Introduction/General considerations

The Richard Wolf GmbH is a manufacturer of medical devices located in Germany. The company's focus is on medical devices for the use in minimally invasive endoscopic surgeries. The products are, among others, endoscopes, surgical instruments and accessory needed for minimally invasive surgeries. We support the "Chemicals Strategy for Sustainability" for the protection of humans and the environment. However, we reject a general restriction of all PFAS as a group of several thousand substances, regardless of the proven risk to humans and the environment.

If the manufacture, use or placing on the market of substances presents an "unacceptable risk to human health or the environment" occurring in the community, action must be taken in accordance with the procedures described in Article 68 (1) of Regulation (EC) No 1907/2006. The burden of proof in connection with the possibilities for action lies with the authorities.

In the case of a decision to restrict substances on their own, in mixtures or in articles, the socio-economic impact, including the availability of alternatives, must be "take[n] into account" (Article 68 (1) sentence 2 of the said Regulation). The application and argumentation of the *essential use concept* could be helpful here, if in this context exemptions are granted for certain uses that are "essential" for a society on the basis of evidence. Fundamentally, it is important that the elements of a restriction must continue to apply when the *essential use concept* is applied; evidence of the "unacceptable risk" of a substance by itself, in mixtures or in articles must be provided, even if the use would turn out to be "non-essential"[1]. The benefits of the measures taken must be proportionate to the risks identified.

The socio-economic impact of a restriction can be massive; therefore, the impact should be clearly provable by facts and figures. Only in these cases is a "substantial" use then also verifiable and to be supported with figures. It is also up to the authorities to subsequently demonstrate that the effects of a restriction, up to and including a ban, will bring benefits and that the risks to health and the environment in the case of a restriction are not disproportionate under these conditions[1]. The principle of proportionality thus requires an analysis of the specific use of each substance, in mixtures and in articles, and a comparison of the benefits of a restriction versus the risks posed by each specific use. This requires a clear case-by-case and use-by-use decision[1].

The PFAS restriction with its proposed narrow and very specific derogations does not do justice to the complexity of the restriction due to the manifold uses in medical devices and other products. This document provides information about the uses of PFAS in the products of the Richard Wolf GmbH and the drastic socio-economic impacts of the proposed restriction on our company and the society. For information about the whole sector and further information, please refer to the documents submitted by SPECTARIS e. V. – German Industry Association for Optics, Photonics, Analytical and Medical Technologies[2].

Uses of PFAS in the products of the Richard Wolf GmbH

Many uses of PFAS in medical devices are not represented by the Annex XV restriction report and the corresponding annexes, although it is stated that medical devices are covered in detail. Therefore, we would like to list the product types where our company uses PFAS. The PFAS used in these products are almost entirely fluoropolymers (PTFE, PVDF, FEP, PFA, and ECTFE) and fluoroelastomers (FKM).

[1] J.-P. Montfort, The Concept of Essential Use to Regulate Chemicals: Legal Considerations, International Chemical Regulatory and Law Review, Issue 1 (2021), pp. 9-20.
[2] Technical Impact Report: reference number 5ce0be14-8e5e-48a3-b33c-490851487ff3; Socioeconomic Impact Report: not yet submitted

Affected product types are (non-exhaustive list):

- HF instruments (electrodes, forceps, dissectors, scissors, knives, sheath tubes, suction/irrigation tubes)
- Rigid and flexible endoscopes
- Working elements and working inserts
- Trocar sleeves and trocar tips
- Laser fibers
- Adapters for endoscopes, cannulae and other endoscopic accessory
- Stopcock plugs
- Electric medical devices (e. g. camera heads, camera controller)
- Other not yet identified PFAS-containing products

For the last bullet point, it is very important to note that up to now, there is no obligation to report all PFAS in the supply chain. The only exceptions are the currently regulated PFAS like PFOA and PFOS. Therefore, it is not possible to gather all the relevant information now in order to evaluate if a bought complex article (especially electric/electronic and other complex products and components) contains PFAS as an intended constituent or even as an unwanted constituent above the extremely low thresholds proposed in the restriction report.

