Submission on REACH restrictions on PFA Compounds

Pfizer - Ringaskiddy
RNG Engineering Services - EHS
IE0310927-22-RP-0019, Issue: A

Issue date: 05 Sep 2023

Document Sign Off

Submission on REACH restrictions on PFA Compounds

Pfizer - Ringaskiddy
RNG Engineering Services - EHS
IE0310927-22-RP-0019, Issue A

File No:IE0310927.22.010

CURRENT ISSUE					
Issue No: A	Date: 05 Sep 2023	Reason for issue: Information			
Sign Off	Originator	Checker	Reviewer	Approver	Customer Approval (if required)
Print Name	PAT.SWORDS	BRIAN.STUART		NOEL.GALVIN	
Signature	**Authorised Electronically**				
Date	25 AUG 2023	05 Sep 2023		05 Sep 2023	

PREVIOUS ISSUES							
Issue No	Date	Originator	Checker	Reviewer	Approver	Customer	Reason for issue

Contents

1 Introduction

The European Union adopted in 2006 Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency (ECHA). As the EU describes it:[1]

- *REACH puts obligations on industry to collect chemical safety information, to use this information to develop and apply appropriate risk management measures, to communicate these measures to users of chemicals and, finally, to document this in registration dossiers submitted to the European Chemicals Agency (ECHA). ECHA or Member States evaluate if the safety information is sufficient and, if not, require additional information.*
- *REACH also establishes two distinct EU risk management approaches:*
  - *Restrictions enable the EU to impose conditions on the manufacturing, placing on the market or use of substances;*
  - *Authorisation is designed to ensure that substances of very high concern (SVHCs) are used safely while promoting substitution by suitable alternatives.*

Currently four Member States, Germany, the Netherlands, Sweden and Denmark and EFTA member Norway have submitted in January 2023 a joint proposal to restrict under REACH per- and polyfluorinated alkyl substances. These per- and poly-fluoroalkyl substances (PFASs) represent a large class of thousands of synthetic chemicals that resist degradation and can pollute water and soil, being known as 'forever chemicals'. However, for the production of small pharmaceutical molecules, where corrosion resistant materials are essential, solid PFAS, such as PTFE and kalrez elastomers, are essential components. Indeed, it is hard to envisage how such synthesis of small molecule pharmaceuticals could be completed in their absence.

On this basis, Pfizer, Ringaskiddy, Ireland, which is an integrated facility for the production of active pharmaceutical ingredients and intermediaries by means of chemical synthesis, has requested PM Group to prepare on its behalf a position paper on the essential usages of PFAS for the industrial sector supporting such synthesis. PM Group is one of the largest design and construction management companies for pharmaceutical facilities with offices in the EU,[2] UK, Switzerland, India, China, Singapore and USA. While Pfizer Ringaskiddy is only one of more than a dozen similar facilities producing pharmaceutical ingredients and intermediates by chemical synthesis in the Republic of Ireland, with several hundred located around the EU. About a hundred of which would be known to PM Group from its fifty years of experience in this sector.

2 Regulatory Context

The details of the proposed restriction of around 10,000 PFASs are available on ECHA's website. ECHA's scientific committees have started evaluating the proposal in terms of the risks to people and the environment, and the impacts on society. A six-month consultation started on 22 March 2023. ECHA's scientific committees for Risk Assessment (RAC) and for Socio-Economic Analysis (SEAC) are evaluating the proposal and submissions received.

- *RAC will form an opinion on whether the proposed restriction is appropriate in reducing the risks to people's health and the environment, while SEAC's opinion will be on the socio-economic impacts, i.e. benefits and costs to society, associated with the proposal. Both committees form their opinions based on the information in the restriction proposal and the comments received during consultations. The committees also consider advice from the Enforcement Forum on the enforceability of the proposed restriction. Once the opinions are*

[1] https://eur-lex.europa.eu/legal-content/en/TXT/PDF/?uri=CELEX:52018DC0116&from=EN

[2] Ireland, Poland, Belgium and Germany.

adopted, they will be sent to the European Commission who, together with the EU Member States, will then decide on the potential restriction.[3]

