Honeywell

LIFE SAFETY DISTRIBUTION GmbH
Z.A. La Pièce 16
1180 Rolle
Switzerland
www.honeywell.com

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PFAS REACH Annex XV Restriction Report

1ST Public Consultation (22 March – 25 September 2023)

Request for exclusion or derogation of certain fluorinated materials used in gas sensor applications from the PFAS REACH restriction Proposal.

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Executive summary

Honeywell International Inc. and its affiliated companies (hereafter "**Honeywell**")[1] are global providers of various electronic and electrical devices ("**EEE**"), including electrochemical Gas Sensors (E-chem "**Gas Sensors**") for numerous downstream sectors, including medical, industrial, safety, aerospace, oil & gas, and other applications. These Gas Sensors contain components (membranes, electrodes, tapes, gaskets, greases, etc.) made of PFAS-related fluoropolymers, (per-)fluoroelastomers and perfluoropolyethers (PTFE, FEP, PFA, PVDF, PVF, PCTFE, PFPE, FKM, FFKM – hereafter "**Fluorinated Materials**")[2]. Unique chemical and physical properties of these materials enable critical technical characteristics, selectivity, measurement precision, reliability, and long service lives for Gas Sensors.

[1] See the list of acronyms and abbreviations (aligned with the Proposal) in **Annex I** below.
[2] The list of PFAS substances containing in components and materials of Gas Sensors is provided in **Annex II** below.

On 13 January 2023, the competent authorities of five EU/EEA states ("**Dossier Submitters**") submitted to the European Chemical Agency ("**ECHA"**) the *PFAS REACH Annex XV Restriction Report* ("**Proposal**").[3] The Proposal covers all PFAS and their uses, including in all Gas Sensor applications.

Honeywell submits that uses of the above fluorinated materials in electrochemical gas sensors should be excluded or made subject to the time-unlimited derogation from potential PFAS REACH restrictions due to the following reasons.

Although the aforementioned Fluorinated Materials can be classified as PFAS based on their molecular structure, their mobility and long-range transport potential (LRTP), bioaccumulation, toxicological, and eco-toxicological profiles are essentially different from the majority of PFAS substances. Moreover, polymers such as PTFE, PCTFE and all other Fluorinated Materials at stake satisfy the OECD criteria for a Polymer of Low Concern (PLC)[4], and are deemed to be environmentally and humanly benign. These substances are non-toxic, non-bioavailable, non-water soluble, and non-mobile, indicating that they do not pose any substantial risks to the environment or human health. They do not exhibit any of the intrinsic hazards assessed in section 1.1.4 of the Proposal and are not substances with similar PBT/vPvB concerns. Their grouping with *"all other PFAS"* for risk assessment purposes is not scientifically and legally justified.[5]

Respective risks for Fluorinated Materials in Gas Sensors across their entire lifecycles are already adequately controlled by virtue of extensive industry manufacturing standards, responsible manufacturing commitments from industry, negligible leakage during the use phase (as well as during landfill) and detailed disposal requirements under EU *WEEE Directive*, *Waste Framework Directive* (WFD) and respective national laws and practices.[6] Incineration of these materials under standard European municipal waste incineration conditions, particularly at temperatures above 850°C, has been assessed under the various EU and national waste legislative frameworks above. Additional Risk Management Measures (RMMs) for these devices are practiced today.[7]

Due to unique physicochemical properties, these materials provide exceptional characteristics for E-chem Gas Sensors indispensable for many applications. Some examples include medical oxygen or anaesthetic devices, industrial (fixed and/or personal/portable) toxic gases detection and alarming (often in harsh temperatures, pressure, and acidic media). For instance, in medical anaesthetic gas applications, only Fluorinated Materials enable conformance to the technical specifications under ISO 80601-2-55 standards.[8]

In the meantime, due to high cost and complexity of processing techniques, these materials are employed only in situations where there are no viable alternatives. Currently, there are no other known or actively developed materials in the market that possess necessary combinations of properties, such as high thermal resistance (~200°C), high flexibility, high mechanical resistance, and high chemical resistance, which are specifically required for applications in E-chem Gas Sensors.[9] These properties are essential for various components thereof such as membranes, electrodes,[10] sealings, o-rings, as well as their external components like tubing, spacers, solenoids, and connectors. Development and commercialisation of such alternatives will require much longer time than envisaged in the Proposal and substantial resources that could be prohibitive for many manufacturers.

As a result, if Fluorinated Materials were banned in Gas Sensors across all applications, industrial production in semiconductors, automotive, medical, petrochemical, and crude oil sectors worth over 2 trillion EUR would be compromised due to the lack of adequate safety-related gas detection systems.

Therefore, the ban on use of Fluorinated Materials in question in E-chem Gas Sensor applications is disproportionate to alleged risks for health and the environment due to the lack of persistency, mobility, or toxicity of the PFAS

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[3] On 22 March 2023, ECHA published the *PFAS REACH Annex XV Restriction Report* in the Registry of restriction intentions until outcome and started the 1st *Annex XV report consultation* with a final deadline for comments on 25 September 2023.

[4] See detailed analysis in *A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers*, Stephen H. Korzeniowski *at al.*, Integrated Environmental Assessment and Management — Volume 19, Number 2—pp. 326–354, 2022.

[5] *Ibid.*, page 348-349.

[6] *Ibid.*, page 350.

[7] See additional details in section 4.1.2 below.

[8] ISO 80601-2-55:2018, Medical electrical equipment — Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors.

[9] See e.g., in section 2.1.1 of *Risk management options analysis (RMOA),* Fluoropolymer Products Group of Plastics Europe (FPG), 2021, or at page 347 of the study in footnote 4 above.

