



September 17, 2026

The Honorable James C. Kenny
New Mexico Environment Department (NMED)
Harold Runnels Building
1190 St. Francis Dr., Suite N4050
Santa Fe, NM 87502-5469

Re: Comments in Support of HB 212 Legislative Exemptions

Dear Secretary Kenny,

The Complex Products Manufacturers Coalition¹ (CPMC or Coalition) appreciates the opportunity to provide comments to inform the New Mexico Environment Department's (NMED) development of the report required under the House Joint Memorial 3 (HJM 3) which evaluates the current exemptions in the statute.² As outlined below, CPMC strongly supports all of the exemptions in the Per- and Poly-Fluoroalkyl Substances Protection Act (HB 212), which have also been incorporated through rulemaking into Section 20.13.2.10 of the New Mexico Administrative Code.

I. Executive Summary

The legislatively-approved exemptions in HB 212 are critical to the reasonable implementation of the law. Without them, the continued availability of complex durable goods that support nearly every major sector in the nation, providing critical and often life-saving services, faces an uncertain future in New Mexico. These products include appliances, electronics, space and water heating, refrigeration, air conditioning, ventilation, regulated engines, outboard

¹ CPMC is a coalition of trade associations/groups/companies that seeks to engage with state decision makers to urge harmonized, risk-based approaches that help ensure legislation and regulations intended to protect human health and the environment are feasible, achievable and have no disproportionately negative impact on the state's economy. CPMC member companies manufacture complex durable goods, assembled from hundreds to thousands of individual components and parts that form finished products. These products support a healthy, safe, and functioning society. Complex durable goods include appliances, on and off-road vehicles, recreational and commercial vessels, motors and components, outdoor power tools and equipment, lighting, heating, ventilation, cooling, refrigeration, and water heating equipment (HVACR-WH), robotics, food processing equipment, commercial foodservice equipment and supplies, electronics, building fire prevention and suppression systems, and their replacement parts. They are used in all vital sectors of the economy including government, military, law enforcement, first responders, food and agriculture, commercial foodservice, energy, transportation and logistics, public works and infrastructure support, critical manufacturing, the defense industrial base, conservation, life-saving climate control and ventilation in homes, emergency backup power for hospitals, schools and universities, eldercare facilities, food preservation and processing, and laboratory and life sciences facilities.

² H.J. Mem'l 3, 57th Leg., 2d Sess. (N.M. 2026).

motors, lighting and security, power tools and equipment, electric power generation, communication devices, vehicles, vessels, their components and replacement parts.

The exemptions reflect legal realities, practical implementation considerations, and a risk-based approach with respect to complex durable goods. These exemptions serve many important purposes by:

- (1) Providing a workable regulatory approach for complex durable goods;
- (2) Avoiding conflicts with federal safety, performance, emissions, and other product requirements;
- (3) Recognizing science-based approach to PFAS that effectively distinguish fluoropolymers and Significant New Alternatives Policy (SNAP)-regulated refrigerants and F-gases, which are the majority of PFAS used in complex durable goods, from other PFAS types that partition to water and bioaccumulate; and
- (4) Avoiding the potential for significant economic disruption in New Mexico.

As mentioned in NMED's analysis of HB 212, "...these exemptions are products where PFAS is essential to its function – like medical devices, semiconductors, or motor vehicles."³ CPMC respectfully urges NMED to recommend that the Legislature retain these legislatively-approved exemptions without narrowing them and find that replacement parts have the same exempt status as the internal components they supplant.

Relying on federal preemption and the currently unavoidable use (CUU) application process alone to keep essential products available to New Mexicans will not work given the sheer number and diversity of products, components, and suppliers involved. At the current scale, delay, uncertainty, and disruption to the availability of critical products would seem certain to transpire. The breadth of complex durable goods—spanning nearly every major sector of the economy—means that the administrative and technical demands of the CUU process, without further guardrails, will quickly exceed what NMED or manufacturers can realistically manage.

CPMC recommends that NMED establish specific criteria to evaluate the exemptions. These criteria should include avoiding conflicts with international, federal, national, state, or local laws, regulations, standards, and codes that govern the product's performance, safety, emissions, durability, reliability, or other requirements. In addition, if the scientific literature, systematically reviewed, demonstrates that the PFAS does not partition to water or bioaccumulate, the exemption should be retained. If there are economic consequences for New Mexico above \$100 million annually, the exemption should be retained, and if the CUU process would be rendered

³ Agency Bill Analysis – 2025 Regular Session, Bill Number HB 212 Committee Substitute, New Mexico Environment Department, March 17, 2025, Section III: Narrative; ¶ 2.

administratively unworkable by including the exempt products, the exemption should be retained. In addition, CPMC has identified some targeted areas where the legislatively- approved exemptions can be improved. Finally, CPMC requests that NMED and the EIB provide additional opportunities for stakeholders to provide public comment on the processes and criteria and final reports before they are submitted to the Legislature.

II. The exemptions recognize essential products and without them, the CUU process would be unworkable.

The exemptions codified in HB 212 and included in Section 20.13.2.10 NMAC appropriately recognize the practical implementation challenges for subjecting certain products to the product ban and reporting requirements in HB 212. These legislatively-approved exemptions are important for many kinds of complex durable goods, defined in NMAC 20.13.2.7(C) as products that are composed of 100 or more manufactured components, with an intended useful life of five or more years, and are not consumed, destroyed, or discarded after a single use. An outboard engine alone has 1,400 components. The Legislature also limited the law’s reporting and restriction provisions to non-exempt consumer products. The HJM 3 review should not recommend expansion of those requirements to non-consumer products outside the statute’s intended scope

Complex durable goods have long-term product development cycles on the order of 7 to 20 years. Electrical manufacturers report that equivalent alternatives may be unavailable or require substantial redesign, qualification, and third-party recertification. Removing the legislatively-approved exemptions could affect product safety and reliability, restrict replacement parts for equipment operating for 20–30 years, and disrupt systems supporting power, water treatment, refrigeration, healthcare facilities, HVAC, and industrial manufacturing. A framework without exemptions would not account for these realities and risks incentivizing market withdrawal. The legislatively-approved exemptions and their relationship to complex durable goods is illustrated in Table 1.

Table 1. Exemptions in HB 212. Provisions in bold denote importance to complex durable goods.

Legislatively-approved Exemption/Rule Citation	Provision
N.M. Stat. Ann. § 74-15-3(A)(1); N.M. Admin. Code § 20.13.2.10(A)	A product for which federal law governs the presence of a per- or poly-fluoroalkyl substance in the product in a manner that preempts state authority.
N.M. Stat. Ann. § 74-15-3(A)(2); N.M. Admin. Code § 20.13.2.10(B)	Used products offered for sale or resale.

Legislatively-approved Exemption/Rule Citation	Provision
N.M. Stat. Ann. § 74-15-3(A)(3); N.M. Admin. Code § 20.13.2.10(C)	Medical devices or drugs and the packaging of the medical devices or drugs that are regulated by the United States food and drug administration, including prosthetic and orthotic devices.
N.M. Stat. Ann. § 74-15-3(A)(4); N.M. Admin. Code § 20.13.2.10(D)	Cooling, heating, ventilation, air conditioning or refrigeration equipment that contains intentionally added per- or poly-fluoroalkyl substances or refrigerants listed as acceptable, acceptable subject to use conditions or acceptable to narrowed use limits by the United States environmental protection agency pursuant to the significant new alternatives policy program, Subpart G of 40 CFR Part 82, and sold, offered for sale, distributed or distributed for sale for the use for which the refrigerant is listed pursuant to that program.
N.M. Stat. Ann. § 74-15-3(A)(5); N.M. Admin. Code § 20.13.2.10(E)	A veterinary product and its packaging intended for use in or on animals, including diagnostic equipment or test kits and the veterinary product's components and any product that is a veterinary medical device, drug, biologic or parasiticide or that is otherwise used in a veterinary medical setting or in veterinary medical applications that are regulated by or under the jurisdiction of [see provision for complete language]
N.M. Stat. Ann. § 74-15-3(A)(6); N.M. Admin. Code § 20.13.2.10(F)	A product developed or manufactured for the purpose of public health or environmental or water quality testing.
N.M. Stat. Ann. § 74-15-3(A)(7); N.M. Admin. Code § 20.13.2.10(G)	A motor vehicle or motor vehicle equipment regulated under a federal motor vehicle safety standard, as defined in 49 United States Code, Section 30102(a)(10), except that the exemption under this paragraph does not apply to any textile article or refrigerant that is included in or as a component part of such products.
N.M. Stat. Ann. § 74-15-3(A)(8); N.M. Admin. Code § 20.13.2.10(H)	Any other motor vehicle, including an off-highway vehicle or a specialty motor vehicle, such as an all-terrain vehicle, a side by-side vehicle, farm equipment or a personal assistive mobility device.

Legislatively-approved Exemption/Rule Citation	Provision
N.M. Stat. Ann. § 74-15-3(A)(9); N.M. Admin. Code § 20.13.2.10(I)	A watercraft, an aircraft, a lighter-than air aircraft or a seaplane.
N.M. Stat. Ann. § 74-15-3(A)(10); N.M. Admin. Code § 20.13.2.10(J)	A semiconductor, including semiconductors incorporated in electronic equipment, and materials used in the manufacture of semiconductors.
N.M. Stat. Ann. § 74-15-3(A)(11); N.M. Admin. Code § 20.13.2.10(K)	Non-consumer electronics and non-consumer laboratory equipment not ordinarily used for personal, family or household purposes.
N.M. Stat. Ann. § 74-15-3(A)(12); N.M. Admin. Code § 20.13.2.10(L)	A product that contains intentionally added per- or poly-fluoroalkyl substances with uses that are currently listed as acceptable, acceptable subject to use conditions or acceptable subject to narrowed use limits in the United States environmental protection agency's rules under the significant new alternatives policy program; provided that the product contains per- or poly-fluoroalkyl substances that are being used as substitutes for ozone-depleting substances under the conditions specified in the rules.
N.M. Stat. Ann. § 74-15-3(A)(13); N.M. Admin. Code § 20.13.2.10(M)	A product used for the generation, distribution or storage of electricity.
N.M. Stat. Ann. § 74-15-3(A)(14); N.M. Admin. Code § 20.13.2.10(N)	Equipment directly used in the manufacture or development of the products described above.
N.M. Stat. Ann. § 74-15-3(A)(15); N.M. Admin. Code § 20.13.2.10(O)	A product for which the board has adopted a rule providing that the use of the per- or poly-fluoroalkyl substances in that product is a currently unavoidable use.
N.M. Stat. Ann. § 74-15-3(A)(16); N.M. Admin. Code § 20.13.2.10(P)	A product that contains fluoropolymers consisting of polymeric substances for which the backbone of the polymer is either a per- or polyfluorinated carbon-only backbone or a perfluorinated polyether backbone that is a solid at standard temperature and pressure.

