An analysis of risk and socioeconomic impact for PFAS in rigid gas permeable contact lenses.

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Executive Summary

A ban on the use of PFAS in rigid gas permeable (RGP) contact lenses would be detrimental to wearers as PFAS are critical to device performance and no suitable alternatives are available. Without PFAS, the risks of infection for wearers will increase and fewer people will be able to tolerate using RGP contact lenses. For many current wearers, RGP contact lenses provide a level of vision correction that cannot be matched by alternatives such as soft contact lenses or spectacles.

It is estimated that for 214,007 RGP contact lens wearers in the EU a ban on PFAS would be devastating as not only would they no longer be able to wear their lenses, but also they would no longer be able to work, drive and enjoy the same quality of life, as vision correction with soft contact lenses or spectacles would be inadequate. The corresponding economic cost to the EU is estimated to be €5.68 billion per year.

There is a significant risk that a PFAS ban would result in the collapse of the RGP contact lens sector. If RGP lenses were unavailable in the EU, the estimated number of current wearers who would no longer able to work and drive would increase to 1.43 million, with a corresponding economic cost to the EU of €37.8 billion per year.

The PFAS used in RGP contact lenses are not considered to be harmful to workers or to contact lens wearers. In the environment, the polymer manufactured for use in RGP contact lenses each year will degrade to generate 1.44 tonnes of trifluoroacetic acid. This is a small percentage of the trifluoroacetic acid which is produced each year by natural processes (3,432 tonnes) and by other industries (50,000 tonnes produced from refrigerants alone).

The environmental risks associated with trifluoroacetic acid are currently minimal, and even if remediation were required in future, the proportion of the associated costs attributable to RGP contact lenses would be thousands of times lower than those anticipated for the EU if PFAS use in RGP contact lenses were banned.

The balance of risk and socioeconomic impact strongly favour the continued use of PFAS in RGP contact lenses. Moreover, it is estimated that the health cost associated with environmental emissions of PFAS, extrapolated from figures in the PFAS Annex XV report to the manufacture of RGP contact lenses each year, calculated over the entire lifetime of that PFAS, is €73.71, so anything other than a full, non-time limited derogation would be disproportionate.

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1. Evaluation of risk

1.1 Risks associated with continued use of PFAS in RGP contact lenses

There are an estimated 3.24 million wearers of RGP contact lenses in the EU. This figure is based on reports that 13% of contact lens wearers are fit with RGP contact lenses[1] and that the total number of soft contact lens wearers in Europe is 21.7 million.[2] This indicates that the total number of contact lens wearers in the EU is around 24.94 million (13% of this figure being 3.24 million).

Almost all of the RGP contact lenses worn by these patients are manufactured from PFAS (fluorinated side-chain) polymers.

1.1.1 Environmental risks

Generally, the manufacture of RGP contact lenses generates solid PFAS waste from three main sources:

- Waste swarf generated during the manufacture of polymer buttons (5 main polymer manufacturers, all located outside the EU).
- Waste swarf generated during lens manufacture from polymer buttons (60 lens manufacturers located in the EU).
- Contact lenses discarded after 1-2 years of use (see Figure 1).

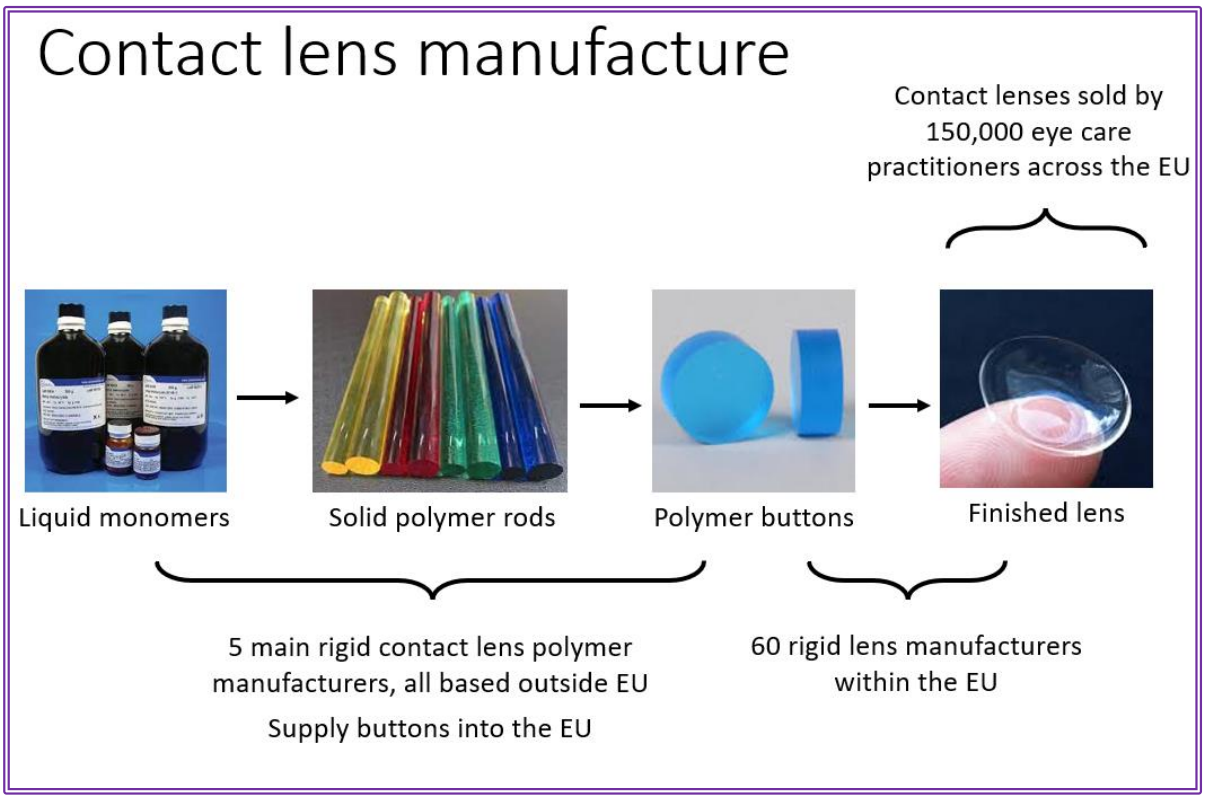

Figure 1. An overview of the RGP contact lens manufacturing process.

A survey of RGP contact lens polymer manufacturers and finished contact lens manufacturers identified that approximately 2.74 tonnes of waste is generated from the production of RGP contact lenses for the EU market each year by the 37 companies who responded to the survey.[3] Given that not all of the around 65 relevant manufacturers responded to the survey, that the respondents were typically the larger companies, and that the survey did not take into account finished contact lenses (which make up around 5% of the mass of the polymer used in their manufacture), it can be estimated that **the total mass of PFAS used in the manufacture of RGP contact lenses for the EU market is approximately 4 tonnes per annum.**

During RGP lens polymer manufacture, liquid monomers, some of which are PFAS,[4] are polymerised to generate solid rods which are then trimmed/lathed down into buttons (see Figure 1). This trimming process is approximately 50% efficient. As the five main manufacturers of polymer buttons for the EU market are located outside the EU, this indicates that only 2 tonnes of PFAS for RGP contact lens manufacture are utilised within the EU each year.

The liquid PFAS monomers which are used in RGP contact lens manufacture, hexafluoroisopropyl methacrylate (HFPM, CAS 3063-94-3), trifluoroethyl methacrylate (TFEM, CAS 352-87-4) and bis-hexafluoroisopropyl itaconate (BHI, CAS 98452-82-5), are not predicted to meet the criteria for classification as bioaccumulating or toxic.[4]

RGP contact lens PFAS polymers have undergone numerous cycles of safety testing, including cytotoxicity and ocular irritation assessment, as part of regulatory submissions over the past 40 years, without adverse findings, and are regarded to be inert and harmless in their as-prepared solid form.

In the environment, breakdown of RGP contact lens polymer is expected to be slow, but eventually the fluorinated groups within the polymer will be liberated and ultimately converted into the arrowhead PFAS species, trifluoroacetic acid (TFA).[4]

It is calculated that for every 1 tonne of RGP contact lens polymer, 0.36 tonnes of TFA will ultimately be generated from environmental breakdown (see Figure 2). This suggests that **the annual manufacture of RGP contact lens polymer for the EU market (4 tonnes per year) may ultimately lead to the release of 1.44 tonnes of TFA (of which approximately half, 0.72 tonnes, may be released within the EU from the manufacture of finished lenses)**. This is a worst-case scenario, which assumes that none of the RGP contact lens PFAS waste is converted into non-PFAS products through incineration.