The six-month consultation closes on 25 September 2023. As ECHA explain: *"The consultation is to give anyone with information on PFAS the opportunity to have their say. Of particular interest is information relevant to the risks, socio-economic aspects, and alternative substances".*

3 Technical Context

3.1 'Small Molecules' Sector

For more than 100 years, pharmaceutical companies such as Pfizer have utilised chemical synthesis for the production of what are now known as 'small molecule' pharmaceuticals. The more recent biotechnology processes produce by biological synthesis large protein molecules and hence are considered as 'large molecule' production facilities. However, despite the strides made by biotechnology, 'small molecule' production remains a key subsector of pharmaceutical manufacturing with new products continuing to being developed. As an example, the Pfizer, Ringaskiddy manufacturing site, continues to be an important production resource within the Pfizer network. In the Republic of Ireland as a whole, there are a dozen such facilities known to PM Group, with several hundred located in the EU at large.[4] PM Group's experience running globally to some hundred such facilities.

In the EU Commission's own 'Best Available Techniques Reference Document for the Organic Fine Chemicals Sector', it is stated in its 'scope':[5]

- *The chemical industry is Europe's third largest industry, employing 1.7 million people directly and with an additional 3 million jobs directly supporting the chemical industry. The Organic Fine Chemicals sector employ over 0.6 million people with a turnover of EUR 125000 million. Typical employers include large multinationals with organic fine chemical business units, but over 90 % of all sector companies are either middle-sized or SMEs.*

The Pfizer, Ringaskiddy facility, along with other production sites for small molecules, falls within the scope of organic fine chemicals. Indeed, many companies in this organic fine chemicals sector operate equipment and utilise chemicals in a similar fashion to those dedicated to the manufacture of 'small molecules'. The importance of this sector for 'small molecules' can be deducted from a 2009 report of the EU Commission entitled ' Pharmaceutical Sector Inquiry', which was a time when 'small molecule' production still dominated pharmaceutical manufacturing.[6]

- *The pharmaceutical sector is essential for the health of Europe's citizens who need access to innovative, safe and affordable medicines. On average approximately € 430 was spent on medicines in 2007 for each European and this amount will likely continue to increase as the population in Europe ages. Overall, in 2007, the market for prescription and non-prescription medicines for human use in the EU was worth over € 138 billion ex-factory and € 214 billion at retail prices. Put differently, the pharmaceutical market accounted for close to 2% of annual EU GDP.*

As is explained in the next sections, a total ban on PFAS threatens the viability of the whole sector above.

[3] https://echa.europa.eu/-/echa-publishes-PFAS-restriction-proposal

[4] For example Eurostat was reporting in 2005: Italy had 704 pharmaceutical enterprises, compared to 586 enterprises in France, 481 in the United Kingdom and 425 in Germany.

[5] https://eippcb.jrc.ec.europa.eu/sites/default/files/2019-11/ofc_bref_0806.pdf

[6] https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf

3.2 Chemical Synthesis

The production of such 'small molecules' by chemical synthesis is a batch process. In a step by step process intermediates are reacted together and purified with isolation steps, such as crystallisation, to produce the 'building blocks' of the desired molecule. While these compounds are characterised by the carbon – carbon bonds of organic chemistry, the intermediate steps and compounds frequently contain inorganic compounds as side chains, which are the reactive sites for the subsequent chemical synthesis. A frequent by-product of such synthesis are salts, such as sodium chloride or other halogenated inorganics, formed from the reaction of these inorganic side chains. These have to be rinsed out of the crystallised organic compounds, which ultimately form the desired product.

3.3 Materials of Construction

3.3.1 Metallic Systems

Purity is an essential parameter with pharmaceutical production, which requires rigorous attention to 'Good Manufacturing Practices' (GMP). Product contact surfaces must therefore be smooth and cleanable. Such facilities manufacture products on a campaign basis and the equipment must be fully cleaned and free from residues before reconfiguration for producing a different product. Contact surfaces must therefore be smooth and free from penetration while also being highly chemical resistant to the aggressive nature of the chemicals it is exposed to. PTFE lined pipe and gaskets, Kalrez and Viton seals are all PFAS utilised in such facilities. While production equipment, such as reactor vessels, are either carbon steel with glass lining or highly polished metallic surfaces. This prevents materials adhering to the surfaces and facilitates the cleaning of the rig between batches.