Legislatively-approved Exemption/Rule Citation	Provision
N.M. Stat. Ann. § 74-15-3(F); N.M. Admin. Code § 20.13.2.10(Q)	A pesticide that is regulated by or under the jurisdiction of the Federal Insecticide, Fungicide, and Rodenticide Act.

To obtain a CUU exemption, the law requires that manufacturers demonstrate that the PFAS use is essential for health, safety or the functioning of society. However, the State Legislature already has made this determination in enacting these exemptions.⁴ The alternative would be unworkable for both complex durable goods and NMED. A separate CUU proposal is required for each product category and associated industry section (NAICS code). NMED would be tasked with reviewing and making timely determinations on each request. Given the sheer numbers of products and components involved, it would be an impossible task.

The information requirements for the CUU and reporting process are extensive, and it would be extremely challenging for manufacturers of the exempt products to collect and submit the extensive information needed for potentially hundreds or thousands of product components. Complex durable goods manufacturers are assemblers of finished goods. The components are sourced through global, multi-tier distribution and supply chains. The finished good manufacturer does not have detailed information on the design and construction of every component. That information may be stored (and protected as proprietary information) two to seven commercial distribution agreements away, in another company, and in another country. In addition, with respect to demonstrating that no alternatives exist, it is important to recognize that not all complex durable goods manufacturers have decision-making authority on the composition of a component or the timing of changes to a component. In addition, to avoid supply chain disruptions, alternatives must be readily available in sufficient quantities. Adequate time must be allowed to safely redesign and requalify the component(s) and the finished product(s) on the order of 7 – 20 years.

Therefore, the CUU process alone is inadequate to take in all of the other exemptions on the list. If any one of the exemptions are narrowed or removed, the affected products containing intentionally added PFAS would be subject to the January 1, 2032, restriction unless the manufacturer receives a CUU determination. The CUU process in New Mexico does not take into account the complexities associated with exempt products which can contain hundreds or

⁴ Agency Bill Analysis – 2025 Regular Session, Bill Number HB 212 Committee Substitute, New Mexico Environment Department, March 17, 2025, Section III: Narrative; ¶ 2.

thousands of parts and would lead to an overwhelming number of CUU requests. The exemptions codified in HB 212 and included in Section 20.13.2.10 NMAC appropriately recognize these practical implementation challenges and acknowledge that product bans are not workable for these products where there is no or low potential for consumer exposure and substitution may be technically infeasible and inconsistent with other legal and performance obligations. CPMC asks NMED to recommend that the exemptions be continued to ensure a workable CUU process for both complex durable goods manufacturers and NMED.⁵

In summary, for manufacturers of complex durable goods, identifying, evaluating, and substituting intentionally added PFAS in supplier-produced components presents multiple challenges. First, manufacturers must determine whether components and parts they do not produce contain intentionally added PFAS; information that may not be readily available from multi-tiered supply chains. Second, even if suppliers can confirm that a component contains intentionally added PFAS, manufacturers must identify whether technically feasible alternatives exist for components they did not design or manufacture. Third, if an alternative is identified, and in many cases alternatives do not currently exist, manufacturers must confirm that substituting the material will allow the component to function properly within the finished product and will not impair the product's ability to meet applicable safety, performance, durability, reliability, environmental requirements. Due to the complexity of these products and safety and performance demands, design timelines for complex durable goods can be difficult to predict and may extend for many years.

III. CPMC interprets the exemptions for specific products to include all replacement parts, spare parts, accessories, attachments, implements, service parts, and maintenance parts required to service the covered product.

Replacement parts should be covered by the exemption applicable to the underlying durable good. Long-lived electrical, lighting, automation, welding, and industrial systems may remain in service for decades and depend on replacement components that preserve the original system's safety, certification, interoperability, and performance. Requiring manufacturers to reformulate or redesign a replacement part can trigger extensive testing, recertification, customer approval, and compatibility review and may leave owners without a practical means to maintain otherwise serviceable equipment. Extending the underlying exemption to replacement

⁵ The CUU process also cannot substitute for categorical exemptions where the evidence needed to support a request is proprietary or controlled by suppliers. The final rule recognizes that confidentiality claims may leave NMED with insufficient publicly available information to evaluate a CUU proposal. Manufacturers relying on proprietary designs, formulations, qualification data, or supplier information may therefore face an untenable choice between disclosing sensitive information and submitting a record that NMED considers inadequate. This practical constraint further supports retaining the existing exemptions.

parts avoids premature equipment retirement, protects the installed base, and supports continued system reliability.

The definition of “complex durable good” included in the regulations recognizes the unique circumstance of these products; that they are composed of 100 or more manufactured components, with an intended useful life of five or more years, and are not typically consumed, destroyed, or discarded after a single use. By their nature, complex durable goods require ongoing maintenance, repair, refurbishment, and replacement of worn or damaged components throughout their service life. As a result, the legislatively approved exemptions for specific complex durable goods, such as motor vehicles, off-highway vehicles, watercraft, and aircraft encompass the replacement parts, spare parts, accessories, attachments, implements, service parts, and maintenance parts required to operate, maintain, and repair those products. Interpreting the exemptions otherwise would undermine their purpose by allowing the exempt product itself to remain in commerce while restricting the parts necessary to keep that product operational throughout its useful life.

Service, warranty, and maintenance is an essential reality for complex durable goods. For example, Exemption G for motor vehicles provides a clear example of legislative intent, by exempting motor vehicles and motor vehicle equipment. The federal definition of "motor vehicle equipment" expressly includes replacement parts, replacement components, improvements, accessories, and additions to a motor vehicle. 49 U.S.C. § 30102(a). Thus, the Legislature did not limit the exemption solely to the finished vehicle but extended it to the parts needed to maintain, repair, improve, and operate that vehicle throughout its service life. Given the definition of "complex durable good," which recognizes products with long useful lives consisting of numerous manufactured components, the same principle should apply to other exempt complex durable goods. The exemptions should therefore be understood to encompass the replacement parts, spare parts, accessories, attachments, implements, service parts, and maintenance parts necessary to keep those exempt products in service.

IV. The exemptions appropriately recognize federal preemption and avoid conflicts with other international, federal, state and local laws, rules, codes and standards.

These exemptions appropriately avoid conflicts with federal law by recognizing preemption and other requirements which effectively function in the same manner to control the design and performance of many products that are essential for the health, safety and functioning of society. Without these exemptions, there would be tremendous business uncertainty whether

materials could continue to be used that are necessary to satisfy federally mandated safety, emissions, durability, reliability, and performance standards.⁶

The general federal preemption exemption in Section 3(A)(1), together with the product-specific exemptions in Sections 3(A)(3)–(14), reflects circumstances in which federal law occupies the field or otherwise preempts state requirements. However, federal preemption does not account for the myriad of additional laws, regulations, codes and standards that underly these legislatively-approved exemptions. These exemptions are not merely a policy choice; they reflect legal and conformity requirements with which manufacturers must comply.

Preemption in practical terms frequently arises from performance-based regulations rather than express mandates that a particular chemical be present in a product. This distinction is important because the CUU provisions in Section 20.13.2.11 NMAC include an overly narrow reading of when PFAS is “required” by law, and indicate that the applicable statute or regulation has to specifically state that PFAS must be present in the product. This narrow reading of federal preemption is in direct conflict with the seminal Supreme Court ruling in this area, and cannot be used as a guidepost for these determinations. There are many cases in which performance, safety, emissions, durability, or reliability requirements are uniformly established and manufactures must determine which technologies are necessary to comply:

- **Automotive**: The exemptions in Sections 3(A)(7) and 3(A)(8) of HB 212, which apply to motor vehicles, motor vehicle equipment, and other motorized vehicles such as all-terrain vehicles, acknowledge the preemption provisions included in the National Traffic and Motor Vehicle Safety Act of 1966, P.L. 89-563, 49 U.S.C. Chap. 301 (NTMVA). The scope of these requirements includes all parts of the vehicle throughout its lifespan per the definition of motor vehicle equipment in 49 C.F.R. § 30102(a). Changes to these exemptions would lead to confusion concerning whether cars in New Mexico could continue to meet applicable Federal Motor Vehicle Safety Standards (FMVSSs) as defined in 49 U.S.C. § 30102(a)(10). The NTMVA contains an express preemption provision providing that a state may prescribe a standard addressing the same aspect of performance only if the state requirement is identical to the FMVSS. 49 U.S.C. § 30103(b)(1). FMVSS 209 requires that materials used in seat belts be capable of sustaining minimum restraint forces; be treated to prevent unraveling; and be resistant to abrasion, light, and micro-organisms. 49 C.F.R. § 571.209. Similarly, FMVSS 302 governs flammability of interior materials and requires, among other things, that an interior material “not burn or transmit a flame front across its surface at a rate of more than 102 mm per minute.” 49 C.F.R. § 571.302. Fluoropolymers and elastomers are typically used to meet these

⁶ Agency Bill Analysis – 2025 Regular Session, Bill Number HB 212 Committee Substitute, New Mexico Environment Department, March 17, 2025, Section III: Narrative; ¶ 2.

standards, even though they are not listed in the standard itself. Additionally, FMVSS No. 106 (Brake Hoses) establishes detailed performance and durability requirements for hydraulic, air, and vacuum brake hoses and brake hose assemblies used in passenger vehicles, trucks, buses, and motorcycles. 49 C.F.R. § 571.106. Compliance with FMVSS 106 requires manufacturers to subject brake hoses and hose assemblies to extensive testing, including pressure and burst strength tests, expansion tests, whip and fatigue testing, temperature resistance testing, ozone resistance testing, corrosion resistance testing of end fittings, and compatibility testing with brake fluids. These tests are designed to simulate real-world operating conditions and ensure that brake system components do not fail under stress, as such failures could result in loss of braking capability and serious safety risks. Because brake hoses are safety-critical components, any change in materials—such as substituting an elastomer, coating, or reinforcement layer—would generally require a manufacturer to reestablish compliance with FMVSS 106 through repeat testing and validation. Additionally, automobiles must comply with certain Clean Air Act regulations and state environmental emission requirements, and PFAS containing materials are often necessary to meet these requirements. These examples illustrate that alternatives, if available, will trigger a lengthy process of re-certification. Recertification includes redesigning components and extensive testing and it cannot be accelerated without compromising public safety.

