Impacts of restrictions of per- and polyfluoroalkyl substances (PFAS) on process instrumentation & control equipment

22/09/2023

Executive Summary

GAMBICA's Process Instrumentation & Control (PIC) sector has provided feedback on the Annex XV restriction report concerning per- and polyfluoroalkyl substances (PFAS). This document emphasises the crucial role of PFAS in ensuring the safety and efficiency of key process industries, which are essential for the ongoing operation of modern society.

It elaborates on the significance of PIC equipment in process operations and underscores the socioeconomic impacts of downtime in process industries. The document offers an overview of PFAS characteristics that make them indispensable in process applications and the specific uses of PFAS in PIC equipment. It also discusses the challenges and concerns related to PFAS restrictions in the PIC equipment domain, from insurmountable certification issues to concerns about the understanding of PFAS emission risks. An illustrative overview of the potential costs associated with PFAS restrictions is also provided.

This report aims to complement individual submissions from GAMBICA PIC members and industry suppliers to the ECHA consultation on the Annex XV restriction report.

Recommendations from GAMBICA's PIC sector:

1. A risk-based approach to restrictions - GAMBICA's PIC sector advocates for a more nuanced and pragmatic approach to restrictions, recommending adopting a risk-based strategy on per- and polyfluoroalkyl substances (PFAS) restrictions rather than broad restrictive measures. Restrictions in product areas with low emissions potential, where products are critical to the ongoing operation of critical infrastructure, and where PFAS have been proven to improve safety and performance should be assessed carefully to fully determine the suitability of restrictions.

2. Define 'essential-use' criteria - GAMBICA's PIC sector advocates for the establishment and application of universally accepted 'essential-use' criteria within REACH to exempt PFAS uses from restrictions when these criteria are fulfilled. GAMBICA recommends using the criteria outlined in the Montreal Protocol Decision IV/25: Essential uses, as a foundation.

3. Time-limited derogation if deemed necessary - After conducting a comprehensive impact assessment, if it is determined that restrictions are necessary for PIC equipment, the PIC sector of GAMBICA formally requests a 12-year derogation for PIC equipment to enable manufacturers to:
   a) research alternatives to PFAS and assess their compatibility with PIC applications
   b) implement necessary design modifications, and obtain re-certifications where required
   c) prepare process industries for product design changes that could impact control schemes, overall performance, and safety.

Suggested wording for derogations:

1. *By way of derogation, paragraphs 1 and 2 shall not apply to fluoropolymers and perfluoropolyethers for use in process instrumentation and control equipment until 13.5 years after EiF.*
2. *By way of derogation, paragraphs 1 and 2 shall not apply to PFAS uses essential for the manufacture of components used within process instrumentation and control equipment until 13.5 years after EiF.*

Contents

Responses to specific information requests:

Specific Information request	Summary	Location in report
1 Sector and sub-uses	New sector, "process instrumentation and control", containing twelve process industries. Sub-uses are given broadly as this is a generic document. GAMBICA members will submit further details specific to their organisation.	Section 2 Section 4 Section 6.1-6-5
2 Emissions in end-of-life phase	Emissions during manufacturing phase covered by supplier submissions. Emissions during use phase are minimal but limited detail available. Emissions at end-of-life mostly understood.	Section 5 Section 6.6
3 Emissions in end-of-life phase	Mangaged under the WEEE directive or hazardous waste regulations.	Section 6.6
4 Impacts on the recycling industry	Limited impacts due to waste already being managed as already detailed.	-
5 Proposed derogations – Tonnage and emissions	Some of the proposed derogations are suitable for some uses of PIC equipment, however not all uses are covered.	Section 3 Section 5
6 Missing uses – analysis of alternatives and socioeconomic analysis:	For most applications, suitable alternatives are not yet available. GAMBICA members will submit further details specific to their organisation.	Section 3 Section 5 Section 6.1-6-5
7 Potential derogations marked for reconsideration	None of the potential derogations are suitable for PIC equipment.	-
8 Other identified uses	Detail to be submitted by suppliers or in GAMBICA members' individual submissions if appropriate.	-
9 Degradation potential of specific PFAS sub-groups	We do not have information on this topic.	-
10 Analytical methods	We do not have information on this topic.	-

1. Introduction

GAMBICA is the UK trade association for instrumentation, control, automation and laboratory technology. GAMBICA is a membership organisation with over 220 member organisations across four key industrial sectors: Process Instrumentation & Control, Industrial Automation, Test & Measurement and Laboratory Technology. Our members serve almost all industrial sectors, and an estimated 30% of all products are exported globally, most of which are destined for the EU. Many of the businesses represented by GAMBICA are large multinationals with globally dispersed manufacturing activities.

GAMBICA's Process Instrumentation & Control sector represents manufacturers and suppliers of equipment used within process industries. Equipment in this area may be referred to as:

- Process instrumentation & control (PIC) equipment
- Industrial process measurement, control and automation equipment (IEC definition)
- Industrial process control equipment
- Industrial automation, measurement and control equipment
- Process automation technologies/equipment

2. Process instrumentation & control equipment

The use of PIC equipment is vital in enabling process manufacturing facilities to operate in a consistent, efficient and safe manner. Without PIC equipment, process industries would not be able to operate. PIC equipment covers all aspects of an industrial control system, the essential components of which are:

Measurement devices - used to measure process variables such as temperature, pressure, level, flow rate and analytical properties (pH, chemical composition). Terminology use in industry can be inconsistent, but the following terms are often used in referring to this equipment: instrumentation, sensor, transmitter, transducer, element, switch, analyser.

Final control elements - devices used to implement a change in process conditions, typically through changing the flow rate of part of the process. The following terms are often used in referring to this equipment: valves (of all types), regulators, actuators, solenoids, positioners.

Controllers - provide an interface between the measurement and final control signals by performing application-specific calculations to enable the process variable to be controlled at the desired set point. Controllers can range from to complex and may utilise advanced process control techniques such as model predictive control or AI computing techniques. The following terms are often used in referring to this equipment: control systems, DCS (distributed control system), controllers.

To control a process variable, each of these elements is combined into a control loop, a simple form of which is shown in *Figure 1* where a level transmitter measures the level of liquid in a tank, feeding that value to a controller, which is then outputting a control signal to a control valve which will open or close to maintain the level in the tank at the desired level.