Key features of the PFAS materials that are essential for the safety and performance of our medical devices are:

- Electric insulation
  - high frequency (HF) alternating currents, 100 kHz–5 MHz
- Chemical resistance
  - reprocessing of reusable devices: cleaning and disinfection chemicals
- Thermal resistance
  - steam sterilization at 134 °C
  - thermal heating during use due to HF currents
- Low friction
  - Low stick-slip effect
  - Low generation of force or torque
  - Low power loss
  - Low heat generation
- Biocompatibility
  - biological safety of our devices according to the international standard series ISO 10993
- Combination of these features
  - Safe, high-performing, durable and reusable medical devices which avoids waste in comparison to less durable single-use devices

Exemplary surgeries that are performed by use of PFAS-containing medical devices of our company are:

- Laparoscopic cholecystectomy (removal of gallbladder for symptomatic gallstone disease)
- Laparoscopic appendectomy (removal of the appendix for acute appendicitis/inflammation)
- Laparoscopic inguinal hernia: treatment of inguinal hernia
- Total laparoscopic hysterectomy (TLH): complete removal of the uterus, e.g. for benign tumors, excessive menstrual cramps
- Laparoscopic Supracervical Hysterectomy (LASH): removal of the uterus while preserving the cervix – same indication as TLH
- Laparoscopic sterilization: tubal occlusion
- TUR-P: Transurethral resection of the prostate for benign prostatic hyperplasia

- TUR-B: Transurethral resection of a bladder tumor
- AEEP: Anatomical Endoscopic Enucleation of the Prostate for Benign Prostatic Hyperplasia
- URS: Ureterorenoscopy with semirigid and/or flexible endoscopy for stone therapy
- Diagnostic hysteroscopy: uterine endoscopy for diagnosis
- Surgical hysteroscopy: removal of polyps, fibroids, endometrial ablation

The non-exhaustive product list above shows a broad variety of PFAS-containing medical devices (total number in our company: several hundred). Considering the medical device sector as a whole with estimated 500,000 medical devices sold in Germany (according to *Bundesverband Medizintechnologie e.V. BVMed*), it can be assumed that ten thousands of medical devices would be affected by the restriction directly. In the light of the broad variety and the high number of medical devices, together with the uncertainty in the supply chain of PFAS-containing articles, the proposed narrow and very specific derogations does not seem appropriate to the use of PFAS in medical devices. For the socioeconomic impacts please refer to the corresponding section below.

Tonnage and emissions

The Richard Wolf GmbH uses approximately 1 t of PFAS (almost exclusively fluoropolymers) in our products per year. During the manufacture phase of our products the emissions are likely to be negligible since we almost exclusively use fluoropolymers for the production of our medical devices. In the use phase the emissions are estimated to be maximum 2 % due to the potential release of unbound molecules[3].

The end-of-life phase is the only stage where considerable emissions are potentially possible. However, a proper disposal of our medical devices is required according to the instructions of use. So far, these do not yet contain specific information on PFAS-containing components. Controlled high-temperature incineration seems to be the most appropriate way for a complete destruction of PFAS[3,4].

It has to be noted, that in the Annex XV restriction report the medical device sector is denoted as one of the sectors with the highest tonnages and emissions. However, according to Table 1 and Table 3 of the restriction report, this is mainly due to F gases that are not relevant for our company and many other medical device manufacturers. According to Table 1 of the restriction report, polymeric PFAS in medical devices contribute only 0.3–0.4 % to the total estimated polymeric PFAS emissions.

Socio-economic impacts

As stated in the section “Uses of PFAS in the products of the Richard Wolf GmbH”, the proposed narrow and very specific derogations does not seem appropriate to the diverse use of PFAS in medical devices. Most of our PFAS-containing products are not covered by the proposed derogations. This would mean that these products will disappear from the EU market after the transition period of 18 months. Since the affected products are mostly used in complex surgeries with many different devices needed, also not PFAS-containing products would be affected by the restriction. Of course, this would have a dramatic impact on our business and the number of jobs.

