Section III Submission

Scope of restriction option analysis

As drafted, the scope of the Annex XV restriction proposal concerning polyfluoroalkyl substances (PFASs) covers a wide range of chemicals including gases, liquids and solids.

These PFAS's have significantly different properties and are utilised in a very wide range of industries and applications.

This submission is particularly concerned with the inclusion of fluoropolymers (such as PTFE and PFA) in the restriction proposal, specifically used in the lining of process pipework and associated equipment in the pharmaceutical, semiconductor, fine chemicals manufacture[1], bulk chemicals manufacture, water treatment and the oil and gas industries.

PTFE / PFA fluoropolymer lined pipework and valves are used in the production of semi-conductors, medicines, drugs, food stuffs, petrochemicals, and fresh water. In general, they convey highly corrosive media such as hydrochloric, sulfuric, nitric acids etc, prevent spillage and leakage of these substances whilst maintaining their purity by preventing contamination from the steel pipework structure.

At present, PTFE / PFA fluoropolymers are the only pipe / valve lining that can withstand the nature of the corrosive media, maintain the required purity levels, and tolerate wide-temperature variations necessary in many of the processes. These fluoropolymers are the only sustainable material of choice for almost every process industry, where they serve as linings for vessels, piping, pumps, valves, columns, column internals, hoses, expansion joints, seals and gaskets. They provide durable low cost, low maintenance, reliable alternatives to more expensive and unsustainable exotic metal alloys.

The current scope of the restriction fails to consider these very significant uses of fluoropolymers, and the significant consequences of the proposed ban. Therefore, it is necessary that such PTFE / PFA fluoropolymers should be removed from the current restriction proposal.

Hazard or exposure

The production of PTFE is now possible without the use of any surfactants such as perfluorooctanoic acid (PFOA), which has been associated with environmental and health concerns. So, when carried out in a suitable environment PTFE and PFA manufacture is a considered to be a safe process. In addition, use as pipe and associated equipment linings, PTFE / PFA fluoropolymers are electrochemically, biochemically, enzymatically and chemically virtually inert. Unlike some other PFAS molecules, fluoropolymers are considered to be non-bio-accumulative, non-bio-available, non-

[1] Fine chemicals are typically high purity, complex molecules that are used as active ingredients, intermediates, or raw materials in the manufacture of pharmaceuticals, agrochemicals, flavours, fragrances, and other specialty chemicals. They are often produced through multi-step chemical synthesis and require specialized expertise and equipment for their production.

hazardous, insoluble (and therefore not mobile in water), non-toxic (locally or systemically), and are classed as polymers of low concern by the OECD[2].

CRP has been processing fluoropolymers for over 40 years with annual staff health checks with no related ill health incidents. Many of the staff have worked for the company for more than 20 years.

Information on alternatives

At present there are no known pipe/valve lining materials in development that will provide equivalent, or similar, properties, able to withstand such harsh environments and high temperatures to fluoropolymers irrespective of cost/price.

More expensive options include glass lined steel, or exotic metal pipes/coatings and in some circumstances, these materials may be suitable alternatives for handling particular individual chemicals (see attached Flowserve documents, "Selecting Corrosion Resisting Alloys" and "Guide to the Selection of Corrosion Resisting Non-Metallics"). However, even these alternatives are more limited in the type of media and temperatures they can withstand.

Turning to consider the alternative materials in a little more detail:

> **Glass lined piping.** Over the last 2 – 3 decades industry has largely moved away from this product range, simply because the glass linings are brittle and can be easily damaged. Damaged linings lead to product failure, varying from minor leaks, product contamination through to catastrophic failures. Such events result in environmental damage and potentially loss of human life.
>
> **Exotic metallic pipework** (such as hastelloy, inconel, incoloy, titanium, and tantalum). This pipework is in the order of 2 to 10 times more expensive than fluoropolymer lined pipework, making it economically unviable compared to PTFE / PFA fluoropolymer lined in almost all circumstances. In addition, while each individual material may be suitable for a specific duty, often it is not suitable for the range of duties that individual manufacturers require. Also, due to its lack of universal corrosion resistance there is a danger that an unsuitable chemical will be put through such pipework, leading to failure, with all of the associated costs and hazards to personnel and the environment. Finally, the extraction and processing of these rare metals brings additional environmental considerations, particularly when this is done in countries with less stringent environmental protection legislation, such as: Khazakstan, India, Albania (chromium); Indonesia, Russia (nickel); Sierra Leone, Russia (titanium); Democratic Republic of Congo, Rwanda, Brazil (tantalum).

Please refer to the following documents which accompany this submission:

(i) Summary of Flowserve Corrosion Data. This provides a summary of the data found in the additional two documents. It highlights the different performance characteristics of PTFE / PFA fluoropolymers compared to the various alternatives available today. This shows how every other alternative has inferior performance characteristics to that of PTFE / PFA fluoropolymers. Add in the implications in terms of cost and physical performance then it is clear that there isn't a viable alternative for many production processes at this time.

---

[2] A Critical Review of the Application of Polymer of Low Concern and Regulatory Criteria to Fluoropolymers. *Barbara J Henry, Joseph P Carlin, Jon A Hammerschmidt, Robert C Buck, L William Buxton, Heidelore Fiedler, Jennifer Seed, and Oscar Hernandez*

(ii) Flowserve Publication, “Guide to the Selection of Corrosion Resisting Alloys”
(iii) Flowserve Publication, “Guide to the Selection of Corrosion Resisting Non-Metallics”

Consequently, if PTFE / PFA fluoropolymers were to be banned, leaving only glass or exotic metal lining options there are a number of consequences:

(i) Many pharmaceutical plants run a batch manufacturing process, making a batch of one drug, followed by a batch of a different type with a different set of parameters. Piping lined with PTFE / PFA fluoropolymer can easily accommodate this due to its broad suitability to cope with a wide range of circumstance. If fluoropolymers were to be banned, such multipurpose plant would cease to be possible, again making such manufacturing less competitive in the EU.
(ii) To cope with a particular set of process chemistry, it would be necessary to double up on piping, pumps, valves etc., to allow each chemical to be handled through an individual set of pipework, with the additional costs associated with such a set-up, thus increasing manufacturing costs and reducing efficiency. This would make EU production uneconomic and could result in production being moved to non-EU based factories.