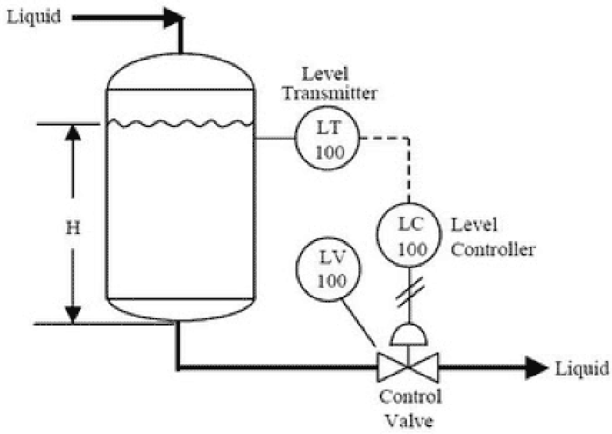

Figure 1 - Basic control loop piping & instrumentation diagram (P&ID)

The level of complexity of control schemes, and therefore the presence of PIC equipment, depends on the process, but any given process manufacturing facility can expect to have hundreds, thousands or tens of thousands of measurement and control points, all interacting with each other through their influence on process variables throughout the whole manufacturing facility. A generic example piping and instrumentation diagram for a single unit operation is shown in *Figure 2,* with instrumentation and final control points in direct contact with process fluids highlighted.

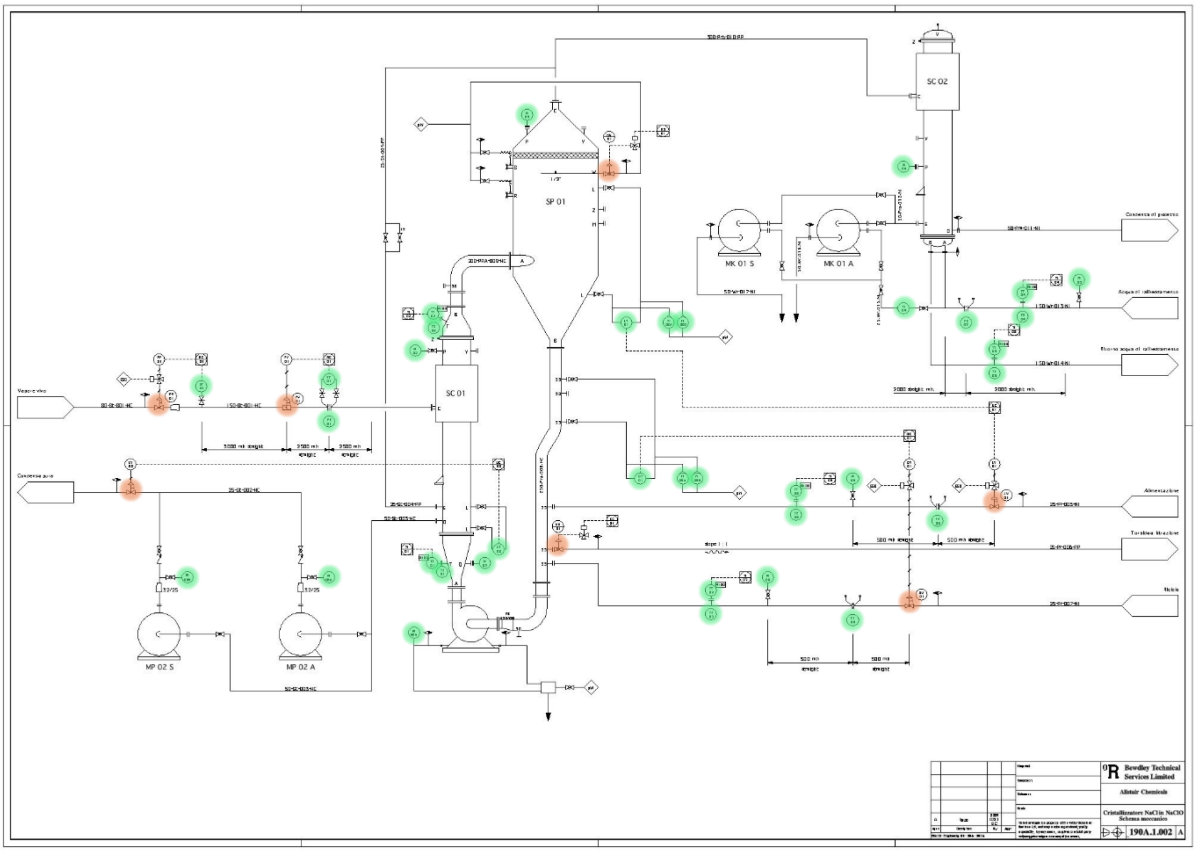

Figure 2 - More complex P&ID for a single unit operation

The inability of even one of these control loops to operate effectively affects the whole system, hence the importance of reliability in all aspects of the industrial control system.

In the example shown in *Figure 1*, the failure of the level transmitter would mean an unknown required flow rate to maintain a safe level in the tank - a situation similar to the 2005 Buncefield oil storage facility disaster where a failed level sensor and high-level switch led to an overflow of petrol and an eventual explosion that was the biggest of its kind in peacetime Europe – 43 people were injured in the explosion and resultant fires which burned for five days.

Figure 3 - Buncefield fire, England (2005). Caused by instrumentation failure.

PIC equipment is, therefore, designed in such a way that it can maintain the control and safety of process manufacturing sites under extremely hazardous conditions, and most PIC equipment is certified for use in potentially explosive atmospheres through compliance with the ATEX directive[1]. The use of PFAS is vital in ensuring PIC equipment maintains the highest level of safety and performance.

For the purposes of this report, the following industries are considered to be within the umbrella of 'process industries'.

1. Oil & Gas Upstream and Midstream
2. Chemical & Petrochemical
3. Pulp & Paper
4. Food & Beverages
5. Life Sciences (Pharmaceuticals)
6. Power Generation & Distribution
7. Water & Wastewater
8. Environmental Monitoring
9. Marine
10. Glass
11. Metals, Mining, Aggregates & Cement
12. Energy Transition

The specific risks associated with PFAS restrictions in PIC equipment to these industries are covered in *Section 3 - Process industries – socioeconomic impact assessment.*

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014L0034

3. Process industries – socioeconomic impact assessment

Process industries cannot function without PIC equipment, so the risks of not having appropriately specified PIC equipment are akin to the risks of downtime in these industries. Process industries encompass public services providers like water and wastewater treatment and power generation, as well as sectors engaged in altering raw materials through continuous and batch processes to produce materials or intermediates with improved properties and functions. These industries are typically recognised as foundational, given their critical role in supporting secondary and tertiary sectors by supplying essential feedstocks necessary for subsequent processing. In the UK, several process industries are classed as Critical National Infrastructure - these are "…critical elements of Infrastructure (facilities, systems, sites, property, information, people, networks and processes), the loss or compromise of which would result in major detrimental impact on the availability, delivery or integrity of essential services, leading to severe economic or social consequences or to loss of life."[2]. The impacts of no availability of suitably specified PIC equipment are highlighted below, along with a brief overview of each industrial sector.

