Comment on Proposed Restriction of PFAS

Shandong Huaxia Shenzhou New Material Co., Ltd.

As a fluorine chemical enterprise,we have supported EU's ambitious attempts to reduce risks from hazardous substances and have carefully studied the relevant regulatory proposals and conducted thorough research and discussion to meet the requirements of EU chemical regulations such as REACH.Firstly, we strongly agree with the EU's view on environmental protection, but we do not agree with “inferring guilt” without sufficient factual evidence,prohibiting the production, use, and sale of over 10000 PFAS chemicals. Once implemented, the ban will have a significant impact.If the recommendation be adoptted , relevant chemical manufacturers will be forced to find about 10000 PFAS alternatives in the fields where these substances are applied. In many application scenarios, such alternatives are almost non-existent, and in some fields, substitutes may never be found.

The proposed Restriction fails to adequately identify and list the specific chemical substances proposed to be restricted. Instead, it prohibits the manufacturing, use or placing on the market of any substance "that contains at least one fully fluorinated methyl(CF3-) or methylene (-CF2-) carbon atom, without any H/Cl/Br/I attached to it" . It does not provide the names or identification numbers of the specific substances that are covered by this broad definition, as required.

[1 Robert C Buck,y James Franklin,et al. Perfluoroalkyl and Polyfluoroalkyl Substances in the Environment: Terminology, Classification, and Origins.Integr Environ Assess Manag 7, 2011] [2 Robert C. Buck, Stephen H. Korzeniowski, et al. Identification and classification of commercially relevant per- and poly-fluoroalkyl substances (PFAS).Integr Environ Assess Manag :1045–1055] [3 Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance]

1.Research has shown that fluoropolymers themselves are safe and belong to the category of "low concern substances". There is no data indicating tthat fluoropolymers are hazardous and should not be included in the jurisdiction.

Fluoropolymers have a molecular weight far exceeding 10000 and cannot penetrate the cell membrane. Due to the inability of high molecular weight polymers to enter cells, they cannot react with "target cells" (such as germ cells) and therefore cannot be biologically utilized.Fluoropolymers are highly stable and long-lasting, and are stable in hydrolysis, oxidation, and light exposure. At the same time, fluoropolymers are insoluble in water, making them difficult to move in daily environments. Moreover, the migration rate of fluoropolymers is lower than the migration standard proposed by UBA, and they are not toxic to the human body. These results indicate that fluoropolymers should not be considered for regulation as a group with PFOA and PFOS.

[4 Barbara J Henry, Joseph P Carlin,et al. A Critical Review of the Application of Polymer of Low Concern and Regulatory Criteria to Fluoropolymers. Integr Environ Assess Manag 2018:316-334]

At the same time, in terms of the preparation process of fluoropolymers, the types and quantities of formulations used can be artificially controlled, and countries have previously issued prohibitions and replacement orders for potentially harmful additives in the production process. Based on the above facts, we apply for a permanent exemption, including but not limited to the

following fluoropolymers.

(1)Application for exclusion by Polyvinylidene fluoride.

Firstly, as the second largest fluoropolymer used,Polyvinylidene fluoride(PVDF) has been widely used in most fields and is difficult to replace in a short space of time. For example, PVDF is widely used in the semiconductor field, used in pure water or acidic detergent transportation and pipe fittings for cleaning processes with an annual consumption of 3000-5000t.Since most of the solvent delivered by the cleaning section is high-purity solvent, the pump body, liquid tank and other materials of the transmission pipeline need to meet the requirements of high purity, low precipitation, solvent resistance, heat resistance. The performance of the above requirements directly affects the yield of semiconductor field products, especially some high-precision chips. These applications are difficult to replace with non fluorinated substances. PVDF has a significant effect on lithium-ion new energy batteries, as an binder and separator for lithium-ion battery materials, especially positive electrode adhesive, with a global annual demand of 60000 t. PVDF, due to its solvent resistance, good thermal stability, and strong adhesion, accounts for over 90% of lithium battery binder, occupying the dominant position in lithium battery binder, directly affecting the safety and stability of new energy vehicles. Although alternatives such as Styrene-butadiene and Carboxymethyl cellulose sodium are being studied, there is a large gap between their performance with PVDF, and their market share is far lower than PVDF. At present, mainstream new energy vehicle manufacturers are using PVDF, and the certification cycle in the automotive field is long. If other products are used as substitutes, it will seriously limit the rapid development of new energy vehicles. So, all the above aspects have verified the irreplaceability of PVDF in a short period of time.

（2）Application for exclusion by Fluoroelastomers.

