The cost of removing PFAS from medical devices

Executive Summary

The socioeconomic benefit of the use of PFAS in medical devices in the EU was calculated using three different methodologies to be €14.2 trillion per year (minimum €1.21 trillion per year, maximum €61.2 trillion per year), €1.99 trillion per year and €15.5 trillion per year (minimum €469 billion per year, maximum €38.6 trillion per year) respectively. This analysis takes into account the alternatives that have been suggested in the Annex XV report and elsewhere.

Human health costs resulting from environmental emissions of PFAS from the manufacture of medical devices for the EU market each year were estimated to be €25.1 million, calculated over the entire lifetime of that PFAS in the environment. The benefits of the continued use of PFAS in medical devices, therefore, significantly outweigh the costs. It is proposed that medical devices should be derogated from the PFAS restriction, and PFAS use should only be restricted for those medical devices where it can be robustly demonstrated that this will not negatively impact patients.

There is a strong case for medical devices to be granted an unconditional (time-unlimited) derogation from the PFAS restriction from the perspective of both reduced risk and reduced negative socioeconomic impact. PFAS are chemically unique and bring a level of performance to medical devices that is unlikely to ever be replicated. Even a 1% drop in effectiveness for patients is calculated to have a negative socioeconomic impact of between €469 and €773 billion per year. This suggests that the justification for the proportionality of a PFAS restriction given in the Annex XV report, that "eventually the societal cost of inaction will always surpass the costs of a ban on the use of PFASs", is not valid for medical devices. Furthermore, considering that over 100 million medical device users have been put at risk by this restriction, that there is a severe lack of knowledge (about the uses of PFAS in medical devices, the appropriateness of proposed alternatives and the availability of suitable alternatives in general) and that remediation to mitigate the possible environmental impacts of the continued use of PFAS in medical devices would be cost effective, the granting of an unconditional derogation is justified.

An alternative restriction option, RO3, which includes an unconditional (time-unlimited) derogation for medical device users, as well as measures to provide environmental protection through remediation, is presented and shown to have socioeconomic benefits over current restriction option RO2 not only for medical device users, but also for the EU economy and for the environment.

Medical device users need to be protected from the negative consequences of the loss of PFAS from devices in the absence of equivalently performing alternatives. Such PFAS loss may end up being driven not only by restriction, but also by commercial or political pressure, or by principles such as 'polluter pays', which don't take into account that PFAS are primarily utilised in medical devices to benefit patients. Steps should be taken to avoid such scenarios.

The current REACH revision should be used to address the serious issues over availability of data, for example on uses and alternatives, during REACH restrictions, perhaps by introducing compulsory reporting of such information at an early stage of the process, as has been attempted in the US. Moreover, there should be an EU body within the restriction process which is given responsibility for ensuring that the best possible cases for derogations are compiled wherever the safety and quality of life of consumers such as medical device users are put as risk (ideally forming active collaborations with stakeholders), rather than this responsibility ending up resting with industry or ending up being entirely unmet.

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1. Introduction

From an environmental viewpoint the desire to limit the use of PFAS is entirely understandable, and a strong case for their almost complete restriction is made in the Annex XV report.

When considered from the perspective of medical device users, however, restriction takes on a different complexion. It is postulated that the current REACH PFAS restriction process has put at risk the safety, health, quality of life, productivity and even life expectancy of the well over 100 million EU citizens who use PFAS containing medical devices each year.

PFAS are unique chemicals that bring critical improvements to the performance of many medical devices. There is a clear danger that removing PFAS will have negative consequences for medical device users. Within the REACH restriction framework there is the option to allow the use of chemicals to continue, by way of derogation. Currently, however, there is no plan to put in place a general derogation for medical devices, rather derogations will only be considered for individual medical device types, or small groupings of devices, and only if sufficient justification can be made. As things stand, information is lacking on the types of medical device that utilise PFAS, preventing sound assessments of where derogations might be needed to protect patient health and safety, as is the data required to justify such derogations. It appears that the provision of such justifications has been largely left to stakeholders, such as companies and trade associations working in the medical device sector. The burden of proof that a derogation is needed is high as "a full risk and socio-economic justification"[1] is deemed necessary, yet it has not been made clear exactly what type and quality of data would be accepted as sufficient. Presumably, such proof would need to include evidenced calculations of the volumes of PFAS used, control of emissions, numbers of medical device patients potentially affected and the quantified severity of negative impacts for patients if PFAS are removed from medical devices, as well as detailed assessments of the availability and suitability of alternatives. Arguably, such evidenced and detailed justifications are unlikely to be forthcoming from the current PFAS consultation, and the requisite supporting data may be almost impossible to compile for many medical device applications, even where derogations would be warranted to protect patient safety, meaning that the dangers facing medical device users posed by the REACH restriction are unlikely to be adequately mitigated. These points are explored in greater detail below. This is not an acceptable situation and could have catastrophic consequences for medical device users.

Large numbers of PFAS are already restricted in the EU, including those containing relatively long chains of fluorinated carbon atoms (from C8 up to C14, and precursors),[2-4] which pose the greatest hazard.[5-8] Restriction of undecafluorohexanoic acid (PFHxA, C6) and precursors is ongoing.[9] It is notable that SEAC and the submitter of the PFHxA Annex XV report, Germany, have recommended that medical devices should be exempt from this restriction (i.e. given a time-unlimited derogation with reporting requirements).[10] The reasons given for not restricting the use of PFHxA in medical devices centre around lacking information, including that "there are most probably current (and future) uses not identified in the public consultation" and that "considering possible negative impacts from limited use-specific derogations this [a derogation for all medical devices] seems to be a proportionate approach under uncertainty".[11] This strongly indicates that there is a lack of knowledge regarding the uses of PFHxA and precursors in medical devices. It was also acknowledged that the restriction of PFHxA was "one of the most technically challenging evaluations that RAC and SEAC have undertaken".[12] The current PFAS restriction is much broader in scope, incorporating several times the number of compounds and uses, and it is highly likely that this will not only lead to greater issues over knowledge gaps, but also present a much greater technical challenge. Furthermore, the stakes are higher. The negative consequences of restricting PFHxA in medical devices could be anticipated to be small due to the strong probability that replacement with a shorter-chain PFAS would be feasible, and so alternatives would be expected to be available within a period of time not much greater than that needed for regulatory approval. In contrast, with the current broad PFAS restriction, the unique chemical nature of PFAS means that their replacement is unlikely to be immediately achievable,[6,13-20] and may well not be possible at all (see Section 4.2.1 below).[13,15] This adds an additional layer of complexity and risk to the restriction process, especially in relation to medical devices users whose health, safety and quality of life are currently improved though the use of PFAS.

It is, therefore, surprising that a general derogation for the use of PFAS in medical devices has not been proposed, especially as it appears there has been limited contribution from stakeholders to calls for

evidence/consultations during the preparation of the Annex XV report, so the knowledge gaps highlighted during the PFHxA restriction are unlikely to have been filled. Annex G of the PFAS Annex XV report (page 6) states that 89 medical device and medicinal product companies responded to the call for evidence saying that they utilise PFAS.[21] If it is assumed that half are medical device companies, this represents just 0.07% of the 66,000 such companies based in the EU.[22] This could be taken as an indication that PFAS are seldom used in medical devices, but given how ubiquitous PFAS are in other sectors it is far more likely that engagement was low and the risk of data gaps is high. Evidence to support this assertion can be seen from recent lists of the uses of PFAS in medical devices,[15,23] which are far more comprehensive than the list given in the PFAS Annex XV report (p127-131),[24] yet are themselves likely to be incomplete.[22] Several of the uses 'missing' from the Annex XV report are critically important, such as minimally invasive surgery,[15,22] medical imaging[25] and endoscopy, an application where PFAS are not only currently vital,[15,22] but also likely to drive future developments,[26] and where clinical outcomes are highly reliant on the performance level of devices and practitioners.[27] Moreover, in Annex G of the PFAS Annex XV report, when commenting on responses to the calls for evidence, it was conceded that "this combined information did not fully cover the whole market of medical devices and pharmaceuticals in the European Union, as a comparison with ECHA data revealed",[21] again indicating that there are major gaps in the data underpinning the Annex XV report. There is also lack of understanding within the Annex XV report, as highlighted by a derogation being proposed for the use of 'fluoropolymers and perfluoropolyethers' in Rigid gas permeable contact lenses (page 7),[24] despite these types of PFAS not even being used in Rigid gas permeable contact lenses. Lack of critical information has been recognised to be a common feature of REACH restrictions by the German Environment Agency (Umwelt Bundesamt),[28-29] who made a study of previous restrictions and found that "The lack of use and exposure information hinders a proper scoping of a restriction proposal, the demonstration of unacceptable risks, the assessment of alternatives as well as the socio-economic analyses. Therefore, this information is essential for any restriction proposal. However, the case studies and the literature review showed that exactly this information is frequently not available to the authorities" and "In the analysed cases, the lack of use and exposure information resulted in uncertainties about the appropriateness of a restriction scope".[28] Furthermore, they acknowledge that such data gaps are not typically improved substantially during the 6-month consultation phase of a restriction "The public consultations during the discussion of the restriction dossiers in RAC and SEAC, which are intended as an instrument to close information gaps, were observed as no significant contribution to closing these gaps".[28]