Oil & gas upstream and midstream* - Upstream production covers the extraction of hydrocarbon products from the ground. This covers drilling wells (either onshore or offshore) or fracking. Midstream operations cover the initial processing, storage, and transportation of the materials to sites for further refining. Hydrocarbons are used as feedstocks for further chemical petrochemical processing or electricity generation.

Impacts of no availability of suitably specified PIC Equipment:

- No product availability for downstream processes - enormous knock-on effects for national and global economies, including inflation due to supply pressures.
- No supply of electricity-generating products - energy shortages and blackouts.
- Highly costly shutdown remediation.
- Greater levels of pollution and a significantly higher chance of gas flaring due to loss of efficient steady-state operation.

Chemical & petrochemical* - Uses chemical and physical processes to transform raw materials into products used by consumers or, more often, as inputs to downstream manufacturing activities. The chemical processing industry has various unique pollution problems due to the vast number of products manufactured.

Impacts of no availability of suitably specified PIC Equipment:

- No product availability for downstream processes - enormous knock-on effects for national and global economies.
- Inability to produce products that can potentially replace PFAS in other applications
- Consumer chemicals production impacted, including detergents, soaps, fragrances etc.
- Inflation due to supply pressures
- Significant impact on export revenue

[2] https://www.npsa.gov.uk/critical-national-infrastructure-0

Pulp & paper - Processing of wood or recycled fibre into pulps and finished paper products from tissue to product packaging. Processes use a variety of speciality chemicals.

Impacts of no availability of suitably specified PIC Equipment:

- No product availability for downstream processes - significant knock-on effects for national and global economies.
- Reduced recycling capabilities

Food & beverage* - Often considered a 'hybrid' sector due to the presence of both process and discrete manufacturing activities. Initial process manufacturing activities include following recipes/formulas to process raw materials into a product that is packaged or assembled in discrete manufacturing operations to produce a final product in a form used by consumers.

Impacts of no availability of suitably specified PIC Equipment:

- Inability to produce food or drink products vital to sustain a country's population
- Inflation due to supply pressures

Life sciences (Pharmaceuticals) - Includes facilities involved in the industrial-scale synthesis of pharmaceutical drugs and is considered another hybrid industry with both process and discrete manufacturing activities. Process manufacturing activities include scale-up, active pharmaceutical ingredients (APIs) production, excipient production and blending and mixing processes.

Impacts of no availability of suitably specified PIC Equipment:

- Inability to produce drugs to treat illnesses and medical conditions
- Diminished research capabilities and inability to capitalise on research strengths locally
- Offshoring of production to world areas with potentially lower production standards
- Inflation due to supply pressures

Power generation - Encompasses electricity generation activities followed by the transmission and distribution of this electricity through grids to homes, businesses, and industries, enabling access to energy for societal needs and economic growth. Process applications are currently used to generate the majority of the electricity worldwide, including in facilities utilising fossil fuels (coal, oil, natural gas), nuclear power plants, and biomass and energy from waste facilities.

Impacts of no availability of suitably specified PIC Equipment:

- Inability to effectively monitor and control generation processes leading to a higher likelihood of downtime, resulting in unreliable electricity output, energy shortages, brownouts and blackouts
- Lack of reliable power delivery to industry, infrastructure, healthcare, education and agriculture leading to limited economic growth, population health and education decline

Water & wastewater - The water and wastewater industry encompasses the management of water resources, treatment of water for safe consumption, and wastewater disposal to safeguard public health and the environment. It involves purification, distribution, sewage treatment, and recycling to ensure access to clean water and effective removal of pollutants from used water before its return to nature or reuse.

Impacts of no availability of suitably specified PIC Equipment:

- No clean water or sanitation, resulting in widespread disease
- Greater levels of environmental pollution and build-up of harmful chemicals

Environmental monitoring – Environmental monitoring refers to the measuring and tracking of various pollutants, gases, or particles released into the environment. In a process industry context, these are generally from industrial sources (rather than transportation etc.). Emissions monitoring aids in assessing air and water quality, regulatory compliance, and environmental impact and enables better control and mitigation of harmful emissions to minimise their adverse effects on human health and ecosystems.

Impacts of no availability of suitably specified PIC Equipment:

- Poorer air and water quality negatively impacting population health and the natural environment
- Inability to ensure compliance with environmental regulatory requirements and the inability of regulatory bodies to monitor and enforce legislative requirements on emissions

Marine transport - The marine transport industry involves the movement of goods, people, and resources across bodies of water using ships, boats, and other vessels. It encompasses shipping, cruise lines and offshore activities. This industry plays a crucial role in global trade, commerce, and tourism, facilitating the efficient movement of goods and connecting various regions.

Impacts of no availability of suitably specified PIC Equipment:

- Greater levels of pollution due to poorer control and inability to effectively monitor emissions

Glass - The glass industry manufactures glass products by melting raw materials (such as silica, soda ash, and limestone) and shaping them into various forms used in construction, packaging, electronics, and more.

Impacts of no availability of suitably specified PIC Equipment:

- No product availability for downstream processes - enormous knock-on effects for national and global economies.
- Production of glass medical instruments and tools impacted, potentially hampering medical research and diagnostics.
- Inability to produce hard-wearing displays for electronic equipment.

Metals, mining, aggregates & cement* - The metals, mining, aggregates, and cement industry encompasses excavating, extracting, and processing valuable minerals, metals, and aggregate raw materials to create metals, construction materials, and cement. It supplies vital materials for buildings, roads, machinery, electronics, and other products that are integral to the daily operations and progress of modern society.

Impacts of no availability of suitably specified PIC Equipment:

- Shortages of construction materials for buildings, roads, bridges, and other infrastructure
- Lower-quality manufactured materials resulting from poorer control
- Slowing of progress towards Net Zero goals due to impacts on battery production

Energy transition - Covers carbon capture, hydrogen, and other energy transition industries focus on mitigating climate change and transitioning to sustainable energy sources. Carbon capture involves capturing CO2 emissions from industrial processes and power plants. Hydrogen technology produces clean energy through electrolysis or reforming processes. These sectors explore alternative energy sources and storage solutions to reduce greenhouse gas emissions and shift toward a more environmentally friendly and resilient energy landscape.