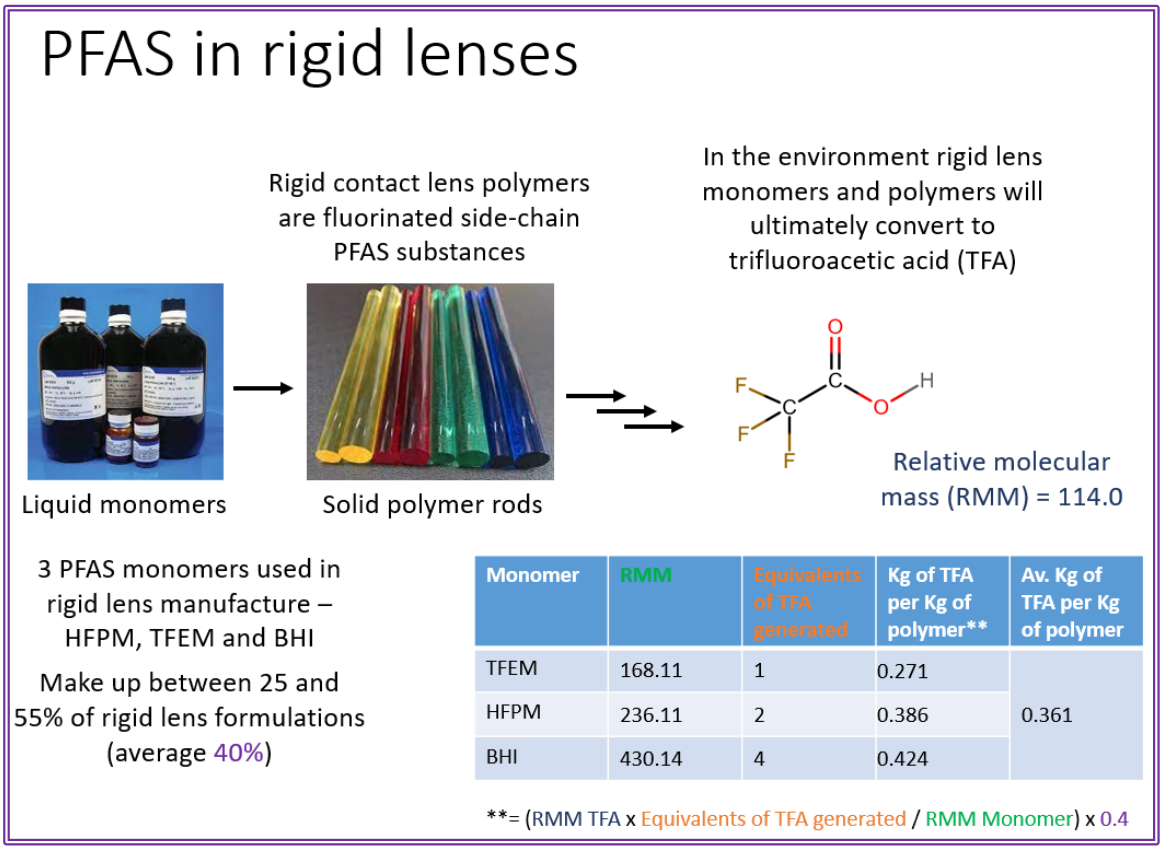

Figure 2. The generation of TFA from the environmental break-down of RGP contact lens monomers and polymers. TFEM = Trifluoroacetic acid, HFPM = hexafluoro-isopropyl methacrylate and BHI = Bis hexafluoroisopropyl itaconate.

TFA is a chemical which is persistent in the environment, despite being broken down by hydroxyl radicals in the troposphere,[4] and therefore presents a risk, as concentrations could potentially increase over time. An assessment by the UN Environment Programme in 2016, however, concluded that TFA is of low toxicity concern and that the environmental risks associated with the amounts of TFA that are generated from anthropogenic sources are “de minimis”, even taking into consideration terminal sinks such as salt lakes.[5-6] The low risk of TFA was recently reiterated,[7] and even when emissions up to the year 2100 are taken into account this substance is not predicted to pose an environmental or health concern.[7] Virtually all TFA generated from anthropogenic sources will end up in the seas and oceans where it will be almost infinitely diluted and will pose little risk as it is non-bioaccumulating.[4-8]

In relative terms, the amount of TFA generated from the manufacture of RGP contact lenses for the EU market is small. For example, it is reported that TFA is produced naturally in the environment at deep ocean hydrothermal vents. Each vent is estimated to produce 6 tonnes of TFA per annum,[5,9] and there are a minimum of 572 vents that have been identified globally (and the total number could be several times greater).[10-11] This suggests that **the amount of TFA resulting from the manufacture of RGP lens polymer for the EU market each year is a small fraction, < 0.042%, of that which is produced by natural processes per annum (minimum 3,432 tonnes), and so is**

insignificant in terms of global TFA levels. The natural production of TFA has recently been questioned,[12] but the existence of natural sources remains the only plausible explanation for many experimental findings.[7]

In addition, TFA is generated in large quantities from anthropogenic sources. It was reported that in 2020 the amount of TFA resulting from the atmospheric breakdown of two refrigerant compounds alone (HFC-134a and HFO-1234yf) totalled between 40,000 and 60,000 tonnes per annum.[7] Taking the mid-point of this range, 50,000 tonnes per annum, this means that **the amount of TFA resulting from the manufacture of RGP lens polymer for the EU market each year is less than 0.0029% of the yearly global total resulting from human activities**, even discounting the many other industrial sources of TFA.

The United Nations Environment Programme has asserted that the amount of TFA being generated from human activity will not cause any negative environmental or human health impacts until at least 2100,[7] even when increasing emission levels of TFA over that period are taken into account. In the 77 years between now and 2100, they predict that between 31.5 and 51.9 million tonnes of TFA will be generated from the breakdown of HFC-134a and HFO-1234yf alone.[7] Taking the mid-point of this range, this indicates that the emission of a further 41.7 million tonnes of TFA does not pose an environmental concern. Hypothetically, therefore, **if RGP contact lens polymer manufacture for the European market somehow became the only human activity generating TFA, and the level of lens production remained constant (which is a reasonable assumption given that the ratio of RGP contact lens sales to soft contact lens sales has decreased dramatically over the past 40 years), resulting in 1.44 tonnes of TFA for each year of RGP contact lens manufacture, this activity could continue for over 28.9 million years without negative environmental impacts occurring**.

In addition, the RGP contact lens sector is committed to improving waste management. It is a realistic target that at least 95% of PFAS waste will be segregated and processed in accordance with best practice in the near future. Given that there is increasing evidence that incineration can be optimised to fully break down PFAS into non-persistent products,[13-14] the already minimal environmental impact of PFAS in RGP contact lenses can likely be reduced by 95% in comparison to the scenario presented in this report.

Moreover, as TFA is broken down slowly by hydroxyl radicals in the troposphere,[4] and so is not a 'forever' chemical, environmental levels will reach a steady state assuming output remains constant. If RGP contact lens polymer manufacture was the only human activity generating TFA, environmental concentrations would equilibrate to far lower levels than are experienced today, and no harmful effects would ever be expected to occur.[4]

Not only is the environmental risk associated with TFA small, but the RGP contact lens sector makes a negligible contribution to that risk, both in comparison to natural and anthropogenic activities.

1.1.2 Risks to workers in the contact lens industry

The two main sources of potential risk to workers are associated with handling liquid PFAS monomers during polymer manufacture and with PFAS polymer dust generated during the lathing of polymer into buttons and into lens shapes.

However, across the industry, liquid handling is performed in fume cupboards and local extraction is used to protect staff from dust during lathing. Operators are trained to handle RGP lens materials and to wear appropriate PPE.

It should also be noted that there are no high toxicity concerns with either the PFAS monomers used in RGP lens polymer manufacture or the resulting polymers themselves.[4] While the toxicity and bioaccumulation of certain PFAS substances is a driving factor behind the proposed PFAS restriction, it has been found that both toxicity and bioaccumulation decrease by orders of magnitude as the length of chains of fluorinated carbon atoms within a PFAS substance decreases.[7,15-19] The fluorinated carbon atom chains in contact lens monomers and polymers are only one carbon atom long, and there is nothing to suggest that the PFAS monomers and polymers used in RGP contact lens manufacture are intrinsically more hazardous than those that are non-PFAS. The factor which distinguishes PFAS, as a group, from typical chemicals is their environmental persistence, and this does not impact people while manufacturing and wearing RGP contact lenses.

An alternative to PFAS RGP contact lens materials which has been proposed by the dossier submitters is silicone methacrylates/acrylates. A switch to silicone methacrylates would mean silicone levels would have to be increased in RGP contact lens formulations to achieve adequate oxygen permeability. The silicone most widely used in RGP contact lenses is 3-methacryloxypropyl tris(trimethylsiloxy)silane (TRIS, CAS 17096-07-0), a compound which has been classified by ECHA both as STOT RE 2 and as fulfilling the bioaccumulation and toxicity criteria of a PBT substance. While TRIS is not a particular health concern, it is noted that the PFAS monomers that are currently used in RGP contact lenses do not meet the criteria for either toxicity or bioaccumulation.[4]

1.1.3 Risks to RGP contact lens wearers

As stated above, RGP contact lens polymers have undergone numerous cycles of safety testing, including cytotoxicity and ocular irritation assessment, as part of regulatory submissions, without adverse findings. RGP contact lenses are expected to be chemically inert and harmless to patients throughout the duration of use. The safety of contact lenses for patients is established during medical device approvals within the EU and is beyond the scope of the REACH restriction process.

1.2 Risks associated with ending the use of PFAS in RGP contact lenses

1.2.1 Risks associated with decreases in lens performance.

Current RGP contact lens polymers typically have an oxygen permeability of around 100 barrers (barrers are a measure of oxygen permeability) and are effective at resisting lens deposits. For most patients, these characteristics enable RGP contact lenses to be worn safely and comfortably all day.

A majority of eye care practitioners (ECPs), however, have small numbers of RGP lens patients for whom additional performance is required in order for lens wear to be tolerated and/or to avoid deteriorating ocular health. These patients are typically treated with RGP lens materials specially designed to maximise oxygen permeability or deposit resistance. Such materials are currently available with oxygen permeabilities of up to 200 barrers (double that of a standard material). Despite this, some patients are unable to tolerate lens wear altogether. For example, in the advanced stages of keratoconus vision correction is only possible with RGP contact lenses, but lens discomfort becomes more prevalent and wear may be almost impossible or be reduced to a few hours per day.[20] Maximising lens performance in such cases is critical.

The European Council for Optometry and Optics (ECOO) estimate there are 150,000 ECPs within the EU,[21] out of whom 50,000 routinely work with RGP contact lenses.[22] Given that there are 3.24 million RGP lens wearers in Europe, this would suggest that every ECP specialising in RGP lenses treats approximately 60 RGP lens patients. Assuming that each of these ECPs has around 3 patients who require a highly oxygen permeable polymer in order to be able to tolerate lenses, it follows that 5% of RGP lens wearing patients have special needs in terms of lens material.

A scientific investigation of the performance characteristics of RGP contact lens polymers with and without PFAS has confirmed that removing PFAS monomers from currently available RGP lens polymers would inevitably result in a decrease in oxygen permeability and/or deposit resistance.[15] Without PFAS, the oxygen permeability of a typical RGP contact lens polymer which is effective at resisting lens deposits would decrease to approximately 30 barrers.[23] The corresponding maximum oxygen permeability achievable for a PFAS free RGP contact lens material might be expected to be 60 barrers (again, double that of the typical material), though such a material would have deficiencies in other aspects of performance, such as deposit resistance, comfort and rigidity. Clearly, the 5% of RGP lens patients who are currently unable to healthily wear materials with an oxygen permeability of 100 barrers would not be able to tolerate PFAS-free RGP contact lenses. Moreover, many patients who are currently wearing RGP contact lenses made from 100 barrer materials may become intolerant.