Fluoroelastomers (FKM) refers to a synthetic polymer elastomer containing fluorine atoms in the main chain or side chain, which has excellent high temperature resistance, high chemical stability, weather resistance, oxidation resistance, oil resistance and low air permeability. In the military industry, FKM is mainly used in aerospace, aviation and launch vehicles, satellites, fighter planes, new tank seals, tubing and electrical line sheath and so on. It is an irreplaceable key material in the cutting-edge industry of national defense. At present, more than 60% of the world's fluoroelastomers are used in the automobile industry. Fluoroelastomer has high heat resistance, low permeability and compatibility with different automotive fluids, making it stand out in the elastomer and almost become the only suitable material. Among them, peroxide fluorine rubber has been widely used in the field of intelligent wear, direct contact with the human body, proved to be safe and reliable. Fluorine thermoplastic elastomer has also been widely used in the medical industry, as an elastic substance embedded in the human body, the performance is stable, and has good biocompatibility. According to the existing studies on the safety of polymers, no adverse effects of FKM were found. Based on the above factors,apply for exclusion by Fluoroelastomers.

（3）Application for exclusion by Polyperfluorinated ethylene propylene.

Polyperfluorinated ethylene propylene (FEP) is obtained by the copolymerization of tetrafluoroethylene (TFE) and hexafluoropropylene (HFP). Generally , the mass percentage of HFP is small, the molecular structure of FEP is almost identical to that of polytetrafluoroethylene (PTFE). FEP has a wide range of applications in the field of medical devices due to its excellent biocompatibility, ultra-low coefficient of friction, and excellent

anti-adhesion properties. Heat shrink tube is an important component used in the construction process of minimally invasive interventional catheter. Taking intravenous infusion indwelling needles as an example, it is estimated that the usage of indwelling needles will reach 655 million by 2025. FEP cannula is an indispensable key component in intravenous infusion indwelling needle. Meanwhile, it has excellent self-lubrication, blood compatibility, biological and chemical stability, good processing performance, and has been widely used in clinical practice. The extensive medical applications of FEP demonstrate its acceptability by the human body. In addition, FEP products have also passed the food contact level certification of the US FDA and the EU. FEP has been extensively tested and complies with the food contact and global medical device regulations of the US and EU (such as the US Food and Drug Administration, CFDA, Korea MFDS, Japan PMDA), ISO 10993 biocompatibility testing, and preclinical animal testing. The toxicological studies of FEP show that it does not have acute or subacute systemic toxicity, irritancy, sensitization, local toxicity upon implantation, genetic toxicity in vitro and in vivo, hemolysis, complement activation or thrombus formation. Scientific data do not support the inclusion of FEP in restricted categories.

FEP has excellent dielectric properties, electrical insulation properties, chemical solvent resistance, flame retardant properties, high and low temperature resistance. Meanwhile, it can be long-term used range from -80 to 200 °C, and its flame retardant grade can also reach V-0 grade in UL94 standard. Polyperfluorinated ethylene propylene resin is a perfluoropolymer with excellent aging resistance and extremely low surface water absorption rate, making it highly adaptable to demanding environments such as moisture, dryness, and strong light. It is widely used in communication cable equipment, signal transmission cables, and electronic wire insulation layers. Polyperfluorinated ethylene propylene can also be used in the processing of corrosive medium conveying pipe, food medium conveying pipe and the application of anti-corrosion coating such as pump valve lining. In addition, in recent years, the use of polyfluorinated ethylene propylene films has gradually begun, and current applications include electronic component release films, equipment protective films, fluoropolymer welding films, and more. Therefore, it is recognized that there are almost no alternatives in these fields, and even if there are substitutes, they cannot meet the various requirements due to certain performance limitations.

（4）Application for exclusion by polytrifluorochloroethylene.

The data show that polytrifluorochloroethylene has thermal,chemical, photochemical, hydrolytic and biological stability, and because of its strong chemical stability, it is difficult to pose a threat to the environment and human health.Its toxicological studies have proved that polytrifluorochloroethylene has almost no toxicological activity under normal conditions.It is physiologically inert and has been approved by the Food &Drug Administration for use in contact with food or for human implants, and widely used in the field of high barrier pharmaceutical packaging film. PCTFE is a partially fluorinated thermoplastic. The preferred methods for disposing PCTFE-based materials are recycling and reusing them. Generally, the clean, unfilled, and unpigmented scrap materials from the manufacturing and processing of PCTFE can be recycled back into raw material to be reused in applications where the quality requirements are much lower. Analysis of the breakdown products shows a large number of different components present which may include small amounts of carbonyl fluoride, COFCl and COCl containing

groups. Consequently, incineration can be used only when the incinerator is equipped by a scrubber for removing hydrogen fluoride, hydrogen chloride, or other acidic products of combustion. If there is no valid recycling or incineration, landfilling of PCTFE waste is justified because it is environmentally stable and contains no harmful substances. PCTFE cannot be a substance of high concern(SVHCs), and does not meet the USB's proposed PM（persistent mobile）and PMT（persistent mobile toxic）.It also does not conform to the criteria for the inclusion of POP under the Stockholm Convention.