The lack of data during restrictions not only applies to the uses of the chemical being regulated, but also to its alternatives,[28-29] as has been noted for medical devices within the current PFAS restriction.[22] Alternatives are a critical safeguard in the REACH restriction process, as their availability means that the risk of negative impacts on consumers and companies who use/manufacture products which face restriction are significantly reduced. Within the PFAS Annex XV report, indicative evidence of the limited availability of information on alternatives for PFAS in medical devices can be found for hernia meshes for which it is noted "No information on alternatives has been received during the CfE or the second stakeholder consultation" (Appendix E, page 318).[30] Moreover, determining the appropriateness of alternatives is challenging, as indicated by Umwelt Bundesamt, who state that "The assessment of alternatives is complex and specific expertise is not accessible for authorities".[29] They also note that "In cases where alternatives were already in use for the to-be-restricted substance, RAC and SEAC pragmatically assumed these alternatives available".[28] Such an approach does not ensure that the level of performance of alternatives is identical to that of existing products, or even that it is adequate for a majority of consumers, and represents a dangerous scenario for medical device users. Legacy products in the medical device sector frequently remain on the market, even when superseded

by better performing devices, and their use may continue indefinitely for low-risk applications. The possibility that such products could be forced back into widespread use by a restriction must be carefully avoided. Moreover, in many cases, medical devices of the same generic type can have subtle but important variations. They may be designed to serve different patient groups or be optimised to treat/diagnose different conditions. Failing to recognise such nuances could be disastrous. This is apparent in the PFAS Annex XV report, where glasses are proposed as an alternative to rigid contact lenses for sight correction, despite being unsuitable for most rigid contact lens wearers, including the one million EU citizens who have keratoconus.[31-33] Again, this example highlights the lack of knowledge/understanding underpinning the PFAS Annex XV report. Furthermore, any situation where an alternative for a PFAS medical device is widely available, but has a lower level of performance, could be anticipated to be a worst-case scenario for medical device patients as device manufacturers could be expected to retain market share simply by switching to the alternative. As a result, there would be no commercial motivation to invest the vast amounts of time, energy and resources, nor to share/divulge confidential information, required to make a case for a derogation, even if the negative impact for patients of adopting the lower performing alternative would justify one.

There is strong evidence that there are gaps in knowledge, data and expertise within the current PFAS restriction process, and for medical device users this will potentially have severe consequences. Medical devices must be proven to be efficacious for patients in order to receive regulatory approval. PFAS medical devices in particular are not legacy products that can be discontinued without concern, they are typically the state of the art and in many cases have facilitated major advances in medical treatments.[15,34] Furthermore, given the expense of PFAS it is unlikely that a product would contain PFAS unless it conferred a performance advantage.[18,35] Without PFAS, the level of safety, health, quality of life, productivity and even life expectancy of the more than 100 million EU citizens using PFAS medical devices each year will be put at risk. Neither should it be assumed that this risk can be adequately mitigated through alternatives. Numerous applications of PFAS have been identified for which no suitable alternatives exist,[6,13-20,35] and given the unique chemical nature of PFAS, in particular the element fluorine which they all incorporate (see Section 4.2.1 below),[36] the performance level of PFAS will never be fully replicated in many instances. Furthermore, even in cases where the performance level could potentially be replicated without PFAS, there is no guarantee that industry will invest the large sums in research and development that might be needed to reach this point, the only responsibility for companies under a REACH restriction being to no longer use PFAS. Moreover, for medical device users, even small decreases in device efficacy are anticipated to have enormous socioeconomic impacts (see Section 2.3 below).

Within the PFAS REACH restriction process, a derogation is the only way that medical device users who are at risk from the potential negative effects of reduced device performance due to removing PFAS can be protected. However, given that many uses of PFAS in medical devices were not identified and evaluated in the PFAS Annex XV report, the protection of medical device users with derogations now cannot be guaranteed. This is because the remit of RAC and SEAC, who lead the subsequent stages of the restriction process, does not include information gathering,[84] so the complex task of justifying derogations *de facto* rests with industry stakeholders (as stated on the PFAS restriction page of the ECHA website "If a derogation is not proposed by the Dossier Submitter then it will be incumbent on the relevant stakeholders to do so during any consultation process with a full risk and socio-economic justification accompanying it.")[1], yet there is no requirement for such stakeholders (interested parties) to engage with the restriction process. The REACH legislation merely dictates that they be 'invited' to contribute (see Article 69).[37] This potential lack of protection for medical device users also applies to the devices described in the PFAS Annex XV report for which it has been noted that removing PFAS could have a negative impact on users, but where information is currently deemed to be insufficient

to justify a derogation (i.e. a derogation was tentatively proposed). Only if 'interested parties' provide more data to the current consultation will the risks of harm for medical device users be mitigated, however, there is no obligation for such contributions to be made.

Many medical device manufacturers are unaware of the ongoing PFAS restriction in the EU, many others are still unsure whether their products contain PFAS, still more do not believe that chemicals such as fluoropolymers and trifluoroacetic acid can and will be banned. Even if a company is aware that their device, or a particular device type contains PFAS, and endeavours to make a submission in support of a derogation, they face numerous challenges which reduce the likelihood that the information necessary for making a strong socioeconomic case will be acquired. Firstly, it is estimated that 95% of medical device companies are SMEs,[38] and they are unlikely to have expertise, or even experience with chemical restrictions and with socioeconomic analysis (this may also apply to whole medical device sectors). Moreover, a wide variety of different expertise is necessary to develop a complete understanding of alternatives and impacts on patients and the environment, and then to build a case to justify a derogation, including regulatory, socioeconomic, chemistry, medical, toxicological and environmental, and companies are unlikely to be strong in all of these areas. Supply chains for medical devices are typically several layers deep, meaning that medical device manufacturers may have difficulty even determining if their products contain PFAS,[22] in addition to determining the impact of removing PFAS from component parts and what chemical alternatives may be available. Lines of communication at each layer could be hampered by lack of time and resources, the fact that cooperation is voluntary, and by confidentiality issues. Quantifying the negative impacts of removing PFAS from medical devices for patients, which is necessary in order to prove the proportionality of a derogation, may be impossible as there are very few outcomes for which willingness to pay values have been calculated.[39] In addition, while small drops in device performance without PFAS could be hugely significant when averaged across the medical device sector as a whole (even if as little as 1%, see Section 2.3 below), it would be extremely challenging and costly to substantiate/prove such small performance differences in practise for individual medical devices. Finally, ECHA have requested that data submitted to the current 6-month consultation in support of derogations should ideally be representative of an entire sector, rather than just relating to individual companies.[40] However, confidentially issues make the acquisition of such sector data difficult. The REACH legislation itself highlights types of information which "shall normally be deemed to undermine the protection of the commercial interests of the concerned person" (Article 118), including compositions of mixtures, functions or applications of substances and precise tonnages of substances.[37] It should not, therefore, be expected that companies would share such information with each other, yet this information is critical to be able to build a sector-wide justification for a derogation for a medical device. Individual companies may be able to assess the impacts that a PFAS restriction would have on themselves, but without a detailed knowledge of the whole market, including which competitor products contain PFAS and/or how far competitors are from developing alternatives, they would not be able to make a case that medical device users need protection from the PFAS restriction. Furthermore, globally operating companies may decide to avoid engagement with the EU PFAS restriction process in order to protect IP and other business sensitive information with a view that this would be better in the wider worldwide market and the likelihood of other territories banning the use of PFAS in medical devices is low. More generally, Umwelt bundesamt have recognised that small companies lack the expertise and resources for making applications for authorisation.[28] Within the current PFAS restriction, a similar level of information is required in order to justify a derogation as is typically required for an authorisation application, suggesting that such justifications are unlikely to be received from medical device companies, who, as described above, are mainly SME's.[38]