[10] *Ibid.* at page 82.

materials in question. Respective REACH restrictions envisaged in the Proposal would endanger lives of people and industrial safety inevitably resulting in very high costs on the society. These consequences are in direct contradiction with the wider EU industrialisation and competition policies as well as objectives of the European Green Deal, REPowerEU, European Chips Act, Net Zero Industry Act, and other emerging sustainability laws.[11]

2 Overview of Fluorinated Materials used in E-chem Gas Sensor applications

Honeywell's industrial and medical electrochemical oxygen, toxic, and flammable gas detection sensors (i.e., E-chem **Gas Sensors**) are purposefully designed to measure a variety of toxic and combustible gases to help keep workers safe in harsh conditions and factory environments, in addition to providing life-saving gas mixtures in hospital and patient critical care applications. Often Gas Sensors are used as parts/components of complex detection and control systems/devices. Across industry and healthcare, accidental gas leaks pose a huge threat to human life, the environment, and property. Therefore, Honeywell manufactures a full and comprehensive range of gas detection products dedicated to all types of industrial, medical, and domestic facilities, e.g., from smaller boiler rooms to large petrochemical plants and oil refineries. These technologies and devices include gas detectors, flame detectors, and natural gas alarms that provide exceptional protection at every level of operation, enabling the most favourable coverage, detection, hazard mitigation, and life protection.[12]

These are the main categories of Gas Sensors and application sectors:

- **Medical – life safety critical applications**

For **anaesthetic gases**, E-chem oxygen Gas Sensors are required to meet ISO 80601-2-55 standards in order to be used as components of respiratory medical equipment. The performance requirements set out by this ISO standard require the use of fluoropolymers and other Fluorinated Materials to meet strict control tolerances across a range of gases.

Fluoropolymers and perfluoroelastomers are needed in those demanding medical device applications because of their critical chemical resistance, including low contamination levels/limits. Their uses in pharmaceutical and life sciences applications[13] are assured with approvals of EU Medical Devices Regulation (**MDR**)[14], competent national authorities and U.S. Food and Drug Administration (**FDA**).

Fluoropolymers are (i) durable, stable, and mechanically strong in harsh conditions; (ii) chemically inert, meeting the requirements for low levels of contaminants and particulates in manufacturing environments that are critical to the food and beverage, pharmaceutical, medical, and semiconductor industries; and (iii) biocompatible, nonwetting, nonstick, and highly resistant to temperature, fire, and weather. Fluoropolymers are the preferred choice of material because of their unique combination of properties that are not achievable from other materials or via other functions.[15]

Non-PFAS materials would not enable the Gas Sensors to meet most of these technical specifications. In addition, there are concerns that changes in specific materials would be as large in terms of time and burden as designing new sensors. As highlighted above, there could be interactions between multiple stages in substitution processes that will need to be explored. There are also limitations on the availability of necessary experts given the magnitude and complexity of the task at hand. As such, substitutions timelines are impossible to estimate, although they would be much longer than a 12-year period provided in the Proposal.

In addition, E-chem oxygen Gas Sensors are used with **non-anaesthetic gases** to detect oxygen (O_2) levels and deliver proper dosing required for patient care. Seals and valves made of Fluorinated Materials ensure system

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11 See e.g., *Ibid.* at pages 58, 82 and 85.

12 Detailed descriptions and technical specifications of Honeywell electrochemical industrial sensors are available here - *Industrial Gas Sensors*, and here - *Gas & Flame Detection*.

13 See e.g., in the Product Description section of *DuPont™ Kalrez® Perfluoroelastomer Parts.*

14 *Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC*.

15 See e.g., a page 347 in *A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers*, Stephen H. Korzeniowski *at al.*, Integrated Environmental Assessment and Management — Volume 19, Number 2—pp. 326–354, 2022.

integrity and prevent leaks of oxygen that can become explosive at elevated concentrations. Seal materials must be non-reactive to clinical gases and inert under operational conditions.

The **inhaled nitric oxide (NO) therapy** was developed for the treatment of **neonates with respiratory failure**. Due to the recent COVID pandemic, acute respiratory distress is on the rise, and patients require inhaled nitric oxide (NO) therapy to improve their treatment outcome. Fractional Exhaled Nitric Oxide measurement is used to **tailor asthma drug therapies** that can be properly delivered only by monitoring ppb-level emissions of NO in the breath of patients using Gas Sensors that contain fluoropolymers.

- **Industrial Safety – fixed Gas Sensors**

This application covers a huge range of gases and environments. E-Chem Gas Sensors detect a gas in question, and once the gas is detected, the device will send a signal to the processing component and then will raise an alarm in the appropriate system. Fixed gas detectors are intended to be located at a fixed spot and are defined as life critical safety equipment.

There are also flammable/pellistor Gas Sensors - miniature catalytic oxidation sensors, or pellistors, designed to measure combustible gases (or vapours) in air. They operate at concentrations below the Lower Explosive Limit (LEL) of a gas, which triggers an early warning prior to the build-up of an explosive atmosphere.

- **Industrial Safety – portable Gas Sensors**

Similar to fixed Gas Sensors above, portable gas detectors are intended to be worn as personal protective equipment (PPE), as such they are defined as a life critical safety application. Once the gas is detected, the device will emit auditory, visual, and tactile (vibration) signals.

- **Air Quality Ambient**

Those applications provide for detection of environmentally important gases (*inter alia* Ozone, Nitrogen Dioxide, Sulphur Dioxide, etc.). These gases are detected in urban environments and once detected are reported to a central information control service or environmental monitoring establishment.

- **Air Quality Emissions**

These applications provide for detection and measurement of gases important for air quality (*inter alia* Nitrogen Dioxide, Sulphur Dioxide, Carbon Monoxide, Hydrogen, etc.). The gases are detected directly from industrial burners and compared to regulated allowable levels of emissions.

- **Automotive**

This application covers the use of Oxygen and Nitric Oxide (NO) measurement in exhaust fumes of vehicles with internal combustion engines (ICE-powered). This technology is used to assess whether vehicle emissions are within regulated EU emissions standards.

3 Why Fluorinated Materials are indispensable for Gas Sensors?

Gas Sensors are used in critical lifesaving applications and harsh environments. Therefore, all components in the device need to be safe, durable, and non-reactive across a broad range of temperatures, chemical environments, radiation levels and other environmental exposure that arises from various downstream applications. Fluorinated Materials are the only plastics that can meet all these characteristics.

Table 1 below summarises PFAS materials (i.e., Fluorinated Materials) and their uses in components of E-chem Gas Sensors as well as their respective unique characteristics and benefits.

