

European Chemicals Agency (ECHA)
Telakkakatu 6, P.O. Box 400
FI-00121 Helsinki
Finland

PFAS Restriction Proposal - Public Comment Phase
2023-04-20

Dear Ladies and Gentlemen,

Rest assured that we are more than aware of the serious problems associated with indestructible products damaging the world's natural environment, and that we make every effort to support keeping the necessary use of toxic, bioaccumulable materials down to an absolute minimum. However, we are also extremely concerned about ensuring access to the essential products that we require to adequately care for our patients with eye diseases. It was in this context that we were recently informed about your intentions to restrict the use of fully fluorinated alkanes. We find that what has unfortunately been missing entirely in the current discussion is any consideration of the possibility of chemical recovery and safe disposal. We would be compelled to reject a total ban of such substances, especially used as medical devices, as we feel it would be unjustifiable.

Please allow us to clarify our position. Ocular endotamponades belong to the group of compound substance classes. Even at this late stage in the decision-making process, we wish to emphasize how significant and important these compounds are to our field of medicine, namely ophthalmology, as they are administered regularly – daily, in fact – when we carry out eye surgery on the retina and vitreous body. Our patients are suffering from serious vision-impairing eye diseases, and the risk-benefit ratio of having to rely on these substances lies without a doubt entirely in our patients' well-being.

Liquid endotamponades like perfluorodecalin (PFD) and perfluorooctane (PFO) as well as gaseous endotamponades like perfluorocarbon, hexafluoroethane (C₂F₆), and octafluoropropane (C₃F₈) have become indispensable curative tools in the surgical therapy of serious and severe retinal diseases during the last few decades. The introduction of these substances in retinal surgery was in fact a sea change, a genuine paradigm shift, and modern vitreoretinal surgery cannot be imagined without them.

The introduction of intravitreal *liquid perfluorocarbons* as intraoperative devices in the 1990s proved to be a milestone in the development of surgery of the retina and vitreous body for complex eye diseases as until then, we could not adequately treat surgically. Their intraoperative application is vital to help us cure or at least alleviate these eye diseases sufficiently. Moreover, in the surgical therapy of rhegmatogenous retinal detachments – one of the most frequent operative indications of all – they make the procedure more controllable and safer or make surgical therapy possible in the first place, and the success rates of these operations have increased dramatically since their introduction. Our ability to use these substances as intraoperative tools is mandatory because without them, our patients will suffer much poorer operative outcomes and worse vision.

For the last 40 years, *gaseous tamponades like C₂F₆ and C₃F₈* have become indispensable, and there is to date no alternative to using them as tamponade substances in about half of vitreoretinal interventions. Without such tamponades, the surgeon's operative concept is incomplete and doomed to fail with the result that the affected eye will very probably go blind. In other words, we would have to take such operations off the list of indicated surgeries we perform – a step backwards from a medical point of view, and incomprehensible and unjustifiable from the patient's view.

Heavy oil, with per- and polyfluorinated components like perfluorohexyloctane or perfluorooctyl-2-methyl-4-ene, is employed as a short-term tamponade to treat the most severe types of retinal detachments, and there is no substitute for it to alleviate this particular condition.

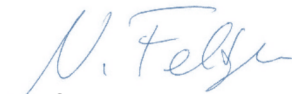
Back before these effective substances became available for intraocular tamponades, we had to tolerate much higher rates of blinded patients. That is why we cannot imagine modern vitreoretinal surgery without them. Their abolition would lead to a dramatic and incalculable rise in permanent severe vision impairments and even total blindness. We would be unable to handle the rising numbers of vitreous body interventions without relying on per- and polyfluorinated substances (PFAS). We see no alternatives. Another factor to consider is that the learning curves of young up-and-coming eye doctors (when operating on patients with retinal diseases) would be much longer.

We kindly request that you take our justifiable concerns into account when making your decision, and we would be happy to provide you with further information on the ophthalmological application of these substances if you wish.

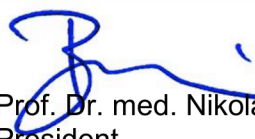
Based on the above-mentioned data, we request the inclusion of a sub-item 4. d) (derogation without time limit) in the list of derogations:

"substantial medical devices for use as ocular endotamponades (perfluorodecalin, perfluorooctane, hexafluoroethane (C₂F₆), octafluoropropane (C₃F₈), perfluorohexyloctane (F₆H₈), and perfluorooctyl-2-methyl-4-ene (RMN-3)) according to EU Regulation 745/2017."

Yours sincerely



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