Compiling credible justifications for derogations, on the basis of the negative impacts that PFAS restriction will have on medical device users, is likely to require the involvement of trade associations. Trade associations typically have experience of regulatory processes and may be able to compile data from multiple companies within a medical device sector in an anonymised manner in order to mitigate confidentiality issues. However, according to Annex G of the PFAS Annex XV report, only 10 trade associations from the medical device and pharmaceutical industries combined contributed to consultations during the preparation of the report (Page 6).[21] This figure is far fewer than the number of medical device types known to contain PFAS (see references 15, 22 and 23), so for many uses there will not be a trade association focussed on seeking a derogation solely for that application. Large EU-wide or national trade associations, therefore, represent the most likely source of justifications for derogations to protect medical device users. The challenge for such companies is that there are around 7,000 different types of medical device in use.[41] Ideally, each should be considered individually, as when bundled together into groups concepts such as alternatives, essential use and socioeconomic costs/benefits are likely to become incoherent. Having been involved in putting together a case for a derogation for a single medical device, including understanding the sector landscape, compiling information from device manufacturers, chemical companies and doctors, reviewing the scientific literature, analysing factors such as alternatives, essential use, environmental impacts and impacts on patients, as well as performing a socioeconomic analysis, it is clear that it is an enormous undertaking to produce a credible output. The amount and complexity of work was more than is involved in a typical Master's degree project and thesis, and completion took over two years, even with the commitment of 2-3 people at any time (and even though supply chains were extremely short and that by chance the way these products are classified for the US market made it obvious that all contemporary devices contained PFAS, so confidentiality issues, although highly challenging, were not as prohibitive as they might have been). External consultants were able to help with some aspects, but while familiar with assessing the impacts of restriction on companies, were not experienced with doing so for patients, and were hindered by a lack of knowledge of the sector. Even if it is assumed that trade organisations would be more efficient, and could compile a justification for a derogation for a medical device within 3-4 months, that only 10% of medical devices contain PFAS and have no obvious alternatives, so a majority could be quickly disregarded, and that such organisations could commit 10 employees to work on the PFAS restriction, a thorough analysis of the medical device industry would take decades rather than the 6 months available in the ongoing consultation. The conclusion that there is insufficient time for investigating in detail all uses of PFAS in medical devices during the PFAS restriction is also made elsewhere.[22] In summary, an absence of data cannot be taken as an indication that a derogation is not required to protect the users of a medical device.

Decisions on whether to restrict or derogate PFAS in medical devices can be anticipated to affect over half of the EU population, either through being a medical device user or through being at risk of environmental exposure.[42] These decisions are of upmost importance, yet no calculations or estimates of the socioeconomic costs of the continued use of currently unrestricted PFAS in the environment have been presented in the PFAS Annex XV report, nor are there any calculations of the negative socioeconomic costs of removing PFAS from medical devices. Taking into account also the lacking information and expertise on uses and alternatives for PFAS in medical devices, and the low likelihood that data gaps will be resolved during the current consultation,[28] it is difficult to see how rational and credible decisions on derogation/restriction can be made for medical devices. Indeed, it is considered that if individual uses of PFAS in medical devices each require separate consideration, as is currently the case, that it is inevitable that there will be deficiencies in the allocation of derogations.[22]

Arguably, the protection of medical device users and other consumers at risk from restrictions is a serious weakness of the REACH legislation and its implementation, especially for chemicals such as

PFAS where there is a real risk that developing alternatives of the same performance level will be impossible to achieve. Within the current EU PFAS restriction process, as things stand, in the absence of overwhelming evidence that it should be otherwise (evidence which is unlikely to be forthcoming) it is the environment, and citizens at risk of environmental exposure to PFAS, who will be protected in preference to medical device users. Though the dangers of this PFAS restriction for medical device users are, therefore, stark, it could be argued that this should be overlooked if restricting PFAS was guaranteed to bring a net benefit. Such an assertion of the proportionality of restriction is made in the PFAS Annex XV report, which states "eventually the societal cost of inaction will always surpass the costs of a ban on the use of PFASs" (page 3). However, no proof, or supporting data, or even detailed analysis of why costs of inaction might always be higher, has been presented. Moreover, there are examples which suggest that this statement is inaccurate, at least in certain cases. For example, environmentalists from the UNEP (United Nations Environment Programme) have concluded that the continued use, as refrigerants, of trifluoroacetic acid (TFA) precursors, which are classified as PFAS under the OECD definition,[43] has a net benefit as not only do they mitigate ozone depletion, but also TFA poses a minimal risk to the environment and to human health.[44-45] They also suggest that authorities should not classify TFA with other PFAS for regulatory purposes.[45-46] In addition, for rigid gas permeable contact lenses, it has been calculated that the socioeconomic costs of restricting the use of PFAS are greater than those of continued use by several orders of magnitude, even when the entire lifetime of that PFAS in the environment is taken into account.[33] It is, therefore, highly likely that the above claim of the proportionality of restriction, from the PFAS Annex XV report, will also be invalid for many other medical devices.

The aim of this report is to evaluate the risks and socioeconomic cost impacts of the continued use, and of the restriction, of PFAS in medical devices for patients and for people at risk of environmental exposure to PFAS in the EU. The methodologies employed in this analysis are imperfect, but provide a clearer picture of the socioeconomic landscape of PFAS use in medical devices than is available in the PFAS Annex XV report (and if further improvements can be made this would be welcomed). The results suggest that the risks and negative socioeconomic impacts of restriction are potentially far greater than those of continued use, suggesting that wherever there is insufficient data to make fully informed decisions over restriction/derogation of the use of PFAS in medical devices it is derogation that should be favoured.

2. Estimated socioeconomic benefits of PFAS in medical devices

2.1 Benefits from extrapolation based on value per tonne

In an earlier submission to the PFAS consultation made by Euromcontact,[33] the socioeconomic benefit of PFAS in rigid gas permeable (RGP) contact lenses in the EU was reported to be €5.68 billion per year, a figure which was calculated taking into account the potential alternatives which were identified in the PFAS Annex XV report, and also those suggested by independent consultants.[20] The amount of PFAS used in the manufacture of RGP contact lenses for the EU market each year is 4 tonnes,[33] indicating that the socioeconomic value of PFAS in RGPs is €1.42 billion per tonne per year.

If it is assumed that the socioeconomic value of PFAS in other medical devices is similar, using the figure for the annual volume of PFAS used in medical devices in the EU included in the PFAS Annex XV report, of 43,100 tonnes (Table 3, p55),[24] it can be estimated that the socioeconomic benefit of the use of PFAS in medical devices in the EU is €61.2 trillion per year. Even if the PFAS gases used in the medical device sector are excluded from the calculation, as their mode of action might be expected to

be significantly different, the remaining 10,020 tonnes of PFAS used annually in medical devices in the EU would have a socioeconomic benefit of €14.2 trillion per year, a figure only slightly below EU GDP. A minimum estimate can be obtained by combining the lowest figure for the socioeconomic benefit of PFAS in RGP contact lenses, of €1.08 billion per year,[33] with the low estimate of the annual volume of PFAS used in medical devices in the EU, excluding gases, of 4,512 tonnes (see Table 3 of the Annex XV report, p55),[24] to give €1.21 trillion per year.

It is possible that the use of PFAS in RGP contact lenses has a particularly beneficial effect on device performance, but there is no reason to assume that this is the case.

2.2 Benefits from extrapolation based on number of medical device types

Another way to extrapolate the socioeconomic benefit of RGP contact lenses to medical devices in general is by considering the overall number of different medical device types.

The percentage of medical devices types which contain PFAS does not appear to be known,[47] which is a concern in and of itself, but based on lists of PFAS containing medical devices,[15,23] it can be concluded that the figure is at least 10%. There are approximately 7,000 different types of medical device,[41] and even if low-risk devices (Class I), which make up almost half of medical devices,[48] are excluded, the use of PFAS in the remaining 350 devices can be calculated to have a socioeconomic benefit of €1.99 trillion per year within the EU (by extrapolation from the figure of €5.68 billion for RGP contact lenses).

It is, of course, likely that for some medical devices appropriate alternatives are available, but equally, for other medical devices the available alternatives may be less effective than those proposed for RGPs. Moreover, restricting the use of PFAS in low-risk medical devices may have an unexpectedly large negative impact in some cases. For example, PFAS are currently used to coat almost all spectacle lenses[49-50] as it makes them more resistant to scratches, less prone to picking up dust/dirt and easier to clean. While spectacle lenses were already ubiquitous before such PFAS coatings were developed, suggesting that the coatings might not be a necessary feature, there are safety implications of omitting them as scratched and/or dirty lenses would make driving at night more hazardous and may cause issues such as headaches for wearers during the day. Furthermore, around half (over 200 million) EU citizens own spectacles.[51-52] If it is assumed that 100 million of these spectacle wearers require them for work, and if it is conjectured that without PFAS they would spend at least an additional 30 seconds each day cleaning their spectacle lenses (which equates to 0.104% of an 8-hour working day), the resulting cost of restricting PFAS in spectacles to the EU economy would be anticipated to be at least €4.18 billion per year (given that the annual output of an employee for socioeconomic analysis purposes is reported to be €40,120)[53].

2.3 Benefits calculated using willingness to pay figures

Very few willingness to pay values have been calculated for human health impacts to date.[39] This is a major impediment to the feasibility of quantifying the detrimental impacts of removing PFAS from medical devices for patients. As it has been asserted that socioeconomic data is required in order to obtain a derogation from the PFAS restriction,[1] this means that there is a risk that some derogations will not be granted even if they are warranted to protect patient health/safety. In order that medical device users are not disadvantaged simply because of such an absence of data, here, the negative impact of removing PFAS will be modelled using the average of the willingness to pay figures that have been generated to date (Table 1).

