NATIONAL ASSOCIATION OF Manufacturers

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Sept. 25, 2023

Dr. Sharon McGuinness
Executive Director
European Chemicals Agency
Registry of the Board of Appeal
P.O. Box 400
FI-00121 Helsinki, Finland

Re: Consultation for European Chemicals Agency Phase 1 Restrictions on the manufacture, placing on the market and use of per- and polyfluoroalkyl substances (PFAS).

Dr. McGuinness:

The National Association of Manufacturers appreciates the opportunity to comment on the EU Universal PFAS restriction proposal published Feb. 7, 2023 (https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18663449b).

The NAM is the largest manufacturing association in the United States, representing manufacturers of all sizes and in every industrial sector. The NAM is the voice of the manufacturing community and the leading advocate for a policy agenda that helps manufacturers compete in the global economy.

PFAS substances are critical to numerous EU priorities and any restrictions on them should also be balanced with numerous other EU policy priorities. The NAM urges time-unlimited exemptions for multiple sectors that are vital to the EU economy.

Criticality of PFAS substances

PFAS are a diverse group of chemicals that are critical to manufacturers, consumers and families. PFAS are necessary to a range of essential items, such as modern infrastructure, including water distribution systems, the electric grid as well as the equipment and machinery necessary for these developments; energy production, usage and storage, including batteries, electric vehicles, green hydrogen, semiconductors and solar components; medical devices; active pharmaceutical ingredients and their manufacturing and items necessary for national defense, such as aircraft, wearable batteries for members of the military and communications devices.

Complicating the efforts to regulate PFAS chemicals is the fact that the carbon-fluorine bond that is the hallmark of PFAS is unmatched in chemistry, meaning that for many of the current uses of

PFAS, there are no existing replacements. The NAM supports commonsense regulations on PFAS that ensure that manufacturers continue to be excellent environmental stewards while recognizing that in many cases we will need to continue to use these chemicals for the foreseeable future. However, the proposals to ban products and broad substances without consideration of risk will have significant consequences throughout the manufacturing industry and economy overall.

Product bans are not the appropriate tool

Any action on PFAS should utilize the best available science, but that action should also be balanced with numerous other EU policy priorities that would be impossible to accomplish without PFAS substances, including the European Chips Act. Semiconductors cannot be made currently without PFAS substances, and any possible alternative is easily more than a decade away. If the EU moves to ban all PFAS substances, they will also cripple the ability to fabricate semiconductors based on the current state-of-the-art technology. The Semiconductor Industry Association concluded simply, "Without PFAS, the ability to produce semiconductors (and the facilities and equipment related to supporting semiconductor manufacturing) would be put at risk."[1]

The EU proposed an EU hydrogen strategy and REPowerEU to develop a comprehensive framework to support low-carbon hydrogen to decarbonize the EU in a cost-effective way. However, electrolyzers and fuel cell applications, the hydrogen industry's fundamental technologies, use fluoropolymers. No alternative exists today or in the foreseeable future for these highly specialized materials, central to the functioning of the hydrogen value chain. Hydrogen Europe said the potential PFAS restrictions could have "catastrophic consequences for the EU's nascent hydrogen sector."[2]

PFAS substances are critical to many medical technologies, such as grafts/stents, catheter tubing for IV fluids, medication, surgical drapes and gowns, medical tapes and wound dressings, medical imaging devices, such as ultrasounds, and many more. MedTech Europe commented that PFAS were used in these products because of their properties, such as chemical and heat resistance and lubrication, and that "PFAS substances play a key role in achieving the required high performance and durability of the technologies which are critical e.g. for precision and reliability of medical applications, especially in the light of the applicable sectoral legislations, Regulation (EU) 2017/745 on Medical Devices (MDR) and Regulation (EU) 2017/746 on In-Vitro Diagnostics (IVDR). These regulations lay down strict requirements for the design, safety, quality, performance, alternatives assessment and validation of MDs and IVDs to ensure the protection of patients' lives"[3]

The proposed restriction includes a proposal for a time-unlimited derogation for active pharmaceutical ingredients (API) in the draft restriction, recognizing the essential role of

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[1] https://www.semiconductors.org/wp-content/uploads/2023/04/Impact-of-a-Potential-PFAS-Restriction-on-the-Semiconductor-Sector-04_14_2023.pdf
[2] https://hydrogeneurope.eu/wp-content/uploads/2023/02/Hydrogen-Europe-position-paper-on-PFAS-ban_v12_FINAL.pdf
[3] https://www.eflm.eu/upload/docs/230227_MTE_PFAS_Briefing_DRAFT_V3.pdf

fluorinated compounds in medicinal products. However, the full supply chain and development of medicinal products must also be considered. The continued research, development and manufacturing of innovative medicines in Europe require an appropriate time-unlimited derogation, including all steps which are necessary for manufacturing medicinal products including biopharmaceuticals and vaccines in the EEA. Due to the unique properties of individual molecular structures containing fluorine, alternatives for API, development products and their starting materials and intermediates do not exist, as the function of the substances is on the chemical molecular level.