PFAS Material	Where it is used	Unique properties for this application
PTFE - liquid for dispersion	All E-chem Gas Sensors electrodes	Gas permeable, hydrophobic channels within hydrophilic catalytic material. Aids bonding to the PTFE electrode support membrane.
PTFE - tapes	All E-chem Gas Sensors electrodes and sensor dust caps	Inert, gas permeable, hydrophobic, electrode support membrane and sensor seal.

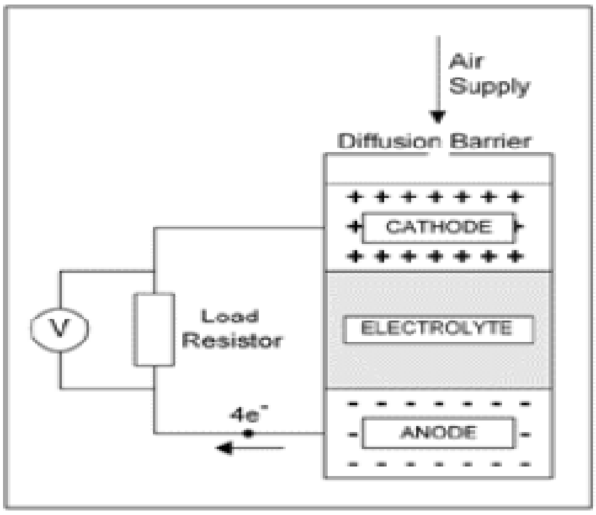
PTFE - surfactants	E-chem Electrode manufacturing	Inert, gas permeable, hydrophobic surfactant to keep precious metal in suspension for electrode manufacturing process.
PTFE - powders	Filtered Gas Sensors/Toxic Gas Sensors	Create inert, gas permeable, hydrophobic channels through active filter material.
PTFE/PFA/FEP - membranes	Medical & Automotive O_2 and Pb sensors	Inert, solid state gas diffusion barrier
PTFE/PFPE - greases	Several E-chem Gas Sensor product ranges	Hydrophobic barrier
PCTFE – gas barriers and valve seats	O_2 pump Gas Sensors	Gas barriers and valve seats for internal gas management
FKM/FFKM – o-rings, gaskets, seals	Sensor internal and external sealing	Internal sensor sealing. External sealing into instrumentation.
PVDF – spacer	Pellistor Gas Sensors	Inert, high temperature internal spacer.
PTFE – spacer	Pellistor Gas Sensors	Inert, high temperature internal spacer.
PTFE/PFA – tubing/connector	External connections of Gas Sensors within fixed and portable test equipment	Inert, chemical resistance, high pressure rated gas tubing
PTFE – solenoids	External connections of Gas Sensors within fixed and portable test equipment	Inert, chemical resistance, high pressure rated gas solenoid
PTFE/FKM – seals	External connections of Gas Sensors within fixed and portable test equipment	Inert, chemical resistance seals

Unique characteristics of these Fluorinated Materials for E-chem Gas Sensor applications are explained below.

3.1 Key components and operating principles

In its simplest form, an oxygen electrochemical Gas Sensor consists of a **diffusion barrier *(membrane)*** – controlling the diffusion of the reactant gas to the sensing electrode, two similar gas diffusion fuel cell **electrodes** (sensing electrodes (*cathode*): situated such that external gases have relatively easy access and counter electrodes (*anode*): located deep within the cell interior, where diffusion access by ambient atmospheric gases is highly restricted), an ionically conducting, concentrated aqueous *electrolyte* separating the two electrodes, for example; a solution of sulfuric acid or alkaline sodium hydroxide or potassium hydroxide. Finally, a low-impedance external *electrical circuit* is used to connect the sensing and counter electrodes and to provide a voltage output across *a load resistor* to measure the current output of the cell (e.g., simplest form, a load resistor for oxygen sensors).

Figure 1 Gas Sensors Schematic

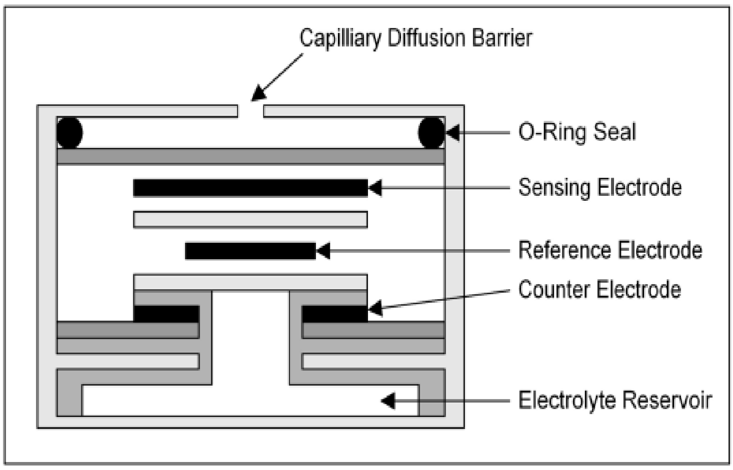


Oxygen Sensor Schematic

This cell can be considered as a **sealed enclosure** which holds two electrodes: the cathode (a flat PTFE tape coated with an active catalyst) and the anode (Pb (lead)). This enclosure is air-tight apart from a small capillary at the top of the cell which allows oxygen access to the working electrode. The two electrodes are connected, via current collectors, to pins which protrude externally and allow the sensor to be electronically connected to an instrument. The entire cell is filled with a conductive electrolyte which allows transfer of ionic species between the electrodes. The rate at which oxygen can enter the cell is controlled by the size of the capillary hole at the top of the sensor.

In clean air, when reactant gases are absent, both electrodes will assume the same potential and no (minor) current will flow in the external circuit. If an electrochemically oxidable gas (reducing gas), such as, e.g., carbon monoxide (CO) is present in the ambient air, it will diffuse to the sensing electrode first and cause its potential to shift in a cathodic direction. The resulting potential difference between the sensing and the counter electrode will then cause a current to flow in the external circuit, sustained by electrochemical oxidation of a reactant gas at the sensing electrode, and matched by an equivalent amount of reduction at the counter.

For certain toxic gases and specific applications, there are three electrode Gas Sensors. The limitation imposed by the counter electrode polarization can be avoided by introducing a third, reference electrode, and by using an external potentiostatic operating circuit. By controlling the potential of the sensing electrode, the potentiostatic circuit allows greater selectivity and improved response to the target gas. The same circuit is used to measure the current flow between the sensing and counter electrodes.