Contact lens intolerance is an even greater issue for ECPs who specialise in scleral lenses, which are used to treat conditions such as keratoconus and dry eye disease. Scleral lenses bridge over the cornea and so have to be made from rigid lens materials. They are larger than conventional RGP contact lenses, making them both expensive and difficult for wearers to insert into the eye, and they tend to be prescribed only when all other options have failed. They also tend to be much thicker, so oxygen

permeability is even more critical for the safety of wearers. It has been established that scleral lenses need to be made from materials which have an oxygen permeability of at least 125 barrers in order to maintain eye health.[24-25] As removing PFAS from RGP contact lenses would lead to materials having oxygen permeabilities of around 30 barrers,[23] it is expected that well over half of wearers of scleral lenses would become intolerant to their lenses. Given that 23% of all RGP contact lenses are scleral lenses,[1] these intolerant patients would equate to over 10% of the total population of RGP contact lens wearers.

Taking into consideration both conventional RGP contact lenses (who represent 77% of all RGP lens wearers, with over 5% expected to be intolerant) and scleral contact lenses (23% of all RGP lens wearers, over 50% expected to be intolerant), it is anticipated that the percentage of RGP contact lens wearers who would be intolerant to PFAS-free RGP contact lenses is at least 15% (minimum estimate = 5%, maximum estimate = 25%).

The greater comfort and convenience of soft contact lenses and glasses tends to mean that ECPs and patients only turn to RGP contact lenses when there is real need to do so, typically to achieve better visual acuity.[26] Putting this another way, any RGP lens patient who is no longer able to tolerate their lenses is at risk of a loss of visual acuity. It is expected that over half of RGP contact lens wearers would suffer a significant reduction in visual acuity if they were no longer able to wear their lenses (even if replaced by soft contact lenses or glasses). Among keratoconic patients, the proportion for whom RGP lenses provide better visual acuity has been found to be around 60%.[26-27] As the prevalence of keratoconus in the general public has been reported to be 1 in 375 in a European study,[28] and the 2022 EU population is 446,828,800 ,[29] the number of keratoconic patients alone within the EU whose eyesight is significantly improved by RGP contact lenses is estimated to be 714,926. In data provided by a UK hospital eye care clinic,[30] the numbers are higher still, with 71 out of 100 patients requiring RGP contact lenses for acceptable visual acuity. Each of these patients was first fit with soft contact lenses (being the quickest and most comfortable option), and only moved on to RGP lenses if vision was poor with the soft lenses (visual acuity Snellen score less than or equal to 6/12).

A survey of eyecare practitioners has established that, of the current RGP contact lens wearers who would no longer be able to tolerate their lenses without PFAS, 44% would be subjected to life-changing vision loss as a result (defined as a visual acuity of < 6/12 in both eyes. Minimum estimate = 25%, maximum estimate = 60%).[3] Such vision loss would compromise their capacity to drive, to work and/or to enjoy the same quality of life. In support of these estimates, a second UK hospital eye care practitioner has calculated that around 50% of their patients would have a visual acuity of 6/36 or less without RGP contact lenses, stating “If I was unable to correct these patients with RGP lenses their ability to function as a member of society would be severely diminished, they would be unable to drive and would almost certainly be unable to work”.[31] An estimated 3% of current RGP lens wearers would become clinically blind if they had to instead use soft contact lenses or glasses (defined as a visual acuity of < 6/60 in both eyes).

Using the conservative assumptions that 15% of the 3.24 million RGP contact lens wearers in the EU would be unable to tolerate PFAS-free lenses, that 60% of these intolerant patients would suffer a significant reduction in visual acuity without RGP lenses, that 44% of these intolerant patients would suffer severe sight loss and that 3% of these intolerant patients would suffer clinical blindness, it is calculated that **a ban on the use of PFAS in RGP contact lenses risks condemning 291,828 EU citizens to a significant degree of sight loss, of whom 214,007 would suffer a life-changing reduction in vision, with 14,591 becoming clinically blind** (if defined as a visual acuity of < 6/60 in both eyes).

A statement by the UK Hospital Optometrists Committee,[32] who estimate there are 60,000 wearers of medically necessary contact lenses in the UK hospital system alone who could be negatively affected by any PFAS restriction, provides further evidence that these estimates are reflective of reality.

1.2.2 Risks of increased incidence of contact lens related infections

The decreased performance of RGP contact lenses prepared without PFAS monomers will cause incidences of infection to increase amongst lens wearers. The lower oxygen permeabilities of PFAS free lens materials will cause a greater hypoxic challenge to patients, resulting in their cornea becoming more permeable to microbes and less able to fight infection.[15,23,33-36] Hypoxia also causes secretion of norepinephrine,[37-38] a hormone which is causally linked to eye infections.[37,39] In addition, the lower deposit resistance of PFAS-free materials will enable greater build-up of both lipids and proteins on lenses, promoting the adherence of microbes and increasing risks of infection.[23,40-41]

Microbial keratitis (MK) is the most serious form of contact lens related infection, and is sight threatening. The reported incidence rate with RGP contact lenses is 1.2 cases per 10,000 patients annually.[42] Among the 3.24 million RGP lens wearers in the EU this equates to 389 cases per year. A previous study found that 14.3% of MK infections result in sight loss,[43] suggesting that there are 56 incidences of MK related sight loss in the EU annually. **It is estimated that removing PFAS from RGP contact lenses would increase infection rates by an order of magnitude, resulting in an additional 3500 MK infections and 500 sight loss incidences per year**.

1.2.3 Risk of collapse of the RGP contact lens sector

There is a significant risk that the decrease in performance of RGP contact lenses caused by removing PFAS will drive practitioners into prescribing other forms of vision correction, such as daily disposable lenses to avoid putting at risk patient safety and eye health, even if the visual outcome is worse for patients, and that in turn the manufacture of RGP lenses will no longer be cost effective.

The RGP contact lens sector may collapse entirely leaving the 3.24 million patients that it serves without the lenses that they rely on for adequate sight correction.[23]

Another factor which increases the risk of the loss of the RGP contact lens sector enormously is the expected future restriction on PBT substances. The analysis of risk in Section 1.2.1 above assumes that silicones can be used to increase oxygen permeability in the absence of PFAS. However, TRIS, the silicone most widely used in RGP contact lenses, has been classified by ECHA as STOT RE 2 and as fulfilling the bioaccumulation and toxicity criteria of a PBT substance.[23] RGP contact lenses without both PFAS and silicone do not have enough oxygen permeability to maintain the eye health of wearers. Eye care practitioners would have no choice but to prescribe other correction methods to their patients, such as soft contact lenses, despite the accompanying loss of visual acuity, and the RGP contact sector would no longer be viable.[23]

1.2.4 No mitigation of the above risks through identification of alternatives to PFAS

PFAS monomers confer a uniquely diverse range of beneficial properties to RGP contact lenses.[23] Searches for potential alternatives have determined that none are currently available.[15,23] This is a conclusion which has been corroborated by an independent consultancy, Fresh Perspectiv (see confidential attachments). Although silicone methacrylates have been proposed by the Dossier Submitters as an alternative to PFAS, the use of such materials has been all but phased out in the RGP contact lens sector due to higher risks of infection, poor eye health and lens intolerance.[15,23] The development of a viable PFAS-free alternative is not anticipated to be possible in the short-to-medium term (within 10 years) and may not even be achievable in the long-term. The critical benefits of PFAS result from the uniquely advantageous properties of the element fluorine, which cannot be replicated by any other chemical element.[23] As a result, no matter how much research is performed, removing PFAS from RGP contact lenses is likely to lead to a significant and permanent decrease in efficacy for wearers.[23]

1.2.5 The greater degree of risk associated with a time-limited derogation for RGP contact lenses (RO2) than with an unconditional derogation

A 13.5-year derogation has been tentatively proposed for RGP contact lenses by the submitters of the PFAS Restriction Dossier under Restriction Option RO2. A potential advantage of the time-limited nature of this potential derogation might be that it could encourage, or speed up, the development and adoption of non-PFAS alternatives, mitigating the environmental risks posed by PFAS use continuing indefinitely in RGP contact lenses. This is, however, a small risk to mitigate as RGP contact lens PFAS, and their arrowhead species TFA, have a minimal environmental impact.[4-5] A time-limited derogation would also introduce a far larger risk, that by the end of the potential 13.5-year derogation period there is no viable non-PFAS alternative available for RGP contact lens wearers, or that alternatives which can be developed have a much-reduced level of performance.[15,23] This could severely compromise the safety and/or quality of life of tens of thousands of RGP contact lens wearers and, in the worst-case, lead to the collapse of the entire RGP contact lens sector. This strongly

suggests that RO2 is not an acceptable or proportionate option for managing the use of PFAS in RGP contact lenses, especially as it was confirmed during the ECHA webinar in April that there would be absolutely no possibility of continuing PFAS use at the end of a 13.5-year derogation (if granted). An unconditional derogation would, therefore, be a far more appropriate management option as it is the only way to guarantee that the safety and quality of life of RGP contact lens wearers is protected.

1.2.5.1 The risk of alternatives not being developed and adopted if an unconditional derogation is granted is small.

Within the contact lens sector there is already strong motivation to develop PFAS-free alternatives. Firstly, avoiding the use of persistent chemicals is desirable and commercially beneficial,[44] as highlighted by the independent consultants Fresh Perspectiv in a confidential attachment to this submission, even if they are of low risk. Moreover, PFAS use has received extremely bad press over recent years. Non-PFAS alternatives, if discovered, are likely to be commercially successful and could mitigate a shrinkage of sector due to patients moving to spectacles. For the same reason, it is expected that if developments in other industries were to yield alternatives that could outperform PFAS within RGP contact lenses, they would be adopted by the contact lens industry even if a non-time-limited derogation was in place.

Furthermore, applying a time-limit to force the development and adoption of alternatives within 13.5 years is considered to be unnecessary with regard to RGP contact lenses as it has been determined by the United Nations Environment Programme that the arrowhead PFAS, TFA, does not pose an environmental risk until at least 2100,[7] so there is little to be gained.

