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Berlin, 20 September 2023

Submission
Suggestion regarding the proposed PFAS ban: no blanket ban – exemption for medical devices

To whom it may concern

This submission refers to the proposed restriction of per- and polyfluoroalkyl substances (PFAS) published on 7th February 2023. If this proposal remains unchanged, it will have far-reaching consequences for medical science, patients and the industry as a whole.

eurocom generally welcomes all measures contributing to greater patient safety, environmental protection and sustainability. However, the PFAS group comprises thousands of different chemicals, which are used in a wide range of industrial production processes for various purposes ranging from the production of fertilisers to cosmetics to medical devices. From our perspective, the proposed blanket ban on PFAS would repeat a big mistake at the EU level by pursuing a sweeping regulation without further differentiating the applications and careful appraisal of the benefit-risk ratio.

Only after the adoption of the EU-wide Medical Device Regulation (MDR), the persons responsible became aware of unintended consequences contrary to the intended objectives. Instead of improving patient safety, the MDR, which is far too little differentiated in parts, results in a lack of treatment options to the detriment of patients. This is due to the fact that the wide range of applications of medical devices was not sufficiently taken into account during the legislative procedure for the MDR, considering the original objective of the Regulation.

To prevent yet another regulation that is generally to be welcomed from resulting in major disadvantages and/or risks due to its blanket application at the EU level, or in this case at the ECHA level, we expressly request that a comprehensive evaluation of the different applications of the PFAS substance group as well as of the consequences of the ban on consumers and enterprises located in the EU is conducted.

We therefore strongly suggest an exemption for medical devices. Otherwise, we fear that the security of supply for patients in need of orthopaedic aids is at risk. Due to the relatively small amount of orthopaedic aids affected, even though they are of great necessity to the patients, no material manufacturer will feel compelled to develop alternatives. This would affect, e.g., people in need of a leg prosthesis after amputation, since it will enable them to participate in society again.

eurocom wholeheartedly agrees with the, in our opinion, excellent description of the facts and the resulting position of SPECTARIS – German Industry Association for Optics, Photonics, Analytical and Medical Technology e. V. (enclosed).

Yours faithfully

Oda Hagemeier
Managing director

Enclosed: SPECTARIS position on the blanket ban of per- and polyfluoroalkyl substances (PFAS)