Toxic Gas CiTiceL® Schematic Drawing

There are also four electrode Gas Sensors that have an additional sensing electrode known as the auxiliary electrode, which allows it to detect two gases simultaneously (e.g., CO and H2S). The two sensing electrodes provide distinct output signals for the two different gases. Other 4-electrode sensor designs utilize an auxiliary electrode which can provide detection for hydrogen compensation, baseline compensation or scavenging of oxidation by-products.

As a part of larger/complex gas detection and control systems, Gas Sensors use attached external components such as spacers, tubing, connections, valves, solenoids, and other conduits that deliver the targeted gas to the sensor.

3.1.1 Key requirements for the diffusion barrier (membrane)

This electrochemical power source is converted to a sensor by the inclusion of the **diffusion barrier (*membrane*)** at the sensing electrode of the cell. The chemical nature of this barrier is fundamentally important to the operation of the sensor and is designed to severely restrict access of the reactant gas that becomes completely oxidised as it arrives at the sensing electrode. Under these conditions, the concentration of reacting gas at the sensing electrode approaches zero; not only does this condition prevent reactant gas from accessing the counter electrode and setting up a reverse reaction, but also prevents the sensing electrode reaction and resultant current from becoming limited solely by the rate of gas diffusion through the barrier.

Highly resistant and inert Fluorinated Materials (i.e., PTFE powders) are also needed for special filters that are often used in Gas Sensors to control purity (dust, etc.) of the target reactant gas.

The diffusion barrier and its gas properties exert a profound influence on the characteristics of the sensor. Two broad categories of diffusion barriers have been used and have been identified according to the diffusion process through the barrier.

In the first type, the rate controlling process is the one of diffusion in solution, sometimes called activated diffusion. It is characterized by a *high exponential response to temperature*. Two variants of activated diffusion barriers exist involving, firstly, diffusion in solution through an electrolyte film and, secondly, diffusion in solution through a solid polymer membrane.

In the second type, the gas remains in the gas phase as it diffuses through a porous barrier. It is characterized by a relatively low temperature coefficient and exists in two variants involving, either macropores or micropores.

In practice, these membranes have low diffusibilities and need to be very thin to achieve practical sensitivities for sensor applications. Such thin films can cause handling difficulties due to static charge, fragility, and problems with cracks, pinholes, and other defects. The purpose of the solid-state diffusion has an inherently high exponential temperature coefficient and sensor outputs can vary with temperature by as much as 3-4 % $C^{\circ -1}$ at or near 20°C. Solid membranes have been widely employed in the past but have been extensively replaced by porous barriers which are easier to fabricate and possess superior detection properties. The principal advantage of the solid membrane barrier is that it furnishes a true partial pressure measurement which is linear over the complete concentration range 0-100%, and this is a critical property for many downstream applications.

Only PTFE/PFA/FEP membrane materials that are electrically inert, gas permeable as well as temperature and chemical resistant (i.e., to electrolytes, etc.) can provide such stable characteristics for solid membrane barriers in E-chem Gas Sensors, particularly for automotive and medical partial pressure oxygen sensors (see below).

PTFE Membranes are crucial in the manufacture of partial pressure oxygen Gas Sensors. They control the access of oxygen into the sensors. Currently, no suitable alternatives exist to replace these membranes. In addition, membranes have to be chemically compatible with (medical) anaesthetic gases and have low oxygen permeability. PTFE, FEP & PFA (all PFAS materials) fit these requirements and completely meet ISO 80601-2-55 standards. In these applications, changes in components of Gas Sensors require long and burdensome recertification, as they are life critical safety components within respirators and ventilators.

3.1.2 Crucial characteristics of electrodes

A reactant gas molecule present in ambient air passes through the following series of stages to undergo detection by an electrochemical sensor:

a) mass transport in the gas phase to the diffusion barrier.

b) diffusion, under a concentration gradient, through the sensor barrier (this may involve either diffusion in the gas or solid phase, depending on the nature of the barrier).

c) gas phase diffusion from the barrier to the electrode, through any porous electrode support and into the electrode structure itself.

d) diffusion through an aqueous electrolyte film to the catalyst surface.

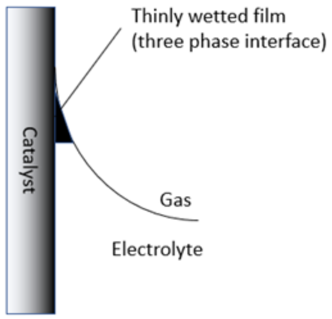
e) adsorption from the liquid phase onto the catalyst surface; followed by surface migration to the catalyst "active sites."

f) electron transfer between the catalyst surface and adsorbate, at the active center, to form detection products (this may also involve processes such as desolvation, electrode surface reactions, involving adsorbed and/or electrolyte species, etc.).

g) desorption of detection products and their subsequent transport back into the bulk electrolyte.

In a Gas Sensor, the principal rate-controlling step should be diffusion through the barrier component (see step c) above), as all other stages should have rate capabilities far in excess of the main diffusion barrier. Of prime importance, to achieve this, is that the electrode material must have a high catalytic activity towards the electron transfer reaction, and any other reactions involved in the overall electrochemical reaction by which the gas is detected. Only PTFE based materials can provide required characteristics for gas electrodes as explained below.

