Regulation (EC) No. 1907/2006 (REACH)
Proposal for a restriction of Per- and polyfluoroalkyl substances (PFASs)
submitted by
BAuA - Federal Institute for Occupational Safety and Health
Bureau REACH, National Institute for Public Health and the Environment (RIVM)
Swedish Chemicals Agency (KEMI)
Norwegian Environment Agency
The Danish Environmental Protection Agency
Date: 07.02.2023

22 March 2023

Dear Sir or Madam,

We welcome the opportunity to contribute to the public consultation initiated by the European Chemicals Agency regarding potential restriction of Per- and polyfluoroalkyl substances (PFASs) according to Regulation (EC) No. 1907/2006 ("REACH").

We understand that an online information session will be organised on 5 April 2023 to explain the restriction process and to help those interested in participating in the consultation. We will submit a more detailed statement in the follow-up to this event and in consideration of the further indications in order to address specific details of the proposal and to emphasize the special interest of our company. This notwithstanding, we submit the following observations in advance as a first indication and without limiting or determining our further submissions.

With regard to the proposed restriction on the manufacture, placing on the market or use of PFASs we submit that medical devices subject to Regulation (EU) 2017/745[1] (MDR) should be generally exempted from the restriction. In any event, at least a derogation by means of a further transitional period with a minimum of 13,5 years seems to be appropriate for medical devices.

I. Request for exemption

(1) We propose that the following wording should be incorporated into the potential REACH Annex XVII entry regarding PFASs:

> *"Paragraph 1 / the restriction shall not apply to medical devices within the scope of Article 2(1) of Regulation (EU) 2017/745"*

(2) Medical devices within the scope of Article 2(1) of Regulation (EU) 2017/745 should be exempt from the restriction for a variety of reasons, but principally because Regulation (EU) 2017/745 already provides for a restrictive framework addressing potential hazardous materials such as PFASs.

(3) Unlike many other products within the scope of the proposed restriction, medical devices make an objectively measurable contribution to one of the fundamental values of the European Union, by ensuring a high level of human health (cf. Article 35 of the Charter of Fundamental Rights of the European Union). This aspect must be taken into account in

[1] Similar considerations might apply to in-vitro-diagnostics regulated by Regulation (EU) 2017/746, although this submission does not entail any specific reference to corresponding products.

connection with the further assessment and evaluation of the restriction proposal and all considerations regarding the consultation process.

(4) While we understand the rather generic approach of the proposal, it needs to be stated that medical devices contribute to public health systems by their specific purposes as addressed in Article 2(1) of Regulation (EU) 2017/745.

(5) We further submit that the purpose of Regulation (EC) No. 1907/2006 is to ensure, inter alia, a high level of protection of human health (cf. Article 1(1) of Regulation (EC) No. 1907/2006), while its provisions are underpinned by the precautionary principle (cf. Article 1(3) of Regulation (EC) No. 1907/2006). Regulation (EU) 2017/745 already establishes a specific regulatory framework for medical devices that focuses on ensuring a high level of protection of health for patients and users (cf. Recital (2) of Regulation (EU) 2017/745). Against this background, any concerns with the hazards of specific substances, including PFASs, in medical devices are best addressed under Regulation (EU) 2017/745.

(6) Regulation (EU) 2017/745 already provides for a special regulatory framework for medical devices and in particular for all components and substances of medical devices. All medical devices must be certified before being placed on the market, whereby a risk-based approach is applied with the effect that a detailed assessment of benefits and risks is required before the product is placed on the market.

(7) According to Annex I Section 1 to Regulation (EU) 2017/745, medical devices must be designed and manufactured in such a way that they are safe and shall not compromise the safety of patients, users or other persons that is not justifiable in terms of the benefit to patients. In principle, according to Annex I Section 2 to Regulation (EU) 2017/745, risks must be reduced as far as possible without adversely affecting the risk-benefit ratio. For this purpose, manufacturers must implement a risk management system (Annex I Section 3 to Regulation (EU) 2017/745) that is updated throughout the product life cycle. For this reason, manufacturers can and must respond to new scientific findings, for example on specific substances or components.