At present, there are no substances that may belong to PFAS in the preparation process of polytrifluorochloroethylene. Based on the above two points, apply for exclusion by PCTFE,and it should be permitted from production and use.

[5 H. A. Birnbaum , L. D. Scheel & W. E. Coleman (1968) The Toxicology of the Pyrolysis Products of Polychlorotrifluoroethylene, American Industrial Hygiene Association Journal,29:1, 61-65]

[6 Jiajia Zou *, Maocheng Zhang, Mengqiu Huang, Dan Zhao and Yinhai Dai，Structure, Properties, and Modification of Polytrifluorochloroethylene: A Review，Frontiers in Materials ，2022-3 ,9]

(5)Application for exclusion by FEVE

FEVE is mainly used as a high-end super weathering coating, which contains the -CF2-CF2- group in its structure, but exists in solid form. With the passage of time, the literature proves that -CF2-CF2- will gradually decrease, which may be due to the degradation of polymer on the surface of the coating under UV irradiation, under the combined action of oxygen and water, etc., the structure changes and produces urea groups that are easier to decompose, and -CF2-CF2- will be shed with the degraded substances, and -CE2- will eventually degrade to inorganic acid with the passage of time, and the inorganic acid will rapidly exist in the form of inorganic fluorination salt, which does not cause any environmental impacts. This inorganic acid will quickly become inorganic fluoride salts and will not be harmful to the environment or humans. It does not meet the basis of the European PFAS proposal that "the final degradation product is highly persistent" and should be exempted.

[7 Soshana Smith, Stefan Mitterhofer，et al. Long-term durability of transparent backsheets for bifacialphotovoltaics:An in-depth degradation analysis, Solar Energy Materials and Solar Cells, Volume 256,1 July 2023. 112309.]

(6)Application for exclusion of perfluoropolyether and its related series of products

From the properties of perfluoropolyether, This series of substances were safe and stable. Data shown that perfluoropolyethers have thermostability, chemical stability, photostability, hydrolysis resistant and biostability. Due to its strong chemical stability, they were difficult to endanger the environment and physical health. The toxicological studies shown that perfluoropolyether liquid was non-toxic, non irritating to the eyes and skin, and has no bioavailability or bioaccumulation, as demonstrated by oral, inhalation, and intraperitoneal injection. Clinical studies on patients receiving perfluoropolyether skin care products shown that they have no chronic toxicity or carcinogenicity, nor developmental or endocrine toxicity. This product don't meet the PM (persistent mobile) and PMT (persistent mobile toxic) standards proposed by UBA, also don't comply with the POP listing criteria specified in the Stockholm Convention on Persistent Organic Pollutants. Therefore, this series of products should not be included in the control.

[8 Malinverno G, Pantini G, Bootman J. Safety evaluation ofperfluoropolyethers, liquid

polymers used in barrier creams and other skin care products. Food Chem Toxicol 1996; 34: 639-650.]

[9 Treatment of irritant contact dermatitis in workmen with perfluoropolymethyl-isopropylether. Int J Cosmet Sci 1990; 12: 273-279.]

[10 Nobuhiko Tsuda a, Yoshitaka Honda a, et al.The environmental degradability of DEMNUM, a typical PFPE polymer. Chemosphere 337 (2023) 139331]

3.Once fluoropolymers are restricted, the impact on human society will be profound.

Fluoropolymers are the only materials that simultaneously possess heat resistance, weather resistance, chemical resistance, water repellency, lubricity, and unique optoelectronic properties. They are used in the fields of semiconductors (cleaning, etching), electrical and electronic communication (wire cladding materials and liquid crystal materials), transportation (automobiles, airplanes, railways, ships), and medical (conduits, protective clothing, medical packaging). Taking the semiconductor industry as an example, PFAS is crucial for chip manufacturing, especially for key fluoropolymers that are resistant to high temperatures, acids, and alkalis. Given that there are currently no alternatives, and the performance and safety verification of alternatives are a long-term process, a comprehensive ban will lead to very serious industry chain disruption in the semiconductor industry, which will further lead to a setback in technological innovation in fields such as aerospace, 5G communication, integrated circuits, and medical testing, with far-reaching impacts.