The approach to managing the use of PFAS in RGP contact lenses which minimises the overall risk of negative impacts on human health and well-being would be to allow PFAS to continue to be used in RGP contact lenses until PFAS-free alternatives are available that can outperform PFAS in terms of performance. This point might never be reached, but commercial pressures mean that it is likely that PFAS-free alternatives would be widely utilised within the industry anyway for those patients who are able to tolerate them.[23,44]

1.2.5.2 The risk that a time-limited derogation would be detrimental to RGP contact lens patients is significant

Developing PFAS-free alternative materials for RGP contact lenses will be a particular challenge as PFAS provide so many beneficial properties to these materials enabling lenses to be worn safely and healthily.[15,23] These properties include 'non-stick' qualities (deposit resistance), an essential contribution to oxygen permeability (mainly through -CF_3 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.[23]

In addition, the size of the R&D capability within the RGP lens sector is small,[15] so there is concern that the development of viable non-PFAS alternatives will rely on innovations from other industries and will be a long-term process, potentially taking significantly more than 13.5 years. Few, if any, of these industries will be focussed on replicating the oxygen permeability and rigidity which is achievable with PFAS materials, and which is critical for RGP contact lens performance, so there is no guarantee that an innovation suitable for the RGP lens sector will be forthcoming at all.[15,23]

PFAS are completely unique as no other chemical element is as electronegative or displays as little polarizability as fluorine, nor forms stronger bonds to carbon atoms, and so their advantageous properties will never be matched by other substances.[23] It is unlikely that their level of performance in RGP contact lenses could be fully replicated by a non-PFAS alternative, no matter how much research is performed. There is a greater chance that a time-limited derogation, rather than sparking the development of new non-PFAS materials which are equal to or better in efficacy than current polymers, will force the adoption of lower performance products within the RGP contact lens sector to the great detriment of lens wearers.

A time-limited derogation would also have a highly negative impact through prolonging uncertainty over PFAS and the future of RGP contact lenses within the eye care sector (even if viable alternative RGP contact lens materials can be developed, this process is likely to take many years)[15]. This uncertainty is expected to generate reluctance amongst contact lens manufacturers to register RGP lens products under the new Medical Device Regulation (MDR) framework because of the high costs of doing so. Also, amongst eye care practitioners, it is expected to generate reluctance to prescribe RGP lenses to new patients (as practitioners can't be sure that these lenses will still be available in a few years' time) and reluctance to invest in the training required for working with RGP lenses. The uncertainty risks causing a significant shrinkage of the RGP contact lens sector and making RGP lenses unavailable to many patients whose eyesight could be improved with these lenses if used instead of spectacles or soft lenses. An unconditional derogation would remove this uncertainty/risk at the earliest possible opportunity.

1.3 The balance of risk

To date, no link has been established between environmental exposure to RGP contact lens PFAS, or to the corresponding arrowhead species TFA, and human harm. Given the minimal risks associated with continued PFAS usage in RGP contact lenses, compared with the substantial risks of sight loss, blindness and reduced quality of life in current RGP lens patients if PFAS use is stopped, any restriction on PFAS in this sector is considered to be highly disproportionate.

2. Evaluation of socioeconomic impact

2.1 The aim of the socioeconomic analysis

The aim of this analysis is to support the case for the continued use of PFAS in RGP contact lenses.

Avoidance of risk (adequate control) is not possible in this instance. This study aims to quantify and compare the health, safety and quality of life benefits of the continued use of PFAS in RGP contact lenses for wearers with the potential environmental impacts and health costs of this continued use.

2.2 The scope of the socioeconomic analysis

The baseline scenario is that the use of PFAS in RGP contact lenses continues without restriction (this is equivalent to an unconditional derogation being granted for the use of PFAS in RGP contact lenses).

There are two proposed options for restricting the use of PFAS in RGP contact lenses: (A) No derogation is granted and the use is stopped at the end of an 18-month transition period and (B) the use is stopped after a 13.5-year derogation period.

Three scenarios have been identified in the case of a restriction being introduced and are considered in order of likelihood:

1. The use of RGP contact lenses continues, but with unsuitable, worse-performing PFAS-free lens materials
2. The RGP contact lens sector collapses entirely and rigid lenses are unavailable to patients
3. The use of RGP contact lenses continues, and a PFAS-free lens material which matches the current level of performance is identified and brought to market after approximately 15 years (as described above, it is highly unlikely that developing such an alternative will be achievable in reality)

This ordering takes into account that a rigorous analysis of alternatives has been conducted wherein it was concluded that no viable substitutes are currently available either from the contact lens sector or from other industries.[23] Moreover, given the uniquely advantageous properties of PFAS and the element fluorine it is expected that there will never be alternatives that can match the current level of performance of PFAS RGP contact lenses.[23]

The analysis will focus on potential impacts to health, quality of life and environment and will be limited to the EU over a timescale to the year 2100.

2.3 Identification and assessment of impacts

An analysis of impacts is given in Section 1 above. Uncertainties are addressed through the use of ranges (e.g. minimum and maximum values for numbers or percentages of patients who will be affected under different conditions).

2.3.1 Assessment of potential environmental impacts associated with continued use of PFAS in RGP contact lenses

2.3.1.1 Costs due to potential impact on health

There are no known cases of the PFAS that are used in RGP contact lenses causing harm to workers during polymer/lens manufacture or to contact lens wearers.

Moreover, although the environmental breakdown of RGP contact lens polymers does generate the arrowhead PFAS substance TFA, levels of TFA in the environment are well below the threshholds for causing any negative effects either to flora and fauna or to public health.[5,7]

There are not expected to have been any significant adverse health or environment related impacts due to the use of PFAS in RGP contact lenses to date, and so there are no associated costs (under both the baseline scenario and each of the restriction scenarios).

2.3.1.2 Costs due to potential impact on the environment

The main environmental concern associated with the use of PFAS in RGP contact lenses is the contribution to rising levels of TFA. While it is not expected to happen before the year 2100,[7] and probably not for many years beyond that, eventually TFA concentrations may reach a level of concern.

If this did happen, as a worst-case scenario, it may become necessary to perform PFAS remediation to lower TFA concentrations. The costs of an EU-wide PFAS remediation programme, with associated monitoring of PFAS levels, have been estimated in a report from the Nordic Council of Ministers to total €16,902 million (best estimate), with an upper estimate of €170,821 million.[45] For this analysis, it is assumed that remediation will take place in 2100.

These remediation figures are expected to be overestimates for TFA. The second largest component of remediation costs is estimated to be soil treatment,[45] which would not be necessary with TFA as it rapidly partitions into aqueous compartments.[5] Indeed, a vast majority of TFA ends up in the oceans where it is diluted to non-harmful concentrations.[7] A risk assessment of TFA published in 1999 determined that it is ”highly unlikely” for the conditions necessary for accumulation of TFA in aquatic ecosystems to be met,[6] so there would be few sites to potentially remediate, and only those that are small in volume are likely to contain significantly elevated TFA levels.[6] Several technologies have already been applied successfully to the removal of TFA from drinking water,[46] and low-cost approaches for treating larger water sources are becoming available.[47-48] It is expected that by 2100 appropriate and cost-effective remediation techniques will be available for TFA.

It is appropriate to consider what percentage of TFA remediation costs might be associated with the RGP contact lens sector. As described above, it is expected that 41.7 million tonnes of TFA will be generated from emissions of HFA-134a and HFO-1234yf alone between 2020 and 2100.[7] If it is assumed that EU emissions of

TFA are 20% of global emissions, this equates to 8.34 million tonnes. The amount of TFA resulting from each year of RGP contact lens manufacture is 1.44 tonnes. A period of 80 years of lens manufacture between 2020 and 2100 would be expected to result in 115.4 tonnes of TFA being produced if output remained constant. As over past 40 years the RGP lens sector has been losing market share to soft contact lenses, it is reasonable to surmise that there will be no large-scale increase in output between now and 2100. Assuming that the yearly output trebled over this period, meaning that the total output might approximately double to 230.8 tonnes, this would equate to less than 0.0028% of total EU TFA emissions. **Remediation costs associated with the RGP contact lens sector could, therefore, be calculated to be €467,689 based on the best estimate, or €4.73 million based on the upper estimate**. Note, these are one-off costs, not annual costs. **Averaged up to 2100, this equates to €6,074 per annum (best estimate) or €61,386 per annum (upper estimate).**

It is also likely that the remediation would be used to remove many different PFAS simultaneously. Considering total PFAS volumes, it is reported that 225,105 tonnes of PFAS are newly used in the EU each year,[49] and RGP lens manufacture contributes 4 tonnes, or 0.0018%, of this total. This suggests that the above remediation costs could be overestimated.

Current levels of TFA in the environment are not expected to cause negative environmental or health effects, nor would such effects be anticipated before the end of a 13.5-year derogation period.[5,7] Therefore, there would be no need for remediation to take place under any of the potential restriction scenarios. Remediation costs will only be applied to the baseline scenario.

2.3.2 Assessment of impacts associated with ending the use of PFAS in RGP contact lenses (restriction scenario 1)

2.3.2.1 Costs due to lens intolerance

As described above, if PFAS are removed from RGP contact lenses, it is expected that 214,007 RGP contact lens patients in the EU will be condemned to life-changing sight loss as a result of lens intolerance (40,532 using the minimum estimates from Section 1.2.1, 486,379 using the maximum estimates) and that 4,864 of these patients will effectively be left clinically blind. Studies from Japan, Canada and the UK have calculated the socioeconomic costs associated with severe sight loss/blindness to be £28,672 , £26,587 and £14,549 per person, per annum respectively (severe sight loss defined as above, as a visual acuity of < 6/12 in the better eye, which is the same thing as < 6/12 in both eyes).[50] Taking the average of these figures, £23,269 (€26,527), this would indicate that **banning the use of PFAS in RGP contact lenses within the EU would result in a total economic burden of €5.68 billion per annum due to lens intolerance** (minimum estimate = €1.08 billion per annum, maximum estimate = €12.9 billion per annum). Given that the numbers of current RGP lens patients predicted to suffer some degree of reduction in vision without PFAS due to lens intolerance are even greater, this figure is likely to be a significant underestimate. Moreover, with soft lenses or glasses, the more than 1 million keratoconic patients in the EU are more

likely to suffer vision problems due to higher order aberrations, which is not accounted for in the above calculations.[51-52]

Assuming that the PFAS restriction comes into force in 2026, and that there is no derogation, only a 1.5-year transition period (potential restriction A), the total cost of restriction due to lens intolerance by 2100 would be €409 billion (€5.68 billion per year for 72 years. Minimum estimate = €77.4 billion, maximum estimate = €929 billion). If there is a 13.5-year derogation (potential restriction B), the total cost of restriction due to lens intolerance by 2100 would be €341 billion (€5.68 billion per year for 60 years. Minimum estimate = €64.5 billion, maximum estimate = €774 billion).

