

(English version)

**Question for written answer E-001949/26
to the Commission
Aurelijus Veryga (ECR)
(11 May 2026)**

Subject: Assessment of the impact of the proposed PFAS restriction on critical medical technologies and continuity of patient care

Can the Commission clarify:

1. what methodology the Commission is using to assess the potential impact of the proposed restriction on per- and polyfluoroalkyl substances (PFAS) on the availability, safety, clinical performance and continuity of supply of critical Class IIb and Class III medical devices, including implantable and invasive technologies, and whether this assessment includes an analysis of the cumulative impacts arising from Medical Devices Regulation (MDR) transition requirements, capacity constraints of notified bodies and supply chain dependencies;
2. whether the Commission has assessed the risk that insufficient or narrowly defined derogation periods could result in the withdrawal of clinically established technologies from the EU market before technically and clinically validated alternatives become available, and what specific corrective measures it would consider should such a risk be identified;
3. what measures the Commission intends to put in place to ensure long-term regulatory certainty and continuity of patient access to essential medical technologies, including consideration of: a material-class-based exemption for fluoropolymers; alignment between the REACH Regulation and MDR classifications and definitions; dedicated exemptions for invasive delivery systems required for implantable therapies; and mechanisms to avoid increased reliance on more invasive procedures associated with higher complication rates, longer hospital stays and increased costs for European healthcare systems?

Submitted: 11.5.2026

**Answer given by Executive Vice-President Séjourné on behalf of the European Commission
(6 July 2026)**

The restriction dossier submitted to the European Chemicals Agency (ECHA) by five national authorities in 2023 on per- and polyfluoroalkyl substances (PFAS), the so-called universal PFAS restriction, is still being assessed by the Agency. Medical devices are one of the sectors assessed in detail during this process ⁽¹⁾.

In that context, the availability of alternatives to PFAS and the socioeconomic impacts of the restriction options are evaluated by ECHA's Committee for Socio-Economic Analysis (SEAC). The public consultation on SEAC's draft opinion has closed and SEAC will finalise its opinion considering the comments received.

Once finalised, ECHA's final opinions will be the basis for the Commission to prepare a restriction proposal, taking into account all relevant information.

As announced in the Chemicals Industry Action Plan ⁽²⁾, where adequate alternatives in terms of performance and safety are not available, the continued use of PFAS in industrial applications may be allowed for critical applications, such as health, under strict specific conditions until acceptable substitutes are found.

⁽¹⁾ https://chem.echa.europa.eu/api-activity-list/v1/restrictionProcess/documents?name=90261f0ec4fde13102704a507698a6e6_rest_pfas_09_medical_devices_rac_en.pdf; <https://echa.europa.eu/documents/10162/12ac0720-9282-c62f-1f1d-b8b6325fddd1>.

⁽²⁾ <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52025DC0530>.