Impacts of no availability of suitably specified PIC Equipment:

- Slowing of progress towards Net Zero goals
- Greater levels of carbon emissions

* Some uses of PFAS within this industry will be covered under the proposed derogations in paragraph 6[3]:

a) *By way of derogation, paragraphs 1 and 2 shall not apply to fluoropolymers and perfluoropolyethers for the use in food contact materials for the purpose of industrial and professional food and feed production until 6.5 years after EiF*

f) *By way of derogation, paragraphs 1 and 2 shall not apply to fluoropolymers and perfluoropolyethers for the use in fluoropolymer applications in petroleum and mining industry until 13.5 years after EiF.*

While it is positive that the need for a derogation has been acknowledged, these derogations do not go far enough to mitigate the risks introduced by restrictions, as detailed in this report.

[3] ECHA Annex XV restriction report - https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/72301/term

4. Operating conditions for PIC equipment

Within the above-identified process industries, operational conditions can differ widely, but, in general, operational environments for PIC equipment are very challenging. The following section highlights the key elements of the operational environment for PIC equipment and the properties of PFAS that are pertinent to ensuring safe control and operation.

Highly hazardous chemical compositions of process fluids - Many process applications are centred around transforming raw materials into products beneficial to society at an industrial level. Chemicals of all kinds are necessary as raw materials, which can be extremely hazardous to people, property and processes. Certain process manufacturing sites where highly hazardous materials are used are defined in the UK as COMAH sites from the Control of Major Accident Hazards Regulations 2015[4] – the UK's implementation of the EU Seveso-III Directive[5].

Relevant properties of PFAS products:

- Chemical resistance and inertness
- High levels of bio-resistance

Extreme process fluid temperatures - Process applications are often operated at extremely low or extremely high temperatures and can range from around -200°C to +200°C, and some applications even exceed this upper temperature range, such as steam boilers, where instruments are designed to work up to 560°C. One vital application operating at extremely low cryogenic temperatures is the liquefaction of natural gas to liquified natural gas (LNG) and its transfer and transport. Other cryogenic processes exist in the pharmaceutical and food processing industries.

Relevant properties of PFAS products:

- Thermal stability
- Cryogenic properties

High-pressure operating conditions - High-pressure applications are common in process applications, with pressures often ranging up to 150 bar (15000kPa). Processes such as polymerisation, catalytic reactions, separations, oil and gas recovery, food processing and biocatalysis all often operate under very high pressures. Many high-pressure applications are also operated at high temperatures, such as the above-mentioned boiler level measurement application, where pressures can range up to 450 bar (45000kPa). One noteworthy process operating at extremely high pressure is the Haber-Bosch process, which is used for the industrial production of ammonia for fertiliser worldwide. High temperatures and high pressures are ubiquitous in many process industries as they help improve the efficiency of industrial processes by positively impacting chemical reaction kinetics.

Relevant properties of PFAS products:

- Extrusion resistance
- Rapid gas decompression resistance
- Resistance to compression fluids

[4] https://www.legislation.gov.uk/uksi/2015/483/
[5] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32012L0018

Highly abrasive process fluids - Process fluids often contain particulate matter that makes them highly abrasive. High fluid velocities in pipelines carrying these abrasive fluids make the environment extremely hostile, so equipment must be able to withstand this environment without risk of excessive wear.

Relevant properties of PFAS products:

- Low coefficient of friction
- Mechanical wear resistance

Harsh environmental conditions and flammable atmospheres - Many process facilities operate in harsh environmental conditions from corrosive marine environments to freezing arctic installations and arid desert environments. More often than not, facilities containing process operations will have areas of operation that are designated as flammable or explosive atmospheres. In these areas, products are designed to prevent any sources of ignition that could cause a fire or explosion and must be certified as safe to use in these areas through compliance with regulations such as ATEX.

Relevant properties of PFAS products:

- Resistant to UV degradation
- Flame resistance

Hygienic operation requirements - Some process sectors have hygienic operation requirements that must be met, and products used in these sectors often must be approved and certified as safe to use. Two of the most common methods for assessing equipment suitability are through EHEDG or 3-A; the fundamental purpose is to prevent contamination and ensure products are safe.

Relevant properties of PFAS products:

- Chemical resistance and inertness
- High levels of bio-resistance
- Low coefficient of friction
- Mechanical wear resistance
- Thermal stability

Most products intended for use in these demanding environments undergo an extensive and time-consuming development, testing, and certification process. PFAS restrictions introduce another layer of difficulty tied to these rigorous requirements, as detailed in *Section 6 - Further challenges and concerns of PFAS restrictions in PIC Equipment.*

While applications within each identified process sector exhibit considerable diversity, we provide a general overview of the industries and the commonly encountered operating conditions for PIC equipment in *Table 1*. In all areas highlighted in red or yellow (where the operating condition is present), PFAS restrictions on PIC equipment pose a risk to ongoing safe and efficient operation.

	Hazardous chemical compositions	Extreme process temperatures	High-pressure operating conditions	Highly abrasive process fluids	Harsh environmental conditions and flammable atmospheres	Hygienic operation requirements
Oil & Gas Upstream and Midstream	✓ (common)	✓ (common)	✓ (common)	✓ (common)	✓ (common)	✗
Chemical & Petrochemical	✓ (common)	✓ (common)	✓ (common)	✓ (common)	✓ (common)	✗
Pulp & Paper	✓ (less common)	✓ (less common)	✗	✓ (common)	✗	✗
Food & Beverages	✓ (less common)	✓ (less common)	✓ (less common)	✓ (common)	✗	✓ (common)
Life Sciences (Pharmaceuticals)	✓ (common)	✓ (common)	✗	✗	✗	✓ (common)
Power Generation & Distribution	✓ (common)	✓ (common)	✓ (common)	✓ (less common)	✓ (common)	✗
Water & Wastewater	✓ (common)	✗	✗	✓ (common)	✓ (common)	✓ (less common)
Environmental Emissions Monitoring	✓ (common)	✓ (common)	✗	✗	✓ (common)	✗
Marine	✓ (common)	✓ (common)	✗	✗	✓ (common)	✗
Glass	✓ (common)	✓ (common)	✓ (common)	✓ (common)	✓ (common)	✗
Metals, Mining, Aggregates & Cement	✓ (common)	✗	✗	✓ (common)	✓ (common)	✗
Energy Transition	✓ (less common)	✓ (common)	✓ (common)	✗	✓ (common)	✗

Key: ✓ Present - common (red) | ✓ Present - less common (yellow) | ✗ Not present (green)

Table 1 – Operating conditions for PIC equipment by industry

5. Specific PFAS uses in PIC equipment

Outlined below are some primary component areas that will be affected by PFAS restrictions. It should be noted that GAMBICA members produce PIC equipment, but they source specific components from suppliers. Consequently, insights into the use of PFAS in these components hinge on supplier data. While GAMBICA members may be able to offer their own specific usage data in separate consultation responses, this document offers a general overview. The aim is to highlight the prevalent use of PFAS and its pivotal role in various PIC equipment components.