For gas electrodes, the sites at which electrochemical reactions occur exist at the so called "three phase interface," where a solid catalyst surface, gaseous reactant and liquid electrolyte coexist. This occurs in a thinly wetted area of contact between the catalyst surface, electrolyte, and gas (figure below).[16]



Three phase interface

To maximise the thinly wetted area, "fuel cell" gas diffusion electrodes are employed.[17] These consist of finely divided catalyst powders of large specific surface area, mixed with a polytetrafluoroethylene (PTFE) binder, supported on a highly porous PTFE backing membrane. The catalyst powder forms aggregates of its primary particles which are hydrophilic and therefore wetted by the aqueous electrolyte. The PTFE is a highly hydrophobic material and remains unwetted. The catalyst layer, which is a mixture of these two powder materials, is formulated such that a three-dimensional dual phase structure is formed of interconnecting, hydrophilic, and electrically conducting catalyst aggregates, interwoven by a hydrophobic PTFE network. The latter provides gas channels to the electrode interior and controls the catalyst wetting, preventing complete "flooding" by the electrolyte, thus facilitating gas diffusion into the thinly wetted catalyst aggregates (figure below).[18]

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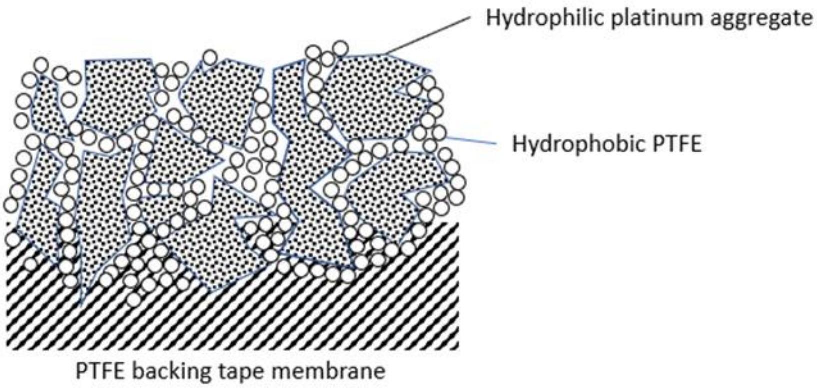
16 See Chapter 6, *Techniques and Mechanisms in Gas Sensing,* Moseley, P. T., et al., 1991.

17 See e.g., *Structure and Performance of Hydrophobic Gas Electrodes*, A. D. S. Tantram and A. C. C. Tseung, 1969.

18 *Ibid.* footnote 16.



2D schematic of a PTFE gas diffusion electrode

The PTFE backing membrane acts as both support for this structure and a final wet proof barrier, preventing electrolyte leakage from the cell, whilst also providing highly diffusive gas access to the electrode catalyst layer. Such electrodes have an extremely high reserve of electrochemical activity which ensures both high sensor signal stability over long periods of time and resistance to electrode poisoning.[19]

Other gas electrode structures have been employed in Gas Sensors consisting of films of metal evaporated onto PTFE backing membranes.[20] However, these lack the activity reserve of the catalyst powder types and consequently do not support the same signal stability and low drift rates observed with current powder catalyst technology. The evaporated film electrodes, having a lower catalyst area, possess a lower electrical capacitance and therefore respond somewhat faster, but this is usually of secondary importance compared with signal stability.

Therefore, PTFE based dispersions, tapes, and surfactants for gas electrodes are indispensable for proper functioning of E-chem Gas Sensors.

For instance, PTFE dispersions are crucial in the manufacture of electrodes; they allow the formation of three phase interfaces. Currently, no suitable alternatives exist to replace these dispersions. The inert chemical nature of PTFE is ideal for the aggressive chemical nature of sensor electrolytes and the materials that they detect. Within Honeywell, more than 22 distinct chemical electrolyte mixtures exist; PTFE is compatible with them all.

3.1.3 Importance of cells sealing

Sealing and gas cell closure within Gas Sensors containing acidic and alkali systems is achieved by techniques such as ultrasonic welding of the PTFE pressure seals used in fuel cells for better performance, rather than the crimped can with bituminized grommet seals used in Ni-Cd batteries.

PTFE electrode support tapes create a physical wet, electrolyte barrier, preventing liquid from leaking from the sensor. Seals and o-rings that are in the direct gas stream are required to be chemically and thermally resistant, inert, and mechanically robust to create a gas tight seal. Seals will be exposed to acidic, corrosive, and chemically aggressive gases including H_2S, NOx, SOx, HCl, HF, HCN to name a few.

For these reasons, only PTFE seals, tapes, and FKM/FFKM o-rings provide the required sealing and resistance properties (moisture, gases, chemicals, etc.). In this regard, the PTFE structure also acts as a support structure for electrode catalyst and sealing mechanism for electrolyte. New sealing materials will require significant time for development and extended safety field trials in order to meet technical specifications and safety reliability requirements.

3.1.4 Other critical components of a Gas Sensor envelope

Many Gas Sensors are expected to work in harsh environments, including very high or low temperatures, high pressure, and the presence of aggressive chemicals. Therefore, all external components of fixed and portable Gas Sensors that are needed to deliver the targeted gas to the sensor (as a part of a larger/complex detection and control

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[19] See e.g., *The Mechanism of Operation of the Teflon-Bonded Gas Diffusion Electrode: A Mathematical Model*, J. Giner and C. Hunter, 1969.

[20] *GB1200595A - Improvements in or relating to membrane electrodes and cells - Google Patents*.

system/equipment) should be highly resistant (mechanical, temperatures, chemicals, etc.) and inert materials. These external components normally include spacers, tubing, connections, valves, solenoids, etc. In this respect, for instance, PTFE and PVDF spacers are indispensable for pellistor sensors. No alternatives currently exist in the market with the required properties and substitution of these materials would require complete redesign of these sensor types and subsequent ATEX recertification.[21]

3.2 Selectivity of Gas Sensors

A key feature of any electrochemical Gas Sensor is that it should be highly specific and possess minimal effects from other cross-interfering gases. This is largely managed in electrochemical sensors by either one or a combination of the following techniques:

a) development of *specific electrode catalysts and electrolyte systems*;

b) control of *operating potentials* for the sensing electrodes;

c) use of *chemical filters* to remove interfering gases' selectivity.

In this respect, chemical filters play a special key role in selectivity of Gas Sensors. Chemical filters placed in the main gas stream of an aspirated system remove cross-interfering gases by selective adsorption or chemical oxidation or reduction. These reactions can be very specific. The main disadvantage with this technique is short filter life; the in-line filter, exposed to the full gas stream, rapidly reaches exhaustion and needs to be replaced typically within a few days, or, at most, weeks. Alternatively, a more efficient method is to incorporate the chemical filter "in-board" of the sensor diffusion barrier,[22] between the electrode and the barrier. In this design, the filter material is exposed to a much smaller amount of interferant gas diffusing to the electrode. Filter life is therefore greatly extended, in many instances in time frame comparable with the sensor's life. This technique is also applicable to non-aspirated diffusion modes of operation. These filters include PTFE powders to create channels if finely divided filter powders are utilized.

