European Chemical Agency (ECHA)

To whom it may concern

Submission of Evidence of the European Society for Gynaecological Endoscopy regarding the proposed PFAS restriction.

Dear Sir/Madam,

The European Society for Gynaecological Endoscopy (ESGE) is a scientific society consisting of more than 6000 members. After consultation with representatives of the medical device industry, we express severest concerns about the proposed and far reaching European PFAS restriction proposal.

Short term action has to be taken to stop foreseeable, irresponsible impact on clinical and medical care in general. Micromanagement with a multitude of fine-granulated additional derogations will end in "regrettable legislation" missing unexpected situations. This seems inevitable due to the highly complex supply chains from base material production via multiple intermediates (semi-finished product producers, manufacturers, medical device industry, dealers) to us as the professional end-users. We as medical professionals need to be extremely precautious not to lose any diagnostics, treatment, or surgery without clinically and technically proven alternative. Patient safety and performance must not be compromised by introducing materials that are deemed to be adequate substitutes.

Generally speaking, Europe would be well advised to take a pioneering role with respect to PFAS and to work on replacement with innovations wherever possible. In the context of sustainable chemicals regulation, substances that pose unmanageable risks due to their properties and use profile should be restricted or regulated based on scientific assessments.

However, we strongly oppose the broad regulation of entire groups of substances even regardless of any proven risk during their use-phase. OECD[1] defines criteria for polymers of low concern and concludes: "Polymers of low concern are those deemed to have insignificant environmental and human health impacts. Therefore, these polymers should have reduced regulatory requirements." Henry[2] and others have further investigated many fluoropolymers and clearly regard them as "Polymers of low concern". Medical devices must prove a favorable risk-benefit ratio and those with body contact additionally have to prove their biocompatibility according to ISO 10993. The authors of the restriction proposal seem to replace a risk assessment by attribute-labeling.

[1] OECD Environment, Health and Safety Publication (2008), Data analyses of the identification of the correlations between polymer characteristics and potential for health or ecotoxicological concern.

[2] Barbara J Henry et al. (2018), A Critical Review of the Application of Polymer of Low Concern and Regulatory Criteria to Fluoropolymers; Integrated Environmental Assessment and Management; Volume 14, Issue 3.

The labeled attribute is “persistence” which means their durability, their longevity and resistance on and in the human body or the environment.

The property “persistence” is inevitably required for our high-end medical applications. It is completely unsuitable as the foundation of a restriction[3].

Persistence is even required for any future replacement material which is not even seen on the scientific horizon for our demanding and often life-saving applications.

Why do we need persistent materials for medical devices?

- Reusable surgical instruments need to be autoclave-stable and absolutely chemically inert w.r.t. cleaning and sterilization chemicals.
- All medical devices in body contact need to be biocompatible which fluoropolymers prove to be.
- Electrosurgical medical devices need high disruptive strength and high kreep resistance.
- Fine motor articulation and movements need lowest possible friction coefficients.
- Catheters and other implants may not stick with the body to allow gentle removal, for long-term-implants additionally decade-long biostability is key where there is plenty of experience with existing fluoropolymers.
- Many medical devices are high value investment goods that have long lifetimes; investment goods need service which is not considered at all.
- Many medical devices need a combination of the unique properties of certain PFAS.
- Only persistent materials enable complex equipment with sealings, bearings, lubrication.

According to our aggregated expert opinion as the **European Society for Gynaecological Endoscopy (ESGE)** we strongly endorse the following statements:

1. Fluoropolymers are used in medical care and surgery since more than six decades.
2. To our knowledge, fluoropolymers like Teflon® and Fluoroelastomers like Viton® are clinically used without any proven negative health issue.
3. The following procedures will no longer be available (without claim to completeness):
   - Any surgery requiring anesthesia and / or ventilation.
   - Any minimally invasive procedure and endoscopy not limited to hysteroscopy or laparoscopy (in- and out-patient settings, with and without anesthesia), including products like:
     - any type of endoscope (rigid, flexible, semirigid, optical or electronic imaging)
     - trocars, obturators, sealings
     - instruments like knot pushers, scissors, forceps, punches, cytology brushes, dilators, hooks, retractors.

   - Any type of electrosurgery (open or minimally invasive).

[3] PFAS restriction proposal, p. 23: “… the **role of persistence** in decision making as the most important criterion or only property to justify regulation.”

- Any type of Laser-surgery (open or minimally invasive).
- Any type of imaging technology like MRT, CT, ultrasound.
- Any type of prenatal and neonatal diagnosis and treatment including incubators for newborns.
- Oncological and other laboratory diagnostics involving e.g. microscopes (H&E sections) or chromatography (used e.g. for the determination of tumor markers)
- Reproductive medicine with instruments or cryogenic equipment.
- Any type of treatment or diagnostics involving electronics.
- Many types of implants or catheters.
- Special types of sutures, wound dressing, products with blood contact or packaging for medical devices placed on the market in sterile condition.

Even if for very selected products (e.g. implants, catheters) extended transitional periods of 5-12 years are foreseen in the proposal, we as clinicians have to obeying the precautionary principle and without any proven material-related risk, we cannot accept any phase-out of any instrument related to PFAS before a validated and clinically accepted replacement is available. We need to reverse the selected order: First proven, safe and durable (persistent) alternatives, then reasonable transition periods and phase out.

By now we cannot foresee at all the cost of the intended change. Anyhow the burden for the healthcare system, the taxpayer and the population will be tremendous.

The fact that legally binding secondary law can cause such severe distortions in the healthcare system, in our view, needs to be urgently addressed by top-level European policy makers. We need crystal-clear political signs that this scenario is not the position of the European Union, this proposal neither. Otherwise, industry will walk away from Europe, with every day no clear decision is taken. Specialized healthcare services in the EU might also be phased-out, with non-EU-regions taking advantage of that. This is not just an early phase of the dossier, with subsequent adjustments to be expected. This type of legislative proposal is in its described parts life-threatening to the population of the Union.

Sincerely,

Prof. Benoit Rabischong
ESGE President

Prof. Grigoris F. Grimbizis
Chair, ESGE Board of Directors