The disappearance of the PFAS-containing medical devices would lead to a deterioration of the health care in the EU. Minimally invasive and endoscopic surgeries, which are well-established, state-of-the-art surgical techniques, could no longer be used in diagnosis and/or therapy in many medical fields. It is estimated that, in Germany alone, 10 million of minimally invasive and/or endoscopic surgeries are performed per year. Minimally invasive surgeries have significantly reduced the postoperative length of stay to the benefit of the patient and thereby reduced the cost of care.

[3] Schwerpunkt 1/2020, Das Magazin des Umweltbundesamtes, PFAS – Gekommen, um zu bleiben.
[4] K. Aleksandrov and others, Waste incineration of Polytetrafluoroethylene (PTFE) to evaluate potential formation of per- and Poly-Fluorinated Alkyl Substances (PFAS) in flue gas, Chemosphere, Issue 226 (2019), pp. 898-906, https://doi.org/10.1016/j.chemosphere.2019.03.191.

For the comparison between minimally invasive surgeries (MIS) and open surgeries two examples were chosen: cholecystectomy (removal of gallbladder) and resection of prostate tissue. The data are taken from the Diagnosis Related Groups (DRG) in Germany for the year 2023.

Surgery	Type	Avg. length of stay / days	Avg. costs of surgery / €	Costs of care at avg. length of stay / €
cholecystectomy	MIS	4	3621	709
cholecystectomy	Open	11	8088	2116
Prostate resection	MIS	4	2762	764
Prostate resection	Open	8	5046	1219

The table demonstrates that the average lengths of stay for MIS are reduced to one half or nearly one third, respectively, in comparison with the open surgery technique. This is accompanied by costs of care which are reduced in the same ratio. The costs of the minimally invasive surgeries are also significantly smaller than for the open surgeries. For the cholecystectomy it could be shown in a study that surgical site infections occur in 4.93 % of open versus 0.64 % in laparoscopic (= minimally invasive) procedures[5].

In conclusion, there is a high benefit for the patients (smaller length of stay, lower incidence of infections) as well as for the society due to substantially lower costs for minimally invasive and endoscopic surgeries. The safety and performance of the devices needed for these surgery techniques relies on the use of fluoropolymers as mentioned above.

The PFAS restriction would have devastating consequences on the innovation capacity of our company and the whole sector. All capabilities in research and development would have to be shifted towards substitution of PFAS materials (if possible at all) instead of the development of innovative medical devices for continuously improving the health care of the EU citizens. This is a huge disadvantage for EU companies and population as innovations are then developed abroad and are then not available for the best possible health care.

Alternatives

As mentioned before, most of the PFAS-containing products of the Richard Wolf GmbH do not fall under the proposed derogations with the negative impacts described in the previous chapter. For our uses of PFAS/fluoropolymers currently no alternatives are known that achieve the unique combination of superior mechanical, chemical, thermal and (di)electrical properties. It is impossible to test, qualify, validate and obtain a registration within 18 months. Even if qualified alternatives were available, the substitution of materials in medical devices takes many years. Details can be found in the technical report of SPECTARIS e. V. – German Industry Association for Optics, Photonics, Analytical and Medical Technologies[2] where a timeframe of 16–21 years is stated including all necessary steps for highly regulated medical devices.

Our company deals with potential alternative materials and is involved in two joint projects with the participation of research institutions, universities and other companies. However, it should be noted that the result of the search for alternatives may also be that there are (currently) no alternatives or alternatives are not suitable for all areas of application with their specific safety and performance requirements.

[5] David K. Warren and others, Risk Factors for Surgical Site Infection After Cholecystectomy, *Open Forum Infectious Diseases*, Volume 4, Issue 2, Spring 2017, ofx036, https://doi.org/10.1093/ofid/ofx036.

Conclusion

We request

- a time-unlimited derogation for medical devices;
- either removing fluoropolymers and fluoroelastomers from the scope of the restriction or an indefinite derogation for these materials.

On the one hand, this would ensure the availability of PFAS materials needed for the safety and performance our products. On the other hand, this would guarantee high-quality medical care for the EU population.