Therefore, PTFE powders are crucial in the manufacture of filter material used within Gas Sensors; they enable the Gas Sensor to be more selective and specific. Currently, no suitable alternatives exist to replace PTFE powders. PTFE powders are used as an inert filter material, and they ensure gas access paths and known chemical retention times within the filter. Their chemical inertness makes them ideal for this use, as the powder does not degrade when exposed to the chemicals that Gas Sensors are designed to detect, thereby providing durability and accuracy across a range of life-critical applications.

4 Absence of unacceptable and not adequately controlled risk

4.1.1 Grouping and risks assessment in the Proposal

PTFE, PCTFE, FEP, PFA, PVDF, PVF, PFPE, FKM and FFKM are polymer-type Fluorinated Materials. Although they are not registered under REACH, they satisfy all criteria of the internationally recognised OECD definition for a Polymer of Low Concern (PLC)[23]. They are scientifically proven to be a low-hazard, non-toxic, non-mobile, extremely inert material without chemical or biological reactivity, and with excellent stability under a range of environmental and normal-use conditions.[24]

All available scientific data unequivocally demonstrates that above fluoropolymer materials do not exhibit any of the hazards assessed in Section 1.1.4 of the Proposal and that their physicochemical, toxicological, and ecotoxicological

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21 *Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (recast).*

22 *Design and development of electrochemical gas sensors,* Robert Yatshen Chan-Henry, 1984.

23 *Data analysis of the identification of correlations between polymer characteristics and potential for health or ecotoxicological concern*, OECD Environment, Health and Safety Publications, ENV/JM/MONO(2009).

24 Please find detailed assessment of PLC criteria of fluoropolymers in *A Critical Review of the Application of Polymer of Low Concern and Regulatory Criteria to Fluoropolymers,* Barbara J Henry et al., Integrated Environmental Assessment and Management — Volume 14, Number 3—pp. 316–334, 2018; and more recent and detailed in *A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers*, Stephen H. Korzeniowski *at al.*, Integrated Environmental Assessment and Management — Volume 19, Number 2—pp. 326–354, 2022.

properties are very different from many other PFAS. It is apparent that these Fluorinated Materials do not exhibit PBT/vPvB equivalent concerns, contrary to the erroneous conclusions in section 1.1.6 of the Proposal.

The substances mentioned above exhibit exceptional stability, as they are solid and inert. They are resistant to deterioration caused by various factors such as acids, bases, oxidants, reductants, light-induced processes, microorganisms, and metabolic processes. As a result, they possess high resistance to thermal, chemical, and biological changes. These materials do not typically degrade under normal environmental conditions or during regular use and processing. They are notably durable and persist over time. However, it is important to note that persistence alone does not indicate any current or future risks to human health or the environment. The persistence of these substances is not inherently hazardous, as it does not automatically imply or indicate the potential for adverse effects or toxicity. The regulation of persistence by REACH takes into consideration other properties that provide insight into potential hazards. Fluoropolymers themselves are persistent, but they are not bioaccumulative, not mobile, and not toxic (not PBT/vPvB or PMT/vPvM) and therefore not SVHCs from a regulatory perspective.[25]

Therefore, grouping of Fluorinated Materials in question with "*all other PFAS*" for REACH restrictions and/or read-across purposes is not supported by available scientific data and ECHA RAAF requirements.[26] Therefore, "*segmentation based on properties should be conducted before performing any grouping-based risk assessment, placing stable, non-hazardous fluoropolymer materials that meet the criteria to be considered PLC in a separate category*."[27]

Furthermore, according to the RAC/SEAC opinions in the Restriction Proposal of microplastics (see the RAC opinion), it is only when a "*polymer*", as defined in Article 3(5) REACH, has specific intrinsic properties of "*microplastics*" (i.e. particles size, (bio)degradation and water solubility thresholds), that these properties may affect its hazard characteristics, resulting in vPvB equivalent concerns.[28] It is evident that Fluorinated Materials in Gas Sensors do not satisfy the above definition of microplastics. Therefore, the blanket application of conclusions regarding PBT/vPvB and non-threshold properties of microplastics, as proxies to unacceptable risk to all fluoropolymer materials without adequate and comprehensive risk assessments of their respective hazards and exposure, is not justified.[29] The adequate scientific assessment of the above Fluorinated Materials, which is required to demonstrate the level of "*unacceptable risk*" under Article 68 REACH, is missing in sections 1.1.4., 1.1.5 and 1.1.6 of the Proposal.

4.1.2 Other effective RMM in place

Electrochemical Gas Sensors are subject to various stringent technical regulations during their production, use, and end-of-life (both landfill and incineration) stages.

Manufacturing processes of Gas Sensors and Fluorinated Materials in question are regulated by the EU Industrial Emissions Directive (IED)[30] and the recent *Responsible Manufacturing Commitment* of the industry.[31]

During the use phase, these materials remain stable and inert. They also contained in closed and rigorously sealed electrochemical cells excluding any PFAS emissions at the use stage (see sections 1.3 and 1.3.3 above).

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25 *Persistent, mobile and toxic substances in the environment: a spotlight on current research and regulatory activities*, Heinz Rüdel et al., Environmental Sciences Europe volume 32, Article number: 5 (2020).

26 See detailed discussion at pages 348-349 and Conclusions in *A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers*, Stephen H. Korzeniowski *at al.*, Integrated Environmental Assessment and Management — Volume 19, Number 2—pp. 326–354, 2022.

27 *Ibid.*, at page 349.

28 In this context RAC concluded in section B.1.2.2 of the Opinion on the *Restriction Proposal of microplastics* that "*although there are uncertainties in the understanding of the hazard and risk of microplastics, there is sufficient evidence to conclude that that they constitute an intrinsic hazard because of their long-term persistence in the environment in combination with their particulate form and potential to cause adverse effects*".

29 See e.g., on three elements of risk - hazard, exposure, and risk based on the hazard manifesting themselves in the exposure in the specific case, *Fidenato v Comune di Padova*, Case C-442/14, *Commission v Germany*, Case C-47/90. *Etimine SA v Secretary of State for Work and Pensions*, C-15/10.