Halogen compounds, particularly chlorides, are a regular feature in the reaction chemistry for production of 'small molecules'. Such chlorides, even at low concentrations, will cause corrosion pitting of stainless steel, in which small cavities are eaten into the metal. Alloys like stainless steel, which are resistant to corrosion due to a passivation layer, are actually the most susceptible to pitting. If the passivation film is compromised and subsequently attacked by corrosion, the corrosion will not spread on the metal's surface, but will instead penetrate inward. Pitting may cause stress cracking, and – if a pit occurs as a critical point – it can cause immense damage.

Figure 4.1: Pitting corrosion of stainless steel

The most commonly used austenic grade stainless steel in pharmaceutical production is 316L (European designation 1.4404). This has 2% manganese, 16.5% to 18.5% chromium, 2% to 2.5% molybdenum, 10% to 13% nickel with the balance being iron (ferric). Yet it is highly susceptible to pitting corrosion once exposed to chlorides. To obtain corrosion resistance to chlorides one has to turn to Alloy 22, which is also sold under the brand names Hastelloy® C-22 and Inconel® 22. This is a fully austenitic nickel-based super alloy containing some 56% nickel, 22% chromium, 13 % molybdenum and 3% tungsten and 2.5% cobalt. While this is resistant to pitting corrosion, a corrosion rate is still occurring for Alloy 22 when exposed to halogenated inorganic compounds, such as chlorides. This rate being dependent on the operating temperature and properties of the compounds within the equipment.

Nickel is an expensive element, as are chromium, molybdenum, cobalt and tungsten. Therefore, it is not surprising that Hastelloy can be some five to eight times more expensive than equivalent components in stainless steel. Furthermore, with the advent of electric battery technology, there is greater competition for the available nickel and cobalt resources, leading to increased price pressure. In the pharmaceutical sector, Hastelloy is used to fabricate equipment, such as filter dryers and centrifuges, which have complex geometries and / or are involved in heat transfer. However, the gaskets and seals used on flanges, valves and rotating shafts comprise elastomers made out of PTFE and other PFAS such as Kalrez and Viton. Without these, such flanges, valves and rotating shafts would be a source of regular leaks.

3.3.2 Piping Systems

Piping systems requiring corrosion resistance are generally assembled out of Polytetrafluoroethylene (PTFE) lined carbon steel pipe segments. These are available in straight sections, bends, tee pieces, etc., and are bolted together to achieve the required piping system. It is also possible to get flexible hoses made out of PTFE or similar corrosion resistant materials. While valves and similar fittings are also available made out of solid PTFE or similar PFAS, such as Polyvinylidene fluoride (PVDF).

3.3.3 Atmospheric Vessels and Scrubbers

In addition to lined piping systems, vessels not subject to heating requirements and scrubbing systems are fabricated out of sheets of PTFE or PVDF, supported by an outer body of Glass Reinforced Plastic (GRP). Such scrubbers are essential to treat process off gases and enable compliance with the stringent environmental emission limit values set for this sector.

3.3.4 Sealing Compounds

PFA compounds are also used as elastomers for sealing, such as gaskets and O-rings. These offer excellent corrosion resistance and longevity, while being ductile enough to form a good seal. The requirement for such effective sealing is to fulfil a number of objectives. Environmentally it is necessary to prevent leaks of hazardous material occurring at rotating seals and equipment and piping joints. The effectiveness of such sealing also being an environmental objective to reduce diffuse emissions of Volatile Organic Compounds (VOCs). For example, the Best Available Techniques (BAT) Conclusions for the ‘Common Waste Water and Waste Gas Treatment/Management Systems in the Chemical Sector’ require ‘High-integrity equipment’, which is highly sealed, and additional Leak Detection and Repair (LDAR) programmes. Where such ‘high-integrity equipment’ includes:

- *high-integrity gaskets (such as spiral wound, ring joints) for critical applications;*
- *corrosion-resistant equipment.*

In addition to purely environmental considerations, effective sealing is essential from the perspective of occupational hygiene. The manufacture of active pharmaceutical ingredients and intermediates by chemical synthesis requires the usage of aggressive chemicals, which often have low exposure limits and are frequently carcinogenic, mutagenic or toxic for reproduction. These latter legislative require a ‘closed system’ of processing, which cannot be realised without effective sealing compounds.