For PIC equipment, many of the most pronounced effects of PFAS restrictions are seen in devices directly interfacing with process fluids. Instrumentation, especially sensing elements and transmitters measuring variables like Pressure, Temperature, Level, Flow, and fluid Analytical properties, face the brunt of these restrictions. Other notably affected devices include valves, actuators, and valve positioners. We've spotlighted these areas for clarity, though they aren't the only affected PIC components.

Electronic componentry - PFAS are commonly used in producing the electronic componentry used in PIC equipment. Some examples of key areas are highlighted below.

> Capacitors - Capacitors are a critical component in all microelectronic devices – they are used for energy storage, power conditioning, and control. Various fluoropolymers are used in capacitors as dielectric films and occasionally as liquid impregnates.
>
> Printed circuit boards (PCBs) - Printed circuit boards (PCBs) are a common component in the electronics industry. PFAS are frequently integrated into the board's laminate material to provide flame retardant and dielectric properties. Once a board is completed, it can be coated with a protective layer called a conformal coating, which shields it from temperature fluctuations, moisture, and dust. While there are alternatives to using PFAS in PCBs, designing without them is not straightforward. This is particularly true in sectors where stringent regulatory compliance and third-party testing are mandatory. Furthermore, in situations where spare parts are needed to extend the lifespan of PIC equipment, maintaining consistent PCB properties is essential.
>
> Semiconductors - Semiconductors are small electronic components primarily constructed from a semiconductive material, such as silicon, with integrated circuits constructed upon the semiconductive substrate (wafer). PFAS chemicals are used extensively in the fabrication process of semiconductors.

Liquid crystal displays (LCDs) - LCD displays are standard across most PIC transmitters and are used to display information and allow an operator to modify and configure instrumentation. PFAS provide the liquid crystal with a dipole moment and are used to provide a moisture-sensitive coating for displays. Some F-gases, which are included in the scope of PFASs, are also used in the manufacture of LCDs.

Polymer optical fibres - Analytical instrumentation utilising optical analytical techniques may rely on the use of PFAS in optical amplifiers, lasers, multiplexers, isolators, interleavers, demultiplexers, filters, photodetectors, and switches.

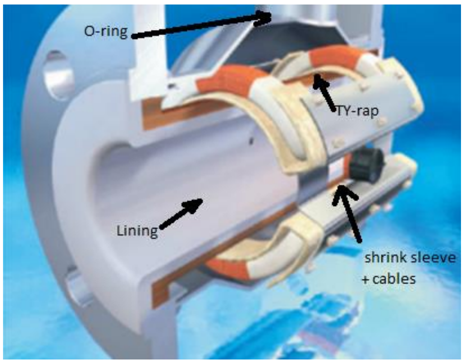

Figure 4 - Magnetic flow meter diagram showing PTFE liner (Krohne Ltd.)

Liners - Liners are integral components in various PIC equipment, with PFAS (fluoropolymers) often being the primary material of choice. Magnetic flow meters, which measure electromagnetic induction to determine flow rates, are especially reliant on liners. A crucial design element of these meters is insulating the measurement electrodes from the process fluid, ensuring there's no short-circuiting of the generated electromotive force. Liners are necessary for these instruments to operate. After decades of research, fluoropolymers have been identified as the most suitable liner material for a wide range of industrial uses. The specific type of fluoropolymer selected depends on the process fluid and its operating conditions. Factors like temperature resistance, resistance to thermal shock, pressure performance, and resistance to abrasion, corrosion, and fluid adhesion are all considered when specifying a liner.

In some applications, the use of liners contributes to the hygienic or sanitary characteristics of a meter (or other PIC equipment) and helps compliance with associated regulations (EHEDG, 3A, Drinking water regulations). Liners used in these kinds of applications would be covered under the proposed derogation in paragraph 6a: *By way of derogation, paragraphs 1 and 2 shall not apply to fluoropolymers and perfluoropolyethers for the use in food contact materials for the purpose of industrial and professional food and feed production until 6.5 years after EiF.* While it is positive that the need for a derogation has been acknowledged, the length of time is unlikely to be sufficient for PIC equipment due to the challenges identified in *Section 6 - Further challenges and concerns of PFAS restrictions in PIC Equipment*.

Most major magnetic flow meter manufacturers have published recommendations on liner use for a wide range of process fluids which have been used to create *Table 2*; a summarised table indicating the suitability of different liner types for common process conditions.

	Property Suitability (1-10, 10 is ideally suited)			
Liner Type	Chemical Resistance	Abrasion Resistance	Temperature Range	Max pressure (line size dependent)
PTFE	9	7	9	6
PFA	10	6	9	5
ETFE	7	8	7	6
Polyurethane	3	9	4	8
Hard rubber	6	9	6	8
Soft rubber	5	8	5	10

Table 2 - Suitability of liner materials by process condition

Liners are in use that are made from non-fluoropolymer materials such as ceramics and natural rubbers, but these are not suitable for all applications and cannot replace the use of fluoropolymers across all applications.

Lubricants - Perfluoropolyether-based lubricants are used as oils and greases in various PIC equipment due to being non-corrosive, non-oxidising, resistant to high temperatures and due to the fact that they do not form sludge or varnish. Perfluoropolyether-based lubricants are likely to be used with valves, bearings, valve packing, gaskets or seal barrier fluids in most hostile operating environments. Lubricants used in PIC equipment should be covered under the proposed derogation in paragraph 5s; *By way of derogation, paragraphs 1 and 2 shall not apply to: lubricants where the use takes place under harsh conditions or the use is needed for safe functioning and safety of equipment until 13.5 years after EIF.*

Figure 5 - Wireless measurement device with energy harvesting and lithium battery (ABB Ltd.)