30 *Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (Recast).*

31 "*As such, all FPG Members have committed voluntarily to responsible manufacturing principles in term of continuously improve and/or develop best available techniques in the manufacturing process, management of environmental emissions, development of R&D programs for the advancement of technologies allowing for the replacement of PFAS-based polymerization aids, and/or the increase recyclability and reuse of its products in line with the objectives of circular economy.*" PlasticsEurope's Fluoropolymers Product Group (FPG) statement, 2021.

Regulations/standards driving demand for PFAS in sensors include: EN 45544, EN 50379, EN60079, AS/NZS 4641, ANSI/ISA 92.00.01, FDA ISO 80601-55-2, BAR, ISO/PAS 19891:2016, SOLAS guideline XI-11/7, IFC 2018, NBIC 2017, NFPA 55 (2016), Nitrogen Storage Guidelines (2016), BS EN 12021 (2014), Safe Work In Confined Spaces (2014) and HSE Confined Spaces Regulations (1997), EH40 (2011, 2005), Workplace Safety and Health Act (2009), BS 6173 (2009), AS5034 - Installation and use of inert gases for beverage dispensing (2005), Health and Safety at Work etc Act (1974), OSHA - permissible exposure limits (1970). These standards guaranty negligible risks and emissions of the Fluorinated Materials in question during the use stage in Gas Sensor applications.

There is also considerable data demonstrating that Fluorinated Materials, e.g., PTFE or PCTFE, do not degrade in the environment or release substances of toxicological or environmental concern during the landfill disposal (i.e., negligibly leachable).[32]

Moreover, many E-chem Gas Sensors are considered as EEE or components thereof. Disposal and waste treatment of EEE at their end-of-life (even as hazardous waste) is subject to the EU *WEEE Directive*, *Waste Framework Directive* (WFD)[33] and national waste related legislation of the EU member states. These regulations could be amended at any time to accommodate appropriate handling of PFAS contained waste streams (collection, disposal, reuse, etc.), if warranted. These will be more proportionate and effective RMMs then the restriction (i.e., complete ban) envisaged in the Proposal as far as uses of Fluorinated Materials in E-chem Gas Sensors are concerned.

Therefore, risks due to uses of Fluorinated Materials in question in Gas Sensors are already adequately controlled throughout all their lifecycle within the meaning of Articles 68 and 69 REACH and the proposed REACH restrictions for respective substances are not justified.

5 Unique characteristics of materials in question and absence of feasible alternatives

It is obvious that there are no functional (not in kind) alternatives for Gas Sensors in applications at stake. While it might be possible to utilize large, expensive desk detection systems, these would not be suitable for many of essential safety and medical applications (see section 1.1 above). Also, Gas chromatography–mass spectrometry (GC-MS), colorimetric detection tunes or infra-red (IR) techniques could be an alternative but the associated issues are high power requirements, size, cost, accuracy, no visual/audible alarm, time required, practicality, etc. Also, some of these alternatives only give qualitative results and not quantitative ones.

In this regard, Fluorinated Materials, such as PTFE, FEP, PFA, PVDF, PVF, PCTFE, PFPE, FKM and FFKM, provide unique properties for critical technical features of E-chem Gas Sensors. These materials could not be substituted by in-kind alternative substances even within the long perspective as demonstrated below.

- **Downsides of PTFE and other fluoropolymers alternatives**

PTFE is a unique inert, gas permeable, hydrophobic, and low flammability material, which is ideal for membranes, electrodes, and other components of electrochemical Gas Sensors. PTFE allows the support of a fuel cell-based electrode, acting as a physical wet barrier for electrolyte containment. Inert and gas permeable, it allows the target gas to diffuse to a three-phase region, where catalyst, gas and electrolyte can react. The electrode structure of hydrophilic catalytic material and hydrophobic PTFE creating channels within the electrode allow gas to access the wetted catalyst material.

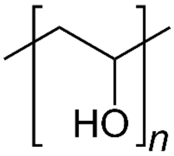
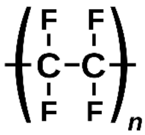
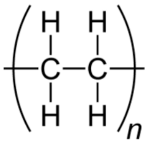
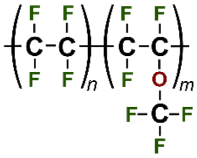
None of other non-PFAS substances (e.g., polymethyl urea (PMU)) are able to provide required technical characteristics, specifically in regard to the hydrophobic, inert, and gas permeable properties of PTFE.

PMU based alternatives to PTFE powders have a lower density and decomposition temperature (>200°C compared to >345°C), which is not suitable for the curing temperature of the electrode process. PMU is a polar polymer and a number of reactive groups (including carboxyl, amine, and hydroxyl groups) may cause side reactions with target gases. PTFE, by contrast, is a non-polar polymer and inert.

[32] Pages 350 in *A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers*, Stephen H. Korzeniowski *at al.*, Integrated Environmental Assessment and Management — Volume 19, Number 2—pp. 326–354, 2022.

[33] *Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives.*

The same is true for PVA materials used in Gas Sensor cell electrodes. They are not as robust, nor as stable, nor efficient or powerful as PTFE based electrodes. They are also hydrophilic and soluble in water as well as toxic (solutions containing more than 5% PVA are toxic to fish)[34] and they biodegrade slowly.[35]

 PVA  PTFE  PE  PFA

In the meantime, PE, LDPE and HDPE plastics are highly flammable, sensitive to stress cracking, lack of resistance to oxidizing agents and chlorinated hydrocarbons that objectively are not able to substitute PTFE in Gas Sensors.

For new material development, producers of Gas Sensors rely upon their material suppliers. However, in the case of PFAS, to the best of our knowledge, respective suppliers have indicated that replacements will be cost prohibitive and periods much longer than the maximal derogation period of 12-years is envisaged. It is also not certain that those alternatives would enable equivalent technical performance while meeting all relevant regulatory standards, particularly in medical and safety applications. Therefore, replacing PTFE in E-chem Gas Sensors in a specified time frame is not feasible.