- **Recreational Boating:** Due to the extraordinary nature of the usage and requirements for boating, there are many requirements integral to maintaining safe and reliable products that operate in water environments. Personal floatation devices must be certified by the United States Coast Guard (USCG) and are required by law to be present in recreational boats for each passenger aboard. Regulatory bodies such as the American Boat and Yacht Council (ABYC), the International Organization for Standardization (ISO), SAE International, the EPA, the California Air Resources Board (CARB), and International and Maritime Laws define conditions and/or test standards for boating that can only be satisfied by using some level of PFAS. Four specific examples are provided below:

COMPONENT	TECHNICAL DRIVER	WHY PFAS?	RISK OF REMOVAL
Fuel Lines	EPA Permeation Limits (15g/m ² /day)	Only material offering low permeation + flexibility.	Non-compliance with EPA air quality regulations.
Engine Seals	Bio-Lubricant Compatibility	Inert to aggressive biodegradable oils. (EPA Vessel General Permit (VGP) mandates the use of Environmental Acceptable Limits (EALs) in oil-to-sea interfaces.	Oil leaks, engine failure, water pollution.
Wire Insulation	Thermal/Chemical Resistance	Non-flammable, resists salt & fuel, high melting point.	Electrical fires, loss of propulsion at sea.
Canvas/Textiles	Water Repellency	Low surface tension resists water/mold without cracking.	Rapid degradation of covers, mold growth.

- Electrical Equipment:** Product safety and performance requirements often do not prescribe a particular chemistry, but they can make material substitution a lengthy engineering and certification exercise. For example, American National Standards Institute (ANSI)/National Electrical Manufacturers Association (NEMA)/ International Electrotechnical Commission (IEC) 60974-1 requires certain non-metallic materials protecting against contact with live parts to achieve a V-0 or better flammability classification under UL 94. Communications cable may be evaluated under Underwriters Laboratory (UL) 444 and National Fire Protection Association (NFPA) 262, with NFPA 262 performance referenced by the National Electrical Code for plenum applications. Fluoropolymers can help products satisfy demanding flame, electrical, and data-transmission requirements. Removing materials may require years of development, testing, qualification, and recertification before a suitable replacement can be deployed. Many exempt uses involve stable fluoropolymers contained within enclosed electrical or industrial equipment, with limited potential for contact or release during intended use. Examples include the use of the fluoropolymer polytetrafluoroethylene (PTFE) in insulated internal wiring, motor-winding insulation, enclosed seals and O-rings, shrink tubing, and fluoropolymer components within lighting fixtures and industrial controls. The assessment should distinguish these uses from consumer-contact or intentionally dispersive

applications and evaluate actual exposure pathways rather than PFAS presence alone. NFPA No. 70, the National Electrical Code (NEC) is the benchmark standard governing the safe design, installation and inspection of electrical wiring and equipment. It is the primary design driver for all commercial and residential electrical installations, including lighting circuits and systems, outdoor lighting, low-voltage security systems, security wiring, grounding, surge protection, burglar alarm system power supplies, camera systems, communication circuits, grounding and bonding requirements, and power supplies. It is the most widely adopted electrical code in the United States and has been adopted by New Mexico in N.M. Admin. Code 14.10.4 (2020)(HOUSING AND CONSTRUCTION ELECTRONICAL CODES). Additionally relevant codes include ANSI/NEMA/IEC 60974-1 and UL 94 V-O for welding equipment, as well as UL 444 and NFPA 262 for wire and cable. Like most codes, these are performance- and safety-based and requires characteristics such as flame resistance, conductor insulation integrity, electrical isolation, durability, weather resistance, grounding, and circuit protection. Certain electrical cables and wiring for alarm systems, sensors, electronics and communication equipment use fluoropolymers (e.g., PTFE) because of their high dielectric strength, thermal stability, low flammability, chemical resistance, and long service life.

- **Commercial and Residential Fire Prevention and Suppression:** Compliance with the adopted performance standards often relies on components that have historically incorporated fluoropolymers because of their durability, electrical, thermal, and chemical-resistance properties. New Mexico requirements incorporate systems designed and installed under NFPA 13, NFPA 14, NFPA 20, NFPA 72, and related standards, and include:
 - 10.25.5 NMAC - Fire Prevention and Public Occupancy
 - 10.25.5.8 NMAC - Adoption of the 2021 International Fire Code (IFC) by reference.
 - 10.25.5.14 NMAC - Fire Protection Systems (Chapter 9 of the IFC as amended by New Mexico)
 - 10.25.5.18 NMAC - Approval of Fire Protection Systems
 - 10.25.2 NMAC - Certificates of Fitness for Fire Protection System Work
 - 59A-52 NMSA 1978 - State Fire Marshal Act
 - 14.7.2 NMAC - New Mexico Building Code. Adopts the International Building Code (IBC) and contains occupancy-specific requirements for:
 - When automatic sprinklers are required.
 - High-rise buildings.
 - Hazardous occupancies.
 - Storage occupancies.

- Means of egress interactions with suppression systems.
- 16.39 NMAC - Engineering Requirements for Fire Protection System Design
 - The New Mexico Fire Code and International Fire Code, New Mexico typically enforces applicable NFPA installation standards. These standards become enforceable when referenced by the adopted IFC/NMFC.

These standards require reliable operation under fire conditions, long service life, resistance to corrosion, compatibility with water and environmental conditions, and dependable operation of alarm and control equipment. Compliance with those criteria may result in the use of products containing PFAS-derived fluoropolymers in electronics, wiring, insulation, seals, gaskets, coatings, and semiconductor-related components, even though the code does not expressly mandate PFAS chemistry. The PFAS use arises from manufacturers' efforts to satisfy performance specifications rather than from an explicit statutory or code requirement for PFAS.⁷

- **HVAC-R**: The ability to meet EPA hydrofluorocarbon (HFC) phasedown and SNAP regulations and Department of Energy (DOE) appliance standards are contingent on maintaining these exemptions, due to the technology required to achieve global warming potential (GWP) reduction and energy efficiency. Also the ability to meet ANSI-approved safety standards under ASHRAE 15 and UL 60335-2-40 require the use of certain materials and sensors to ensure the safety of refrigeration systems that are installed in residential and commercial buildings. These standards are a requirement for manufacture and sale of life-saving appliances for heating, air-conditioning and refrigeration.
- **Non-road Stationary and Mobile Machinery**: Federal and state evaporative emissions standards applicable to fuel systems for nonroad engines illustrate why a chemical identifier requirement is irrelevant for establishing federal preemption. EPA's nonroad evaporative emissions regulations in 40 C.F.R. Part 1060 and corresponding CARB evaporative-emissions requirements establish performance-based limits to control fuel vapors escaping into the air from new and in-use nonroad engines and equipment. These programs do not mandate the use of any particular chemical or material. Instead, they require manufacturers to design fuel systems that achieve specified emissions-reduction outcomes. For many diesel and gasoline fuel-tank applications, manufacturers have demonstrated compliance through the use of

⁷ N.M. Code R. § 10.25.5 NMAC(2022)(PUBLIC SAFETY AND LAW ENFORCEMENT, STATE FIRE MARSHAL, FIRE PREVENTION AND PUBLIC OCCUPANCY) (; N.M. Code R. § 14.7.2.8 (2023)(HOUSING AND CONSTRUCTION, BUILDING CODES GENERAL). More specifically, N.M. Code R. §§ 10.25.5.2(A)(4), 10.25.5.6, 10.25.5.8, 10.25.5.14(E), 10.25.5.18 (2022) and N.M. Code R. §§ 14.7.2.8, 14.7.2.17 (2023) require fire protection systems to be designed, monitored, tested, and approved in accordance with NFPA standards, including monitoring of fire pumps, generators, and related life-safety systems. These references are provided as Attachments to these comments.

treated HDPE tanks with fluorine gas, which creates a barrier limiting fuel permeation through plastic tank walls. In certain applications, fluorinated fuel tanks represent the only commercially demonstrated technology capable of satisfying the applicable evaporative-emissions standards while maintaining product functionality and safety. These products squarely fall within the broad catch-all preemption exemption included in Section 3(A)(1) of HB 212. Otherwise, a state prohibition on PFAS-containing fuel-system components would be in direct conflict with the use of technologies necessary to comply with mandatory emissions requirements.

As a result of the Supreme Court decision, *Geier v. American Honda Motor Co.*, federal requirements may preempt state law where state restrictions would interfere with the methods manufacturers use to satisfy federally established safety and performance objectives.⁸ The NMED report should recognize and clarify that a specific chemical listing is not required to invoke federal preemption. If a PFAS-containing material is deemed necessary by a manufacturer to satisfy a federally mandated performance requirement, there is no requirement to identify a technically feasible alternative, and a state prohibition would create the very conflict that the Legislature sought to avoid. The distinction between “required by the code” and “necessary to meet code-driven performance requirements” is important for the state’s PFAS exemption analyses. The NMED report should recognize international, federal, state and local laws, rules, codes and standards that strictly govern the design and performance of complex durable goods. The existence of these requirements and the need to avoid conflicting state-specific requirement should be a strong basis for maintaining these exemptions.

V. The exemptions for fluoropolymers and SNAP-regulated refrigerants reflect scientific distinctions that should be recognized in the NMED report.

The exemptions for fluoropolymers, and for refrigerants regulated under EPA’s SNAP program, acknowledge the scientific findings for these substances and their distinguishing characteristics. F-gases used for building fire prevention and suppression systems are also regulated by the SNAP program. The Organization for Economic Cooperation and Development (OECD) cautions that the “one fully fluorinated carbon atom” classification is not a proxy for risk. The OECD states that: “[a]s PFASs are a chemical class with diverse molecular structures and physical, chemical and biological properties, it is highly recommended that such diversity be properly recognized and communicated in a clear, specific and descriptive manner.”⁹

⁸ *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000).

⁹ Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance, OECD Series on Risk Management No. 61 (2021), p. 8, OECD Publishing, Paris, <https://doi.org/10.1787/e458e796-en>.

Fluoropolymers should be – and are by jurisdictions such as Canada and Illinois – considered in an entirely separate category from other PFAS. Fluoropolymers are extremely large molecules with repeating units, forming a substance many magnitudes larger than a PFAS molecule such as PFOA or PFOS.¹⁰ Their size, stability, and chemical properties leave fluoropolymers insoluble in water, presenting exceptionally low or no risk of contamination to the environment.¹¹ Fluoropolymers are not bioaccumulative and do not degrade; polytetrafluoroethylene (PTFE) remains intact well above 1000° Fahrenheit, significantly reducing chances of unfavorable degradation in the environment. A recent study on the thermal decomposition of fluoropolymers investigated the thermal stability and degradation products of PTFE, polychlorotrifluoroethylene (PCTFE), and polyvinylidene fluoride (PVDF) across temperatures ranging from 200 to 890 °C.¹² Different from previous studies, no short- or long-chain PFAS were detected under any tested condition, indicating the fluoropolymers did not degrade into smaller, potentially more toxic forms. Among the investigated polymers, PTFE showed high stability, remaining intact until ≥ 550 °C and then largely depolymerizing to tetrafluoroethylene (TFE) (C₂F₄). This study demonstrates that the most commonly used fluoropolymers are stable even at extreme temperatures that almost no products are exposed to during normal use or disposal. For these and several other reasons, fluoropolymers have been used in numerous medical devices, with no observed adverse effects on patients. In fact, the FDA recently released the summary of an extensive nationwide study finding that PTFE has “been safely used for decades” and is “very unlikely to cause toxicity to patients” given its molecular structure. Simultaneously, PTFE is a “critical” material “essential for [medical] devices to function.”¹³

Furthermore, the manufacture of fluoropolymers has greatly evolved in recent years; the use of highly effective water and air emissions controls as well as adoption of non-PFAS

¹⁰ “Given information suggesting their differences from the other PFAS in the class, additional work on fluoropolymers is warranted. PFAS meeting the definition of fluoropolymers are not addressed within the State of PFAS Report or this Risk Management Approach but were added to the Proposed Plan of Priorities for further assessment.” <https://www.canada.ca/en/environment-climate-change/services/evaluating-existing-substances/risk-management-approach-per-polyfluoroalkyl-substances.html>.