Lithium batteries - In recent years, wireless PIC equipment has enabled the use of measurement devices in situations where it may not be cost-effective to run power and signal cabling, such as on large, geographically dispersed, facilities. The use of wireless measurement devices enables processes to be monitored more effectively, and while these devices will not be part of the control loop, they may be able to identify situations that may affect safety and performance, such as leaks, excessive vibration, corrosion etc. These devices require a power source to operate, and many are supplied with industrial Lithium batteries. PVDF and FEP are used as binders for both the negative (anode) and positive (cathode) electrodes in nearly all commercial lithium batteries. Fluorocarbon resins and fluoropolymers are used in lithium batteries to prevent a thermal runaway reaction and combustion of the battery.

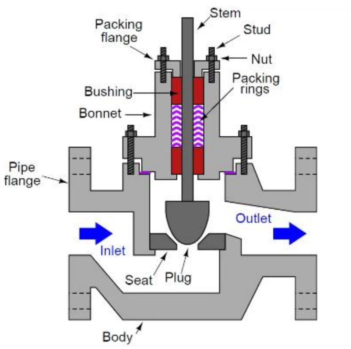

Figure 6 - Control valve diagram showing valve packing (purple)

Seals, packing, sealants and pipes - Fluoroelastomer seals and sealants are frequently employed in PIC equipment because they can endure the harsh chemical conditions typical in process industries and maintain their structural integrity even at elevated temperatures. These properties, along with their low coefficient of friction, also make PFAS-based valve packing materials vital in isolating process fluids from the environment. PFAS-containing pipework is used in certain applications, and especially in certain analytical instrumentation designs for the same reasons.

Waveguides - PTFE is integral to radar and guided wave radar instruments. It insulates the transmitter electronics from the process fluid while simultaneously serving as a waveguide to transmit a low-energy microwave pulse down the probe. When this pulse reaches the liquid level, a portion of the microwave energy reflects back to the transmitter. The liquid level can be determined by calculating the time difference between sending and receiving the pulse. The waveguide material must have a low dielectric constant for accurate measurements, so fluoropolymers are necessary to ensure minimal interference. PTFE waveguides also address two other major challenges for guided wave radars: fouling and corrosion - both can compromise measurement accuracy and overall safety. Much like with magnetic flow meters, PFAS is essential to the functionality of this measurement approach.

Wire and cable - PFAS is ubiquitous in insulated wires and cables due to their high-temperature endurance, fire resistance, high-stress crack resistance, resistance to corrosion, flexibility and low dielectric constant. The combination of these properties makes PFASs perfect for wiring and cabling applications, and their reliability in industrial applications is vital.

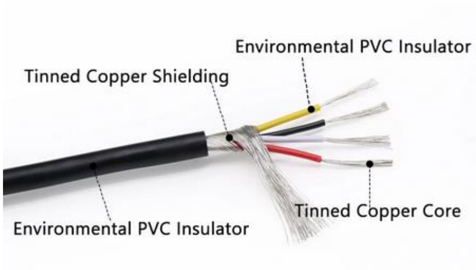

Figure 7 - Example 4-core shielded cable

Table 3 displays the usage of these components in some key instrumentation and final control device categories. For areas marked in red or yellow (indicating component use), restrictions on PFAS in PIC equipment are likely to jeopardise safe and efficient functioning. In certain instances, these restrictions also inhibit the fundamental operation of the instrument.

	Instrumentation (by process variable)					Control Equipment		
Component:	Pressure	Temperature	Level	Flow	Analytical	Valves	Actuators	Valve positioners
Electronic Componentry	✓	✓	✓	✓	✓	✓	✓	✓
Liquid crystal displays (LCDs)	✓	✓	✓	✓	✓	✗	✓	✓
Polymer optical fibres	✗	✗	✗	✗	✓	✗	✗	✗
Liners	✗	✗	✗	✓	✗	✓	✗	✗
Lubricants	✓	✓	✓	✓	✓	✓	✓	✓
Lithium batteries	✓	✓	✓	✓	✓	✗	✗	✗
Seals, seal glands, sealants and pipes	✓	✓	✓	✓	✓	✓	✓	✓
Waveguides	✗	✗	✓	✗	✗	✗	✗	✗
Wire and Cable	✓	✓	✓	✓	✓	✗	✓	✓

Key:	✓ Present - common	✓ Present - less common, or PFAS used in manufacturing process only	✗ Not present

Table 3 – PFAS component requirements for PIC equipment categories

GAMBICA notes that the Annex XV guidance emphasises that the term ‘essential-use’ has not been adopted because there are no established criteria for it with REACH. It’s concerning that restrictions are being considered without a clear definition of essential use. Various suggestions have been made to define 'essential-use', many drawing from the Montreal Protocol Decision IV/25: Essential uses[6]. According to the protocol, a use is deemed essential where, firstly, (i) that the use is necessary for the health, safety or is critical for the functioning of society (encompassing cultural and intellectual aspects), and (ii) that there are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health. Secondly, (i) that all economically feasible steps have been taken to minimize the essential use and any associated emission of the controlled substance; and (ii) that the controlled substance is not available in sufficient quantity and quality from existing stocks of banked or recycled controlled substances, also bearing in mind the developing countries' need for controlled substances. For many components and applications of PIC equipment, these conditions are satisfied.

[6] https://ozone.unep.org/treaties/montreal-protocol/meetings/fourth-meeting-parties/decisions/decision-iv25-essential-uses

6. Further challenges and concerns of PFAS restrictions in PIC Equipment

Section 3 has highlighted the socioeconomic impacts that PFAS restrictions could result in should suitably specified PIC equipment not be available to enable effective control of process operations, but there are further factors that should be acknowledged when assessing the appropriateness of PFAS restrictions for PIC equipment. These are covered in this section and include far-reaching impacts that could make the transition to PFAS alternatives impossible, restrict the ability to enforce restrictions or show that restrictions are not proportionate to the risks posed by potential emissions.

