Section III - Non-Confidential Comment

Biotherapeutic filters are process filters used during the manufacturing of bio-therapeutic drug products or samples such as therapeutic replacement of enzymes, antibodies, blood, derivatives of plasma, and biopharmaceuticals. There are two types of these kind of filters: nanofilters and microfilters (together referred as "biotherapeutic filters").

Biotherapeutic filters are made with hydrophilized polyvinylidene fluoride ("PVDF") and are used in the manufacturing of biopharmaceutical drugs, ensuring that biopharmaceuticals are safe, ultimately protecting human health and patient safety.

The REACH restriction Proposal presents serious flaws in terms of methodology, legal principles and scientific rigour for the following eight reasons:

i. There are inaccuracies in the conditions on the proposed restriction - no exemption or derogations for the biopharmaceutical sector and Asahi Kasei Medical products;
ii. PVDF is generally included among more than 10,000 substances that possess different properties;
iii. PVDF would fall under the scope of the restriction by solely meeting a non-legally binding accepted definition;
iv. The assessment of hazard and risks of PVDF does not appear legally sound;
v. The grouping approach is incorrect;
vi. There is insufficient information on the uses, resulting emissions or exposure of PFAS in the biopharmaceutical manufacture sector;
vii. The information on alternatives is not properly assessed as regards the production of PVDF;
viii. The Proposal does not properly assess the interplay with other EU legislation such as the EU Pharmaceutical legislation.

As a consequence, biotherapeutic filters would unduly fall under the prohibitions laid down in the REACH restriction Proposal.

Within that context, we kindly invite ECHA, in particular RAC and SEAC members, to consider the following options:

a) Option 1: biotherapeutic filters should be exempted from the REACH restriction Proposal *a priori* as they should not be covered by the REACH Regulation; or

b) Option 2: biotherapeutic filters should be exempted from the REACH restriction Proposal *a priori* as they are used in a closed system; in alternative,

c) Option 3: biotherapeutic filters should benefit from a time-unlimited derogation as the same rationale of plant protections products, biocides and human and veterinary medicines should apply.

In support of all three options, ECHA, in particular RAC and SEAC members, should consider that fluoropolymers, such as PVDF, do not pose any risks to the environment and human health.

On a general basis, it is important to note that the restriction of PFASs must be substance-related and risk-based (Article 68 para. 1 of the REACH Regulation). It is clear that not all PFAS pose an unacceptable risk that would justify a restriction. Especially, the restriction must differentiate between the different groups of PFAS and the risks, and the risks posed by their uses. ECHA, in particular RAC and SEAC members, should consider that fluoropolymers, such as PVDF, do not pose any risks to the environment and human health and should be generally exempted from the PFAS Restriction or benefit from a time-unlimited derogation.

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We ask ECHA, in particular RAC and SEAC members, to carefully take this information into account and reflect it in their opinions, in accordance with articles 70 and 71(1) REACH as well as the general principles of EU law, such as due process, right of good administration and right of defence.