Table 1. Averages of willingness to pay values reported by ECHA.[39]

Health endpoint	Reported value / €	Mid-point / €	Minimum / €	Maximum / €
Premature death	3,500,00 to 5,000,000	4,250,000	3,500,000	5,000,000
Cancer morbidity	410,000	410,000	410,000	410,000
Statistical pregnancy	22,000 to 41,000	31,500	22,000	41,000
Very low birth weight	126,000 to 405,000	265,500	126,000	405,000
Minor birth defect	4,300 to 43,000	23,650	4,300	43,000
External birth defect	26,000 to 330,000	178,000	26,000	330,000
Internal birth defect	128,000 to 712,000	420,000	128,000	712,000
Mild, acute dermatitis	250	250	250	250
Severe, chronic dermatitis	2,000 to 12,000	7,000	2,000	12,000
Average	-	**620,656**	468,728	772,583

It is postulated that well over 100 million EU citizens each year use or are treated with PFAS containing medical devices that are not currently covered by a derogation, even if spectacles wearers are excluded. This figure includes, for example, 25 million contact lens wearers,[33] 700 million uses of medical imaging and radiotherapy devices,[25] 14 million endoscopies (from extrapolation of the 2,133,541 procedures performed annually in the UK,[54] population 67.0 million, to the EU, population 446.8 million) and 16.5 million operations utilising PFAS surgical equipment (a figure calculated based on reporting that more than a third of operations utilise PFAS devices[22] and that there are 11,074 operations per 100,000 population in the EU annually)[55].

PFAS are typically expensive in comparison to other substances used in medical devices, and if they could have been removed without impacting device performance, they usually would have been,[18,35] so it can be concluded that alternatives are not typically available for PFAS.[15] For example, a survey of 42 users of fluoropolymers identified just one use for which an alternative was potentially available, although the level of performance of this alternative was reduced in comparison to the fluoropolymer.[35] Further evidence to support this conclusion comes from Annex E of the PFAS Annex XV Report, where for a majority of the medical device applications that are described either PFAS free alternatives are not available or alternatives have been proposed despite conclusions that they have a lower level of performance. For example, it is stated for hernia meshes that "*alternatives to PFAS-based hernia meshes are widely available, but that their functionality is lower and lead to increased risk of adverse health impacts (intestinal damage and fistula formation) in patients*" (page 318)[30] and for Rigid gas permeable contact lenses that "*In short, the 1st generation is an available alternative, but it has lower technical functionality in some respects*" (page 321).[30] Moreover, it is evident that there is little evidence/research on the suitability of the proposed alternatives. For example, glasses have been proposed as an alternative to RGP contact lenses, yet are unsuitable for the million keratoconic patients in the EU.[31-33] This example highlights the danger and unsuitability of making the assumption that just because a non-PFAS alternative is available on the market it can be concluded to be an adequate replacement (assumptions of this sort might be made by authorities during restriction processes)[28], especially when it comes to medical devices. As things stand, hernia meshes and RGP contact lenses will not receive a derogation from the PFAS restriction to protect users of these medical devices from the negative impacts which would inevitably result from the described decreases in performance.

It is, therefore, evident that removing PFAS from medical devices will have a detrimental effect on their efficacy and/or availability for medical device users. If it is assumed that, on average, device effectiveness/availability for patients would drop to 75% of current values, and if the resulting detrimental impact on patients is calculated using the mid-point average of the willingness to pay values from Table 1 (€620,656), when applied to 100 million annual medical device users the socioeconomic benefit of the use of PFAS in medical devices in the EU can be estimated to be €15.5 trillion per year (Table 2).

Table 2. Quantified socioeconomic benefits of PFAS in medical devices calculated using different values for the effectiveness/availability of PFAS-free alternatives for patients.

Willingness to pay Effectiveness of alternatives	Mid-point Benefit per year / €Bn	Minimum Benefit per year / €Bn	Maximum Benefit per year / €Bn
50%	31,033	23,436	38,629
75%	**15,516**	11,718	19,315
90%	6,207	4,687	7,726
99%	621	469	773

2.4 Conclusions about the socioeconomic benefits of PFAS in medical devices

The above calculations of the socioeconomic benefits of the use of PFAS in medical devices from Sections 2.1 to 2.3 make some relatively large assumptions, but all yielded figures that are of a similar magnitude, giving some confidence that they are representative of reality. The benefits of PFAS in medical devices in the EU can be assumed to total in excess of €1 trillion per year (and this could easily be the case for medical imaging and radiotherapy alone)[25].

3. Estimated socioeconomic costs of the continued use of PFAS in medical devices

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, no other costings of the impact of PFAS in the environment are presented. The following is a calculation of the equivalent cost applied to medical device PFAS alone.

The reported health cost was based primarily on the tragic impact of the presence of perfluorooctanoic acid (PFOA) and perfluorosulfonic acid (PFOS), as well as precursor species such as C8 fluorotelomers, in the environment.[42] 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 60-80 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 (this is the average human health cost, €68 billion per year, divided by 30 years of manufacture. Min = €1.7 billion per year, Max = 2.8 billion per year). Hypothetically, this human health impact could increase if large quantities of C8 fluorotelomers in the environment are still undergoing degradation into PFOA/PFOS. However, it is noted that analysis of PFOS levels in leaves

and earthworms do not show that these levels are increasing over time since the PFOS restriction came into force, and that environmental human exposure to PFOA and PFOS has decreased significantly since 1986,[56] indicating that the break-down of C8 fluorotelomers is not an ongoing source of PFOA/PFOS into the environment.

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)[24].

Clearly, medical devices sold in the EU cannot now utilise PFOA or PFAS because these substances have been restricted, as have the longer chain C9-C14 PFAS.[2-4] It is generally accepted that as the length of fluorinated carbon chain within a PFAS molecule decreases so does the hazard posed by the PFAS, as the toxicity and tendency to bioaccumulate decrease,[5-8] so medical device PFAS can be assumed to pose a lower risk than PFOA/PFOS. Arguably, the most hazardous PFAS substances which could reasonably be expected to be widely utilised in medical devices in future are the arrowhead species undecafluorohexanoic acid (PFHxA) and its precursors. This is because perfluorohexanesulfonic acid (PFHxS) is already regulated as a persistent organic pollutant (POP),[57] and the longer-fluorine-chained PFAS perfluoroheptanoic acid (PFHpA) and perfluoroheptanesulfonic acid (PFHpA) are not in widespread use, and are never likely to be, as avoiding contamination with the restricted PFAS PFOA/PFOS would be extremely challenging. For this analysis, it will be assumed that the PFAS used in medical devices is PFHxA as a worst-case scenario.

The potential human health cost of each tonne of PFHxA 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 PFHxA in humans has been estimated to be 32 days,[7] 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).[7] The half-life of PFHxA in humans is, therefore, around 40.8 times shorter than the average for PFOA and PFOS (Min = 31.4 times shorter, Max = 50.2 times shorter).

The toxicity of PFHxA and PFOA have been compared in a mammalian model using rat IPC-81 and C6 cell lines.[8] The EC50 values for IPC-81 were 3715.4µm and 457.1µM for PFHxA and PFOA respectively, and for C6 were 7943.3µM and 676.1µM for PFHxA and PFOA respectively. Taking the averages of these values, PFHxA can be estimated to be 9.9 times less toxic than PFOA.

Combining the half-life and toxicity data together, this would suggest that PFHxA is 405 times less hazardous than PFOA/PFOS on average (40.8 times shorter half-life multiplied by 9.9 times lower toxicity. Min = 312 times less hazardous, Max = 499 times less hazardous). This figure is reasonable given that PFHxA does not meet the criteria for bioaccumulation or toxicity described in Annex XIII of REACH.[58]

Taking the lower hazard of PFHxA into account, it can be estimated that the potential human health cost of PFHxA in the environment is €726 per year for each tonne emitted (€294,105 per year for each tonne of PFOA/PFOS emitted divided by the 405 times lower hazard of PFHxA. Min = €276 per year for each tonne of PFHxA emitted, Max = €3,160 per year for each tonne of PFHxA emitted).

In making such a comparison between the potential health cost of PFHxA 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.[24] 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".[24] The environmental distribution of PFHxA will also be approximately the same as that of PFOA/PFOS given the similarity in their molecular structures and chemical functionality.

