceived as significantly better than lenses with hardcoat only across all assessed criteria and situations. It should be noted that in terms of luminosity, there is no difference as the lenses are clear and to assess this criterion efficiently the use of a tinted lens would be required. This confirmed that lenses with antireflective coating with a topcoat instead of a hardcoat only ensures better safety conditions. A restriction of PFAS use in topcoats would therefore jeopardise 30 years of research and reverting to product performances from before the 1950s.

4.2. Socio-economic impact for Photochromic coatings

Socio-economic impact on ELG customers & wearers for photochromic coatings

One of the major consequences would consist in TOL's direct customers in the EU, comprising both ELG affiliates and non-affiliated entities no longer being able to sell TOL´s most technologically advanced products and this would have a significant detrimental impact on their businesses, bottom line and the wider ophthalmic lens and eyecare industry in Europe. This could have significant wider implications in terms of viability of businesses and job losses across the supply chain (optical wholesalers, laboratories, retailers and eye care professionals) in Europe.

TOL is and has been a market leader in photochromic technology for over 30 years, and further strives to continuously achieve improvements in patients' eye health and vision. To that end, it continues to innovate and provide the best products to consumers amongst other with increased protection against harmful ultra violet (UV) radiation and filtering of blue-violet light inside and outdoors and quick activation of category 3 darkness, and reduced eye sensitivity to light. The newest developments of photochromic resins have also improved benefits in low light conditions and faster visual performance which will allow wearers to see contrasts faster, better and quicker which will increase safety overall.

Such innovation and improvements have also been spurred by identifying patients' perceived challenges and needs in terms of eye health and vision. One such study was carried out on the sentiment and behaviors of eye care professionals and consumers and their perception of challenges and potential opportunities in relation to eye health and vision.

In total for the year 2022, 477 eye care professionals - including in Italy, France and the USA - and 4510 eye glass wearers in nine countries globally participated in the study. The importance of protection and especially the preservation of vision to wearers was evidenced in the results of the study. 84% to 89% of consumers indeed confirmed the importance of an optimal level of protection at all times and the preservation of their vision including from blue-violet light and of preserving the health of their eyes.

Wearers also shared their perception on experienced optical problems. Among the key findings of the report for the year 2022, consumers reported:

- 73% of consumers frequently deal with light sensitivity (with sources of light including glare from natural and unnatural sources, the sun, changes in light, and indoor lighting).
- 83% expressed their preference for one solution to manage both UV and blue-violet light.
- 80% desired eyewear (lenses and frames) with long lasting performance even at a higher cost.
- 36% report discomfort and difficulty seeing in bright sun.

Among the key findings of the report for the year 2022, eyecare professions reported:

- 80% reported that patients are asking more often for solutions to prevent visual fatigue.
- 78% reported that patients are less willing to compromise on eye protection.
- 78% reported that patients were expressing more symptoms related to increased exposure to potentially harmful blue-violet light.
- 69% reported that patients are increasingly interested in light management and protection.
- 69% reported that patients mentioned experiencing eye fatigue more frequently.

This study confirms that both patients and eyecares professional want more from their eyewear than just vision correction.

Concluding remarks

ELG is committed to developing and manufacturing high performance ophthalmic and plano lenses with the most technically advanced methods. In this contribution, two use cases involving PFAS were described for which a very limited use of PFAS is made and which contribute significantly to improving the performance of lenses and thereby support the improvement of eye health and safety of consumers. While striving to achieve the highest standards for our products, great care is dedicated to minimizing waste, handling waste properly and minimising emissions to the environment by using advanced technologies.

In developing our products, ELG has strived to meet the needs of consumers, a majority of which encounters common challenges, including experiencing light sensitivity, eye strain, headaches and exposure to harmful UV radiation and blue-violet light, as well as safety concerns. In response to these challenges, ELG continues in its best efforts to innovate and bring solutions to consumers in terms of vision health and safety.

Topcoats on ophthalmic and plano lenses are required to protect the antireflective layer and reduce the strong tendency for smudge to stick on the lenses. They protect lenses from fingerprints and smudge, and provide easiness to clean properties. Topcoats thereby ensure clearer and safer vision while strength and durability of the lenses are improved.

Photochromic coatings containing are enablers of critical functions in lenses, including outdoor darkness, indoor clarity, blue-violet light filtration and UV protection, faster fade back speed, reactivity in indirect sunlight, durability, in colour consistency.

At present, no PFAS-free alternatives for topcoats have been identified meeting the required functions. No suitable alternatives meeting the required functions have been found for photochromic coatings either.

Therefore, ELG, in line with its industry associations Spectaris, EUROM1 and GIFO, would like to request instead of the proposed derogation under 6k, a derogation under paragraph 5, with a proposed new wording to ensure that topcoats and photochromic coatings with a different chemistry than fluoropolymers and perfluoropolyethers are included:

(5) “By way of derogation, paragraphs 1 and 2 shall not apply to: plano lenses and ophthalmic lenses until 13.5 years after EiF.”