[11 Andrew E. Feiring,Michael K.Crawford, Willian B. Farnham,et al. New Amorphous Fluoropolymers of Tetrafluoroethylene with Fluorinated and Non-Fluorinated Tricylononenes. Semiconductor Photoresists for Imaging at 157 and 193 nm. [J]. Macromolecules, 2006,39, (9):3252-3261Once PFAS substances are strictly prohibited without without reasonable scientific basis, it will lead to a series of problems .]

4.There are many types of fluorinated fine chemicals with a wide range of uses, which are irreplaceable in certain aspects. Once they are all prohibited , the impact is enormous.

Some substances are not prohibited in the proposal, including active substances (PPP) in plant protection products , biological insecticide products (BP) and pharmaceutical products (MP) on human and veterinary. It indicates that PFAS is effective in medicine.Most of these drugs are small molecule PFAS substances, which also indicates that many contain Fluorine small molecule substances are harmless. It is unscientific that the proposal restrict most of PFAS substances in the absence of definite proof . Therefore, we apply that such substances should be exempted without specific harmful evidence , including but not limited to the following substances: (1)Perfluorohexanone should be exempted : ① From the view of protecting environment, perfluorohexanone is an important substitute for Halon extinguishing agent, it is a clear, transparent, colourless and odorless liquid. Its ODP is zero, means do no damage to the ozone layer. Its value of GWP is only 1, the greenhouse effect is negligible. It has a lifetime of just 5 days in the atmosphere (0.014 years). Perfluorohexanone is mainly decomposed by photolysis. ② From a security perspective, under the conditions of acute inhalation toxicity, carcinogenicity and oral toxicity test for perfluorohexanone, there no significant symptoms were observed in rats, which proves that perfluorohexanone is virtually non-toxic. The corrosion performance test of perfluorohexanone showed it had no corrosion on aluminum, copper, steel and carbon steel. There was also no chemical reaction between perfluorohexanone and neoprene, butyl rubber, viton, ethylene propylene, silicon polyester, chemigum. Moreover, perfluorohexanone does not conduct

electricity and does not damage electronic wiring. The working concentration of perfluorohexanone is 4~6%, hence its safety margin is up to 67~150%. Given that perfluorohexanone is safe for human health, the U.S. Environmental Protection Agency has ratified the use of perfluorohexanone in area where people work.

For the above reasons, we apply for an exemption for perfluorohexanone.

[12] Taniguchi T, Wallington T J, Hurley M D, et a1.Atmospheric chemistry of C2F5C(O)CF(CF3)2 photolysis and reaction with C1 atoms,OH radicals, and ozone[J]. Physical Chemistry A, 2003, 107(15): 2674-2679.

[13] Jackson D A, Young C J, Hurley M D, et a1. Atmospheric degradation of perfluoro-2-methyl-3-pentanone:Photolysis, hydrolysis and hydration [J]. Environmental Science, Technology, 2011, 45(19): 8030—8036.(2) Hexafluoropropylene oligomers (mainly including hexafluoropropylene dimers and hexafluoropropylene trimers) should be exempted:

① From the hexafluoropropylene oligomers themselves, such substances have a short atmospheric life, low greenhouse potential (GWP), and atmospheric ozone depletion potential (ODP) is zero. In addition, they are environmentally friendly, and have good thermal stability and chemical stability. Precisely because of their strong chemical stability, they are difficult to pose a threat to the environment and human health. The ecological studies have proved that hexafluoropropylene oligomers are insoluble in water, and unlikely to spill into the soil, and not durable, and do not contain substances that will be dangerous to the environment or substances that cannot be degraded in waste water treatment plants. ② From the applications of hexafluoropropylene oligomers, they have a wide range of important applications. Hexafluoropropylene oligomers can be used as raw materials for a new high-efficiency fire extinguishing agent (perfluorohexanone). And hexafluoropropylene oligomers can also be used as submerged coolants in data centers, which have incomparable advantages and prospects. The immersion cooling technology using fluorinated liquid as the cold medium results in energy saving of more than 70%, the space saving of more than 10 times, and improving server performance by 10%. Moreover, hexafluoropropylene oligomers can be used to produce fluorosurfactants with different functions by introducing different hydrophilic groups through substitution reactions. The fluorosurfactants with the characteristics of "three highs" and "two abominations", which are green substitutes for general hydrocarbon surfactants. In addition, hexafluoropropylene oligomers are also good intermediates of pharmaceutical and pesticide active substances. Based on the above factors, apply for exemption of hexafluoropropylene oligomers.