Each year of medical device manufacture for the EU market is reported to result in the emission of 239 tonnes of 'PFAAs and PFAA precursors' (low estimate = 128 tonnes, high estimate = 350 tonnes), which would include PFHxA. This means that the potential human health cost due to environmental exposure to PFAS resulting from this activity is €173,445 per year (€726 per year for each tonne emitted multiplied by 239 tonnes. Min = €35,384 per year, Max = €1.11 million 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 €173,455 per year by 30 years, suggesting that the equivalent amount relating to medical devices only would be €5.20 million per year. These figures are a worst-case, as much of the 'PFAA and PFAA precursor' PFAS used in medical devices would be substances which are less hazardous than PFHxA. It is noted that emissions of PFAS gases and fluoropolymers from medical device manufacture are not included in the calculations as they pose a much lower hazard than PFHxA due to being shorter-chain PFAS / biologically inert polymers, and their relative contribution to environmental human health costs will be minimal.[33]

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 medical device PFAS for the EU market will cause during the entire lifetime of that PFAS in the environment.

Again, as a worst-case scenario, the PFAS used in medical devices will be assumed to be PFHxA. The persistence of PFHxA has not been well studied, but it is expected to be broken down in the troposphere by hydroxyl radicals based on data for shorter-chain perfluorinated carboxylic acids.[59] It is also reported that PFHxA degraded by 45% during 15 weeks in a closed bottle biotic test (as the ammonia salt).[60] From this data, the half-life of PFHxA under these conditions can be calculated to be 140 days. It is possible that the products of this degradation were also PFAS, but such products would almost certainly have a shorter fluorinated carbon-chain and so be significantly less hazardous than PFHxA.[5-8] Judging by half-life data for other PFAS, however, an environmental half-life of 140 days 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.[24] Also, PFOA has a calculated aqueous half-life of 235 years,[61] 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)[62]. Assuming first-order kinetics, half-lives of 235 years, 100 years (which might represent a realistic absolute worst-case scenario for the persistence of PFHxA, given

that it is broken down by hydroxyl radicals in the troposphere), 10 years and 140 days correspond to degradation rates of 0.29%, 0.69%, 6.7% and 83.5% per year respectively.

As calculated above, the potential human health cost per year resulting from one year of medical device manufacture for the EU market is €173,445 , but this potential health cost would be expected to decrease over time as the amount of PFHxA remaining in the environment reduces due to degradation (for example, due to reaction with hydroxyl radicals or due to the action of bacteria). 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)[63]:

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

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 PFHxA 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 medical device manufacture, calculated for four different potential environmental half-lives of PFHxA, are shown in Table 3.

The maximum level of PFHxA in the environment which could potentially be reached through accumulation, based on yearly emissions of 239 tonnes, was also calculated for the four possible PFHxA environmental half-lives (Table 3) using the following formula:

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

where 's_2' is the maximum amount of PFHxA in the environment and 'a_2' is the output of PFHxA each year. The highest level, 120,690 tonnes, is significantly lower than the 209,500 tonnes of PFOA/PFOS which would be expected to be currently present in the environment (assuming 30 years of emissions of 7,707 tonnes per year and an environmental half-life of 100 years, i.e. a percentage degradation per year of 0.69%).

Clearly, this maximum potential PFHxA amount in the environment would increase if the use of PFAS in the medical device sector were to increase, however, such an increase would suggest more patients were being treated with medical devices, bringing substantial socioeconomic benefits. PFAS use in medical devices would also introduce significant amounts of PFAS gases and fluoropolymers into the environment, but such substances pose a much lower hazard/risk and so will have a lower impact.[33,45]

Table 3. The total human health cost resulting from one year of medical device manufacture for the EU market and the maximum environmental level of PFHxA resulting from continued manufacture of medical devices for the EU market at current volumes.

	Environmental half-life of PFHxA			
	140 days	10 years	**100 years**	235 years
% degradation per year	83.5	6.7	0.69	0.29
PFHxA emissions per year / tonnes	239 (Min = 128, Max = 350)			
Human health cost per year / €	€173,445 (Min = €35,384, Max = €1,106,134)			
Maximum PFHxA level / tonnes	286 (153, 419)	3,567 (1,910, 5,224)	**34,638** (18,551, 50,725)	82,414 (44,138, 120,690)
Total human health cost / € millions	0.208 (0.042, 1.32)	2.59 (0.528, 16.5)	**25.1** (5.13, 160)	59.8 (12.2, 381)

Assuming an environmental half-life of PFHxA of 100 years, the total potential environmental health cost associated with the medical device PFAS manufactured each year for the EU market, across the whole lifetime of that PFAS, is calculated to be €25.1 million. The total amount of 'PFAA and PFAA precursor' PFAS present in the environment resulting from medical device manufacture for the EU market is expected to reach a maximum of 34,638 tonnes, which is significantly less than the amount of PFOA/PFOS currently in the environment assuming that 7,707 tonnes has been emitted each year over a 30-year period.

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 medical device PFAS used each year for the EU market would be within an order of magnitude of €25.1 million.

4. Comparison and discussion of costs/benefits associated with restricting and continuing PFAS use in medical devices

The best estimate of the potential environmental human health costs due to annual PFAS manufacture for the EU medical device market of €25.1 million per year, calculated over the entire lifetime of that PFAS in the environment, is small in comparison to the expected benefits of the continued use of PFAS in medical devices, which are calculated to be over €1 trillion per year by each of the methodologies used in Section 2 above. Also, this environmental human health cost is 18,647 times smaller than the minimum estimate of the socioeconomic benefits of PFAS in medical devices, which is €469 billion per year (see Section 2.3 above). Furthermore, the highest estimate of the environmental human health cost, €381 million per year, is 1,229 times smaller than this minimum estimated annual benefit of PFAS in medical devices.

The estimated environmental human health cost due to medical device PFAS is a relatively small figure, but it should be noted that there are other potential environmental impacts that have not been

considered. Similarly, the calculated socioeconomic benefits of the continued use of PFAS in medical devices described in Section 2 above do not take into account the savings that would be made in the sector from avoiding redundancies and from not having to develop, test and obtain regulatory approval for new medical devices.

It is noted that the estimated environmental human health cost due to medical device PFAS emitted each year of €25.1 million is more than two orders of magnitude smaller than the calculated benefits of PFAS in individual medical devices such as RGP contact lenses[33] and spectacle lenses (see Section 2.2 above).

It may come as a surprise that the estimated human health cost of medical device PFAS in the environment is so much smaller than the socioeconomic benefits that are derived from their use, but this can be rationalised by considering that when PFAS are added to medical devices the type, amount and location 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.

For reference, even the minimum estimate of the socioeconomic benefits of PFAS in medical devices, €469 billion per year, is two orders of magnitude greater than the combined €2.1 billion per year of human health and environmental benefits reported for the 12 REACH restrictions conducted between 2010 and 2020 for which quantification was performed.[64]

4.1 The case for a 13.5-year derogation for medical devices

There is clearly some uncertainty in the above calculations, but they suggest that restricting the use of PFAS in medical devices poses a much greater risk and potential socioeconomic impact than not doing so.

This indicates that in cases where there is a lack of information, risk and negative socioeconomic impact would be reduced by making the assumption that a derogation for a use of PFAS in a medical device is required, in order to protect patients, rather than assuming that one shouldn't be granted. Derogations should only be omitted where there is substantial and robust evidence that non-PFAS alternatives are available and meet the same level of performance as current medical devices.

Given that there is a severe lack of information on PFAS use in medical devices,[22,28-29] with a likelihood that many applications will not be identified during the restriction process,[22] that alternatives have been proposed for medical devices on the basis that they are available or on the market,[28] rather than that they are confirmed to offer the same level of performance, and that the challenge of obtaining socioeconomic data sufficient to demonstrate that a derogation for the use of PFAS in a medical device is required to protect patients is enormous, there is a strong argument that a 13.5-year derogation for medical devices is warranted and justified.

There is a risk that such an approach will act against increasing the likelihood of companies engaging in future restrictions, as a lack of information could be considered to make a derogation more likely, but medical device users need to be protected. Information gathering to ensure that Dossier Submitters, ECHA and the European Commission can make fully informed recommendations and decisions is a weakness in the current REACH restriction framework[28-29] that would be better addressed by other means than the threat that derogations will be withheld. Otherwise, the quality or otherwise of submissions made by interested parties, such as industry, becomes the main determinant of whether medical device users are protected by derogations where necessary, in effect making these interested parties responsible for patient safety. This is presumably not the intention of the REACH

restriction process as it is made clear in Annex XV that interested parties are 'invited' to contribute, rather than being obligated or legally required to do so.[37] It is noted that other authorities considering restricting the use of PFAS have first attempted to introduce a legal requirement for companies to report their utilisation of these chemicals,[65-66] presumably so that the knowledge gap is significantly reduced and the authorities themselves are sufficiently informed to be able to make appropriate socioeconomic analyses before decisions on derogations are made.