3.4 Alternatives

With regard to alternatives to pipe and equipment lined with PFA compounds and elastomers comprising of PFAS, these are limited. A greater use of Hastelloy could be applied, but this comes with a significant cost penalty and delays to project schedules, while it is not suitable for highly acidic solutions of hydrochloric acid. For example, the Engineering Toolbox reports a price ratio of 1.5:1 for stainless steel to carbon steel piping, which increases to 3:1 for PTFE lined carbon steel and 4.5 to 1 for Hastelloy piping.[7] Therefore, there is a 150% price penalty in changing from PTFE lined pipe to Hastelloy. While as previously mentioned gaskets and seals would still need to be manufactured of PTFE and similar PFAS. In a similar fashion, for vessels constructed with a PTFE liner, an alternative would be Hastelloy, but this comes with a significant price penalty, while to reiterate the gaskets and seals would still have to remain as PTFE and similar PFAS. These cost increases and delays to project schedule associated with the greater usage of Hastelloy will inevitably result in some projects being cancelled or relocated to other jurisdictions where PFAS are not banned.

For PFA elastomers, such as Kalrez, there is no effective replacement. As the Du Pont website claims with respect to the advantages of Kalrez:

- *Resists over 1,800 different chemicals*
- *High temperature stability up to 327°C*
- *Maintains seal integrity*
- *Reduces maintenance and operating costs*
- *Long seal life*
- *Meets safety standards for pharmaceutical and food processing*
- *Available in standard and specialty compounds formulated for custom use*

3.5 Implications of a Total Ban on PFAS

A total ban on PFAS would therefore severely affect pharmaceutical facilities operating in the ‘small molecule’ sector. In some cases, more expensive materials and longer schedules could offset this impact, but in other cases, there is no direct replacement. The net result of this blanket ban on PFAS would be to hamper investment in this sector in the EU and even lead to plant closures and relocation of manufacturing to outside the EU.

3.6 Life Cycle

To date limited consideration is given by the pharmaceutical sector to the life cycle of PFAS. In particular to the disposal of PFAS at the end of their life cycle. During the construction and installation phases and the piping / equipment usage, there are no direct emissions of PFAS to the environment. The potential for emissions only arises during the disposal of the system. To date the Pharmaceutical Sector adopts no special measures regarding disposal of PFAS, but these could be developed and implemented. In particular, as this sector has already sophisticated measures in place for dealing with hazardous waste. For example, the procedure for in line filters containing PFAS would already be removing them, bagging them up and disposing them by off-site incineration.

The first step in adopting such control measures would be to complete an inventory of PFAS on site. Then adopt suitable disposal methods when they have reached their end of life. In this manner, the impact of the PFAS on the environment would be greatly reduced.

[7] https://www.engineeringtoolbox.com/piping-materials-cost-ratios-d_864.html

4 Conclusion

A 2005 report by the Irish Pharmaceutical Healthcare Association, at which time the pharmaceutical sector was still dominated by small molecule production, documented how the sector formed 44% of the Republic of Ireland's exports amounting to €34.7 billion.[8] The number of US Food and Drugs Administration (FDA) approved manufacturing facilities in the Republic of Ireland was 24, while 14 out of the 15 largest worldwide pharmaceutical companies were present in the Republic of Ireland.

For the sector as a whole in the EU, Eurostat was reporting in 2005 how in 2002 more than half a million people were employed in the pharmaceutical industry in the EU.[9] This corresponds, on average, to more than a quarter of the total number employed in the whole chemical industry.

A total ban on PFAS would severely threaten the viability of this sector in the EU and investment would more likely flow to outside the EU, where no such ban is applicable, such as to the USA or Singapore.

