

## *Proposed Poly and per Fluoro Alkyl Substances (“PFAS”) Regulations*

Over the past several years, the persistence and/or toxicity of certain fluorocarbon substances has been observed resulting in a proposed ban/regulation of these chemicals in Europe under the auspices of REACH. The *proposed* REACH regulation of fluorocarbons seeks to define “PFAS” as any substance including the chemical moieties of CF<sub>3</sub> or CF<sub>2</sub>. ECHA is currently evaluating thousands of comments submitted by industry participants and other concerned parties. REACH has specifically banned PFOA and PFOS, a well-defined subset of PFAS, while additional regulation is still ***pending***. Seals Eastern does not use PFOA or PFOS in its products.

Concurrently, the US EPA has passed a more measured approach under 40 CFR Part 705 which requires the EPA to promulgate reporting and record keeping requirements for entities that either manufacture or import PFAS for commercial purposes. Similar to the REACH proposal, EPA considers PFAS as any synthetic substance containing the chemical moieties of CF or CF<sub>2</sub>. EPA’s current regulations are designed to collect information about the PFAS supply chain starting from synthesis, to processing and end use including end of life. Ultimately, certain PFAS may be subject to either regulation and/or possible obsolescence pending any future regulation *that has yet to be proposed*.

For our customers who purchase molded fluoroelastomer (i.e., Viton®, Aflas®, Technoflon®) products from us: under the EPA’s regulation, approved as of November 13, 2023, Seals Eastern is considered an importer of PFAS. EPA has not yet clarified exactly the content and mechanism of information to be reported. We are alert to the implementation of the reporting and record keeping requirements and will update our customers as EPA requirements become clear.

From the supply chain perspective, Seals Eastern procures PFAS (fluoropolymers) from several different major producers. We subsequently compound the imported PFAS with other ingredients to ultimately mold and deliver products conforming to our customer’s desired specification. Consequently, upon purchasing molded fluoroelastomer products, you would likewise be considered an importer of PFAS under the current EPA regulations. To be clear, 40 CFR Part 705 does not ban or prohibit the use of PFAS. It does however require, yet to be specified, reporting of importation/purchase of PFAS containing products, subsequent sale of the same, and/or disposal of the same.

Most technical experts in the polymer industry believe the *proposed* PFAS definition of REACH is excessively broad and as a result will aggregate products as diverse as PTFE Tape, fluorinated solvents, refrigerant gases, and fluoropolymers. These products have remarkably different physical and chemical characteristics and remarkably different toxicological profiles. Several scholarly articles have been published to impress this point upon REACH and the EPA. See Regulatory Toxicology and Pharmacology 134 (2022) 105226, “Grouping of PFAS for Human health risk assessment: Findings from an independent panel of experts”<sup>1</sup> (Elsevier July 2022); Integrated Environmental Assessment and Management Vol.14, Number 3, “A Critical Review of the Application of Polymer of Low Concern and Regulatory Criteria to Fluoropolymers”<sup>2</sup> (Jan 2018); Integrated Environmental Assessment and Management Vol.19, Number 2, “A Critical Review of the Application of Polymer of Low Concern Regulatory Criteria to Fluoropolymers II: Fluoroplastics and Fluoroelastomers”<sup>3</sup> (June 2022). These and many other scholarly/professional

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<sup>1</sup> J.K. Anderson, R.W. Brecher, L.T. Cousins, J.DeWitt, H.Fiedler, K. Kannan, C.R. Kirman, J. Lipscomb, B. Priestly, R. Schoeny, J. Seed, M. Verner, S.M. Hays

<sup>2</sup> B.J. Henry, J.P. Carlin, J.A. Hammerschmidt, R.C. Buck, L.W. Buxton, H. Fiedler, J. Seed, & O. Hernandez

<sup>3</sup> S.H. Korzeniowski, R.C. Buck, R.M. Newkold, A.E. Kassmi, E.Laganis, Y. Matsuoka, B. Dinelli, S. Beauchet, F. Adamsky, K. Weilandt, V. Soni, D. Kapoor, P. Gunasekar, M. Malvasi, G. Brinati, S. Musio

publications have been submitted during the rule making process to clarify the inert (as opposed to reactive or toxic) character of fluoroelastomers.

If the *proposed* REACH regulations are approved in their most draconian form, fluoroelastomers could be banned from the European Union in either 5 or 12 years (depending upon their application) following an initial 18-month implementation of these rules. Meanwhile, in the United States, the EPA is still developing an understanding of the PFAS supply chain and how/where PFAS is used.

Seals Eastern believes sound judgement and objective science will prevail as the diverse universe of PFAS becomes more specifically segregated and better understood. We will continue to monitor the proposed REACH legislation and will update our customers regarding EPA's federal reporting requirements as they become clarified by EPA.

Daniel L Hertz III, JD, President  
For Seals Eastern, Inc.  
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