¹¹ Henry, B. et al. A Critical Review of the Application of the Polymer of Low Concern and Regulatory Criteria to Fluoropolymers. *Integr. Environ. Assess. Manag.* 2018:316–334, and Korzeniowski, S. et al. A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers *Integr. Environ. Assess. Manag.* 2023:326–354.

¹² Dolatabad, A. et al. Thermal Decomposition of Fluoropolymers: Stability, Decomposition Products, and Possible PFAS Release. *496 J. Hazardous Materials* 139322 (2025).

¹³ U.S. Food and Drug Administration, [PFAS in Medical Devices](https://www.fda.gov/medical-devices/products-and-medical-procedures/pfas-medical-devices) (August 6, 2025). See FDA, PFAS in Medical Devices, <https://www.fda.gov/medical-devices/products-and-medical-procedures/pfas-medical-devices> (“PFAS are a large group of more than 15,000 chemicals that are used in a variety of products. They are not all the same.”).

polymerization aids are proliferating, together with the phaseout of known toxins PFOA and PFOS. Therefore, it is no longer accurate to regulate fluoropolymers based on historical manufacturing processes and concerns regarding the generation and release of low-molecular-weight or reactive fluorinated molecules during manufacturing.¹⁴ It is reported that more than 80 percent of global fluoropolymer production can be achieved with non-fluorinated polymerization aids, a statistic that includes certain production processes for one of the most common and highest-volume fluoropolymers, PTFE.¹⁵ With this progress, the risk from indirect pollution from fluoropolymers has been significantly reduced.

The exemptions also appropriately recognize the unique characteristics and essential use of refrigerants regulated under EPA's SNAP program. Many refrigerants and F-gases fall within the broad statutory definition of PFAS and possess properties that are critical to achieving the safety, performance, and environmental objectives required under the Clean Air Act's SNAP program. Refrigerants and F-gases approved under SNAP must meet the program's stringent criteria, including low toxicity, low flammability, efficient cycling between liquid and gas phases, and low global warming potential.¹⁶

The SNAP Program is EPA's regulatory approval process for reviewing new refrigerants with lower global warming potential (GWP) and approving the use of these refrigerants if they meet certain environmental and human health criteria. 40 C.F.R. § 82.176(a). The approval status of specific refrigerants is continually reviewed and subject to change as the agency considers new environmental and human health data. The Biden Administration changed the status for several HFC refrigerants used in air conditioning systems from acceptable to unacceptable. 80 Fed. Reg. 42870 (SNAP Rule 20) and 81 Fed. Reg. 86778 (SNAP Rule 21). Before EPA will list a substitute as acceptable under the SNAP program, submitters must provide extensive technical information regarding the substitute's physical and chemical properties, anticipated uses, process and application data, ozone depletion potential, global warming impacts, toxicity, flammability,

¹⁴ See EIB Hearing Transcript, 2/26/2026, Day 4 for the testimony of STEPHEN H. KORZENIOWSKI, PH.D. which begins on p. 1250 of the transcript. On p. 1280, phase out of PFOA and PFOS is explained. On page 1287, discontinuation of fluorinated polymerization aids used to make fluoropolymers is explained. Major U.S. fluoropolymer manufacturers have publicly announced and implemented substantial PFAS emission-control technologies (e.g., [Chemours](#), [Daikin America](#)).

¹⁵ Ameduri, B. et al. Developments in Fluoropolymer Manufacturing Technology to Remove Intentional Use of PFAS as Polymerization Aids, ICRL: 18 – 28 (20230), Section III.2, p. 22.

¹⁶ 40 C.F.R. § 82.178; EPA, *Submit to SNAP*, <https://www.epa.gov/snap/submit-snap> (last updated Apr. 6, 2026).

environmental fate and transport, and potential releases to the environment, among other things.¹⁷

EPA evaluates information on a chemical under SNAP through a comparative risk assessment process and reviews both the environmental and human health impacts of the substitute in the context of its proposed use. As part of that review, EPA evaluates health and safety studies addressing potential effects on humans and other organisms, including data concerning exposure pathways, acute and repeated-dose toxicity, potential cardiotoxicity where relevant, and the toxicity of the substitute's components, impurities, and degradation products.¹⁸ EPA also considers how the public may be exposed during manufacture, servicing, use, and disposal, and evaluates whether the substitute presents lower overall risk than the ozone-depleting substances or other alternatives it is intended to replace.¹⁹ Accordingly, the Legislature's decision to exempt SNAP-regulated refrigerants appropriately recognizes both their essential societal functions and the fact that they have already undergone extensive federal review under a science-based program specifically designed to evaluate environmental and human health risks.

VI. Modifications to exemptions

HJM 3 directs NMED to consider whether the exemptions should be modified. CPMC requests that NMED consider the following refinements to the legislatively- approved exemptions:

- **Recommend that Exemption H includes all products with internal combustion engines.**

Exemption G excludes motor vehicles and motor vehicle equipment while Exemption H excludes any other motor vehicle and lists several examples including off-highway vehicles, and specialty motor vehicles such as all-terrain vehicles, side-by-side vehicles, farm equipment and personal assistive mobility devices. Together, these exemptions recognize that a broad range of engine-powered products rely on PFAS-containing components to meet performance, durability, safety, and regulatory requirements including, for example, EPA regulated engines that must meet tailpipe emission and fuel standards. Engines that are regulated by EPA must have EPA certifications before the engines can be placed on the market and into U.S. commerce. To receive

¹⁷ 40 C.F.R. § 82.178(a).

¹⁸ 40 C.F.R. § 82.178(a)(7).

¹⁹ 40 C.F.R. § 82.170(a).

certification, manufacturers must demonstrate compliance with EPA's requirements, for which certain PFAS chemicals remain critical to meet those requirements.

Exemption H should include more broadly internal combustion engine-powered machinery and equipment, including mobile and stationary products. The use of the phrase "such as" demonstrates that the listed examples are illustrative rather than exhaustive for "specialty vehicles" and contemplates additional engine powered equipment not currently listed in the exemption. Like the vehicles included in Exemption G and H, non-road stationary and mobile machinery are engine powered, complex durable goods that may be required to use PFAS in power systems, emission control systems, or product coatings to ensure adequate the safety and performance of these products. Additionally, these products often share similar or the same multi-tiered supply chains and face the same challenges associated with identifying and substituting PFAS containing components as the vehicles included in Exemption G and H. Exemption H could be clarified to acknowledge all engine powered machinery as follows:

"H. any other motor vehicle, including an off-highway vehicle or a specialty motor vehicle, such as an all-terrain vehicle, a side by-side vehicle, farm equipment or a personal assistive mobility device, *or non-road stationary or mobile machinery such as agricultural, construction, off-highway, and mining power, generators, mixers, drills, cranes, blowers, and mowers.*"

Alternatively, a separate category of exempt complex durable goods could be established as defined as follows:

Non-Road Stationary and Mobile Machinery (NRSMM), to mean agricultural, construction, off-highway truck, mining, stationary power, generator, gravel and concrete mixer, drill, crane, utility vehicle, mower, hand-held equipment, and any other non-road stationary or mobile machinery powered by an internal combustion engine or an alternative power source, including battery or solar power, that uses spare parts, accessories or attachments.

- **CPMC interprets the exemption provided in Section 20.13.2.10 (M) to include batteries, other equipment required to charge, maintain, and utilize the battery in the product, and products that contain batteries.**

Exemption M exempts products used for the generation, distribution or storage of electricity from the requirements of Sections 20.13.2.11 (currently unavoidable use), 20.13.2.12 (reporting), and 20.13.2.14 (testing). Complex durable goods are often powered by batteries which are an integral component of their operation. CPMC interprets Exemption M to include not only the battery itself, but also for rechargeable batteries, the charging equipment, power

adapters, charging stations, cables, and other accessories necessary to charge, maintain, and utilize the battery in the product. CPMC further interprets Exemption M to extend to products that contain such batteries because the battery is an integral component necessary for the product to operate. Collectively, the battery, the product in which it is incorporated, and the associated charging components function as an integrated electricity distribution and storage system and therefore fall within the scope of Exemption M. CPMC asks that NMED confirm this interpretation of exemption M and consider recommending additional clarity to Exemption M as follows:

“M. a product used for the generation, distribution or storage of electricity, including batteries, products power by batteries, battery charging equipment, power adapters, charging stations, cables, and other accessories necessary to charge, maintain, and utilize the battery in the product.”

- **Recommend an exemption for commercial building and residential home fire prevention and suppression systems.**

Commercial and residential fire prevention and suppression systems are lifesaving equipment that depend on the use of fluoropolymers because of their durability, electrical, thermal, and chemical-resistance properties. As noted above, these products are required to meet NFPA standards including NFPA 13, NFPA 14, NFPA 20, NFPA 72, which makes the use of fluoropolymers in these products essential to ensure safe and reliable performance under fire conditions. Other criteria met through the use of these materials include long service life, resistance to corrosion, resistance to flooding and other harsh environmental conditions, and dependable operation of alarm and control equipment. Further, these products are considered complex durable goods which contain hundreds of individual components and parts.

- **Recommend an exemption for electrical equipment.**

Many of the products included in the exemptions uses fluoropolymers contained within enclosed electrical or industrial equipment, with limited potential for contact or release during intended use. Examples include PTFE-insulated internal wiring, motor-winding insulation, enclosed seals and O-rings, shrink tubing, and fluoropolymer components within lighting fixtures and industrial controls. These product components provide essential function to the various complex products included in the exemptions, and must comply with the NEC which is the primary design driver for all commercial and residential electrical installations, including lighting circuits and systems, outdoor lighting, low-voltage security systems, security wiring, grounding, surge protection, burglar alarm system power supplies, camera systems, communication circuits, grounding and bonding requirements, and power supplies. It is not clear that any current exemption encompasses these essential products.