6.1. Regulatory compliance

As highlighted in this document, most products used in process industries are being used in very hostile environments. To ensure that these products are safe, they are assessed by manufacturers according to relevant regulations. Depending on the type of product and its intended use, many must also undergo strict third-party conformity assessment testing – a non-trivial process that requires aspects of a product's design to be assessed to ensure safety. The regulations relevant to PIC are:

- Directive 2014/34/EU - Equipment for potentially explosive atmospheres (ATEX)
- Directive 2014/68/EU - Pressure Equipment Directive (PED)
- Directive 2014/32/EU - Measuring Instruments Directive (MID)
- Directive 2014/35/EU - Low Voltage Directive (LVD)
- Directive 2014/30/EU - Electromagnetic Compatibility (EMC) Directive

Implementing design changes in any of these areas will necessitate the reassessment and, when necessary, re-certification of products. Even in cases where a suitable alternative to PFAS has been identified, the process of incorporating design modifications and undergoing retesting is a time-consuming endeavour. It's particularly important to consider that focusing solely on the effects of PFAS restrictions for a single product type, especially when third-party certification is involved, would be misleading. A more realistic approach is to assess the impact on a specific regulatory area. This is because the work requires collaboration between manufacturers and conformity assessment bodies (CABs). Each regulatory domain has a finite number of CABs, and these organisations have limited capacity. The proposed PFAS regulations will therefore exacerbate an existing challenge in the industry – capacity constraints

CABs lack the capacity to manage the increased workload resulting from PFAS restrictions. The extent of work involved is substantial and largely unpredictable until the restrictions are implemented. This challenge has already been evident in businesses dealing with the UK, thanks to the introduction of UKCA marking. Manufacturers striving for UKCA compliance have faced significant hurdles in certifying products, even when no design changes are involved.

In essence, where viable alternatives to PFAS materials are already identified, the resulting bottleneck in the certification process, driven by both volume and technical constraints, will be difficult to surmount, even if a 12-year derogation is implemented. For equipment where no suitable PFAS alternative has been identified, the process is even more complex - exploring alternatives that meet both performance and safety requirements is a protracted and costly process. Decisions regarding material alternatives, if feasible at all, will likely require significant performance compromises, as safety must remain uncompromised.

6.2. Functional safety

Some PIC equipment is used in applications that are specifically designated as part of a Safety Instrumented System (SIS) – a set of hardware and software controls that exist with the sole purpose of providing a significant level of risk reduction against accident hazards when abnormal operating conditions are detected. Each SIS will contain a set of safety instrumented functions (SIF) which each perform a certain function to maintain system safety. SIS differs from the basic control system function in that the SIS operates independently to ensure any failure in the basic control system does not affect the ability of the SIS to prevent an unsafe condition. Each SIF is credited with a specific safety integrity level (SIL) that is dependent on a hazard analysis, where SIL levels 1-4 dictate the required risk reduction to be provided by the SIF. A SIF will have a defined SIL, with a higher SIL being a more dependable SIF (SIL4 being the most dependable).

All of this matters in the context of the proposed PFAS restrictions because the SIL of a system includes requirements on the hardware within that system that are determined through a probabilistic analysis of the device. To be classified at any SIL level, a device must meet the targets of the probability of failure and minimum safe failure fraction. The certification of a device's SIL is dependent on the ability of the manufacturer to prove that the device meets these targets by demonstrating that the device has sufficient operating history to argue that it has been proven in use. Changing a product design means that there is no operating history for the product and so any hardware used in SIS that undergoes a design change due to PFAS restrictions must be certified and will not be suitable for use in the SIS.

6.3. Production of PFAS and any alternatives

As highlighted within this document, process manufacturing applications play a crucial role in the continuous functioning of facilities engaged in the creation of chemical and petrochemical goods. This encompasses the production of PFAS as well as potential substitutes. Annex A of the restriction report outlines the processes involved in PFAS production, which necessitate the use of extremely corrosive and hazardous chemicals. Without the ability to operate these processes effectively and safely, any derogation proposed in Annex A for uses of PFAS becomes meaningless as there will not be any PFAS available for use anyway because there are no suitable alternatives for use in PIC equipment.

The impact encompasses not just PFAS production but also applies to potential substitutes for PFAS that might rely on similar extremely corrosive and toxic chemicals, leading to the same problem in their production processes: without the ability to safely control a process, it cannot operate.

6.4. Effects on operational efficiency

The primary objective of implementing restrictions on PFAS is to safeguard both the environment and individuals – an objective that GAMBICA's members are wholeheartedly dedicated to. However, the proposed approach for PFAS restriction falls short of achieving this goal, as the broader consequences of these restrictions have not been thoroughly explored. Focusing solely on Process Instrumentation and Control (PIC) equipment, the restrictions will inevitably lead to diminished efficiency in the processes where they are employed and an increased likelihood of incidents that pose risks to people and the environment.

Over the course of decades, process instrumentation and control equipment has undergone significant evolution, incorporating technological innovations. These advancements allow equipment to be used in situations where it was not previously possible and enhance equipment performance to enable meticulous process monitoring and precise control. This enhanced performance contributes to improved efficiency in raw material utilisation and energy consumption. The proposed PFAS restrictions risk rolling back these strides in technology, diminishing the capability of PIC equipment. Consequently, this could lead to reduced insight into process operations and less effective overall control, thereby causing escalated energy usage and unwarranted squandering of raw materials.

It's well understood that energy consumption within process facilities constitutes a substantial portion of global carbon emissions. As a result, those overseeing these facilities consistently strive to improve efficiency by exercising precise control over their processes—aiming to curtail energy waste and decrease overall carbon emissions. All these efforts could be negated if the essential equipment enabling such advancements becomes unavailable.

6.5. Measurement of PFAS

GAMBICA's membership extends into the Laboratory Technology sector – the views of which have been largely excluded here due to the different product focuses (a separate response from GAMBICA Laboratory Technology sector has been submitted). However, one vital argument related to measurement is worth making - that the equipment needed to measure PFAS (and other restricted substances) in products also relies on using PFAS. Therefore, the ability to monitor the impacts of and enforce the proposed restrictions relies on the use of PFAS.

6.6. PIC Equipment end of life treatment

The operational life of PIC equipment far exceeds that of consumer devices, with equipment regularly in operation for 10-15 years and many products exceeding 20 years of operational life. Much of the PIC equipment discussed in this document also falls under the Waste from Electrical and Electronic Equipment (WEEE) Directive. Consequently, they are subject to careful management at the end of their lifecycle. Under the WEEE directive, these products are collected, treated, and recycled whenever possible. If recycling is not feasible, they are disposed of in an environmentally responsible and compliant manner.

Figure 8 illustrates the average annual tonnage of WEEE collections in the UK across the 10-year period 2012-2022 in the UK[7].

