

EuromContact comments on the assessment of the PFAS use in Rigid Gas Permeable (RGP) contact lenses in the restriction proposal

[Rigid gas permeable contact lenses until 13.5 years after Eif] is a potential derogation marked for reconsideration after the Annex XV report consultation in the restriction proposal [Condition of restriction 6.k.]. EuromContact would like to provide below supportive evidence and clarifications on the information or assumptions in the report, to enable robust assessment by the Committees.

EuromContact General Comments:

- The Annex XV Dossier Submitters have proposed a potential 13.5 year derogation for ‘Rigid gas permeable (RGP) contact lenses’. Within this submission, EuromContact has provided evidence that **a time-unlimited (unconditional) derogation for the use of PFAS in RGP contact lenses would be more appropriate and proportional** than a time-limited (13.5 year) derogation, both in terms of risk and potential socioeconomic impact.
- Please note that a derogation, if granted, should **incorporate all types of RGP contact lens**, including scleral lenses, corneoscleral lenses, composite (hybrid) lenses, orthokeratology lenses and corneal contact lenses (which are often referred to as RGPs) as they all utilise the same base materials. This is consistent with the definitions presented in the relevant ISO standard EN ISO 18369-1:2017 Ophthalmic optics — Contact lenses — Part 1: Vocabulary, classification system and recommendations for labelling specifications.
- The proposed potential derogation references fluoropolymers and perfluoropolyethers for use in Rigid gas permeable contact lenses. However, the polymers used in RGP contact lenses are fluorinated side chain polymers, not fluoropolymers. **The derogation should apply to monomers, and to polymers incorporating them**, for use in RGP contact lenses.
- Currently, in the Annex XV report, **RGP contact lenses and ophthalmic lenses (glasses)** are combined together into one category. Please note that these are completely different medical devices and the risks and socioeconomic impacts of restricting PFAS use with each **should be considered separately**.
- EuromContact requests that the Annex XV PFAS Restriction Report is amended, taking into account the responses given below, in order to correct inaccuracies in the current version of the Report.

ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs)

[p. 100] Table 8. RO1 - Summary table of alternatives and cost impacts for PFAS manufacture and major PFAS use sectors resulting from a full ban of PFASs

Use sector (with sub-uses)	Alternatives	Cost impact
Rigid gas permeable (RGP) contact lenses	Alternatives are widely available, but there is weak evidence that these alternatives are not technically and economically feasible. Conclusion: Low substitution potential at Eif [weak evidence]	A transition away from PFASs could lead to some negative socio-economic impacts in terms of: - Quality-of-life reductions for users of RGP contact lenses The information provided does not allow for quantification of these impacts.

EuromContact Response 1, Alternatives:

EuromContact strongly disagrees with the assumption that alternatives are widely available. In reality, no suitable chemical or technical alternatives are currently available, nor have any potentially viable alternatives been identified/proposed.

RGP contact lenses are used to restore vision in the case of **several specific conditions, which cannot be treated alternatively with glasses nor soft contact lenses** (Please see annex Bii of this submission for further details). In a survey ran among 513 Eye Care Professionals through the European Council For Optometry & Optics, 91% of respondents declared that they would no longer be able to treat their patients with irregular corneas if RGP contact lenses were no longer available, 90% that they would no longer be able to treat their patients with keratoconus (over a million people in the EU). The respondents estimated that on average 81% of their current RGP patients could no longer be treated (52%) or would be treated with less effective alternatives (29%).

EuromContact confirms the low substitution potential at EiF of the restriction and calls for a time-unlimited (unconditional) derogation. No technically and economically feasible alternatives to PFAS have been identified to manufacture RGP contact lenses. In a survey ran among polymer manufacturers, all acknowledged, that despite R&D efforts, substitution is not technically or economically feasible (see more details in Response n°3 below).

Replacing the PFAS in RGP contact lenses with any of the currently available chemical alternatives would cause the performance level of RGP contact lenses to drop to a point where the safety and eye health of wearers will be compromised. This has been demonstrated in a scientific paper (Eddleston M. D., Raduly L., Tapper T. T., Hughes R. J., Browne G. M. and Conway M. J. 2023. The Consequences of Removing Fluorinated Compounds from Rigid Gas Permeable Contact Lenses. Journal of Polymer Engineering. <https://doi.org/10.1515/polyeng-2022-0189>. See confidential attachment to this submission).

The current complete absence of viable alternatives and the extreme difficulty of replacing PFAS in RGP contact lenses in future is highlighted both by industry researchers and an independent consultancy in annex E of this submission (Eddleston M. D. 2023. The Essentiality of PFAS for Rigid Contact Lenses) and in a confidential attachment.