VII. NMED should use a transparent, rigorous, and stakeholder-informed process to develop the HJM 3 reports.

Given the impact of the exemptions on the regulated community, CPMC believes NMED's review should include the scientific literature associated with the use of PFAS in the products subject to these exemption and that the data NMED selects for use should be held to a rigorous standard. CPMC recommends a systematic literature review approach, in which the search and selection process for scientific literature are planned and documented; this reduces bias when considering literature to include in addressing the outstanding research question at hand. The scientific literature used by NMED should be held to the same high standards to which the scientific community and federal agencies adhere.²⁰

HJM 3 does not identify the criteria NMED should use to evaluate the public health, environmental, and economic risks associated with the exemptions, nor does it explain how NMED should weigh those factors when recommending whether the exemptions should be retained, modified, expanded, or removed. Because the exemptions have significant legal, technical, supply-chain, and economic implications for the regulated community, NMED should establish the evaluation criteria it will use and provide stakeholders with a meaningful opportunity to comment on those criteria before they are applied. Doing so would improve transparency, allow affected manufacturers and technical experts to provide relevant data, and help ensure that any recommendations to the Legislature are based on a complete and well-developed record. CPMC also requests that the Legislature clarify how it intends to use the interim and final reports so stakeholders can provide information responsive to the Legislature's decision-making needs. At a minimum, CPMC recommends the following factors for consideration:

- (1) If other international, federal, national, state, or local laws, regulations, standards, and codes govern the product's performance, safety, emissions, durability, reliability, or other requirements in a manner that would be affected by restrictions on intentionally added PFAS in the product the exemption should be retained;
- (2) If the scientific literature, systematically reviewed, demonstrates that the PFAS does not partition to water or bioaccumulate, the exemption should be retained;
- (3) If there are economic consequences for New Mexico above \$100 million annually, the exemption should be retained; and
- (4) If the CUU process would be rendered administratively unworkable by including the exempt products, the exemption should be retained.

²⁰ The White House, Restoring Gold Standard Science (May 23, 2025), <https://www.whitehouse.gov/presidential-actions/2025/05/restoring-gold-standard-science/>.

CPMC's comments have addressed the need for criteria (1), (2), and (4). With respect to the third criterion, CPMC respectfully submits that the legislatively-approved exemptions are necessary to avoid significant economic disruption in New Mexico. CPMC members support substantial employment, income, tax revenue and economic activity in the state. These examples demonstrate the significant contribution that many complex durable goods to New Mexico's economy:

- **Electrical manufacturing** contributes approximately \$178 million in income, \$312 million in GDP, and support approximately 2,440 jobs in New Mexico.
- The **recreational vehicle industry** supports 508 businesses, 3,420 jobs, \$208.7 million in wages, and \$92.1 million in taxes paid in New Mexico.
- The **recreational boating industry** contributes \$335.2 million annually to the economy in New Mexico. The industry supports 1,244 jobs and 43 businesses. There are 27,956 registered boats in the state and \$46.4 million is spent annually on new boat, engine, trailer, and accessory sales.
- The **automotive industry** supports 35 thousand jobs, \$3.8 billion in gross domestic product, and over \$2 billion in total labor income annually in New Mexico.²¹

These statistics illustrate the economic risks that New Mexico could face if the exemptions are limited or removed and affected products do not receive CUU determinations.

VIII. Provide additional opportunities for comment.

NMED should ensure that affected stakeholders have a full opportunity to review and comment on the information, methodology, and preliminary conclusions that form the basis for the reports. Specifically, we strongly encourage NMED to provide stakeholders with an opportunity to comment on a draft report. Public review will allow the public to identify factual gaps, provide sector-specific data, and address technical or scientific assumptions. This improves the accuracy and usefulness of the report and would help ensure that any recommendations to the Legislature are supported by a complete record. Providing these additional comment opportunities will help ensure that NMED is using accurate information, appropriate scientific standards, and provides an objective understanding of the legal, technical, and economic consequences of any proposed changes.

²¹ <https://www.autosinnovate.org/resources/insights/nm>.

IX. Conclusion

HB 212 and NMED's implementing rules and guidance frame the program around consumer products. NMED should recommend preserving that statutory scope and should not extend reporting or restriction requirements to industrial, commercial, or other non-consumer products. The current scope reflects sound risk-based policy. Non-consumer electrical equipment is generally installed, maintained, and deinstalled by trained professionals. PFAS, when present, is commonly embedded in internal components and is not intended to be released or contacted during ordinary use. These products may depend on high-performance fluoropolymers and SNAP refrigerants and F-gases for electrical insulation, fire resistance, sealing, chemical resistance, corrosion protection, lubrication, and long-term reliability.

CPMC appreciates the opportunity to provide comments on the Proposed Regulations. CPMC supports continued inclusion of all of the current exemptions, which are necessary to (1) provide a workable regulatory approach for complex durable goods; (2) avoid conflicts with international, federal, state and local laws, rules, codes, and standards that govern safety, performance, emissions, and other product requirements; (3) recognize important scientific distinctions among PFAS uses, including fluoropolymers and SNAP-regulated refrigerants and F-gases; and (4) avoid significant economic disruption in New Mexico. Additionally, the CPMC recommends establishing and following procedural guideposts to ensure transparency and science-based decision making. Finally, the CPMC requests that NMED and the EIB provide additional opportunities for stakeholders to provide public comments on the processes and criteria and final reports before they are submitted to the Legislature.

The CPMC remains committed to working collaboratively with NMED and the Board to develop PFAS regulations that are scientifically sound, risk-based, and practicable for manufacturers with complex, global supply chains while still advancing the shared goal of protecting New Mexicans. Should you have any questions on our comments, please contact Martha Marrapese, Counsel to CPMC (mmarrapese@wiley.law/2020-719-7156).

NOTE: Copies of the scientific publications and NM codes and standards referenced in these comments are provided with these comments.

Attachments

LFC Requester:

Davidson

AGENCY BILL ANALYSIS - 2025 REGULAR SESSION**WITHIN 24 HOURS OF BILL POSTING, UPLOAD ANALYSIS TO****[AgencyAnalysis.nmlegis.gov](https://agencyanalysis.nmlegis.gov) and email to billanalysis@dfa.nm.gov****(Analysis must be uploaded as a PDF)****SECTION I: GENERAL INFORMATION***{Indicate if analysis is on an original bill, amendment, substitute or a correction of a previous bill}***Date Prepared:** 3/17/2025*Check all that apply:*HB212 Committee

Original

Correction ☐**Bill Number:** SubstituteAmendment ☐ Substitute ☒

Sponsor:	Ferrary, Hochman-Vigil,	Agency Name	New Mexico Environment
	Sarinana, Cates	and Code	
Short Title:	PER- & POLY-FLOUROALKYL	Number:	Department 667
	PROTECTION ACT	Person Writing	Greg Smithkier
			gregory.smithkier@e
		Phone: <u>505-531-7736</u>	Email: <u>env.nm.gov</u>

SECTION II: FISCAL IMPACT**APPROPRIATION (dollars in thousands)**

Appropriation		Recurring or Nonrecurring	Fund Affected
FY25	FY26		

(Parenthesis () indicate expenditure decreases)

REVENUE (dollars in thousands)

Estimated Revenue			Recurring or Nonrecurring	Fund Affected
FY25	FY26	FY27		
0	0	0		

(Parenthesis () indicate revenue decreases)

ESTIMATED ADDITIONAL OPERATING BUDGET IMPACT (dollars in thousands)

	FY25	FY26	FY27	3 Year Total Cost	Recurring or Nonrecurring	Fund Affected
Total	\$0	\$1,400	\$1,400	\$2,800	Recurring	GF

(Parenthesis () Indicate Expenditure Decreases)

(Parenthesis () Indicate Expenditure Decreases)

Duplicates/Conflicts with/Companion to/Relates to:
Duplicates/Relates to Appropriation in the General Appropriation Act

SECTION III: NARRATIVE

BILL SUMMARY

The committee substitute for House Bill (“HB”) 212 maintains the same structure of the bill but modifies definitions, exemptions, etc. House Bill 212 works as follows:

If a product does not have intentionally added PFAS, House Bill 212 does not apply. If a product contains intentionally added PFAS, then one 16 exceptions may apply. These exceptions are products where PFAS is essential to its function – like medical devices, semiconductors, or motor vehicles. If a product has intentionally added PFAS and one of the 16 exemptions does not apply, the product may be subject to prohibitions under House Bill 212.

Starting in 2027, products in the following categories with PFAS are prohibited. These categories include: Cookware, Food packaging, Dental Floss, Juvenile products, and Firefighting foam. Then, starting in 2028, products in the following categories with PFAS are prohibited. These categories include: Carpets or rugs, Cleaning products, Cosmetics, Fabric treatments, Feminine hygiene products, Textiles, Upholstered furniture, and Ski wax. Finally, in 2032, other products with intentionally added PFAS may be prohibited.

The committee substitute modified four definitions:

- It modified “cookware” to include the words “intended for direct food contact.”
- It replaces the current definition of “firefighting foam” with the one in House Bill 140.
- It defines “official compendium” as it relates to the exemption for medical devices.
- The definition of “PFAS” was modified for consistency with other states.

The committee substitute also extended the timeframe for compliance from January 1, 2029 to January 1, 2032 for certain types of PFAS-containing products. The committee substitute also allowed for additional exemptions when PFAS is unavoidable in certain products. The committee substitute addresses confidential business information and trade secrets.

FISCAL IMPLICATIONS

The New Mexico Environment Department (“NMED”) will hire temporary full-time employees (FTE), contractors, or combination thereof to implement the work identified in House Bill 212. Technical and legal staff will need to hold stakeholder meetings, draft rules, petition the board, etc. NMED estimates \$140,000 per year for salary, benefits, and overhead (i.e., \$1.4M annually for 8-10 employees); \$10,000 for computers, software, equipment, office spaces, vehicles, etc. (\$10,000 annually), and \$400,000 per year for two years in contractual support.

The three-year cost to the State of New Mexico to prevent PFAS contamination of water and land is \$2.8M. However, the cost to the State of New Mexico to remove and destroy one pound of PFAS from water is between \$2.7M to \$18M. With approximately 1,100 public drinking water systems in New Mexico serving 94% of our residents, preventing contamination is the only affordable means of securing our drinking water supply. Further, biosolids from water treatment are widely

used in support New Mexico's agricultural industry so preventing PFAS contamination of our drinking water and wastewater will further protect this \$3.99 billion industry.

At least 16 states adopted 22 PFAS-related measures. At least 13 state legislatures have enacted laws to restrict the use of PFAS in everyday consumer products. Since 2007, 30 states have approved 155 PFAS policies, most of them in the past five years. These laws, rules, and policies generally recognize the fiscal prudence of eliminating PFAS pollution to avoid exorbitant taxpayer costs of remediation and disposal.