2.3.2.2 Costs due to increased rates of contact lens related infections

Each case of microbial keratitis (MK) costs approximately AUD1,227 (€847) to treat.[43] **The additional 3500 MK infections per year resulting from removing PFAS from RGP contact lenses will, therefore, result in healthcare expenditure of €2.97 million annually**. Moreover, there are financial implications of the sight loss caused by MK infections. With 500 patients suffering sight loss each year due to the removal of PFAS from RGP contact lenses, the total number of affected patients in the population will increase year on year, and may ultimately reach a figure of around 20,000 (assuming patients live with the sight loss for 40 years on average). Costs per patient will be lower than for lens intolerance, as typically only one eye is affected by MK infections, and are estimated to be €5,000 per annum. **The total economic cost of increased infection levels and resulting sight loss due to banning the use of PFAS in RGP contact lenses is expected to ultimately reach €100 million per annum**.

Assuming that the PFAS restriction comes into force in 2026, and that there is no derogation, only a 1.5-year transition period (potential restriction A), the total cost of restriction due to MK infections by 2100 would be estimated to be €5.46 billion (based on 3500 additional infections at a cost of €2.97 million per year and 500 additional patients per year suffering sight loss, each at a cost of €5000 per year for 40 years, over a period of 72 years). If there is a 13.5-year derogation (potential restriction B), the total cost of restriction due to MK infections by 2100 would be estimated to be €4.23 billion (based on 3500 additional infections at a cost of €2.97 million per year and 500 additional patients per year suffering sight loss, each at a cost of €5000 per year for 40 years, over a period of 60 years).

2.3.2.3 Impact on current orthokeratology and scleral contact lens wearers

Both orthokeratology contact lenses and scleral contact lenses can only be made from RGP lens materials, and are thicker than typical contact lenses, meaning that greater oxygen permeabilities are required in order to maintain eye health.[15] These types of lenses are growing in importance within the eye care sector, but neither is expected to be viable without PFAS due to the corresponding decrease in the oxygen

permeability of RGP lens materials, at least not without greatly increased risks of impaired eye health and infection.

Orthokeratology lenses are worn overnight to reshape the eye giving clear vision when removed upon waking.[53] A major advantage of orthokeratology is that no lenses or glasses need to be worn during the day, making it a more comfortable option for many patients, and ideal for people who are engaged in sports such as swimming or skiing or who work in dusty environments. Orthokeratology is also a powerful tool for slowing myopia progression in children and thus to combat the growing global myopia epidemic, which is set to become a major healthcare burden globally.[53-55] Although myopia progression can be controlled using other methods, such as specially designed glasses or soft contact lenses, it is imperative that children are compliant with treatment and having a variety of different options available, so that they can find one which they are comfortable with, is of huge importance.

Scleral lenses bridge over the cornea and sit under the eyelids, making them less prone to causing discomfort than conventional RGP lenses.[25,56] These lenses are also less prone to decentration in patients with irregular cornea, including those with keratoconus, and in the medium to advanced stages of this disorder they become essential for achieving adequate visual acuity.[25] As scleral lenses are worn with a fluid reservoir between the lens and eye surface they are also increasingly being used to relieve the symptoms of dry eye sufferers, of whom there are an estimated 36 million within the EU (extrapolating an 8.1% prevalence rate in the US to the EU population),[57] and of patients with Sjögren's syndrome,[56] who number over 1 million within the EU.[58-60]

It is reported that 3% of all contact lens fittings are for orthokeratology lenses and that out of those patients fitted with RGP contact lenses, 23% are fitted with scleral lenses.[1] Given that the total number of contact lens wearers in the EU is 24.94 million (21.7 soft lens wearers[2] plus 3.24 million RGP lens wearers), it follows that **the numbers of current orthokeratology and scleral lens wearers whose lives will be disrupted by having to use a different form of vision correction as a result of a PFAS ban are 748,246 and 745,782 respectively**.

2.3.3 Assessment of impacts associated with a collapse of the RGP contact lens sector (restriction scenario 2)

The total costs to the five main RGP lens polymer producers, and 60 principal lens manufacturers, of developing a new ranges of PFAS-free RGP lens materials, and obtaining new medical device approvals for lenses manufactured from these materials through MDR, is predicted to be a minimum of €100 million.

For many of the small businesses in the eye care sector in the EU these costs will be prohibitive. Many other businesses will be unable to justify spending huge amounts of money to develop new PFAS-free products which are vastly inferior in performance to their current products. Eye care practitioners will no longer be able to justify the training costs and training time that are needed to specialise in RGP contact lenses. There is

a high possibility that the RGP contact lens industry will collapse entirely, as described above and elsewhere.[23]

2.3.3.1 Health costs of RGP contact lens no longer being available to wearers

If RGP contact lenses are no longer available, it is expected that 44% of the 3.24 million RGP lens patients in the EU will be condemned to life-changing sight loss (minimum estimate = 25%, maximum estimate = 60%),[3] and 3% of these patients condemned to clinical blindness, equating to 1,426,713 patients and 97,276 patients respectively. Using the figure of €26,527 per patient, per annum for the socioeconomic costs associated with such sight loss calculated above, it follows that **banning the use of PFAS for RGP contact lenses within the EU could lead to a total economic burden of €37.8 billion per year, assuming that a collapse of the RGP lens sector is triggered** (minimum estimate = €21.5 billion per annum, maximum estimate = €51.6 billion per annum). Given that over 1.9 million current RGP contact lens patients are expected to suffer some reduction in vision if RGP lenses are no longer available, albeit to a lesser degree, this figure is likely to be a significant underestimate.

Assuming that the PFAS restriction comes into force in 2026, that there is no derogation, only a 1.5-year transition period (potential restriction A) and that RGP contact lenses are no longer available to patients from the end of this period, the associated health costs by 2100 would be €2.72 trillion (€37.8 billion per year for 72 years. Minimum estimate = €1.55 trillion, maximum estimate = €3.72 trillion). If there is a 13.5-year derogation (potential restriction B) and RGP contact lenses are no longer available to patients from the end of this period, the associated health costs by 2100 would be €2.27 trillion (€37.8 billion per year for 60 years. Minimum estimate = €1.29 trillion, maximum estimate = €3.10 trillion).

2.3.3.2 Social cost of redundancies triggered by a collapse of the RGP lens sector

A collapse of the RGP contact lens market would be expected to have a highly detrimental impact on the optical sector in the EU, and the 150,000 eye care practitioners it employs (of whom 50,000 are directly engaged with RGP contact lenses)[21-22]. The results of an industry-wide survey suggest that over 1/3 of employees would be made redundant.[3] This suggests that there would be around 17,000 redundancies amongst eye care practitioners. In addition, surveys have identified that 2,278 contact lens manufacturers would be made redundant in the EU, giving a total of 19,278 job losses across the sector. The social cost of a single redundancy has been calculated to be €86,827,[61] indicating a **total cost of €1.67 billion .**

In addition to causing the loss of thousands of eye care practices, a collapse of the RGP contact lens sector would have a highly negative impact on the approximately 60 lens manufacturing companies, 36 trade associations, 26 academic institutions and 25 machine tool companies that it supports in the EU according to data compiled by the European Federation of the Contact Lens and IOL Industries (EFCLIN).

2.3.4 Assessment of impacts associated with ending the use of PFAS in RGP contact lenses and a viable alternative being identified (restriction scenario 3)

2.3.4.1 Costs due to lens intolerance

As calculated above, banning the use of PFAS in RGP contact lenses within the EU is estimated to result in a socioeconomic burden of €5.68 billion per annum due to lens intolerance (minimum estimate = €1.08 billion per annum, maximum estimate = €12.9 billion per annum).

Assuming that the PFAS restriction comes into force in 2026, that there is no derogation, only a 1.5-year transition period (potential restriction A), and that after 15 years a viable alternative has been identified and regulatory approvals have been obtained (there is currently no viable substitute for PFAS in RGP contact lenses and little chance that one will become available within a small number of years). Using the highly unlikely scenario that the alternative performs as well as current materials, the total cost of patient sight-loss due to lens intolerance would be €73.8 billion (€5.68 billion per year for 13 years. Minimum estimate = €14.0 billion, maximum estimate = €168 billion). If there is a 13.5-year derogation (potential restriction B), and after 15 years a viable alternative has been identified and regulatory approvals have been obtained the total cost of patient sight loss due to lens intolerance would be €8.52 billion (€5.68 billion per year for 1.5 years. Minimum estimate = €1.61 billion, maximum estimate = €19.4 billion).

2.3.4.2 Costs due to increased rates of contact lens related infections

As calculated above, the additional 3500 MK infections per year expected to result from removing PFAS from RGP contact lenses will result in healthcare expenditure of €2.97 million annually. Also the additional 500 patients suffering sight loss each year due to the removal of PFAS from RGP contact lenses will cost an estimated €5,000 per annum.

Assuming that the PFAS restriction comes into force in 2026, that there is no derogation, only a 1.5-year transition period (potential restriction A), and that after 15 years a viable alternative becomes available. Using the unlikely scenario that the alternative performs as well as current materials, the total cost of restricting PFAS due to MK infections by 2100 would be €1.34 billion (calculated for infections occurring over a 13-year period and sight loss thereafter). If there is a 13.5-year derogation (potential restriction B), and after 15 years a viable alternative becomes available the total cost of PFAS restriction due to MK infections by 2100 would be €155 million (calculated for infections occurring over a 1.5-year period and sight loss thereafter).

2.4 The balance of socioeconomic costs (interpretation and conclusions)

The aggregated costs associated with the baseline and restriction scenarios are shown in Table 1. It is evident that costs due to an increased number of RGP contact lens patients being subjected to sight loss and blindness in the EU as a result of the

lower performance of PFAS-free RGP contact lenses (restriction scenarios) far outweigh possible costs associated with environmental monitoring and remediation of the TFA resulting from RGP contact lens manufacture (the worst-case baseline scenario).

As described above, restriction scenario 1 is considered to be the most likely outcome in the event of a PFAS ban and restriction scenario 3 is considered the least likely due to the extreme challenges associated with replacing PFAS in RGP contact lenses. Non-use scenario 2 would become the most likely outcome if TRIS, the potentially PBT silicone used in RGP contact lenses, were to also be restricted in future.