(8) In addition to these general risk-based requirements, Annex I MDR also contains specific requirements for substances which are used in medical devices. According to Section 10.4.1 in Annex I to Regulation (EU) 2017/745, devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by substances or particles, including wear debris, degradation products and processing residues, that may be released from the device. Therefore, the consideration of the substances used in the manufacture of a medical device is an essential part of the quality management.

(9) We further submit that Regulation (EU) 2017/745 also provides for a selective regime with respect to the use of hazardous substances in medical devices, which applies only to substances with specific hazard properties used in specific medical devices (cf. Sections 10.4.1 and 10.4.2 in Annex I to Regulation (EU) 2017/745).

(10) This approach, involving a need to justify the use of certain hazardous substances above and beyond the general risk-benefit ratio analysis, would be jeopardized if a generic restriction of PFASs would be extended to medical devices.

(11) Regulation (EU) 2017/745 makes a concrete determination as to which substances in which medical products require further measures and which do not. This fine-grained differentiation must not be undermined by a generic, undifferentiated restriction under REACH. Therefore, and similar to other provisions in Regulation (EC) No. 1907/2006, like e.g. in Annex XIV as well as Annex XVII, an exemption for medical devices within the meaning of Regulation (EU) 2017/745 is reasonable.

(12) In this context, we submit that Article 60(2) and Article 62(6) of Regulation (EC) No. 1907/2006 stipulate that the Commission shall not consider the risks to human health arising from the use of a substance in a medical device in an application for authorisation. Accordingly, the ECHA Guidance on the preparation of an application for authorisation states in Section 2.2.3.3. that the use of a substance in a medical device qualifies as a use "for which authorisation application is not required". This is based on the consideration that at least the risks to human health have already been examined in the context of the specific requirements for medical devices under Regulation (EU) 2017/745. This general consideration can also be transferred to the restriction proposal at hand insofar as the proposal aims at a prohibition of the placing on the market of PFAS in another substance, as a constituent, in a mixture or in an article above specific concentration limits, with only few derogations. The restriction proposal, thus, establishes a general prohibition comparable to Article 56 of Regulation (EC) No. 1907/2006.

(13) Finally, it should also be noted that the decision of a restriction without a general exemption for medical devices would be difficult to revise. Once the restriction comes into effect, negative effects on public health and health care systems cannot be resolved retroactively. Therefore, it would make more sense to include a general exemption first and review in 5 or 10 years whether a need for a restriction of PFAS used or contained in medical devices remains.

II. Alternative: Derogation for a minimum of 13,5 years

(14) An alternative approach could be to establish a derogation of at least 13,5 years for medical devices. Corresponding derogations are already proposed for other uses of PFAS and it would be reasonable to establish a similar derogation for the use of PFAS in medical devices.

(15) In particular, the current regulatory and factual realities of the medical device industry argue for a sufficient derogation. The industry is still implementing Regulation (EU) 2017/745. There is a lack of Notified Bodies for certification procedures. In addition, there are not yet enough harmonized standards and the European medical device database Eudamed is not yet fully operational. For these reasons, there is already a shortage of medical devices, so that the EU Parliament voted to extend corresponding transitional periods. Specifically, the certification periods for manufacturers will be extended (depending on the classification of the device). Against this background, a restriction without a further derogation for medical devices would be counterproductive.

III. Further submissions

(16) The above statements and observations will be further substantiated in the course of the consultation process having regard to the instructions to be provided in the online information session on 5 April 2023. In particular, we will provide further comments on the proposal and the effects of the contemplated restriction on medical devices as well as the requested

exemptions or, alternatively, derogations. We will also provide further justifications as regards the details to be considered for exemptions or derogations. In addition, we are prepared to provide further comments on the impact of the restriction and the justification of a derogation regarding specific product groups. For the time being, we kindly request ECHA, including RAC and SEAC, as well Member States to consider this initial submission as a preliminary statement.

We would be happy to assist in case there are any further questions. Please do not hesitate to contact us, in case specific contributions might be considered helpful.

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