

Dear ECHA Risk Assessment & Socio-economic committees,

GAMBICA is the association for manufacturers of Instrumentation, Control, Automation, and laboratory equipment in the UK. Membership comprises over 200 companies from large multinationals to over half being SME's, exporting around half of products to the EU. Compared to large volume consumer products, our members' products are relatively low volume industrial products sold to other businesses.

GAMBICA members are passionate about protecting people, animals, and the environment from harm. In fact, some members' instruments are used to detect the presence of PFAS and other SVHC's.

However, we believe that the restriction should be for PFAS's which are proven to cause harm and applications where harmful PFAS is released into the air, water, soil or directly to humans.

- Certain compounds with a single isolated -CF₂- group are generally understood not to degrade to any of the highly persistent substances that have given rise to the environmental and/or human health i.e., they do not degrade into 'arrowhead substances'.
- Low volume essential industrial applications of PFAS are subject to special handling at end of life and are not disposed of at municipal consumer waste collection sites.
- PFAS's are environmentally persistent and resilient so therefore alternatives are likely to have similar properties. Therefore, a comprehensive analysis is required before alternatives are used to avoid 'regrettable substitution'.

Below is a non-exhaustive list of PFAS presence in GAMBICA members' products. Detailed derogation requests have been submitted to ECHA for individual applications and industry sectors. Members are largely reliant on components supplied to them and therefore we request at least a 12-year derogation for all industrial instrumentation, control, automation, and laboratory equipment whilst viable alternatives are investigated and validated.

- PTFE in laboratory **filters**
- PTFE coated oxygen permeable **membranes**.
- PTFE **tape**
- PTFE, FEP **tubing**
- FKM, FFKM, PTFE, PCTFE **O-rings & seals**
- PTFE, PFA, FEP, ETFE valve **liners** for harsh chemical environments
- PTFE valve **packing**
- PCTFE, PTFE, ETFE valve **seats**
- In general, substances from the PFAS group are contained in materials such as PTFE, FEP & FKM. These materials are used, for example, for seals in glands and connectors, but also for cable sheaths and for components in the cable (tapes) that are used in particularly challenging environments.

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- PTFE, PFA, FEP cable & wiring **insulation**
- PTFE in **PCB's**, capacitors, LCD's, etc...
- **Refrigerants** in laboratory refrigerators (see proposed derogation in annex XV).
- vaccine and **medicine research and development**.
- large bore **NMR probes**.
- PTFE coated **stirring bars**.
- Laboratory Metalware consumables with PTFE coating.

We could not live with a situation where equipment manufacturers have a shorter derogation than the components used, such as those above, because we would be presented with a situation where non-PFAS components are not available for assembling products.

Furthermore, if no viable alternatives can be found before the end of the derogation period without 'regrettable substitution', a review for a further derogation period should be provisioned for.

In 1987, the [United Nations Brundtland Commission](#) defined sustainability as "meeting the needs of the present without compromising the ability of future generations to meet their own needs."

A blanket restriction would also jeopardise circular economy initiatives where durable, reliable, repairable, long lifecycle products are being placed on the market. An exemption would also need to be in place to allow the supply of spare parts and components, such as those mentioned above, to extend the lifetime of perfectly serviceable equipment and avoid unnecessary scrappage. For example, an alternative seal for a harsh environment, may be of different dimensions to attain the same level of performance to meet internationally recognised standards.

Finally, any regulation without effective enforcement creates a financial and time-consuming burden for responsible manufacturers whilst non-compliant suppliers take advantage. There needs to be a thorough review of existing REACH enforcement, presence of SVHC's in products and article 33 information before any new authorisations or restrictions are added.

Thank you for your consideration,
Best regards,

Andrew Evans, technical director
On behalf of GAMBICA