What has been said thus far is generic and covers a wide range of uses for fluoropolymer lined piping. What follows are a couple of specific examples of uses where there are no suitable alternative materials:

Production of electronic chips – requiring High Purity Acid:

The etching of microchips in the electronic industry requires high purity (sulfuric and hydrofluoric) acids with less than 36ppt (parts per trillion) contamination. As the circuits on the chips get smaller, so the purity of acid required gets higher. The only pipework suitable to handle these acids and maintain the purity required are fluoropolymer lined pipework. If fluoropolymers were to be banned, then electronic chip & computer manufacture is unlikely to be sustainable within the EU compared to manufacturing in other countries.

Process:
The normal “dirty” acid which is available after the standard acid production process needs to be refined by evaporation followed by absorption/condensing. This process runs at around 150°C and requires corrosion resistant material of construction. Glass or glass lined steel cannot be used, because the acids leach out chemical elements from the glass (glass lining) which are harmful to the electronic circuits on the electronic chips. Exotic metal lining (including tantalum) cannot be used either, because metal ions they release would generate short circuits in the electronic chips after etching. Other plastics are clearly not temperature or chemical resistant enough for this application.

Production of Toluene Diisocyanate (TDI) and Methylene diphenyl diisocyanate (MDI) for Polyurethane production:

Polyurethane is a common base material for many things including advanced glues used in products such as light weight high tech designs like cars, airplanes and buildings, as well as in the manufacture of high-performance insulation.

Process:

Manufacturing polyurethane is a highly corrosive process running at temperatures between 100° and 150°C. Here glass lined steel pipework is used for the chemical reaction and transportation for these highly corrosive chemicals. However, this 'stress sensitive' material needs expansion joints and bellows made from a material able to withstand the chemicals and temperatures used to prevent cracks in the pipework and vessels. PTFE is used to manufacture such bellows and maintain the cleanliness criteria needed. Any materials other than PTFE, such as rubber, would not survive more than a few months in this application, while PTFE bellows have a lifetime of around ten years.

Information on benefits

Due to the properties, uses and importance of PTFE / PFA fluoropolymers we can see no benefit to the inclusion of such fluoropolymers in the scope of Annex XV.

Other socio-economic analysis (SEA) issues

If PTFE / PFA fluoropolymers were to be included in the scope of Annex XV as proposed, there are several foreseeable consequences:

Our business would not be able to continue selling PTFE / PFA fluoropolymer lined pipework and valves and as this constitutes 95% of our sales then the business would not be able to continue resulting in the loss of 70+ direct jobs plus as at least that many again in the local economy as sub-suppliers.

In the UK there are over 700 businesses that manufacture pharmaceutical and chemical products. Their combined turnover is almost £10 billion, employing over 136,000 people[3]. In Europe, there are over 2,100 businesses that manufacture pharmaceutical products. Their combined turnover is almost £300 billion, employing approximately 840,000 people[4], almost all of which use PTFE / PFA fluoropolymer lined pipework and fittings in one form or another. If the cost of production of such products increases significantly then the 'attractiveness' of Europe (and the UK) as a pharmaceutical and chemical manufacturing centre will reduce resulting in plant closures as they migrate to cheaper locations. The size of any socio-economic impact of such a ban is difficult to estimate but given intense commercial pressure under which these companies operate, the impact will be significant and detrimental.

Having to replace PTFE / PFA fluoropolymer lined pipework with less effective alternatives, where this is even possible, will result in less reliable process plant. This in turn will lead to more failures/leaks, leading to more damage to the surrounding equipment, more potential for leaks of hazardous chemicals into the environment, more potential injuries to personnel, more repair/rectification costs. Also, the replacement process pipework will have shorter lifetimes, leading to higher costs due to increased maintenance costs, more frequent replacement of equipment, the increased use of scarce resources to produce replacement parts, and additional disposal costs of the scrap products.

[3] Reference: Statistica - Pharmaceutical industry in the United Kingdom (UK) - Statistics & Facts https://www.statista.com/topics/5056/pharmaceutical-industry-in-the-uk/

[4] Reference: Statistica - Pharmaceutical industry in Europe - Statistics & Facts, https://www.statista.com/topics/8631/pharmaceutical-industry-in-europe/#topicOverview

Transitional period

Given the current lack of suitable alternatives to PTFE / PFA fluoropolymers it is not appropriate to implement a ban in any form on these substances as used in lined pipework and associated equipment. The restrictions it would place on critical industries and the impact of their movement of production centres to non-European locations would be catastrophic both in economic and social terms. The industries that would be affected by such a ban (even over an extended period) are key to the success of any Western economy and critical to the wellbeing and standard of living for its citizens.

On that basis it is suggested that a transitional period would not be appropriate for PTFE / PFA fluoropolymer pipe lined products at least until a commercially viable alternative has been identified.

Request for exemption

In conclusion to the information provided above, PTFE / PFA fluoropolymers are polymers of low concern. Their properties are completely different from many of the other PFAS molecules that the current restriction proposal is designed to ban. It is therefore requested that they be excluded from the current restriction proposal, since to include them would create massive unintended consequences for both industry and wider society within the EU.