[8] https://issuu.com/ipha/docs/pharma_ireland_-_an_industry_report

[9] https://ec.europa.eu/eurostat/web/products-statistics-in-focus/-/KS-NP-05-044

Appendix A
Consultation Entries for ECHA Website

1. ***Sectors and (sub-)uses:***

Please specify the sectors and (sub-)uses to which your comment applies according to the sectors and (sub-)uses identified in the Annex XV restriction report (Table 9). If your comment applies to several sectors and (sub-)uses, please make sure to specify all of them.

I have information on this topic

The Annex XV restriction report did not identify the sector to which Pfizer Ringaskiddy belongs, which is the chemical synthesis of pharmaceuticals. PM Group, who have prepared this submission on behalf of Pfizer Ringaskiddy, are one of the largest design and construction management companies for pharmaceutical facilities with offices in the EU, UK, Switzerland, India, China, Singapore and USA.

The production of pharmaceuticals and their intermediates can be based on either biological processes, which leads to large molecules like proteins, or chemical synthesis, which leads to complex small molecules. Chemical synthesis is the more traditional route, which utilises reactive chemicals requiring advanced materials of construction for equipment, such as for piping and vessels. Pfizer, Ringaskiddy, is one of a dozen significantly sized pharmaceutical manufacturing sites in the Republic of Ireland, with several hundred located in the EU as a whole. The importance of this sector to the European economy can be seen from a 2009 report of the EU Commission, which was a time when small molecule manufacturing still dominated this sector:

- *The pharmaceutical sector is essential for the health of Europe's citizens who need access to innovative, safe and affordable medicines. On average approximately € 430 was spent on medicines in 2007 for each European and this amount will likely continue to increase as the population in Europe ages. Overall, in 2007, the market for prescription and non-prescription medicines for human use in the EU was worth over € 138 billion ex-factory and € 214 billion at retail prices. Put differently, the pharmaceutical market accounted for close to 2% of annual EU GDP.*

Therefore, this submission reflects the concerns of a wider sector rather than just Pfizer, Ringaskiddy. A sector characterised by a requirement for advanced materials of construction, which include PTFE and PDVF. While elastomers such as Perfluoroelastomer (FFKM/FFPM), e.g. Kalrez®, are also essential for ensuring sealing of equipment containing reactive chemicals. Indeed, the absence of such materials of construction due to a ban on PFAS would effectively wipe out this sector of 'small molecule' manufacturing, as substitutes in these applications are not available for all of these PFAS. The importance of this sector now under threat is visible in other initiatives of the EU Commission, such as its pharmaceutical strategy for Europe.[10] In particular its Section 3.1 'Providing a fertile environment for Europe's industry':

- *A competitive and resource-efficient EU pharmaceutical industry is of strategic interest for public health, economic growth, jobs, trade and science. The EU aims to support industry to be competitive and resilient so that, in turn, it can better respond to patients' needs.*

Without access to PFAS as a construction material, 'small molecule' pharmaceutical production in the EU would have to close or relocate to other jurisdictions, which do not have such a ban on these materials of construction.

2. ***Emissions in the end-of-life phase:***

The environmental impact assessment does not cover emissions resulting from the end-of-life phase. To get a better understanding of the extent of the resulting underestimation, (sub-)use-specific information is requested on emissions across the different stages of the lifecycle of products, i.e. the manufacture phase, the use phase and the end-of-life phase. Please provide justifications for the representativeness of the provided information. In particular:

[10] https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe_en

- *Please provide, at the (sub-)useould essentially level, an indication of the share of emissions (as percentages) attributable to these three different stages. An indication of annual emission volumes in the end-of-life phase at sector or sub-sector level would also be appreciated.*
- *If possible, please provide for each (sub-) use what share of the waste (as percentages) is treated through incineration, landfilling and recycling. Please provide information to justify the estimates as well as information on the form of recycling referred to.*

I have information on this topic

The use of PTFE and similar PFAS in the sector of chemical synthesis of pharmaceuticals is restricted solely to materials of construction. The only emissions arising occur when the equipment is disposed of. This could be either by incineration, landfilling or recycling. To date no special requirements are employed with the disposal of PTFE and similar compounds.

3. ***Emissions in the end-of-life phase:***

With respect to waste management options, additional information is requested on the effectiveness of incineration under normal operational conditions (for different waste types, e.g. hazardous, municipal) with respect to the destruction of PFAS and the prevention of PFAS emissions.