(2)Hydrofluorinated ethers should be treated differently: Hydrofluorinated ethers are a general term for a class of compounds with a wide range of types, most of which are considered safe and reliable.① Environmentally friendly[1-3]: From the perspective of chemical structure and physical properties, because hydrofluoroether contains easily broken ether bonds, its global warming potential (GWP) is much lower than chlorofluorocarbon (CFCs) and hydrogen chlorofluorocarbon (HCFCs), and it does not contain chlorine atoms, and its ozone depletion potential (ODP) is zero. HFE is volatile and insoluble in water. After being released into the environment, HFE will reside in the lower atmosphere (i.e. troposphere), where it is photochemically oxidized into various degradation products. However, the atmospheric concentrations of these degradation products will be very low (on the order of ppb or ppt), indicating that these compounds will not have significant adverse effects on the environment at such low concentrations.There is a literature table that the contribution of HFE to Summer smog can be ignored.

②Toxicity[4-5]: Since the physical and chemical properties of HFE are similar to hydrofluorocarbons, the toxicity of hydrofluorocarbons to human body is very low according to the test results of mammals, and HFE compounds are not expected to pose a major risk to health. Based on limited references, there is no significant evidence to support the hypothesis that HFE has carcinogenicity, mutagenicity, reproductive/developmental, and other chronic effects. Based on the above factors, hydrofluoroether should be exempted, and only when the specific structure is proven to be hazardous, this type of structure needs to be restricted.

[14] D.A. Good, J.S. Francisco, A.K. Jain, D.J. Wuebbles, Lifetimes and global warming potentials for dimethyl ether and fluorinated ethers: CH3OCF3 (E143a), CHF2OCHF2 (E134), CHF2OCF3 (E125), J. Geophys. Res. 103 (D 21) (1998) 28181.

[15] V.L. Orkin, E. Villenave, R.E. Huie, M.J. Kurylo, Atmospheric life- times and global warming potentials of hydrofluoroethers: reactivity toward OH, UV spectra, and IR absorption cross sections, J. Phys. Chem. A 103 (1999) 9770.

[16] D.A. Good, M. Kamboures, R. Santiano, J.S. Francisco, Atmo- spheric oxidation of fluorinated ethers, E143a (CH3OCF3), E134 (CHF2OCHF2), and E125 (CHF2OCF3), J. Phys. Chem. A 103 (1999) 9230.

[17] Dekant, Toxicology of chlorofluorocarbon replacements, Environ. Health Persp. 104 (Suppl. 1) (1996) 75.

5.The harmless solutions of PFAS is also gradually maturing, which can solve persistent problems.

Fluorine-containing material recycling and utilization technology is gradually maturing to achieve recycling and reduce the inventory in the environment. *Science* has published an article on the degradation of PFAS,《Low-temperature mineralization of perfluorocarboxylic acids》. The method proposed in this paper can achieve harmless treatment of PFAS by releasing all fluoride atoms from the chain. The processed products contain some inorganic fluoride ions and some organic small molecules. Some studies have confirmed that perfluoroalkyl carboxylic acids compounds can achieve low-temperature mineralization through some technical means, and the degradation rate is very fast. These methods can also be extended to degrade other perfluorinated and polyfluoroalkyl substances, which will fundamentally solve the persistent problem of organic fluorinated substances in the environment.[18 Brittany Trang and et al, Low-temperature mineralization of perfluorocarboxylic acid, Science 377, 839-845 (2022), 10 August 2022] Moreover, with the deepening understanding of fluorinated substances and the emphasis on environmental issues, degradation treatment technology will become more mature. Therefore, fluorinated substances that have no conclusive evidence to prove their harmfulness, have adverse effects on the future environment, and can achieve harmless treatment should not be blindly prohibited.

6.The harmful reasoning is extremely wrong and it is not in line with the scientific basis.

This proposal lacks sufficient research to prohibit over 10000 PFAS substances, relying solely on research for 15 purposes. Some scholars have studied over 1400 PFAS substances, 200 uses and secondary uses, and still believe that the evidence for PFAS is insufficient. [19 JulianneGl ü geand et al., An overview of the uses of per and polyfluoroalkysubstances(PFAS), EnvironmentalScienceandProcesses&Impacts, 2020,222345-2373] . The proposal does not adequately collect information on products and uses, and is not sufficient.It is highly unscientific

to make restrictions on the PFAS, and we suggest that this information should continue to be collected.Restrictions should be taken on PFAS substances that are indeed harmful.

Based on the above analysis, we oppose the proposal to put all PFAS on an equal footing, arguing to distinguish highly stable fluorine-containing polymers from other PFAS,and advocate small molecule organic fluorine compounds should be also distinguished according to specific research and actual risks.