The automotive industry is also crucial for Europe's prosperity, providing direct and indirect jobs to 13.8 million Europeans, representing 6.1% of total EU employment.[4] Just like numerous other industries vital to achieving Europe's goals, the automotive industry relies on PFAS to make their products. Because PFAS are unique in offering fire, weather, temperature and chemical resistance and high-performance dielectric properties, they are used everywhere in vehicles, including fuel lines, fuel hoses, hydraulic systems, break lines, sealants, GHG controls, fuel cells, batteries and many more. The German Association of the Automotive Industry has said "the use of PFAS will remain essential for achieving the targets of the EU's European Green Deal."[5]

The EU launched a battery alliance, identifying batteries as a strategic part of Europe's clean transition and key enabling technology. The commission's aim is to make Europe a global leader in sustainable battery production and use.[6] However, that is not possible without PFAS production. RECHARGE, the advanced rechargeable and lithium batteries association, commented that there are "no alternatives available for the use of PTFE and of PVDF (types of PFAS) in primary Lithium and Lithium-ion technologies."[7]

If the REACH process ends in a total ban of PFAS production and usage, within 12 years batteries, semiconductors, hydrogen energy, medical products and more could no longer be manufactured in the EU using current or near future technologies.

Need for true sector derogations

With a ban on PFAS, there will be broad effects across the economy, not just within hydrogen, chips, medical devices and automotive, but throughout the entire supply chain that supplies these vital industries. The NAM encourages the development of true sector derogations that reflect the availability of potential replacements, not just an arbitrary deadline that can make it impossible to manufacture vital products. Similar to previous REACH restrictions, any PFAS restrictions should exempt industrial uses provided that manufacturers supply information on risk management measures and emissions controls.

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[4] https://single-market-economy.ec.europa.eu/sectors/automotive-industry_en
[5] https://www.vda.de/dam/jcr:0e95a041-1cc3-432c-b6ac-915788e5ead8/Position_PFAS_2021-09-20_EN.pdf?mode=view
[6] https://single-market-economy.ec.europa.eu/industry/strategy/industrial-alliances/european-battery-alliance_en
[7] https://rechargebatteries.org/wp-content/uploads/2022/09/Call-for-Evidence_RECHARGE-_-PFAS-restriction-V1.pdf

Furthermore, reasonable proof is available to demonstrate the safe uses of fluoropolymers and low global warming potential gases.[8] It would be appropriate to have a differentiated approach to high risk and low risk PFAS in line with Article 68.1 REACH, which requires proof of "unacceptable risk" for enacting a REACH Restriction. Low risk PFAS should benefit from a differentiated approach, including broader exemptions or timelines.

The NAM urges time-unlimited exemptions for the following sectors (including products and necessary supply chain):

- Electronics and semiconductors
- Energy applications (batteries and hydrogen)
- Transportation
- Aerospace and aviation
- Plastics (anti-drip/fire retardants in high-end plastic materials)
- Active pharmaceutical ingredients and their manufacturing
- Medical devices and products (including In-vitro Diagnostics (IVD) and Research Use Only (RUO) (NonIVD))
- Chemical processing
- Refrigerants, HVAC and use of fluorinated gases
- Food and water protection
- Fluoropolymer manufacturing
- Military and defense
- Oil and gas and mining
- Materials used at industrial sites
- Lubricants
- Electrical and association components including insultation, sealing and friction reduction

Conclusion

The NAM appreciates the opportunity to engage on this proposal and looks forward to working with ECHA to protect human health and the environment, while ensuring that manufacturers can continue to create well-paying jobs, lead economic growth and improve the quality of life for all.

Sincerely,

Brandon Farris
Vice President of Domestic Economic Policy
National Association of Manufacturers

[8] Henry, Barbara J., Joseph P. Carlin, Jon A. Hammerschmidt, Robert C. Buck, L. William Buxton, Heidelore Fiedler, Jennifer Seed, and Oscar Hernandez. "A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers." Integrated Environmental Assessment and Management 14, no. 3 (2018): 316-334.