Table 1. Combined environmental and health/quality of life costs calculated for the baseline scenario and for the potential restriction scenarios up to the year 2100.

Scenario	Best estimate of costs (€ millions)	Minimum estimate of costs (€ millions)	Maximum estimate of costs (€ millions)
Baseline	0.468	-	4.73
Restriction scenario A1	414,206	82,877	934,422
Restriction scenario A2	2,726,619	1,549,938	3,717,508
Restriction scenario A3	75,139	15,316	169,067
Restriction scenario B1	344,846	68,739	778,360
Restriction scenario B2	2,272,462	1,291,894	3,098,203
Restriction scenario B3	8,670	1,767	19,508

The only contribution to costs for the baseline scenario is from remediation.

For scenarios A1, A3, B1 and B3 costs resulting from reduced visual acuity due to lens intolerance and from increased numbers of eye infections have been combined.

For scenarios A2 and B2 costs resulting from reduced visual acuity due to RGP lenses no longer being available and from redundancies have been combined.

<u>Comparison of restriction with no derogation (potential restriction A) with other restriction options:</u>

There is no scenario (1, 2 or 3) under which a restriction where no derogation is granted (A) results in a lower cost than a restriction with a 13.5-year derogation (B).

The best estimate of health/quality of life costs resulting from a PFAS restriction where no derogation is granted (restriction scenario A1) is 885,643 times greater than the best estimate of potential environmental remediation costs under the baseline scenario.

Taking into consideration uncertainties, the lowest of the minimum estimates where it is assumed that no derogation is granted (scenario A3) is over three orders of magnitude greater than the maximum estimate of costs from the baseline scenario.

These observations strongly suggest that a restriction on the use of PFAS in RGP contact lenses with no derogation would be inappropriate and highly disproportionate in comparison to either a 13.5-year derogation or to continued PFAS use (i.e. an unconditional derogation).

Comparison of restriction with a 13.5-year derogation (potential restriction B) with the continued use baseline scenario:

The best estimate of health/quality of life costs resulting from a PFAS restriction where a 13.5-year derogation is granted (restriction scenario B1), is 737,341 times greater than the best estimate of potential environmental remediation costs under the baseline (or unconditional derogation) scenario.

Taking into consideration uncertainties, the lowest of the minimum estimates where it is assumed that no derogation is granted (restriction scenario B3) is over two orders of magnitude greater than the maximum estimate of costs from the baseline scenario.

These observations strongly suggest that a restriction on the use of PFAS in RGP contact lenses with a 13.5-year derogation would be inappropriate and highly disproportionate in comparison to continued PFAS use (i.e. an unconditional derogation).

One circumstance under which this might change is if restriction scenario 3 were extrapolated far beyond 2100. After several cycles of EU-wide remediation, potentially over a period of thousands of years, the costs associated with continued PFAS use (baseline scenario) could exceed the health/quality of life costs to RGP lens wearers under the restriction scenario. The same is true in the unlikely event that the development, regulatory approval and bringing to market of the alternative under scenario 3B occurred within 13.5 years. That said, if the PFAS-free alternative developed during restriction scenario 3 was associated with any drop in performance in comparison to current RGP contact lens materials, as is almost inevitable,[15,23] even if only a 1% decrease, the balance of costs switches back in favour of the continued use of PFAS in RGP contact lenses, no matter what timescale is considered. The relative costs and benefits of a 13.5-year derogation in comparison to an unconditional derogation are considered in more detail in Section 2.5 below.

It is noted that the costs of developing and registering new PFAS-free RGP lens materials and devices (€100 million) to industry are over two orders of magnitude greater than the figure that might reasonably be attributed to the activities of the RGP contact lens sector out of the costs of the worst-case scenario, a Europe-wide PFAS remediation programme (€0.468 million).

Although most of the uncertainties in the socioeconomic analysis have been addressed by using ranges incorporating possible values for critical parameters used in the calculations, there are other possible sources of uncertainty. For example, it is possible that by 2100 the relative costs of remediation and of the socioeconomic impact of reduced RGP contact lens performance may change. However, there is no

reason to expect that these two costs would scale differently in the future. Also, the Dossier Submitters have indicated that PFAS production volumes are anticipated to increase in future, so the negative environmental impact of continued PFAS use is expected to increase over time. However, in the case of RGP contact lenses, which are typically only prescribed where there is a clinical need, an increase in PFAS usage would correspond to more patients deriving benefits from these lenses. As shown above, these benefits for wearers far outweigh the corresponding environmental costs, so the conclusions from the socioeconomic analysis are expected to remain valid.

2.5 The socioeconomic case for an unconditional (non-time limited) derogation

As described in Section 1.2.5, the risks associated with a potential 13.5-year derogation for the use of PFAS in RGP contact lenses are far greater than those associated with an unconditional derogation. Moreover, the potential socioeconomic benefits are far smaller. The maximum gain from a time-limited derogation would come from driving the quick adoption of non-PFAS alternatives, preventing potential one-off remediation costs of €0.468 million. The maximum gain from an unconditional derogation would come from preventing the collapse of the RGP contact lens sector in the event that no viable non-PFAS alternative could be developed within 13.5 years, potentially saving €37.8 billion per year thereafter. Additionally, it is more likely that no viable non-PFAS alternatives can be developed within 13.5 years than it is that a time-limited derogation will significantly increase the chances of a non-PFAS alternative being developed and adopted (see above).[15,23]

2.5.1 An unconditional derogation would avoid a reduction in the number of eyecare practitioners working with RGP contact lenses

It is widely known within the industry that the development of suitable PFAS free RGP contact lens materials is by no means guaranteed, and even if it does happen it is likely to take a decade or more. Without an unconditional derogation there will be uncertainty over the future of RGP contact lenses which will continue for many years, potentially causing eye care practitioners to move away from prescribing RGP contact lenses or to not undergo the training required to work with them in the first place.[23] The potential resulting shrinkage of the RGP lens sector may leave many patients without ready access to RGP contact lenses.

Data from a recent survey supports this conclusion. When asked about whether uncertainty over the future of RGP contact lenses due to the PFAS situation would make them less likely to prescribe RGP contact lenses almost half of eye care practitioners responding to the survey (47.4%) answered ‘yes’,[3] highlighting that a time-limited derogation poses a significant threat to patient supply of RGP contact lenses.

The best estimate of costs for EU-wide remediation of TFA that could be associated with PFAS use in the EU RGP contact lens sector, calculated using figures presented in a report from the Nordic Council of Ministers,[45] is €0.468 million. Working under the

optimistic assumption that a new PFAS-free RGP contact lens material will be developed by 2035, significant shrinkage of the RGP contact sector would potentially have occurred up to that point, and would continue to affect patients for the 65 years up to 2100. Using the socioeconomic impact which can be attached to cases of significant visual acuity loss of €26,527 per patient per year (see above), if the number of patients suffering such a loss of visual acuity due to not being able to readily access RGP lenses averages just 0.27 across the 65-year period, the negative impact of the sector shrinkage would be greater than remediation costs. 0.27 patients equates to only 0.000008% of the 3.24 million RGP contact lens wearers in Europe. Considering that almost half of the 50,000 eyecare practitioners in the EU working with RGP contact lenses may no longer do so if uncertainty over RGP contact lenses continues,[3] it is almost certain that many patients will be put in a position where their visual acuity is compromised due to lack of easy access to RGP contact lenses. This strongly indicates that the negative impact which a time-limited derogation would have on RGP lens patients would be greater than the negative impact of an unconditional derogation (in potentially necessitating remediation to protect the environment and prevent an impact on human health).

2.5.2 New non-PFAS alternatives are expected to come from outside the sector, so there is likely to be nothing to be gained from a time-limited derogation

Recent highly negative reporting on PFAS has provided a strong impetus for the development of PFAS-free materials, in addition to the desire and commercial benefits of phasing out persistent chemicals.[23,44] However, the very limited R&D capacity in the RGP contact lens sector means that it is far more likely that suitable non-PFAS alternatives will come from developments in other industries, if at all.[23]

The socioeconomic analysis in sections 2.1 to 2.4 is based on evidence that, without PFAS, the performance of RGP contact lens materials will decrease. In particular, the oxygen permeability is expected to drop by around 70% (for materials with comparable deposit resistance).[23]

Assuming that the drop in the performance of RGP contact lenses is proportional to health/quality of life costs for wearers, it is possible to calculate the crossover point where the health/quality of life costs to wearers will equal remediation costs. Given that a 70% decrease in performance is estimated to result in a health/quality of life cost of €414 billion by the year 2100, the degree of the decrease in performance that is calculated to result in a health/quality of life cost of €0.468 million, equalling that of anticipated remediation costs, is 0.00008%. This means that any non-PFAS alternative RGP contact lens material would have to have a performance level above 99.9999% of that of current PFAS materials in order for there to be a socioeconomic benefit of restricting the use of PFAS.

As described above, there is already significant motivation to replace PFAS in RGP contact lenses and any non-PFAS alternative which performs better than current RGP lens materials would be quickly adopted by the industry with or without a time-limited

derogation. As a result, the only scenario where a time-limited derogation would be expected to generate a socioeconomic benefit is if it encouraged the adoption of a non-PFAS alternative which had a level of performance that is between 99.9999% and 100% of that of existing materials. Such a scenario is highly unlikely to occur in practice.

2.5.3 An unconditional derogation would avoid unnecessary development costs

TFA, the arrowhead substance for RGP contact lens PFAS, is broken down in the troposphere by hydroxyl radicals, which means that concentrations will reach a steady state in the environment if output remains constant.[4] It is likely that one outcome of the current PFAS restriction will be a major reduction in the output of TFA, driven by a decrease in the use of PFAS gases that convert to TFA in the atmosphere, of which thousands of tonnes are used as refrigerants or propellants each year.[5] Under such a scenario, it is expected that levels of TFA in rainwater, drinking water and the environment would decrease to well below current levels. As the current risk due to TFA is widely recognised to be '*de minimis*',[5-8] this would indicate that there would be no need for remediation to take place and little environmental gain from preventing the generation of small amounts of TFA from RGP contact lenses (as described in Section 3 below, derogating RGP contact lenses in preference to other sources of TFA, or possibly instead derogating TFA altogether, can be justified from a socioeconomic perspective).