I don't have information on this topic

4. ***Impacts on the recycling industry:***

To get an understanding of the impacts of the proposed *restriction on the recycling industry, information is requested on:*

The impacts that the concentration limits proposed in paragraph 2 of the proposed restriction entry text (see table starting on page 4 of the summary of the Annex XV restriction report) have on the technical and economic feasibility of recycling processes (together with a clear indication on the waste streams to which the described impacts relate).

The measures that recyclers would need to take to achieve the proposed concentration limits.

The costs associated with these measures.

No detailed information is available on this topic. However, to date most of the PTFE and similar compounds are disposed of when life expired.

5. ***Proposed derogations – Tonnage and emissions:***

Paragraphs 5 and 6 of the proposed restriction entry text (see table starting on page 4 of the summary of the Annex XV restriction report) include several proposed derogations. For these proposed derogations, information is requested on the tonnage of PFAS used per year and the resulting emissions to the environment for the relevant use. Please provide justifications for the representativeness of the provided information.

Such tonnage is not available to Pfizer Ringskiddy as one of many end users. It would have to be obtained from the manufacturers of PTFE lined equipment and elastomers.

6. ***Missing uses – Analysis of alternatives and socio-economic analysis:***

Several PFAS uses have not been covered in detail in the Annex XV restriction report (see uses highlighted in blue and orange in Table A.1 of Annex A of the Annex XV restriction report). In addition, some relevant uses may not have been identified yet. For such uses, specific information is requested on alternatives and socio-economic impacts, covering the following elements:

a. *The annual tonnage and emissions (at sub-sector level) and type of PFAS associated with the relevant use.*

   The tonnage of PFAS used as a construction material for pharmaceutical facilities is currently unknown.

b. *The key functionalities provided by PFAS for the relevant use.*

The PFAS provide corrosion resistant materials of construction, which are widely used in pharmaceutical facilities manufacturing 'small molecules' by chemical synthesis.

c. *The number of companies in the sector estimated to be affected by the restriction.*

PM Group would be aware of several hundred such pharmaceutical facilities operating in the EU. However, exact number not published.

d. *The availability, technical and economic feasibility, hazards and risks of alternatives for the relevant use, including information on the extent (in terms of market shares) to which alternative-based products are already offered on the EU market and whether any shortages in the supply of relevant alternatives are expected.*

The alternative to PTFE and PVDF as a material of construction is for certain, but not all applications, the use of high nickel alloy called Hastelloy. As the document submitted as an appendix shows, this is 1.5 times the cost of PTFE lined systems, such nickel alloys being in scarce supply. There are no equivalent materials for the use of PFAS in elastomers for sealing purposes.

e. *For cases in which **alternatives are not yet available**, information on the status of R&D processes for finding suitable alternatives, including the extent of R&D initiatives in terms of time and/or financial investments, the likelihood of successful completion, the time expected to be required for substitution (including any relevant certification or regulatory approvals) and the major challenges encountered with alternatives which were considered but subsequently disregarded.*

PM Group is not aware of any R&D ongoing to the use of PFAS for elastomers for sealing purposes or as materials of construction in general.

f. *For cases in which **substitution is technically and economically feasible** but more time is required to substitute:*

i. *the type and magnitude of costs (at company level and, if available, at sector level) associated with substitution (e.g. costs for new equipment or changes in operating costs);*

The increased use of hastelloy as a construction material could potentially replace PTFE in this application, as could glass lined carbon steel. However, this would significantly add to the cost, with hastelloy being 1.5 time that of PTFE lines carbon steel and subject to longer delivery times.

ii. *the time required for completing the substitution process (including any relevant certification or regulatory approvals);*

iii. *information on possible differences in functionality and the consequences for downstream users and consumers (e.g. estimations of expected early replacement needs or expected additional energy consumption);*

iv. *information on the benefits for alternative providers.*

g. *For cases in which **substitution is not technically or economically feasible**, information on what the socio-economic impacts would be for companies, consumers, and other affected actors. If available, please provide the annual value of EU sales and profits of the relevant sector, and employment numbers for the sector.*

For cases in which substitution is not technically or economically feasible, such as for the elastomers use as sealants, The consequences for Pfizer, Ringaskiddy and similar facilities would be increased failure of sealing systems, such as on pumps and agitators, leading to leakage of hazardous process fluids. Which is unacceptable from both an environmental and occupational hygiene perspective. Specific costs to the sector are not available, but over time, it would make the sector in the EU uncompetitive and lead to the relocation of investment to jurisdictions where PFAS were not banned. The importance of this sector having already been documented in the answer to Question 1 and the attachment to the submission.