EuromContact Response 2, Cost impact

EuromContact confirms that a transition away from PFAS will have a negative impact on the quality-of-life for users of RGP contact lenses and would like to provide the following additional information to allow quantification of these impacts.

In a survey ran among 513 Eye Care Professionals through the European Council For Optometry & Optics, the anticipated impacts for patients who could no longer be treated with RGP contact lenses due to a total ban on PFAS are :

- **reduced quality of life for 94% of respondents ;**
- **very poor vision for 89% of respondents ;**
- **inability to drive for 78% of respondents ;**
- **inability to work for 74% of respondents.**

They estimated that 44% of their current RGP patients would have a visual acuity of less 6/12 in both eyes if they could only use soft contact lenses or glasses to correct their vision.

95,7% of the respondents identified specific health and safety risks to patients if they can no longer treat them with RGP :

- use of old/out of date medical device for 75% of respondents
- patients will source unregulated devices from outside EU for 65% of respondents.

The socioeconomic cost of these negative impacts on RGP contact lens wearers has been calculated to be over €5.68 billion per year. This exceeds the costs of potential negative health effects from environmental exposure to the PFAS used in RGP contact lenses (and potential remediation costs) by many orders of magnitude. Any form of restriction would, therefore, be highly disproportionate. Please see annex F of this submission for further details (Eddleston M. D. 2023. An analysis of risk and socioeconomic impact for PFAS in RGP contact lenses).

[p. 130] Table 9. RO2 - Summary table of derogations ('proposed' or 'for reconsideration') for PFAS manufacture and major PFAS use sectors, with substantiation for the derogation period (5 or 12 years) and with cost impacts for the 5 and 12 year derogation periods.

Use sector (with sub-uses)	Proposed derogation or derogation for reconsideration	Duration of derogation period, including substantiation	Cost impact of 5 and 12 year derogation periods
Rigid gas permeable (RGP) contact lenses	Given the weak evidence that technically and economically feasible alternatives are not available at EiF, the following potential derogation is marked for reconsideration after the Annex XV report consultation: [Rigid gas permeable (RGP) contact lenses	Ban with a transition period of 18 months and a 12-year derogation, because identification, development and certification of alternatives would take more than five years to complete [weak evidence base]. Continued R&D increases the chance that alternatives for the relevant applications will be identified.	Ban with a transition period of 18 months and a 5-year derogation: Same as under RO1, i.e. uncertain costs. Ban with a transition period of 18 months and a 12-year derogation: If feasible alternatives are identified, developed and approved, the eventual socio-economic costs due to reduced functionality of the devices would be avoided.

EuromContact Response 3:

Despite much research, no non-PFAS contact lens monomer, or combination of monomers, has been identified that comes close to replicating the level of performance which can be achieved using fluorinated species (see annex E of this submission, Eddleston M. D. 2023. The Essentiality of PFAS for RGP Contact Lenses and the scientific paper Eddleston M. D. *et al.* 2023. The Consequences of Removing Fluorinated Compounds from Rigid Gas Permeable Contact Lenses. *Journal of Polymer Engineering*. <https://doi.org/10.1515/polyeng-2022-0189> submitted as a confidential attachment to this submission). In addition, no viable alternatives are apparent from other sectors of industry (see annex E of this submission). **This lack of suitable alternatives has been confirmed in a study conducted by an independent consultancy** (see a confidential attachment to this submission).

Silicone methacrylates/acrylates have been suggested as an alternative to PFAS by the Dossier Submitters, however, they are not effective in preventing eye infections and maintaining the eye health of wearers (see annex E of this submission). **RGP contact lenses present a unique challenge as alternatives must**

replicate not only the inertness and deposit resistance of PFAS, but also the oxygen permeability, optical clarity, dimensional stability and hardness, and there is no guarantee of success.

PFAS are chemically irreplaceable as the element fluorine has unique advantages which can never be replicated, no matter how much research is performed. **Without PFAS, a detrimental and permanent drop in RGP contact lens performance is almost inevitable** (see annex E of this submission).

From a socioeconomic perspective it has been calculated that if removing PFAS causes even a slight drop in the performance of RGP contact lenses (< 1%) the negative impact of restricting the use of PFAS in RGP contact lenses on wearers far outweighs the minimal environmental costs of continued use. Not only is RO1 completely inappropriate in the context of RGP contact lenses, but RO2 is also disproportionate as it introduces the very real danger that patients will be forced to adopt inferior products at the end of the derogation period, a scenario with socioeconomic costs that are greatly in excess of those anticipated with continued PFAS use in RGP contact lenses (see annex F of this submission - Eddleston M. D. 2023. An analysis of risk and socioeconomic impact for PFAS in rigid contact lenses).