Given the large costs involved with developing, testing and gaining regulatory approvals for new RGP contact lens materials and new contact lens products, anticipated to be around €100 million across the industry, anything other than a full, non-time limited derogation from the PFAS restriction would be disproportionate.

2.6 Calculation of the potential human health impact of RGP contact lens PFAS emissions

In the Annex XV Report, the Dossier Submitters quote a value for the socioeconomic impact of PFAS in the environment on human health of €52-84 billion per year in the EU. The following is a calculation of the equivalent cost applied to RGP contact lens PFAS alone.

The reported health cost was based primarily on the tragic impact of the presence of PFOA and PFOS (and precursor species such as fluorotelomers) in the environment.[45] These PFAS were in use in the EU since the 1940s and were employed in increasing amounts until restrictions were recently implemented. For simplification, it will be assumed that this increasing output over a 70-80 year period is equivalent to a constant output over 30 years. It can then be estimated that the PFOA/PFOS that was generated each year causes a human health impact of €2.3 billion per year (€68 billion human health cost divided by 30 years of manufacture. Min = €1.7 billion per year, Max = 2.8 billion per year).

Table 1 on page 41 of the Annex XV Report lists current emission levels for various categories of PFAS. PFOA and PFOS fall into the 'PFAAs and PFAA precursors' category, for which the emission level has been calculated to be 7,707 tonnes per year (Min = 2,842 tonnes per year, Max = 12,571 tonnes per year). Although these PFAS are no longer manufactured, it can be assumed that the current emissions of PFAAs and PFAA precursors reflect the emission levels of PFOA/PFOS prior to restriction. It can, therefore, be estimated that the human health cost of PFOA/PFOS in the environment is €294,105 per year for each tonne emitted (€2.3 billion per year divided by 7,707 tonnes per year. Min = €137,883 per year for each tonne emitted, Max = €985,222 per year for each tonne emitted). This is likely to be an overestimate as emission data for non-researched uses was not included in the figures presented in Table 1, so emissions will be greater in reality (as pointed out on page 42 of the Annex XV Report).

The arrowhead PFAS for RGP contact lens PFAS is TFA,[4] a substance which is considerably less hazardous than PFOA/PFOS (as would be expected given TFA contains just a single fluorinated carbon atom rather than the chains of 7/8 fluorinated carbon atoms present in PFOA/PFOS respectively)[4-5,7,15-19]. The potential human health cost of each tonne of TFA emitted to the environment would be expected to be significantly lower than each tonne of PFOA/PFOS. To estimate how much lower, it is assumed that the amount of potential harm that a substance will cause through environmental exposure is proportional to the half-life of the substance in the body (an indicator of bioaccumulation) and to the toxicity of the substance (how little of the substance is needed to cause a particular effect). The half-life of TFA in humans has been found to be 16 hours,[62] whereas the half-lives of PFOA and PFOS have been estimated to be 2.1-3.8 years and 3.4-5.0 years respectively (giving an overall average of 3.6 years).[19] The half-life of TFA in humans is, therefore, around 1,957 times shorter than the average for PFOA and PFOS (Min = 1,506 times shorter, Max = 2,409 times shorter). No experimental studies on toxicity have been identified which investigate TFA and PFOA/PFOS using the same methodology, so predicted chronic toxicity values have been generated using the ECOSAR software[63] provided by the US Environmental Protection Agency (Table 2). TFA is predicted to be 426 times less toxic than PFOA/PFOS on average.

Table 2. Chronic toxicity values predicted using the ECOSAR software.

Organism	Chronic Toxicity (mg/L)		
	TFA	PFOA	PFOS
Fish	1720	1.34	3.04
Daphnid	680	1.49	3.13
Green Algae	830	7.58	14.3
Fish (SW)	1120	7.83	15.0
Mysid (SW)	7140	0.0536	0.171
Average	2300	5.40	

Combining the half-life and toxicity data together, this would suggest that TFA is 834,031 times less hazardous than PFOA/PFOS on average (1,948 times shorter half-life multiplied by 426 times lower toxicity. Min = 641,570 times less hazardous, Max = 1,026,512 times less hazardous). These values may be underestimates. The US Environmental Protection Agency has recently published new lifetime drinking water advisory limits for four PFAS which range from 2,000 ppt for perfluorobutanesulfonic acid (PFBS) down to 0.004 ppt and 0.02 ppt for PFOA and PFOS respectively.[64] This is a clear indication that the hazards posed by different PFAS are not equivalent, and that they increase as the number of adjacent fluorinated carbon atoms in the PFAS molecule increases. The advisory limits suggest that PFBS (fluorinated chain length 4 carbon atoms) is 100,000 times less hazardous than PFOS (fluorinated chain length 8 carbon atoms). Moreover, although TFA (fluorinated chain length 1 carbon atom) has not been given a drinking water limit in the US, likely because it is not regarded as being enough of a health risk to warrant one, the German Environment Agency (Umweltbundesamt) have set a lifetime drinking water limit of 60 µg per litre (60,000 ppt).[65] This indicates that the hazard posed by TFA is 15 million times lower than that of PFOA (or 9 million times lower than the average for PFOA/PFOS). It should be noted that recent EU PFAS water limits do not vary for different PFAS, but this is understandable in the context of seeking a global PFAS restriction.

Taking the lower hazard of TFA into account, it can be estimated that the potential human health cost of TFA in the environment is €0.35 per year for each tonne emitted (€294,105 per year for each tonne of PFOA/PFOS emitted divided by the 834,031 times lower hazard of TFA. Min = €0.13 per year for each tonne of TFA emitted, Max = €1.54 per year for each tonne of TFA emitted).

In making such a comparison between the potential health cost of TFA and PFOA/PFOS, one which evaluates toxicity, the similarity of the toxic modes of action and of the environmental distributions of these different PFAS need to be considered. Justification that this comparison is appropriate comes from the PFAS Annex XV Report which highlights several times that different PFAS exhibit similar toxic effects. In fact, this is a key argument in restricting PFAS as a group. For example, on page 32 of the PFAS Annex XV Report it is stated “Despite different potencies of different substances, overall effect patterns are similar for a variety of PFASs, especially arrowhead substances”. In addition, again, the lifetime drinking water advisory limits give confidence that the lower toxicity of TFA results in a lower hazard. The environmental distribution of TFA will be different to that of PFOA/PFOS due to its greater hydrophilicity, which will mean it is less likely to contaminate soil, and more likely to ultimately end up in the oceans, where it will be almost infinitely diluted.[7] Arguably, therefore, there is a much-reduced risk of human exposure with TFA than there is with PFOA/PFOS, meaning that the calculated human health cost per year for each tonne of TFA emitted is likely to be an overestimate.

Each year of RGP contact lens manufacture for the EU market was calculated above to result in the generation of 1.44 tonnes of TFA. This means that the potential human health cost due to environmental exposure to TFA resulting from this activity is €0.51 per year (€0.35 per year for each tonne emitted multiplied

by 1.44 tonnes. Min = €0.19 per year, Max = €2.21 per year). A direct comparison to the €52-84 billion human health cost due to environmental exposure to PFAS reported in the PFAS Annex XV Report can be made by multiplying the €1.44 per year by 30 years, suggesting that the equivalent amount relating to RGP contact lenses only would be €15.26 per year.

More importantly, if it is assumed that chemicals in the environment degrade at a rate which follows first order kinetics, i.e. the amount remaining decreases by the same percentage each year, which is a reasonable assumption as concentrations are low, it is possible to calculate the total potential human health cost that a year's manufacture of RGP contact lens PFAS for the EU market will cause during the entire lifetime of the resulting TFA in the environment.

The persistence of TFA has not been well studied, but it is known to be broken down in the troposphere by hydroxyl radicals (generating non-PFAS species),[4] and the environmental half-life has been estimated to be 20 days in a report published by the German Environment Agency (Unweltbundesamt).[66] Judging by half-life data for other PFAS, however, this may be an underestimate. For example, a degradation half-life in water of 10 years was used for calculations involving the PFAS PFBS as described on page 34 of the PFAS Annex XV Report. Also, PFOA has a calculated aqueous half-life of 235 years,[67] which might be thought of as a worst-case value for the environmental persistence of PFAS (note that the atmospheric degradation half-life of PFOA has been postulated to be only 130 days)[68]. Assuming first-order kinetics, half-lives of 235 years, 100 years (which might represent a realistic absolute worst-case scenario for the persistence of TFA, given that it is broken down by hydroxyl radicals in the troposphere), 10 years and 20 days correspond to degradation rates of 0.29%, 0.69%, 6.7% and 99.9% per year respectively.

As calculated above, the potential human health cost per year resulting from one year of RGP contact lens manufacture is €0.51, but this potential health cost would be expected to decrease over time as the amount of TFA remaining in the environment reduces due to degradation (for example, due to reaction with hydroxyl radicals). Importantly, the total potential health impact that will be caused over the entire lifetime of the PFAS in the environment can be calculated using the following formula (that of the sum of a converging geometric series)[69]:

$$s = \frac{a}{1 - r}$$

where ‘s’ is the total human health cost, ‘a’ is the initial human health cost per year and ‘r’ is the inverse of the ratio between the human health cost for any given year and the human health cost for the following year (when an amount of degradation has occurred and the level of TFA in the environment is lower). ‘r’ can also be calculated using the following formula:

$$r = \frac{100 - p}{100}$$

where 'p' is the percentage degradation rate per year. The total potential human health costs resulting from one year of RGP contact lens manufacture, calculated for four different potential environmental half-lives of TFA, are shown in Table 3.

The maximum level of TFA in the environment which could potentially be reached through accumulation, based on a yearly output of 1.44 tonnes, was also calculated for the four possible TFA environmental half-lives (Table 3) using the following formula:

$$s_2 = \frac{a_2}{1 - r}$$

where 's_2' is the maximum amount of TFA in the environment and 'a_2' is the output of TFA each year. The highest level, 497 tonnes, is still over an order of magnitude below the current yearly output of TFA from the PFAS used in the refrigerant sector in the EU (which is over 10,000 tonnes per year, assuming the EU accounts for 20% of the 50,000 tonnes reported to be produced globally)[7], and also less than the amount of TFA produced each year from hydrothermal vents (over 3,432 tonnes per year)[5,9-11]. Clearly, this maximum potential TFA amount would increase if the use of PFAS in the RGP contact lens sector were to increase, however, such an increase would suggest more patients were being treated with RGP contact lenses, bringing substantial socioeconomic benefits.