PTFE and other fluoroplastics like FEP, PFA, PVDF, PVF, and PCTFE have the ability to endure high temperatures during processing. The manufacturing process of E-chemical Gas Sensors electrodes involves one, two, or three stages of elevated temperature, depending on the method used. These stages include sintering, bonding, and sealing, and they necessitate temperatures higher than 150°C. As a result, certain alternative materials such as polypropylene (melting point: 130–171°C) or polyethylene (melting point: 115–135°C) cannot be used, and new sensor designs, and electrode manufacturing processes would be required.

In this respect, other materials such as acrylic copolymers or polyurethanes (PU) also lack chemical compatibility with strong acids, which makes impossible their use with electrolytes in E-chemical Gas Sensors. Materials like expanded polypropylene or polyether-ether-ketone (PEEK) have too high surface energy so they cannot be used as gas porous substrates for membranes.

Certain materials, such as polyurethanes (PU) are also susceptible to degradation by repeated exposure to certain toxic acidic-type gases, including hydrogen cyanide (HCN), hydrochloric acid (HCl), chlorine (Cl2), sulfur dioxide (SO_2). Hence, they physically cannot be used in Gas Sensors (as well as in spacers, tubes, connectors, solenoids, valves, etc.) for detection of toxic gases and thus to substitute fluoropolymers in such applications.

Moreover, for many of the substances concerned there are no alternative theoretical material chemistries which could be used as a basis for invention and the development of a whole new area of chemistry and/or technology will be required. There are also concerns that substitution of certain specific materials would be as large as designing new sensors and would require unpredicted period of time, as highlighted above.

- **Alternatives to (per-)fluoroelastomers (FKM/FFKM) as gaskets, o-rings and sealants**

FKM and FFKM materials are used to seal components inside the Gas Sensor as such and its external components, i.e., between tubes, pumps, solenoids, connectors, etc. They have excellent sealing properties in extreme conditions.

Their unique properties include high oxidation resistance. This makes (per-)fluoroelastomers the only suitable materials for oxygen equipment and oxidising environments, including for medical applications of oxygen Gas Sensors. In addition, it is not feasible to use alternative materials to measure reactive or acidic gases, such as ozone, nitrogen dioxide, chlorine, sulphur dioxide, hydrogen sulphide. Only highly chemically inert seals and other components from FKM/FFKM may be used. No satisfactory alternatives for those applications have been found so far.

- **Alternatives to perfluoropolyether (PFPE) and PTFE greases**

Gas Sensors rely on PFPE and PTFE materials, including powders, due to their remarkable resistance to highly acidic conditions (electrolytes) and fluctuations in temperature. Specifically, PTFE/PFPE greases exhibit consistent viscosity across a wide temperature range spanning from -40°C to +60°C. No viable alternatives currently exist that can provide a grease formulation with a low dependence on viscosity-temperature relationship.

[34] *Polyvinyl Compounds, Others*, Manfred L. Hallensleben, Ullmann's Encyclopedia of Industrial Chemistry, 2000.

[35] *Biochemistry of microbial polyvinyl alcohol degradation*, Applied Microbiology and Biotechnology, Kawai F, Hu X, 2009.

6 Socio-economic impact of the proposed REACH restriction

Fluoropolymers, such as PTFE, (per-)fluoroelastomers and perfluoropolyethers, provide crucial characteristics for key components of E-Chem Gas Sensors, their sealings and external connections/components (tubes, valves, etc.). These chemicals possess high temperature, pressure, chemical, and mechanical resistance, making them ideal for all Gas Sensor applications. Respective characteristics directly influence selectivity, precision, reliability, and longevity of sensors throughout various (harsh) conditions (temperature, humidity, pressures), acidic/toxic environments and critical applications (medical, safety, etc.).

Without above Fluorinated Materials, sensors would likely experience much higher rates of failure, component failures, errors in measurements, false or absent alarms leading to premature obsolescence of other devices/machinery and substantial industrial safety and health incidents. Currently there are no known technically, or economically, feasible alternatives to most of these substances in Gas Sensors. Moreover, there is great uncertainty about successful development of alternatives within the time frames envisaged in the Proposal for most derogations.

While domestic, industrial, and personal safety gas detection are the most important and wide-reaching of the issues of the proposed PFAS ban in Gas Sensors, there are additional risks with shortages of medical respiratory equipment in the EU. It is because the proposed PFAS restriction intends to ban *inter alia* all uses of Gas Sensors with Fluorinated Materials, including as spare parts for repair and maintenance of existing equipment. Although, development and certification of substitutes will take long time and there is a lack of certainty in success as demonstrated within this document.

In case the proposed PFAS restriction would be adopted, the worldwide gas detection industry as a whole would experience tremendous economic and social shock. This consequently cause a huge socio-economic impact to many industries and societies because gas detection is used in essential utilities (power generation, water treatment, etc.), medical devices (respirators and incubators), environmental emissions monitoring (air quality and GHG control), fixed and portable gas detection (life safety in petrochemical plants, semi-conductors manufacturing) and in many other economy sectors. These consequences are certainly in conflict with the wider EU industrialisation and competition policies as well as objectives of the European Green Deal, REPowerEU, European Chips Act, Net Zero Industry Act, and other emerging sustainability laws.

Therefore, the proposed PFAS ban on all Fluorinated Materials in all E-chem Gas Sensors applications would result in too high costs on the society and is disproportionate to the alleged risks for health and the environment due to persistency of the PFAS materials in question.

7 Conclusion

Considering the above, PFAS materials are a critical to the quality and fundamental functionality of E-chem Gas Sensors and submitted information provide the necessary evidence to support either the complete exclusion of Fluorinated Materials in question from the Proposal or to justify respective time-unlimited derogations because there are no available suitable alternatives.

In this respect, the complete ban envisaged for Fluorinated Materials in the Proposal on all uses in the EU of E-chem Gas Sensors would substantially affect essential processes in semiconductors, automotive, medical, petrochemical, and the energy sectors worth over 2 trillion EUR due to the lack of adequate safety-related and critical gas detection systems.

Honeywell requests that PTFE, PCTFE, EFTFE, FEP, PFA, PVDF, PVF, FKM and FFKM based fluorinated materials used in all electrochemical gas sensor applications should be either excluded from the scope of the Proposal or made subject to a time-unlimited derogation.

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Annex I – List of acronyms and abbreviations

Annex II – Lists of fluorinated substances and components of E-chem Gas Sensors