[p. 154] h) Evaluation of environmental impacts of RO2 relating to medical devices

(ix) Potential derogation marked for reconsideration: Rigid gas permeable (RGP) contact lenses and ophthalmic lenses

The derogation is marked for consideration for a duration of 12 years after EiF of the restriction and the 18 months transition period. Compared to a ban (RO1), a derogation will cause additional polymeric PFAS emissions. There is no evidence available about the precise amount of additional emissions from this derogation. However, considering available information about the use quantity of about 1 t/y, it is assumed that additional emissions will be of a small fraction compared to emissions under the reference scenario 16 116 t extra emissions (=full derogation of polymeric PFAS)

EuromContact Response 4:

The environmental impacts of RO2 (or of an unconditional derogation) are expected to be minimal. In the environment, **the monomers and polymers used in RGP contact lenses will eventually degrade to the arrowhead species trifluoroacetic acid (TFA)**. TFA is a naturally occurring PFAS which, though highly persistent, is not toxic or bioaccumulating (and so not PBT or vPvB). A 2023 United Nations Environment Programme report on the risks of trifluoroacetic acid concluded that **global emission levels do not pose a concern for the public or the environment, even when extrapolated to the year 2100**. Moreover, TFA is not a 'forever chemical' as it reacts with hydroxyl radicals in the troposphere to form non-PFAS products. Please see annexes D and F of this submission for further details (Eddleston M. D. 2023. The Fate and Toxicity of Fluorinated Substances in Contact Lenses and Eddleston M. D. 2023. An analysis of risk and socioeconomic impact for PFAS in RGP contact lenses).

The continued use of PFAS in RGP contact lenses does not pose an unacceptable risk to human health and the environment (see annex F of this submission).

**Annex A to the
ANNEX XV RESTRICTION REPORT**

[p. 83] A.3.10.1.10. Vision applications – contact lenses and ophthalmic lenses

Rigid gas permeable contact lenses rely on PFAS currently and typically use fluoromethylacrylates. Major suppliers of the blanks for rigid gas permeable contact lenses are based outside the EU and supply the blanks (referred to as buttons within this industry) into the EU where they are then formed into contact lenses for specific customers by EU companies. The buttons are then converted into contact lenses for two main uses: fitting sets and prescription lenses. Prescription lenses typically may need replacement every 12 months.

[Annex E to the](#)
[ANNEX XV RESTRICTION REPORT](#)

[p. 321] Vision applications – rigid gas permeable contact lenses and ophthalmic lenses

For rigid gas permeable (RGP) contact lenses, both technical and chemical alternatives exist. Technical alternatives include glasses and soft hydrogel contact lenses. In most cases these alternatives are more comfortable, softer or cheaper but have not been a useful solution for the user, implying that RGP contact lenses have superior characteristics.

Fluorinated methacrylate monomers have been introduced into the polymer matrix as a complement to the predominantly silicone methacrylate structure of the 1st generation gas permeable products. The silicone/fluorine part of the polymer gives the product its high oxygen transmissibility, while the methacrylate enhances optical quality and stability. Higher amounts of silicone tend to have detrimental effects on lens performance, including poor surface wettability, greater protein deposition, increased flexure and instability, and decreased lens durability. The incorporation of fluorine monomers helps to overcome many of these shortcomings, thus significantly improving the overall performance of the RGP products. In short, the 1st generation is an available alternative, but it has lower technical functionality in some respects.

The Dossier Submitters note that alternatives are widely available for both applications, but that stakeholder input indicates that these alternatives lead to articles with lower functionality for (some of) the users. The importance of these differences in functionality needs further justification for a derogation to be considered.

The Dossier Submitters conclude that the evidence is [weak] that technically and economically feasible alternatives are [not generally available] for the quantities required for use in [vision applications] and that the substitution potential is [uncertain].

EuromContact Response 5:

While the **technical and chemical alternatives proposed by the Dossier Submitters for RGP contact lenses** are, or could be made, widely available, their adoption **would have devastating consequences for the 3.24 million current wearers of RGP contact lenses in the EU** (see Responses 1-3 above), so they are simply not viable alternatives.