4.2 The case for an unconditional (time-unlimited) derogation for medical devices

4.2.1 The performance benefits of PFAS will never be replicated

Fluorinated chemicals such as PFAS are unique and confer an extraordinary range of beneficial properties to materials including chemical inertness, thermal stability, resistance to acids and bases, immiscibility, repellence to both oil and water, biocompatibility, low toxicity (for many PFAS), optical clarity, durability, low friction, abrasion resistance, electrical resistance, dielectric properties and oxygen permeability. Alternative substances may have a good level of performance in one, or perhaps a few, of these areas but do not perform well in all. Moreover, for some properties, such as chemical inertness or the ability to repel other substances (including both those that are hydrophilic and hydrophobic), there are no other types of organic molecule that match up.

The uniquely beneficial properties of PFAS result from the unique properties of the chemical element fluorine.[36] Fluorine is the most electronegative element (Figure 1), and forms chemical bonds to carbon atoms which are stronger (Table 4) and more polar than between carbon and any other element. Fluorine is the least polarizable element that can bond to carbon atoms (Figure 2), which confers the unique property of being both hydrophobic and hydrophilic. Fluorine also has the shortest Van der Waals radius of any atom that bonds to carbon apart from hydrogen, which results in minimal steric strain and confers temperature stability.[36] Moreover, fluorine and carbon are light elements and so performance-to-weight ratio is high. There is no possibility to extend the toolkit of stable elements available to chemists. No amount of research will ever identify an element as electronegative as fluorine or one that is as non-polarizable. Nor will it ever identify organic chemical single bonds that are as strong, as stable or as polar as those between fluorine and carbon. PFAS are chemically irreplaceable.

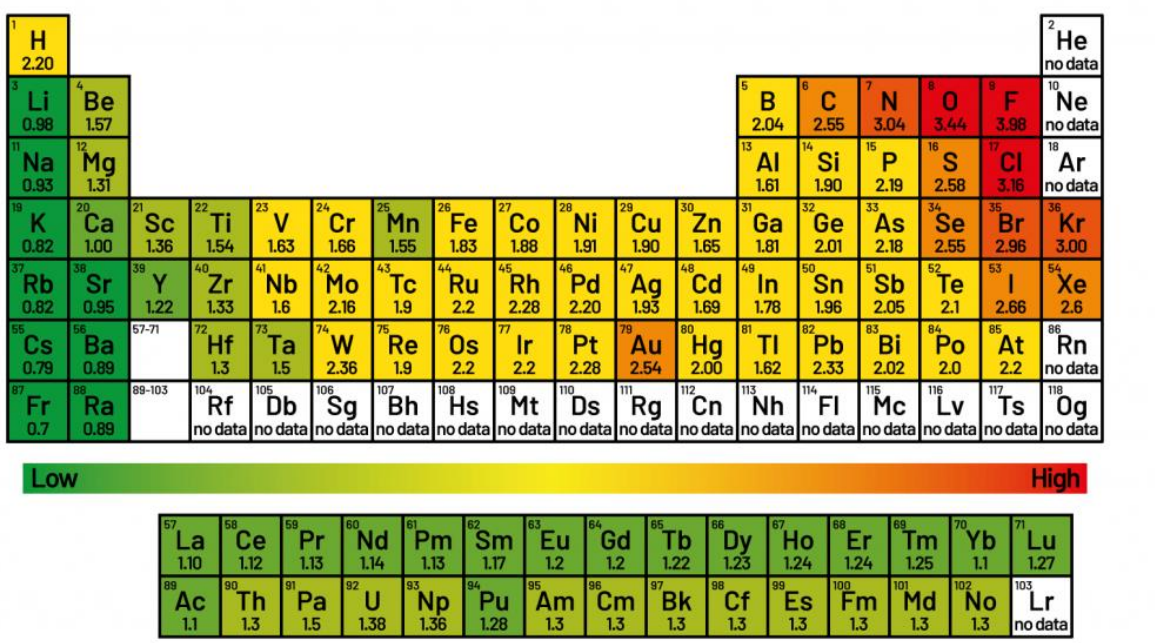

Figure 1. The electronegativity of the chemical elements

Table 4. Bond energies (strengths) of single bonds to carbon atoms (kJ/mol)

*Bond Energies, *D*	
Single	**Bonds**
C—H	414
C—C	348
C—N	293
C—O	351
C—F	439
C—Cl	328
C—Br	276
C—I	238
C—S	259

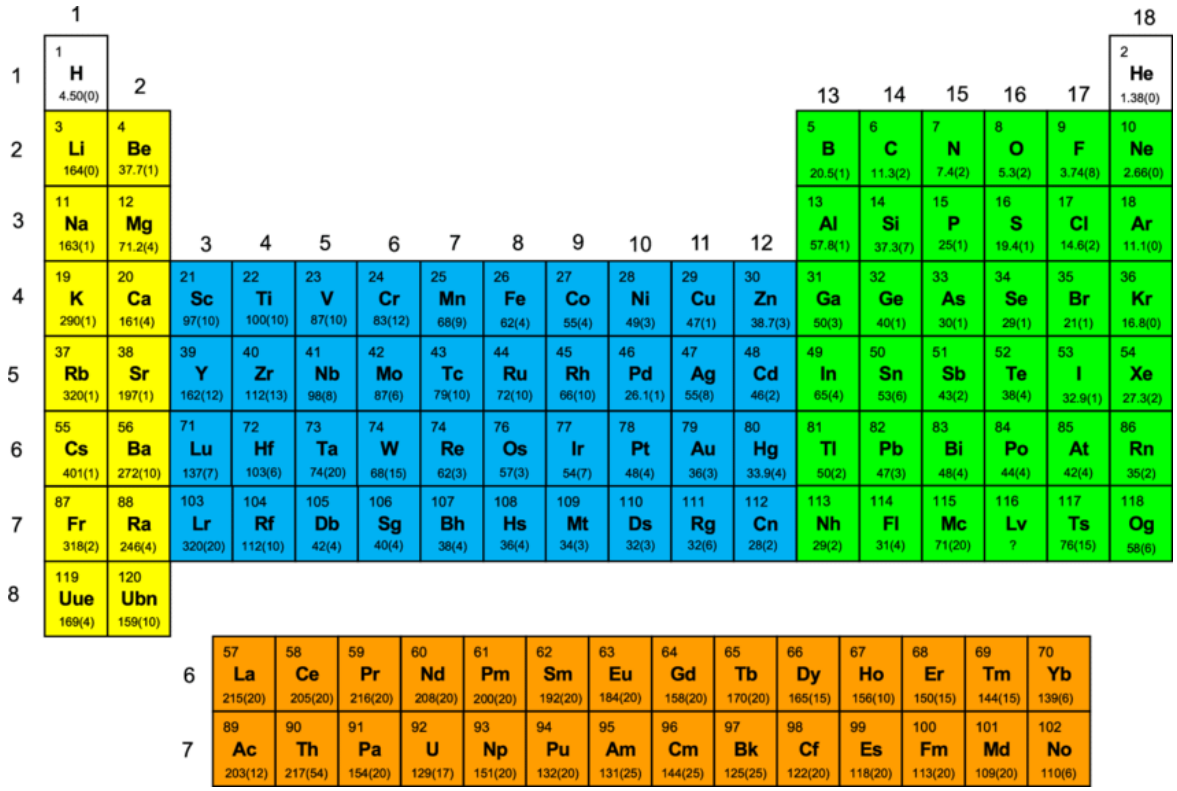

Figure 2. The polarizability of the chemical elements

This irreplaceability is reflected in the difficulties that have been encountered with finding alternatives for antifouling PFAS coatings on protective medical apparel.[30] Finding alternatives for other medical devices may be even more of a challenge as other properties such as biocompatibility and chemical stability may also be required.

For any application where performance is maximised by a particular property of PFAS, or where adequate performance is achieved through a combination of the beneficial properties of PFAS, it is expected that a PFAS ban will lead to a significant and permanent decrease in the effectiveness of that application. For medical devices, such a permanent drop in effectiveness is both unacceptable and likely to be widespread.[16,22]

4.2.2 Proportionality

An unconditional (time-unlimited) derogation is not offered as an option in the PFAS Annex XV report apart from in a small number of cases. Restriction options RO1 (no derogations) and RO2 (limited numbers of time-limited derogations) are justified on the basis that "eventually the societal cost of inaction will always surpass the costs of a ban on the use of PFASs" (see page 3 of the Annex XV report).[24] This is presumably based on a supposition that either alternatives will eventually match the performance of PFAS, or that the environmental cost of PFAS emissions will essentially become infinitely great. As shown above, neither of these scenarios are likely to reflect reality.

Because of the unique chemical nature of PFAS,[36] there is a strong likelihood of a permanent drop in the effectiveness of medical devices if use is restricted. The associated risks to users are greater than those posed to the environment by the continued use of PFAS in medical devices, particularly as the

most hazardous PFAS are already restricted. Moreover, the magnitude of the permanent drop in medical device effectiveness might be expected to be several percent, but even if it is only 1%, the anticipated negative socioeconomic impact of €621 billion per year (Table 2) would dwarf the potential human health costs of the continued use of PFAS in medical devices (which as described in Section 3 above is estimated to be €25.1 million per year, calculated over the entire lifetime of the emitted PFAS in the environment).