SIGNIFICANT ISSUES

None identified.

PERFORMANCE IMPLICATIONS

None identified.

ADMINISTRATIVE IMPLICATIONS

HB 212 establishes most requirements in law and provides limited authority to NMED to administer certain provisions within the context of what the legislature adopts via public rulemaking adopted by the board.

CONFLICT, DUPLICATION, COMPANIONSHIP, RELATIONSHIP

Not applicable.

TECHNICAL ISSUES

None identified.

OTHER SUBSTANTIVE ISSUES

None identified.

ALTERNATIVES

None identified.

WHAT WILL BE THE CONSEQUENCES OF NOT ENACTING THIS BILL

Not enacting this bill will create risk to New Mexicans from PFAS products and increase costs to the state due to public drinking water systems, public wastewater systems, private wells/septic systems, groundwater cleanup, etc. PFAS chemicals are conclusively linked to adverse health impacts, including thyroid disease, cancer, liver damage, birth defects, and increased risk of miscarriage.

AMENDMENTS

None identified.

TITLE 10 PUBLIC SAFETY AND LAW ENFORCEMENT
CHAPTER 25 STATE FIRE MARSHAL
PART 5 FIRE PREVENTION AND PUBLIC OCCUPANCY

10.25.5.1 ISSUING AGENCY: New Mexico Department of Homeland Security and Emergency Management.

[10.25.5.1 NMAC - Rp, 10.25.5.1 NMAC, 11/26/2019; A, 11/01/2022]

10.25.5.2 SCOPE:

A. This rule establishes the state's minimum requirements that apply to structures, processes, premises and safeguards regarding:

- (1) the hazard of fire and explosion arising from the storage, handling or use of structures, materials or devices;
- (2) conditions hazardous to life, property, or public welfare in the occupancy of structures or premises;
- (3) fire hazards in the structure or on the premises from occupancy or operation;
- (4) matters related to the construction, extension, repair, alteration, or removal of fire protection systems; and
- (5) conditions affecting the safety of firefighters and emergency responders during emergency operations.

B. This rule does not apply to detached one- and two-family dwellings and townhouses not more than three stories above grade plane in height with a separate means of egress and their accessory structures not more than three stories above grade in height built to the New Mexico Residential Building Code except for those being used as commercial properties.

C. Other state agencies have adopted rules that may or may not apply and that may or may not affect this rule.

(1) The construction industries division of the New Mexico regulation and licensing department (CID) adopts regulations for all construction pursuant to Title 14 NMAC, Housing and Construction, Chapters 5 through 10 NMAC, setting forth the state's minimum requirements that include provisions on fire prevention.

(2) The New Mexico environmental improvement board has adopted rules for aboveground and underground storage tanks containing petroleum or hazardous substances and rules governing hazardous waste administered by the environment department in Title 20, Chapter 5 NMAC.

(3) The board of licensure for professional engineers and surveyors has adopted rules for the design of fire protection and alarm systems pursuant to Title 16, Chapter 39 NMAC.

(4) CID has jurisdiction over all contractors and journeymen installers of fire protection systems and establishes the minimum requirements for licenses and certificates pursuant to the Construction Industries Licensing Act and to Title 14, Chapter 6, Part 6 NMAC on CID license classifications and scopes.

D. AHJs, defined below, may adopt fire protection requirements that are more stringent than 10.25.5 NMAC, provided such requirements do not conflict with this rule. The authority for administration and interpretation of construction-related sections of the NMFC, defined below, that apply to construction projects requiring a building permit is the responsibility of the chief building official or the AHJ. The FM, defined below, shall have the authority for the administration and interpretation of fire protection systems and the chief building official of an AHJ shall have the authority for the administration and interpretation of building codes other than fire protections systems.

[10.25.5.2 NMAC - Rp, 10.25.5.2 NMAC, 11/26/2019; A, 11/01/2022]

10.25.5.3 STATUTORY AUTHORITY: Sections 8-8-6, 8-8-15, 59A-52-15, and 59A-52-16 NMSA 1978.

[10.25.5.3 NMAC - Rp, 10.25.5.3 NMAC, 11/26/2019]

10.25.5.4 DURATION : Permanent.

[10.25.5.4 NMAC - Rp, 10.25.5.4 NMAC, 11/26/2019]

10.25.5.5 EFFECTIVE DATE: November 1, 2022, unless a later date is cited at the end of a section.
[10.25.5.5 NMAC - Rp, 10.25.5.5 NMAC, 11/26/2019; A, 11/01/2022]

10.25.5.6 OBJECTIVE: The purpose of this rule is to prescribe minimum requirements for the installation, operation and maintenance of fire protection and life safety features in buildings and structures necessary to reasonably protect life and property from the hazards created by fire, explosion, and similar emergencies, and which minimum requirements shall not conflict with the provisions of the Construction Industries Licensing Act.
[10.25.5.6 NMAC - Rp, 10.25.5.6 NMAC, 11/26/2019]

10.25.5.7 DEFINITIONS: In addition to the definitions in 10.25.1 NMAC:

A. "Authority Having Jurisdiction (AHJ)" means an organization, office, or individual responsible for enforcing the minimum requirements of codes, standards and permits for approving equipment, materials and installations or a procedure within its jurisdiction.

B. "Certificate of Fitness" means the State Fire Marshall's verification document of a fire protection installation, maintenance and inspection company's competence in the methods and materials of the specific fire system subject to the permit, which is obtained pursuant to 10.25.2 NMAC.

C. "Fire Code Official" shall have the meaning provided in Section 202 of the IFC.

D. "Fire Marshal (FM)" means the fire marshal with the authority over permitting and inspections of fire systems within a particular political subdivision of the state.

E. "IFC" means the New Mexico currently adopted international fire code, [2015] 2021 edition, published by the International Code Council and is available by contacting: Publications, 4051 West Flossmoor Road, Country Club Hills, IL 60478-5795.

F. "Life Safety Features" means compliance with NFPA 1 and NFPA 101 for structures built on or before November 15, 2007, and the NMFC for structures build after November 15, 2007.

G. "NFPA 1" means the fire prevention code, 1997 edition, published by the National Fire Protection Association and available by contacting: Secretary, Standards Council, National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269-9101.

H. "NFPA 101" means the life safety code, 1997 edition, published by the National Fire Protection Association and available by contacting: Secretary, Standards Council, National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269-9101.

I. "New Mexico Fire Code (NMFC)" means the New Mexico fire code created by this rule including the IFC currently adopted by the construction industries division of the regulation and licensing department in New Mexico by reference.

J. "State Fire Marshal (SFM)" means the director of the state fire marshal division under the department of homeland security and emergency management who has the authority for final determination of the application of the fire provisions of this rule throughout the state.

[10.25.5.7 NMAC - Rp, 10.25.5.7 NMAC, 11/26/2019; A, 11/01/2022]

10.25.5.8 ADOPTION OF NATIONAL STANDARD: The SFM adopts the IFC which is then incorporated by reference as revised in this rule. In this rule, revisions are numbered to correspond with the section numbering of the IFC and such revisions further amend such sections of the IFC. All references in the IFC to the International Mechanical Code mean the New Mexico Mechanical Code, CID rule 14.9.2 NMAC. All references in the IFC to the International Plumbing Code mean the New Mexico Plumbing Code, CID rule 14.8.2 NMAC. For purposes of this rule, the application of building code section 102.4 of the IFC, 2021 edition, means that the design and construction of new structures shall comply with the currently adopted New Mexico Building Code (NMBC), CID rule 14.7.2 NMAC, and any alterations, additions, changes in use or changes in structures required by the NMFC, and shall be made in accordance with the currently adopted NMBC, CID rule 14.7.2 NMAC.

[10.25.5.8 NMAC - Rp, 10.25.5.8 NMAC, 11/26/2019; A, 11/01/2022]

10.25.5.9 CHAPTER 1 ADMINISTRATION:

A. Section 101 General.

- (1) **Section 101.1 Title.** Insert in brackets: New Mexico.
- (2) **Section 101.2 Scope.** This section of the IFC shall not apply. 10.25.5.2 NMAC defines the scope of this rule.
- (3) **Section 101.2.1 Appendices.** The SFM adopts appendices D and I. All other appendices of the IFC shall not apply except where adopted by the local AHJ.
- (4) **Sections 101.3 through 101.5.** See the corresponding sections of the IFC.
- B. Section 102.3 (Applicability, Change in use or occupancy.)** Delete this section and replace with the following: "Changes shall not be made in the use or occupancy of any structure that would place the structure in a different division of the same group or occupancy or in a different group of occupancies, unless such structure is made to comply with the requirements of this code and the NMBC. Subject to the approval of the building code official, the use or occupancy of an existing structure shall be allowed to be changed and the structure allowed to be occupied for purposes in other groups without conforming to all of the requirements of this code and the NMBC for those groups, provided the new or proposed use is less hazardous, based on life and fire risk, than the existing use."
- C. Section 104 Duties and Powers of the Fire Code Official.** If Section 104.6 (official records) or any other provision of the NMFC conflicts with the Inspection of Public Records Act, Sections 14-2-1 through 14-2-12 NMSA 1978, the provisions of the Inspection of Public Records Act shall control.
- D. Section 105 permits.** The following sections of the IFC are deleted: Section 105.3, Section 105.5, Section 105.6.2 through 105.6.3, Section 105.6.5, Section 105.6.8 through 105.6.18, Section 105.6.20 through 105.6.22, and Section 105.6.24. All permits required through the CID permitting process are strictly within the authority of CID. The NMFC establishes the state minimum fire code allowing local jurisdictions and political subdivisions the ability to enact stricter ordinances provided the state minimum is complied with by all such jurisdictions. The SFM requires permits and licenses for fireworks as provided in 10.25.6 NMAC.
- E. Certificates of fitness.** The SFM requires certificates of fitness for the installation, inspection, maintenance and repair of fire protection systems as provided in 10.25.2 NMAC.
- F. Section 105.3 Conditions of a Permit.** This section is deleted in its entirety.
- G. Section 106.1 Construction documents: submittals.** This section is deleted in its entirety and replaced with the following language:
 - (1) One set of construction documents shall be submitted to the Building Official, SFM or FM, who is the AHJ for the construction project.
 - (2) All construction documents that are submitted to the SFM shall comply with the plans submittal information provided by the SFM on their respective website and shall be submitted with the applicant's certificate of fitness number, permit application and permit number or building official unique identifier and shall comply with the approval process provided in 10.25.5.16 NMAC and with the CID regulation on permits, CID rule 14.5.2 NMAC.
- H. Section 107 Fees.** This section of the IFC shall not apply.
- I. Section 108.2.2 Approval Required.** Change the last sentence to read, "Any portions that do not comply shall be corrected and such portion shall not be covered or concealed prior to inspection as required by the fire code official."
- J. Section 111 Means of Appeals.** This section is deleted in its entirety and replaced with the following language: The appeal processes provided in Sections 59A-52-21 and 59A-52-22 NMSA 1978 shall apply and may be initiated by filing an appeal as provided in 10.25.1 NMAC.
- K. Section 112 Violations.** The penalties listed in section 109.4 of the IFC shall not apply in New Mexico. The penalties authorized in Sections 59A-52-24 and 59A-52-25 NMSA 1978 shall apply.
- L. Section 113 Stop work order.** The penalties listed in section 111.4 of the IFC shall not apply. The penalties authorized in Sections 59A-52-24 and 59A-52-25 NMSA 1978 shall apply.
[10.25.5.9 NMAC - Rp, 10.25.5.9 NMAC, 11/26/2019; A, 11/01/2022]