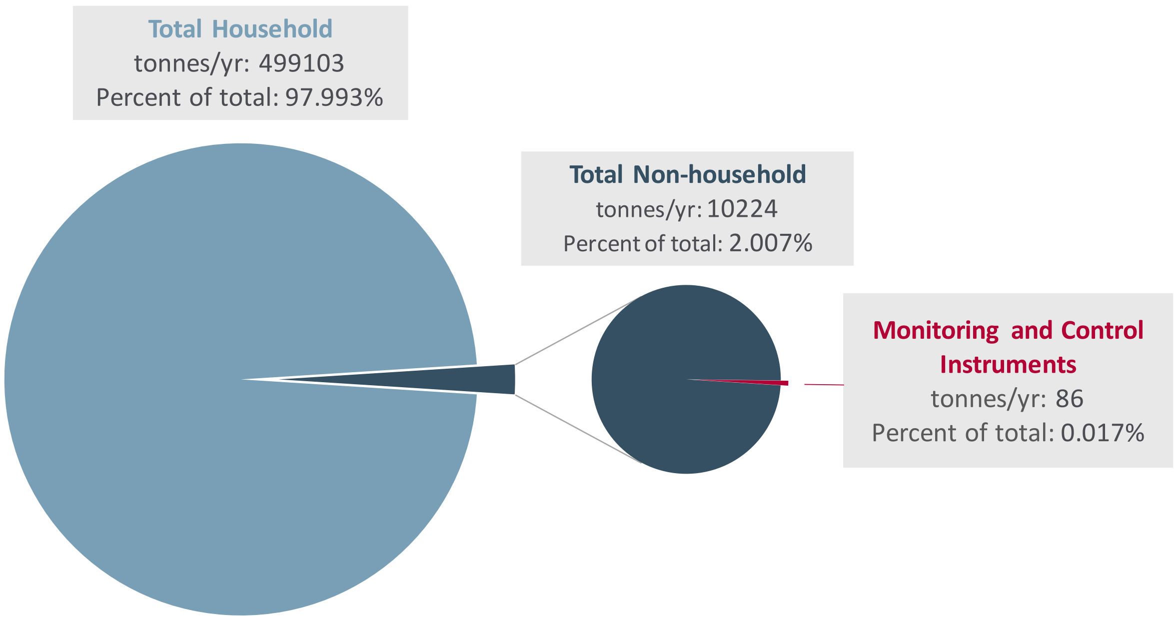

Figure 8 - Average annual WEEE collections in UK (2012-2022)[5]

The above shows that collections for household WEEE greatly surpass those for non-household (B2B) products and collections for 'Monitoring and Control Instruments' within the non-household category are another several orders of magnitude lower. The 'Monitoring and Control Instruments' category

[7] https://www.gov.uk/government/statistical-data-sets/waste-electrical-and-electronic-equipment-weee-in-the-uk

includes PIC equipment but also other equipment[8]; therefore, the collection figures for PIC equipment are lower still.

WEEE collections cover only electrical waste, which is only a very small proportion of general waste. Looking at PFAS emissions, the risk posed by consumer waste dwarfs waste associated with high-specification technologies used in industrial applications. When measuring societal value against emissions risk, the two are at opposite ends of the spectrum. PIC equipment is low emissions risk and high societal value, whereas consumer products are high emissions risk and low societal value. Essentially, the disposal of PIC equipment rare and is subject to stringent regulations, including EU rules governing hazardous waste. As a result, there is minimal risk of exposure to humans or the environment at the end of the equipment's life cycle.

[8] https://www.daera-ni.gov.uk/articles/annex-ii-list-products-which-fall-under-each-weee-directive-category

7. Conclusions

This high-level overview document has highlighted the importance of process instrumentation and control equipment in the safe and efficient operation of process industries which are in turn necessary for the ongoing functioning of modern society. The potential risks introduced by the broad restrictive measures on per- and polyfluoroalkyl substances (PFAS) cannot be understated, and while GAMBICA and its members strongly support the goal of minimising environmental and human exposure to these substances, the proposed approach is not an appropriate method for doing this.

GAMBICA's PIC sector advocates for a more nuanced and pragmatic approach to restrictions, recommending the adoption of a risk-based strategy for PFAS restrictions, rather than broad restrictive measures. Restrictions in product areas with negligible emissions potential, where products are critical to the ongoing operation of critical infrastructure, and where PFASs have demonstrated improvement in safety and performance, should be assessed carefully to fully determine the suitability of restrictions.

GAMBICA's PIC sector recommends adopting an internationally recognized, clear definition of 'essential-use' criteria within REACH. The choice of the Dossier Submitter to exclude the concept of essential-use when drafting the restriction proposal is a significant oversight. GAMBICA strongly suggests the establishment and application of universally accepted 'essential-use' criteria within REACH to exempt PFAS uses from restrictions when these criteria are fulfilled. GAMBICA recommends using the criteria outlined in the Montreal Protocol Decision IV/25: Essential uses, as a foundation, whereby PFAS uses are deemed essential where, firstly, (i) that the use is necessary for the health, safety or is critical for the functioning of society (encompassing cultural and intellectual aspects), and (ii) that there are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health. Secondly, (i) that all economically feasible steps have been taken to minimize the essential use and any associated emission of the controlled substance; and (ii) that the controlled substance is not available in sufficient quantity and quality from existing stocks of banked or recycled controlled substances, also bearing in mind the developing countries' need for controlled substances. For the majority of uses associated with PIC equipment, these conditions are satisfied.

Although the Annex XV report provides exceptions for some uses of PFAS in sectors utilising PIC equipment, these exceptions are not comprehensive enough to address the risks posed by the proposed restrictions. If a thorough impact assessment, which includes all feedback from this consultation, concludes that PFAS uses in PIC-related areas are not deemed essential and restrictions are warranted, then GAMBICA's PIC sector officially seeks a 12-year derogation for PIC equipment. This duration would allow manufacturers to: Investigate alternatives to PFAS and assess their compatibility with PIC applications, implement necessary design modifications, and obtain re-certifications for their products where required.

A 12-year window provides time for PIC manufacturers to collaborate with suppliers, find potential replacement components, and prepare process industries for product design changes that could impact control schemes, overall performance, and safety.

Report signatories:

This report has been developed with significant support and input from experts from across the Process Instrumentation & Control sector. Explicit support and input has been gathered from the experts and business leaders from the following companies:

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KROHNE	**Edward Jukes** General Manager & Technical Director KROHNE Ltd
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Implicit support is also given from companies and experts from the broader membership of GAMBICA's Process Instrumentation & Control sector.

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