4.2.3 Comparison of the socioeconomic benefits of PFAS in medical devices with remediation costs

The cost of an EU-wide PFAS remediation programme has been estimated to be €16.9 billion, with an upper limit of €171 billion.[42] Although these are enormous sums, they are significantly smaller than the lowest estimate of the benefit of the use of PFAS in medical devices each year, of €469 billion (Table 2). If the use of PFAS in medical devices continues, remediation could be performed at regular intervals to reduce PFAS levels in the environment, while still being highly beneficial from a socioeconomic perspective.

The fact that remediation is viable from a cost perspective dramatically reduces the risk associated with the continued use of PFAS in medical devices. Even if, in future, additional human health effects of PFAS are identified, making continued use completely unacceptable, remediation could be applied to mitigate the impacts from environmental exposure. This removes many potential objections to an unconditional derogation for the use of PFAS in medical devices.

4.2.4 Un unconditional derogation should be granted on the basis of the precautionary principle

If no further action is taken, the use of PFAS in medical devices will be terminated according to restriction option RO1 or RO2. Such a restriction puts at risk the health, safety, productivity and quality of life of over a hundred million EU citizens who use medical devices each year. As described above, there is considerable scientific uncertainty over whether it will ever be possible to adequately replace PFAS in medical devices. Fluorine is a unique chemical element which gives PFAS substances an unrivalled level of performance in many critical areas. Even a 1% drop in the average efficacy of medical devices for patients would be catastrophic and disproportionate in comparison to the environmental concerns of the PFAS used in these devices. If nothing changes, such a drop in performance is an almost inevitable outcome of the current approach to restricting PFAS, even if time-limited derogations are applied under RO2, as it has been confirmed that there will be no possibility of extending derogations beyond 13.5 years.[40] It is clear, therefore, that the conditions for applying the Precautionary Principle are met,[67] and that action must be taken to protect medical device users or to prove the absence of danger. Within the PFAS restriction, an action which would be appropriate would be the granting of an unconditional (time-unlimited) derogation for the use of PFAS in medical devices. Exceptions could be made to this derogation for any type of medical device where it can be adequately proven either that PFAS-free alternatives do not perform at a lower level for any patient group or that the negative consequences for patients of moving to PFAS-free alternatives are smaller than the environmental impact of continued PFAS use.

5. A new restriction option which benefits both medical device users and the environment

An alternative restriction option, RO3, is proposed. Under this option, the use of PFAS in medical devices is given an unconditional (time-unlimited) derogation. In addition, a small proportion of the savings from the healthcare costs and decreased economic productivity which are avoided by not restricting the use of PFAS in medical devices are put into remediation and into scientific research to improve remediation efficiency and cost-effectiveness.

A socioeconomic analysis has been performed to determine whether RO3 is beneficial in comparison to Restriction Option RO2 and in comparison to the baseline scenario (i.e. no restriction of the use of PFAS in medical devices).

5.1 The aim of the socioeconomic analysis

This study aims to quantify and compare the health, safety and quality of life costs of restricting the use of PFAS in medical devices for users with the potential environmental human health costs and remediation costs of this continued use under different scenarios.

5.2 The scope of the socioeconomic analysis

The baseline scenario is that the use of PFAS in medical devices continues without restriction. Within the baseline scenario it is recognised that the PFAS already in the environment in the EU is currently estimated to have a human health cost of €52-84 billion per year.[24,42]

There are two proposed options for restricting the use of PFAS in medical devices: RO2 - the use is stopped after a 13.5-year derogation period, and RO3 - an unconditional (time-unlimited) derogation is granted for the use of PFAS in medical devices, and the environmental impact of the PFAS resulting from continued use is instead controlled by EU-wide remediation performed every 10 years.

For this analysis it is assumed that the efficacy of PFAS-free alternative medical devices for patients will never match that of PFAS containing devices, and that on average the drop in performance without PFAS will be 1% (see Section 4 above for a rationale).

It is also assumed that the half-life of PFAS in the environment is 100 years (see Section 3 above for a rationale).

The analysis will focus on potential impacts to health, quality of life and environment and will be limited to the EU at the years 2040, when the 13.5-year derogation might be expected to end, at 2050, after one cycle of remediation has been performed under RO3, and at 2140.

5.3 Identification and assessment of impacts

An analysis of impacts is given in Section 1-4 above.

Uncertainties in the analysis are addressed through the use of ranges (e.g. minimum and maximum values for the cost impact of PFAS restriction on patients).

5.3.1 Assessment of costs under the baseline scenario

5.3.1.1 Human health costs due to PFAS already in the environment

This has been estimated to be €52-84 billion per year in the EU.[24,42] As described in Section 3, these costs refer primarily to PFOA/PFOS, and precursor species, which are already restricted and so are not expected to increase in concentration in the environment. In fact, taking the assumption that the half-life of PFAS in the environment is 100 years, and degradation follows first-order kinetics, the amount of PFOA/PFOS in the environment should decrease by 0.69% per year. The human health cost would be predicted to decrease by the same proportion.

The middle of the range proposed for the current human health cost due to PFAS in the environment in the EU is €68 billion per year. The health cost after degradation has occurred over a given number of years can be calculated by using the following formula:[68]

$$a_n = a.r^{n-1}$$

Where 'a_n' is the human health cost after a number of years, 'a' is the initial human health cost, '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 PFAS in the environment is lower) and 'n' is the number of years.

By 2040, the human health cost can be estimated to have reduced from €68 billion per year to €60.4 billion per year (Minimum estimate, based on an initial value of €52 billion per year, = €46.2 billion per year, Maximum estimate, based on an initial value of €84 billion per year, = €74.7 billion per year).

By 2050, the human health cost is estimated to have reduced to €56.4 billion per year (Minimum estimate = €43.1 billion per year, Maximum estimate = €69.7 billion per year).

By 2140, the human health cost is estimated to have reduced to €30.2 billion per year (Minimum estimate = €23.1 billion per year, Maximum estimate = €37.4 billion per year).

5.3.1.2 Human health costs due to the continued use of PFAS in medical devices

As described in Section 3, PFAS emissions from medical device manufacture each year are estimated to potentially result in human health costs of €25.1 million when calculated over the entire lifetime of that PFAS in the environment (Min = €5.13 million, Max = €160 million).

5.3.2 Assessment of costs under restriction option RO2

5.3.2.1 Human health costs due to PFAS already in the environment

These costs are the same as calculated in Section 5.3.1.1 above.

5.3.2.2 Socioeconomic costs of restricting the use of PFAS in medical devices for patients

Under the assumption that such a restriction leads to on average a permanent 1% drop in medical device efficacy, the socioeconomic costs are estimated to be €621 billion per year by 2040 when any derogations have expired (Table 2. Min = €469 billion per year, Max = €773 billion per year).

5.3.3 Assessment of costs under restriction option RO3

This analysis will assume a highly pessimistic scenario, that an EU-wide remediation programme is only 20% effective at removing PFAS from the environment and that such a programme will need to be performed regularly to control PFAS levels, in this case every 10 years.

5.3.3.1 Costs of remediation

The cost of an EU-wide PFAS remediation programme has been estimated to be €16.9 billion (Min = €821 million, Max = €171 billion).

If such a programme were to be performed every 10 years, the cost per year would be €1.69 billion per year (Min = €82.1 million per year, Max = €17.1 billion per year).

5.3.3.2 Costs of research and development

Under restriction option RO3, investment is made into research and development with the aim of improving the effectiveness of PFAS remediation chemistry and technology and of identifying biological mechanisms for breaking down PFAS in the environment. There have been several recent innovations relating to chemically breaking down PFAS into harmless components,[13, 69-72] and further research investment would expand knowledge and enable technologies to become more effective at larger scales. The persistence of PFAS in the environment stems from the strength of the carbon-fluorine chemical bond and the challenge that it poses bacteria to break it down.[73] There are, however, previous examples of recalcitrant chemicals that have become readily biodegradable once bacteria have become sufficiently exposed to them to them.[74] PFAS, as relatively recently invented chemicals, could follow a similar pattern, especially as examples of bacterial breakdown have been reported.[13, 75-79] Identifying or selectively breeding bacteria with the right characteristics for breaking down PFAS in the environment is thought to be feasible,[13, 80] and this process could be accelerated with increased research funding.

If the amount spent on R&D is approximately the same as on remediation, the European research budget could be increased significantly. A figure of €1.36 billion per year is proposed for this analysis, which would increase the EU research budget by 10% (Minimum R&D investment, 5% of current EU budget, = €0.68 billion per year, Maximum R&D investment, 25% of current EU budget, = €3.40 billion per year).[81]

This investment would be expected to reduce remediation costs in future and potentially to reduce the recalcitrance of PFAS in the environment to the point where their risk is reduced by orders of magnitude. Arguably, it is more likely that R&D will lead to a major reduction in the persistence of PFAS in the environment than it is to lead to the identification of non-PFAS alternatives that match the level of performance of PFAS in medical devices.