Table 3. The total human health cost resulting from one year of RGP contact lens manufacture for the EU market and the maximum environmental level of TFA resulting from continued manufacture of RGP contact lenses for the EU market at current volumes.

	Environmental half-life of TFA			
	20 days	10 years	100 years	235 years
% degradation per year	99.9	6.7	0.69	0.29
TFA output per year / tonnes	1.44			
Human health cost per year / €	€0.51 (Min = €0.19, Max = €2.21)			
Maximum TFA level / tonnes	1.44	21.5	209	497
Total human health cost / €	€0.51 (€0.19, €2.22)	€7.59 (€2.89, €33.06)	€73.71 (€28.08, €321.00)	€175.38 (€66.81, €763.76)

Assuming an environmental half-life of TFA of 100 years, the total potential environmental health cost associated with the RGP contact lens PFAS manufactured each year for the EU market, across the whole lifetime of that PFAS, is calculated to be €73.71. The total amount of TFA present in the environment resulting from RGP contact lens manufacture for the EU market is

expected to reach a maximum of 209 tonnes, which is significantly less than the current yearly emissions of TFA from refrigerants.

There are several assumptions that have been used in these calculations, but all are supported by a degree of evidence, giving confidence that the lifetime potential environmental health impact of the RGP contact lens PFAS used each year for the EU market would be within an order of magnitude of €73.71. This value is 77 million times smaller than the estimated €5.68 billion per year of socioeconomic costs associated with restricting the use of PFAS in RGP contact lenses. Even if the calculated value is an underestimate by two orders of magnitude, it would still be less than the socioeconomic cost of one RGP contact lens wearer being left with significantly reduced visual acuity (€26,527, see above).

It is noted that a value of €0 was used for the environmental impact of the use of PFAS in RGP contact lenses in the socioeconomic analysis in Section 2.3.1 above. Changing this value to €73.71 per year would have no effect on the findings of the socioeconomic analysis.

It may come as a surprise that the estimated human health cost of RGP contact lens PFAS in the environment is so much smaller than the socioeconomic benefit that is derived from their use, but it makes sense considering that when PFAS are added to medical devices the type, amount and positioning are precisely controlled to have the optimal benefit for device users, whereas in the environment they are diluted to vanishingly small concentrations and are not intended to do harm.

The above calculations suggest that there is little value in restricting the use of PFAS in RGP contact lenses in the EU from a human health perspective. The application of a time-limited derogation (RO2), which would force the RGP contact lens industry to spend millions of euros to develop and approve PFAS free alternatives, can be concluded to be unjustified. More importantly, such a derogation would force what would almost certainly be lower performing alternatives onto RGP contact lens patients, undermining safety, eye health and quality of life, making it an option which is both highly disproportionate and highly inappropriate.

3. The ECHA criteria for an unconditional derogation are met

The ECHA guidance document on preparing dossiers for REACH restrictions describes that an unconditional derogation can be used to allow a use of a substance to continue without conditions attached, stating that “This type of derogation may result from a combination of high criticality and importance of the application of concern, a recognised lack of suitable and safer alternatives and high associated costs of the proposed restriction”.[70] RGP contact lenses are critical for the millions of wearers who have keratoconus or dry eye disease in the EU. Also, not only are no viable PFAS alternatives currently available for RGP contact lenses, but there is a strong possibility that they never will be. In addition, whereas the potential environmental risks of RGP contact lens PFAS are minimal, the socioeconomic costs that the proposed restriction could cause (even with a 13.5-year derogation) through forcing wearers to adopt

worse performing RGP contact lenses could be as much as €5.68 billion per year. PFAS use in RGP contact lenses, therefore, certainly meets the conditions for an unconditional derogation.

Moreover, medical devices are set to be fully derogated from a restriction on the use of undecafluorohexanoic acid (PFHxA) in the EU.[71] PFHxA is orders of magnitude more toxic and bioaccumulating than RGP contact lens monomers/polymers (and their ultimate environmental break-down product, TFA).[5,15-19] In this context, it would be nonsensical if RGP contact lenses, which are regulated as medical devices, were not granted a total derogation from the PFAS restriction.

In addition, a United Nations Environment Program panel has recently published an assessment for policymakers where they advise that TFA has natural sources and poses a minimal risk to human health according to the available evidence.[72] United Nations environmentalists also recently stated that "We are of the opinion that the properties of TFA indicate that it should not be included in this class [PFAS] for the purposes of generic regulatory risk assessment."[7]

RGP contact lenses are only one of many anthropogenic sources of TFA, so cannot be considered in isolation. However, RGP lenses in the EU bring a large socioeconomic benefit of €5.68 billion per year for a small emission level of 1.44 tonnes per year. If it is assumed that all sources of TFA are equally valuable, the socioeconomic benefit of TFA to the EU would be over €39.4 trillion per year (assuming that 10,000 tonnes of TFA is generated in the EU each year, i.e. 20% of the 50,000 tonnes of TFA which is reported to be generated globally from two refrigerants alone)[7], and restriction would simply be too costly. Alternatively, if other sources provide less of a socioeconomic benefit, then it would be appropriate to restrict these uses while fully derogating RGP contact lenses.

Unconditional derogations are currently not supported by the Submitters of the PFAS Annex XV Report in their preferred restriction option, RO2, except in a small number of exceptional cases. Critically, however, this approach of strictly limiting the use of unconditional derogations is not appropriately justified with evidence or with socioeconomic data, and is presumably being adopted because the Dossier Submitters did not foresee a case where a restriction on PFAS could do more harm than good in the long term. As shown above, however, if PFAS use in RGP contact lenses is restricted it will almost certainly cause a permanent drop in device performance which is significantly more detrimental to lens wearers than a restriction would be beneficial to the environment.

The main justification for the proportionality of the PFAS restriction is given on page 3 of the PFAS Annex XV Report, where it is stated that "Both RO1 and RO2 are deemed proportionate to the risk, as eventually the societal cost of inaction will always surpass the costs of a ban on the use of PFASs. This has its basis in the persistence of PFASs and their degradation products in the environment." No evidence or calculations are presented to support this assertion, however, so it is unsubstantiated. Moreover, the detailed socioeconomic analysis presented in this report demonstrates that this justification of proportionality is not valid in the context of RGP contact lenses. As described in Sections 1.1.1 and 2.6 above, TFA does not last forever in the

environment and so there is a finite societal cost to the continued use of precursor PFAS in RGP contact lenses, a cost which can be estimated and which is small in magnitude. The only way that this societal cost would surpass the costs of a ban, which are expected to be substantial given the potentially highly detrimental impact on RGP contact lens wearers, is if alternatives to PFAS are developed which enable the current level of performance of PFAS RGP contact lenses to be matched. Given that the benefits of PFAS result from the element fluorine, which is unique and chemically irreplaceable, and that so many of the advantageous properties of PFAS are critical for the performance of RGP contact lenses for wearers, this is highly unlikely to happen.[23] Furthermore, other environment agencies have concluded that the continued use of the PFAS TFA (and TFA precursors) has a net benefit in the context of ozone depletion and global warming,[7] which further refutes and discredits the above generic justification of proportionality from the PFAS Annex XV Report.

The PFAS Annex XV Report (page 190) claims that a non-threshold approach to risk is justified with PFAS, even if they are not PBT substances, meaning that any release poses an unacceptable risk. Neither RGP contact lens PFAS nor the corresponding arrowhead species, TFA, fulfil the B and T criteria for being PBT substances.[4] Furthermore, TFA is broken down to non-PFAS species by reaction with hydroxyl radicals in the troposphere,[4] and has a high threshold for environmental effects to be observed.[5,7] As shown in Section 2.6 above, the maximum possible environmental level of TFA which will result from continued use of PFAS in RGP contact lenses can be calculated and is well below current yearly TFA emissions from both anthropogenic and natural sources. Given that these emission levels have been determined to cause minimal environmental impact,[5,7,72] it can be concluded that RGP contact lens PFAS do not pose an unacceptable risk. In addition, with regards to TFA, the proposed non-threshold approach to risk is completely at odds with that being utilised by other environment agencies.[7,73]

The health hazards outlined in the PFAS Annex XV Report almost exclusively relate to long chain PFAS, so are not reflective of the much lower risk posed by the ultra-short chain PFAS used in RGP contact lenses (with the exception of persistence).[7]

No socioeconomic analysis has been presented in the PFAS Annex XV Report to demonstrate that restricting the use of PFAS in RGP contact lenses, or in medical devices in general, will not do more harm than good. Moreover, the socioeconomic analysis presented above in this document clearly demonstrates that PFAS restriction is not justified for RGP contact lenses (in the context of RO1, and almost certainly RO2 too), and extrapolation strongly suggests that it may not be justified for medical devices in general. The only socioeconomic data that is actually presented in the PFAS Annex XV Report, a human health cost due to environmental exposure to PFAS of up to €84 billion per year, refers primarily to PFAS that are already banned (PFOA and PFOS), to environmental levels of PFAS which have been building up over the past 80 years (i.e. it is not made clear that the health cost does not refer to one year of PFAS manufacture), and to existing contamination which cannot be undone by the proposed PFAS restriction. The PFAS which have not been restricted to date, which are not in the process of being restricted and which are actually in use in the EU are thousands of times less hazardous than PFOA and PFOS. Even if they persist in the

environment for hundreds of years, they will never come close to causing as much of a negative health impact as that currently seen with PFOA and PFOS. The implied €52-84 billion per year benefit of the PFAS restriction is, therefore, overstated.

4. Conclusions

It is evident that the risks and socioeconomic costs associated with banning the use of PFAS substances within the RGP contact lens sector, both under RO1 or RO2, are disproportionate and orders of magnitude greater than those associated with continued use.

Given that RGP contact lens PFAS, and the corresponding arrowhead species TFA, are not currently considered to be health concern, that volumes are relatively small, that TFA is a naturally occurring substance which is broken down by hydroxyl radicals in the troposphere and that remediation would be cost effective if ever new hazard information came to light, it is clear that continued use does not pose an unacceptable risk.

There is an overwhelming case for RGP contact lenses to be granted an unconditional derogation (with no time limit) from the upcoming restriction on the use of PFAS.

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