10.25.5.10 CHAPTER 2 DEFINITIONS:

A. Definitions defined by the SFM or the NMFC shall apply specifically to the enforcement and requirements of 10.25.5 NMAC. Terms not defined in this rule but defined in the New Mexico Building Code, CID rule 14.7.2 NMAC, the New Mexico Residential Building Code, CID rule 14.7.3 NMAC, the New Mexico Existing Building Code, CID rule 14.7.7 NMAC, the New Mexico Mechanical Code, CID rule 14.9.2 NMAC, the New Mexico Plumbing Code, CID rule 14.8.2 NMAC, the New Mexico Electrical Code, CID rule 14.10.4

NMAC, or the National Fire Protection Association's (NFPA) NFPA 54 shall have the meanings as ascribed in those codes.

B. Section 202 General Definitions. The definition of "record drawings" is deleted in its entirety and replaced with the following language: "record drawings" means submittals and amended submittals that document the location of all appurtenances of fire protection systems to include any corrections incurred during final acceptance.

[10.25.5.10 NMAC - Rp, 10.25.5.10 NMAC, 11/26/2019]

10.25.5.11 CHAPTER 3 GENERAL REQUIREMENTS:

- A. Section 301.1 Scope.** This section applies as mandated by the local AHJ.
- B. Section 301.2 Permits.** This Section shall apply to the extent mandated by the local AHJ.
- C. Section 304.1.2 Vegetation.** This section applies to the extent mandated by the local AHJ.
- D. Section 307 Open burning, recreational fires and portable outdoor fireplaces.** This section of the IFC applies only and to the extent mandated by the local AHJ.
- E. Section 308.1.6.3 Sky lanterns.** Add "unless approved by the local AHJ" at the end of section.
- F. Section 308.3 Group A Occupancies Exception #2.** Delete the word "international" and replace with the word "New Mexico".

G. Section 319.2 Permit required. This section applies as mandated by the local AHJ.
[10.25.5.11 NMAC - Rp, 10.25.5.11 NMAC, 11/26/2019; A, 11/01/2022]

10.25.5.12 CHAPTER 4 EMERGENCY PLANNING AND PREPAREDNESS:

- A. Section 405.3 Frequency.** Add Exception: "E" occupancies shall comply with PED rule 6.29.1.8 NMAC emergency drills and practiced evacuations.
- B. Section 405.6 Record keeping.** Item number 7 is deleted and replaced with the following language: "Problems encountered and corrective actions for the problems encountered."

[10.25.5.12 NMAC - Rp, 10.25.5.12 NMAC, 11/26/2019; A, 11/01/2022]

10.25.5.13 CHAPTER 6 BUILDING SERVICES AND SYSTEMS: Amend section 605.9 to add "if required by the fire code official" at the end of the section.

[10.25.5.13 NMAC - Rp, 10.25.5.13 NMAC, 11/26/2019; A, 11/01/2022]

10.25.5.14 CHAPTER 9 FIRE PROTECTION SYSTEMS: Throughout chapter 9, the following shall apply:

- A.** Delete the term "International Mechanical Code" where used in this chapter and replace with the term "New Mexico Mechanical Code".
- B.** Delete the term "International Plumbing Code" where used in this chapter and replace with the term "New Mexico Plumbing Code".
- C. Section 904.12 Commercial cooking systems.** The replacement of commercial cooking equipment, including but not limited to a stove, hood, deep fryer, grill, griddle, or any other device used in the cooking process, shall comply with this Section and with the Uniform Mechanical Code as adopted by reference in CID rule 14.9.2.13 NMAC.

D. Section 905.3.4.1 Hose and Cabinet. Insert the following sentence at the end of this section, "Unless required by a fire code official, one and one-half inch hoses and hose cabinets are not required for class II and class III standpipe systems.

E. Section 903.3.8.5 Calculations. Add "A 10 psi safety factor shall be added to all hydraulic calculations as mandated by the AHJ".

[10.25.5.14 NMAC - Rp, 10.25.5.13 NMAC, 11/26/2019; A, 11/01/2022]

10.25.5.15 CHAPTER 10 MEANS OF EGRESS: See Section 10 of the NMBC, CID rule 14.7.2 NMAC, and IFC section 1032, Maintenance of the Means of Egress.

[10.25.5.15 NMAC - Rp, 10.25.5.14 NMAC, 11/26/2019; A, 11/01/2022]

10.25.5.16 CHAPTER 56 EXPLOSIVES AND FIREWORKS: This chapter of the IFC and 10.25.6 NMAC apply to fireworks. If there is any conflict between this chapter of the IFC and the Fireworks Licensing and Safety Act, Sections 60-2C-1 through 60-2C-11 NMSA 1978, the Fireworks Licensing and Safety Act shall control.

[10.25.5.16 NMAC - Rp, 10.25.5.16 NMAC, 11/26/2019]

10.25.5.17 REPEAL OF CODES: NFPA 1 and NFPA 101 are repealed except as provided in 10.25.5.19 NMAC.

[10.25.5.17 NMAC - Rp, 10.25.5.16 NMAC, 11/26/2019]

10.25.5.18 APPROVAL OF FIRE PROTECTION SYSTEMS: Prior to beginning construction or occupancy of any building or structure regulated by the currently adopted New Mexico Building Codes and the NMFC, the contractor shall apply for a permit and submit drawings for plan review by the AHJ and approval of the fire protection system from the SFM or FM, as appropriate, of [a] all fire protection system for the building or structure. The review and approval of fire protection systems is in addition to all review required by CID pursuant to Title 14 of the New Mexico administrative code.

A. Filing drawings with the SFM for review.

(1) **Documents required.** The contractor shall submit one set of drawings for the building or structure. Submittals shall be in accordance with "Plans Submittal Information" obtained via the SFM website and this rule. For convenience, a contractor may submit additional sets of drawings and an envelope with prepaid postage directly to the SFM for the SFM's use in returning the drawings after review. Electronic filing of fire protection plans will be accepted via electronic plans review software that is compatible with software used by the SFM.

(2) **Where to submit.** The contractor shall submit drawings of the fire protection system to the fire code enforcement bureau of the SFM in compliance with 10.25.1 NMAC or to an AHJ as required by the AHJ. The SFM shall not accept drawings by facsimile transmission.

(3) **Requirements for drawings.** The drawings shall clearly indicate fire protection systems in sufficient detail to establish compliance with applicable codes and standards, and shall include the signature and seal of the licensed professional engineer in accordance with the New Mexico Engineering and Surveying Practice Act (found at Chapter 61, Article 23 NMSA 1978) that prepared the drawings. Drawings submitted shall comply with plans submittal information provided by the SFM on its website.

(4) **Fees.** The SFM does not require any fees for review of fire protection systems.

B. Third party review. The FM or FM, as appropriate, in their sole discretion, may require third party review of drawings if specialized expertise or knowledge is needed, and shall so notify the contractor in writing with a cost estimate if so determined. If the contractor agrees to proceed with review, the contractor shall file written approval by the method provided in 10.25.1.8 NMAC and shall pay directly to the third party the cost of such review before the SFM or FM, as appropriate, returns the drawings.

C. Return of drawings. If the SFM or FM, as appropriate, approves the drawings, the drawings shall be stamped "approved", with the SFM or FM, as appropriate, retaining one complete set of drawings or submittals. If the SFM or FM, as appropriate, rejects the drawings or submittals or does not approve the drawings, an explanation for the basis for rejection or non approval shall be given to the contractor. The contractor shall pick up approved drawings if prior arrangements have not been agreed to for return by mail.

D. Rejection. The SFM or FM, as appropriate, may reject fire protection system drawings for the following reasons:

- (1) the drawings are incomplete;
- (2) the drawings indicate a violation of these rules or applicable codes and standards;
- (3) the submitted drawings are not in accordance with Title 16, Chapter 39 NMAC;
- (4) no certificate of fitness is on file with the SFM;
- (5) the drawings or submittals contain a misrepresentation or inaccuracy;
- (6) third party review of the drawings or submittals reveals a violation of these rules, applicable codes or standards;
- (7) all SFM or FM requirements have not been included in the submittals; or
- (8) any other valid reason as determined by the SFM.

E. Re-submission. If drawings are rejected, the contractor may correct the deficiencies noted in the rejection letter. New submittals shall be submitted by the same process for filing original drawings for review.

F. Construction.

(1) Construction may commence upon approval of plans and issuance of the proper permits.

(2) After installation of the fire protection system has been completed, a request for inspection shall be made to the FM. The request may be made orally or in writing to the FM or as otherwise required by the SFM.

G. Inspection and testing. The SFM or FM, as appropriate, will inspect the fire protection system of a building or structure within a reasonable period of time after a request for inspection. The SFM or FM, as appropriate, shall notify the AHJ of approval or rejection of drawings or of the fire protection system, and, if applicable, the AHJ may request a letter indicating the system is in compliance with approved plans and applicable codes and standards. The SFM or FM, as appropriate, shall not approve the installation if the inspection indicates:

- (1) a violation of this rule or applicable codes and standards;
- (2) the fire protection system was not installed in compliance with the drawings;
- (3) the fire protection system was not installed by a licensed entity and certified journeyman;
- (4) no valid certificate of fitness is on file with the SFM;
- (5) the final acceptance testing of each fire protection system is not recorded as complete; or
- (6) any other valid reason as determined by the SFM.

H. Re-inspection. If the FM does not approve the installation of the fire protection system and the responsible party corrects the deficiencies noted in the inspection, the responsible party may re-apply for inspection following the same procedure as for the initial inspection.

[10.25.5.18 NMAC - Rp, 10.25.5.18 NMAC, 11/26/2019; A, 11/01/2022]

10.25.5.19 CODE REQUIREMENTS FOR EXISTING BUILDINGS AND STRUCTURES: For purposes of this section, "constructed" shall mean that the contractor has begun any substantial portion in the design, permitting or building of a building or structure. A change in occupancy requires approval from the appropriate building code official. All new construction, alteration, repair, and additions require adherence to applicable building codes and laws.