7. ***Potential derogations marked for reconsideration – Analysis of alternatives and socio-economic analysis:***

Paragraphs 5 and 6 of the proposed restriction entry text (see table starting on page 4 of the summary of the Annex XV restriction report) include several potential derogations for reconsideration after the consultation (in [square brackets]). These are uses of PFAS where the evidence underlying the assessment of the substitution potential was weak. The substitution potential is determined on the basis of i) whether technically and economically feasible alternatives have already been identified or alternative-based products are available on the market at the assumed entry into force of the proposed restriction, ii) whether known alternatives can be implemented before the transition period ends (taking into account time requirements for substitution and certification or regulatory approval), and iii) whether known alternatives are available in sufficient quantities on the market at the assumed entry into force to allow affected companies to substitute.

A summary of the available evidence as well as the key aspects based on which a derogation is potentially warranted are presented in Table 8 in the Annex XV restriction report, with further details being provided in the respective sections in Annex E.

To strengthen the justifications for a derogation for these uses, additional specific information is requested on alternatives and socio-economic impacts covering the elements described in points a) to g) in question 6 above.

As an end user of PTFE and PDVF materials of construction and PFA based elastomers, Pfizer Ringaskiddy and similar facilities in this sector would find itself compromised on new projects and the maintenance of existing equipment, if the proposed ban on PFA products was to proceed. This would affect its ability to produce pharmaceutical products with the necessary quality and protection of the environment. Such a derogation is necessary to allow for upstream manufacturers to develop suitable alternatives to PTFE and PVDF materials of construction and PFA based elastomers.

8. ***Other identified uses – Analysis of alternatives and socio-economic analysis:***

Table 8 in the Annex XV restriction report provides a summary of the identified sectors and (sub-) uses of PFAS, their alternatives and the costs expected from a ban of PFAS. More details on the available evidence are provided in the respective sections in Annex E.

For many of the (sub-)uses, the information on alternatives and socio-economic impacts was generic and mainly qualitative. In particular, evidence on alternatives was inconclusive for some applications falling under the following (sub-)uses: technical textiles, electronics, the energy sector, PTFE thread sealing tape, non-polymeric PFAS processing aids for production of acrylic foam tape, window film manufacturing, and lubricants not used under harsh conditions.

More information is needed on alternatives and socio-economic impacts to conclude on substitution potential, proportionality, and the need for specific time-limited derogations. Therefore, specific information (if not already included in the Annex XV restriction report or covered in the questions above) is requested on alternatives and socio-economic impacts covering the elements listed in points a) to g) in question 6 above.

While nickel based alloys such as Hastelloy can be used for some, but not all, chlorine based chemistry it has a cost basis of 4.5 times that of steel and is subject to longer delivery times. Furthermore, new battery types also utilise nickel-based chemistry, so as the switch to electric vehicles occurs, there will be increased supply pressure on nickel resources.

9. ***Degradation potential of specific PFAS sub-groups:***

A few specific PFAS sub-groups are excluded from the scope of the restriction proposal because of a combination of key structural elements for which it can be expected that they will ultimately mineralize in the environment. RAC would appreciate to receive any further information that may be available regarding the potential degradation pathways, kinetics or produced metabolites in relevant environmental conditions and compartments for trifluoromethoxy, trifluoromethylamino- and difluoromethanedioxy-derivatives.

I don't have information on this topic.

10. ***Analytical methods:***

Annex E of the Annex XV restriction report contains an assessment of the availability of analytical methods for PFAS. Analytical methods are rapidly evolving. Please provide any new or additional information on new developments in analytics not yet considered in the Annex XV restriction report.

I don't have information on this topic.