5.3.3.3 Human health costs due to PFAS already in the environment

In 2040, the human health cost would be the same as described in Sections 5.3.1.1 and 5.3.2.1 above. The cost in 2050, however, would be reduced by 20% due to the action of remediation, from €56.4 billion per year to €45.1 billion per year (Min = €34.5 billion per year, Max = 55.7 billion per year).

This equates to a 25.4% reduction in human health costs over a 10-year period. The cost in 2140 can therefore be calculated to be €3.25 billion per year (Min = €2.48 billion per year, Max = €4.21 billion per year).

5.3.3.4 Human health costs due to the continued use of PFAS in medical devices

As described in Section 3 above, the expected human health cost of PFAS emissions each year associated with medical devices is €173,445, and the total human health cost of this PFAS over its entire lifetime in the environment is calculated to be €25.1 million.

If remediation is performed, the total human health cost would be expected to be lower.

Assuming the amount of PFAS remaining in the environment reduces by 0.69% per year (half-life of 100 years), the sum of the human health cost of the PFAS emitted over the first 10 years can be calculated to be €1.68 million. As calculated in Section 5.3.3.3, the human health costs decrease by 25.4% every 10 years if remediation is performed. The total human health cost can then be calculated using the formula for a geometric series as applied in Section 3:[63]

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

but here 'a' is the sum of the human health costs over the first 10 years and 'r' is the inverse of the ratio between the human health costs for the first 10 years and the human health costs for the following 10 years (which will be 25.4% lower).

Using this formula, it is calculated that with remediation, the potential human health cost of PFAS emissions from medical device manufacture each year will be €6.63 million, when calculated over the entire lifetime of that PFAS in the environment (Min = €1.35 million, Max = €42.3 million), a significant reduction from the €25.1 million estimated human health cost without remediation.

5.4 The balance of socioeconomic costs (interpretation and conclusions)

The costs under each scenario have been summed together in Table 5.

<u>Comparison of restriction option RO2 with restriction option RO3:</u>

At all time-points restriction option RO2 is more costly than restriction option RO3 by more than an order of magnitude. By 2140, this difference increases to two orders of magnitude.

The maximum estimate of costs under RO3 is lower than the minimum estimate of costs under RO2 at each time-point.

From a socioeconomic perspective, RO3 is both significantly more beneficial for the environment and significantly more beneficial for medical device users than RO2.

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. Inflation is not taken into account in this analysis, and the costs of remediation, R&D and health impacts could change at different rates over the coming years, though there is no reason to expect this to be the case. PFAS volumes are expected to increase in medical devices in future, so the negative environmental impact of continued use would be expected to increase. However, if volumes do increase it would be expected that medical device users would derive benefits from this increase which far outweigh the greater environmental costs. It would be expected that remediation would become more effective each cycle as a result of the significant resources devoted to research under RO3. This would have the effect of reducing costs for RO3, in particular at the 2140 time-point, but has not been accounted for in this analysis.

It is noted that the environmental half-life of PFAS has been assumed to be 100 years. If in reality the half-life is shorter, remediation would be less cost effective, and vice-versa.

Table 5. Combined environmental and health/quality of life annual costs calculated for the baseline scenario and under the potential restriction options for the years 2040, 2050 and 2140.

2040 Scenario	Best estimate of costs (€ billions)	Minimum estimate of costs (€ billions)	Maximum estimate of costs (€ billions)
Baseline	60.5	46.2	74.8
Restriction option RO2	681	515	848
Restriction option RO3	63.5	47.0	95.2
2050 Scenario	Best estimate of costs (€ billions)	Minimum estimate of costs (€ billions)	Maximum estimate of costs (€ billions)
Baseline	56.4	43.1	69.8
Restriction option RO2	677	512	843
Restriction option RO3	48.2	35.3	76.3
2140 Scenario	Best estimate of costs (€ billions)	Minimum estimate of costs (€ billions)	Maximum estimate of costs (€ billions)
Baseline	30.3	23.1	37.5
Restriction option RO2	651	492	810
Restriction option RO3	6.31	3.25	24.5

<u>Comparison of restriction option RO3 with the baseline scenario:</u>

In 2040, RO3 is slightly more costly than the baseline scenario, but by 2050 it is less costly and by 2140 it is almost 5 times less costly. This is due to remediation reducing the amount of PFOA and PFOS in the environment.

As shown in Section 5.3.3.3 above, remediation is predicted to reduce the human health cost of PFAS already in the environment from €56.4 billion per year to €45.1 billion per year by 2050. If no further remediation was performed at this point, the total human health cost of this PFAS during its lifetime in the environment, assuming a half-life of 100 years, would be €8.17 trillion without remediation and €6.54 trillion with remediation, a saving of €1.63 trillion. Remediation is highly cost effective at this time point, but becomes less so over time, and should be performed less frequently after 2140.

Restriction option RO3 is a cost-effective way of reducing the negative environmental impact of PFAS in the environment while protecting medical device users.

Although remediation would be costly for the EU, the spending can be justified on the basis of the overall savings that can be made. Moreover, the EU has gained enormously from reduced healthcare costs and increased productivity due to the PFAS in medical devices improving people's lives over recent decades. Noting that these reduced costs could be around €15.5 trillion per year (Table 3), it can be concluded that, in total, the use of PFAS in medical devices has saved the EU hundreds of trillions of Euros. Putting a small proportion of this sum back into PFAS remediation would not be unreasonable.

6. Conclusions

There is a strong case for medical devices to be granted an unconditional (time-unlimited) derogation from the PFAS restriction in order to reduce both risk and negative socioeconomic impact. Restriction should only be applied for those medical devices where it is adequately demonstrated that PFAS-free alternatives match or exceed the current level of performance for all patient groups and indications. Even this may be unnecessary as the current consumer desire for PFAS-free products means that any alternatives which are as good as, or better than, existing PFAS medical devices would inevitably be a commercial success.

Medical device users need to be protected from the negative consequences of losing PFAS from products in the absence of equivalently performing alternatives. Such PFAS loss may end up being driven not only by restriction, but also by commercial or political pressure, or by principles such as 'polluter pays', which don't take into account that PFAS are primarily used in medical devices to benefit patients. Steps should be taken to avoid such scenarios.

More generally, in the EU Charter of Fundamental Rights, Article 35 on 'Health care' states "A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities".[82] It is hard to imagine how a process such as REACH restriction, which is acknowledged to be deeply flawed,[28-29] yet which can put at risk the level of health care provision for hundreds of millions of EU citizens (i.e. users of PFAS medical devices), without either ensuring that these people will be identified and protected, or ensuring that they will only be allowed to be negatively impacted if it is rigorously demonstrated that the environmental benefits of doing so are greater, and without even guaranteeing that sufficient information and expertise is made available to support well-reasoned decision making,[28-29, 83] meets this criteria.

The ongoing REACH revision should be utilised to address the serious issues over availability of data, for example on uses and alternatives, during REACH restrictions, perhaps by introducing compulsory reporting of such information at an early stage of the process, as has been attempted in the US.[65-66] Moreover, there should be an EU body within the restriction process which is given responsibility for ensuring that the best possible cases for derogations are compiled wherever the safety and quality of life of consumers such as medical device users are put as risk (ideally forming active collaborations with stakeholders), rather than this responsibility ending up being pushed onto industry,[1] or ending up being entirely unmet.

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83. The following is given as an illustrative example: During the 2021 consultation on the PFAS restriction two trade associations submitted concerns that the ability to safely and effectively correct the eyesight of current rigid contact lens (RGP) wearers would be impacted by the loss of PFAS, supported by a scientifically referenced report. The PFAS Annex XV report tentatively proposes a 13.5-year derogation, but it is stated that further information would be required if one is to be granted. As things stand, RGP wearers will not be protected from the negative impact of the PFAS restriction. Moreover, the type of socioeconomic data that seems to be considered necessary for a derogation to be granted can be nigh on impossible to acquire, and at this stage of a REACH restriction process there is no EU body or other stakeholder who is responsible for collecting this data,[37,84] as described in the introduction above. Furthermore, in this case, interested parties (who are not experienced with socioeconomic analysis) have subsequently made multiple requests to the Dossier Submitters and ECHA for assistance and for further details of what additional information would be required in order that RGP patients could be protected with a derogation, yet no assistance was offered other than highly generic responses that data should be submitted to the consultation, or that guidance documents should be consulted (even when it was made explicit that the guidance documents do not cover many relevant aspects and that the 'interested parties' were trying to make as strong a case as possible to protect the "safety and quality of life of several million people who currently benefit from having PFAS in their medical device").

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