The 1st generation of rigid contact lenses cannot be considered as an available alternative. Polymethylmethacrylate (PMMA) and silicone methacrylate contact lenses do not allow sufficient oxygen to pass through. Their inability to allow in oxygen makes them hard to wear and adapt. **Wearing lenses with a low oxygen permeability can compromise eye health and increase susceptibility to infections.** The essentiality of PFAS for achieving the beneficial properties in RGP contact lens materials (including 'non-stick' qualities (deposit resistance), oxygen permeability (mainly through -CF₃ groups), biocompatibility, chemical inertness (to resist tear fluids, UV from sunlight and atmospheric pollutants over 1-3 years), comfort, wettability, rigidity, manufacturability, hardness, durability, scratch resistance and shape (dimensional) stability) has been demonstrated in a scientific study (attached to this contribution as a

confidential attachment (Eddleston M. D., Raduly L., Tapper T. T., Hughes R. J., Browne G. M. and Conway M. J. 2023. The Consequences of Removing Fluorinated Compounds from Rigid Gas Permeable Contact Lenses. Journal of Polymer Engineering. <https://doi.org/10.1515/polyeng-2022-0189>). The criticality of these properties for the effective performance of RGP contact lenses has been confirmed by many leading eye care professionals. For example, “If these very important material properties are reduced or eliminated, then a significant number of patients with very challenging eye conditions simply will not be able to function visually and leaving them without being able to maintain their work. It would reduce quality of life dramatically” and “[a]fter years of research to optimize the characteristics of RGP materials, guaranteeing greater oxygenation of the cornea and reducing the interaction of materials with lipid and protein deposits, these indications [banning of PFAS used in RGP contact lenses] from the EU take us back 50 years.” (see annex E of this submission)

The importance of the differences in functionality between current PFAS devices and alternatives is described above and in annexes E and F of this submission. In particular:

- **glasses and soft contact lenses cannot restore proper vision (a visual acuity of 6/12, which equates to the ability to drive) for 44% of current RGP users;**
- PMMA and silicone methacrylate rigid contact lenses are not viable alternatives considering the risks posed by their low oxygen permeability.

Both Euromcontact and Spectaris submitted reports to the 2021 PFAS consultation which evidenced why the alternatives mentioned above by the Dossier Submitters are unsuitable and/or insufficiently safe and protective of eye health for rigid contact lens wearers. The Dossier Submitters have made the conclusion that ‘alternatives are widely available’ without offering any corroborating evidence or assurance that these alternatives are appropriate and safe for rigid contact lens wearers. This conclusion is inaccurate, and potentially damaging to RGP contact lens wearers.

[p. 335] E.2.9.4.9. Vision applications – rigid gas permeable contact lenses

For rigid gas permeable (RGP) contact lenses, the assessment of alternatives indicates that both technical and chemical alternatives are widely available. According to information provided by the sector organisation Spectaris the technical alternatives (including eyeglasses and soft hydrogel contact lenses) are generally more comfortable or cheaper, but users still prefer RGP contact lenses, which indicates that RGP contact lenses have other superior characteristics (RINA, 2021). Spectaris also claims that the chemical alternative has lower technical functionality in some respects. The Dossier Submitters note that a ban on PFAS could have negative impacts on the quality of life for users of RGP contact lenses, but the severity of these impacts is unclear.

According to the sector organisation EUROMCONTACT, a ban on PFAS in RGP contact lenses soft contact lenses and ophthalmic solutions packaging would result in job losses in a range of 1 800 to 2 000 across production, packaging and distribution operations for the affected products sold within the EU, assuming that no alternatives are available (second stakeholder consultation).

The Dossier Submitters note that alternatives are available, but that a transition away from PFAS could lead to some negative socio-economic impacts. The information provided does not allow for quantification of these impacts. Further justification on the severity of the quality-of-life reductions and the increased costs due to more frequent replacements of eyeglasses is required to conclude on the magnitude of the socio-economic impacts of a ban on PFAS in these applications.

The Dossier Submitters conclude that the socio-economic costs of a ban on PFAS in these applications is [uncertain].

EuromContact Response 6:

It should be noted that the 3.24 million users of RGP contact lenses do not ‘prefer’ them over other forms of vision correction, they have a **medical need** for them.

The severity of impacts on users of RGP contact lenses has been outlined in Response 2 above and is described in detail in annex F of this submission (Eddleston M. D. 2023. An analysis of risk and socioeconomic impact for PFAS in RGP contact lenses).

In the light of the comments above, the socioeconomic impact of the quality-of-life reductions faced by RGP contact lens wearers if PFAS use is restricted far exceeds the environmental impact of the use of the ultra-short chain PFAS in RGP contact lenses (emission of only 4t/year, which will degrade to the low-risk arrowhead species trifluoroacetic acid). A full socioeconomic analysis has been performed, see annex F of this submission.