A. Existing buildings and structures.

(1) Upon an inspection being conducted by the FM, an owner or contractor is not required to renovate or adapt an existing building or structure to comply with the currently adopted NMFC but shall comply with the requirements in place when the existing building or structure was constructed. See IFC, Section 104.

(2) Following the adoption of this provision, an existing structure or part of a structure that changes its occupancy classification, however done, must comply with the currently-adopted NMFC.

(3) Following the adoption of this provision, an existing fire protection system that is replaced, repaired, or altered by the FM, whose classification has not changed, shall comply with the currently-adopted NMFC. The system shall comply with the currently adopted New Mexico Existing Building Code.

(4) Fire protection systems constructed prior to November 15, 2007, which fall under NFPA 1, 1997 edition, and NFPA 101, 1997 edition, shall be required to have a permit using the requirements of the currently-adopted NMFC, section 105, for the installation of any new, altered, remodeled, repaired or partial fire protection system.

(5) Fire protection systems plans which were initially submitted to the AHJ for review under the currently adopted NMFC as per the requirements for new construction under Subsection B of 10.25.2.19 NMAC will be inspected per the currently adopted NMFC.

B. New construction. Any new building, new alteration, new addition, or new structure after the effective date of the adoption of the currently adopted NMFC shall comply with the currently adopted NMFC.

C. Variance. The SFM may grant a variance from any of the requirements of this subsection if the applicant demonstrates to the SFM's satisfaction that the variance sought does not degrade the overall

protection of individuals from fire and similar emergencies.

D. Hazard to life or property. Notwithstanding any other provision of these rules, if the FM or AHJ determines that a nonconforming facility constitutes an immediate hazard to life or property, the FM or AHJ shall so notify the contractor or owner of the facility in writing, and shall permit the contractor a reasonable period of time to comply with current rules. If the contractor does not comply with the notification and its requirements within the time specified, the FM or AHJ may order the owner or contractor to take the facility out of service.

[10.25.5.19 NMAC - Rp, 10.25.5.19 NMAC, 11/26/2019; A, 11/01/2022]

10.25.5.20 CHAPTER 23 MOTOR FUEL-DISPENSING FACILITIES AND REPAIR GARAGES:

Section 2311.2.3 applies as mandated by the local AHJ.

[10.25.5.20 NMAC – N, 11/01/2022]

HISTORY OF 10.25.5 NMAC:

Pre-NMAC History: none.

History of Repealed Material:

10 NMAC 25.5, Fire Prevention (filed 05/09/1997) repealed 11/15/2007.

10.25.5 NMAC, Fire Prevention and Public Occupancy (filed 11/1/2007) repealed, effective 6/28/2019.

10.25.5 NMAC, Fire Prevention and Public Occupancy (filed 1/28/2019) repealed, effective 11/26/2019.

NMAC History:

10 NMAC 25.6, Safe Handling and Sale of Fireworks, effective 6/9/1997.

10 NMAC 25.5, Fire Prevention (filed 05/09/1997) was replaced by 10.25.5 NMAC, Fire Prevention and Public Occupancy, effective 11/15/2007.

10.25.5 NMAC, Fire Prevention and Public Occupancy (filed 11/1/2007) was replaced by 10.25.5 NMAC, Fire Prevention and Public Occupancy, effective 6/28/2019.

10.25.5 NMAC, Fire Prevention and Public Occupancy (filed 6/28/2019), as emergency, was replaced by 10.25.5 NMAC, Fire Prevention and Public Occupancy, effective 11/26/2019.

New Mexico Register / Volume XXXIV, Issue 11 / June 13, 2023

TITLE 14 HOUSING AND CONSTRUCTION
CHAPTER 7 BUILDING CODES GENERAL
PART 2 2021 NEW MEXICO COMMERCIAL BUILDING CODE

14.7.2.1 ISSUING AGENCY: Construction Industries Division (CID) of the Regulation and Licensing Department.
 [14.7.2.1 NMAC - Rp, 14.7.2.1 NMAC, 7/14/2023]

14.7.2.2 SCOPE: This rule applies to the construction, alteration, relocation, enlargement, replacement, repair, equipment, use and occupancy, location, removal and demolition of every building or structure or any appurtenances connected or attached to such building or structure performed in New Mexico on or after July, 14, 2023, that is subject to the jurisdiction of CID, unless performed pursuant to a permit for which an application was received by CID before that date.

A. Exception 1. Detached one and two-family dwellings and multiple single-family dwellings (town houses) not more than three stories high with separate means of egress, and their accessory structures shall comply with the 14.7.3 NMAC, currently adopted New Mexico Residential Building Code (NMRBC).

B. Exception 2. Existing buildings, not subject to the NMRBC, undergoing a change of occupancy, repair, alterations or additions shall comply with either 14.7.2 NMAC, currently adopted New Mexico Commercial Building Code, or 14.7.7 NMAC, currently adopted New Mexico Existing Building Code, as applicable.
 [14.7.2.2 NMAC - Rp, 14.7.2.2 NMAC, 7/14/2023]

14.7.2.3 STATUTORY AUTHORITY: Sections 60-13-9, 60-13-10.3 and 60-13-44 NMSA 1978.
 [14.7.2.3 NMAC - Rp, 14.7.2.3 NMAC, 7/14/2023]

14.7.2.4 DURATION: Permanent.
 [14.7.2.4 NMAC - Rp, 14.7.2.4 NMAC, 7/14/2023]

14.7.2.5 EFFECTIVE DATE: July, 14, 2023, unless a later date is cited at the end of a section.
 [14.7.2.5 NMAC - Rp, 14.7.2.5 NMAC, 7/14/2023]

14.7.2.6 OBJECTIVE: The purpose of this rule is to establish minimum standards for the general construction of commercial buildings in New Mexico.
 [14.7.2.6 NMAC - Rp, 14.7.2.6 NMAC, 7/14/2023]

14.7.2.7 DEFINITIONS: See 14.5.1 NMAC, General Provisions and Chapter 2 of the 2021 International Building Code (IBC) as amended in 14.7.2.10 NMAC.
 [14.7.2.7 NMAC - Rp, 14.7.2.7 NMAC, 7/14/2023]

14.7.2.8 ADOPTION OF THE 2021 INTERNATIONAL BUILDING CODE:

A. This rule adopts by reference the 2021 International Building Code, as amended by this rule.

B. In this rule, each provision is numbered to correspond with the numbering of the 2021 International Building Code.

C. This rule is to be applied in conjunction with 14.7.9 NMAC, the current adopted New Mexico Commercial Energy Conservation Code.

[14.7.2.8 NMAC - Rp, 14.7.2.8 NMAC, 7/14/2023]

14.7.2.9 CHAPTER 1 - ADMINISTRATION:

A. Section 101 - Scope and General Requirements.

(1) Section 101.1 - Title. Delete this section of the IBC and substitute: This code shall be known as the 2021 New Mexico Commercial Building Code (NMCBC).

- Scope.
- herein:
- NMAC, Objective.
- (2) **Section 101.2 - Scope.** Delete this section of the IBC and see 14.7.2.2 NMAC,
 - (3) **Section 101.2.1 - Appendices.** This rule adopts the following appendices as amended
 - (a) **Appendix C** - Group U - Agricultural Buildings
 - (b) **Appendix E** - Supplementary Accessibility Requirements
 - (c) **Appendix G** - Flood-Resistant Construction
 - (d) **Appendix H** - Signs
 - (e) **Appendix I** - Patio Covers
 - (f) **Appendix J** - Grading
 - (4) **Section 101.3 – Purpose.** Delete this section of the IBC and see section 14.7.2.6
 - (5) **Section 101.4 - Referenced codes.** The codes referenced in the NMCBC are:
 - (a) **Section 101.4.1 - Gas.** Delete this section of the IBC and substitute: the currently adopted New Mexico Mechanical Code (NMMC) applies to “gas fittings” as that term is defined in CILA Section 60-13-32. All references in the IBC to the International Fuel Gas Code are deemed references to the NMMC or the LPG standards, 19.15.40 NMAC and Section 70-5-1 et seq. NMSA 1978, collectively. Gas piping systems and appliances for use with liquefied propane gas (LPG), or compressed natural gas (CNG), shall be governed by the LPG standards.
 - (b) **Section 101.4.2 - Mechanical.** Delete this section of the IBC and substitute: The currently adopted NMMC applies to the installation, repair and replacement of mechanical systems including piping systems, equipment, appliances, fixtures, fittings, and appurtenances including ventilating, heating, cooling, air conditioning and refrigeration systems, incinerators, and other energy related systems. All references in the IBC to the International Mechanical Code are deemed references to the NMMC.
 - (c) **Section 101.4.3 - Plumbing.** Delete this section of the IBC and substitute: the currently adopted New Mexico Plumbing Code (NMPD) applies to the installation, alterations, repairs, and replacement of plumbing systems, including piping systems, equipment, appliances, fixtures, fittings and appurtenances, and where connected to a water or sewage system and all aspects of a medical gas system. All references in the IBC to the International Plumbing Code are deemed references to the NMPD.
 - (d) **Section 101.4.4 - Property maintenance.** Delete this section of the IBC.
 - (e) **Section 101.4.5 - Fire prevention.** Delete this section of the IBC.
 - (f) **Section 101.4.6 - Energy.** Delete this section of the IBC and substitute: the provisions of the current adopted New Mexico commercial energy conservation code (NMCECC) shall apply to the energy conservation aspects of general commercial construction.
 - B. Section 102 - Applicability.** See this section of the IBC except as provided below.
 - (1) **Section 102.1 - General.** Delete this section of the IBC and see 14.5.1 NMAC,
 - (2) **Section 102.2 - Other laws.** Delete this section of the IBC and see 14.5.1 NMAC,
 - (3) **Section 102.3 - Application of references.** Delete this section of the IBC and see 14.5.1 NMAC, General Provisions.
 - (4) **Section 102.4 - Referenced codes and standards.** Delete this section of the IBC and see 14.5.1 NMAC, General Provisions.
 - (5) **Section 102.5 - Partial invalidity.** Delete this section of the IBC and see 14.5.1 NMAC, General Provisions.
 - (6) **Section 102.6 - Existing structures.** Delete this section of the IBC and substitute: the legal occupancy of any structure existing on the effective date of this rule shall be authorized to continue without change, except as specifically provided in this rule, in the current adopted New Mexico Existing Building Code, or by the building official in consideration of the general safety and welfare of the occupants of any such building and the general public.
 - C. Section 103 - Code Compliance Agency.** Delete this section of the IBC.
 - D. Section 104 - Duties and Powers of Building Official.** Delete this section of the IBC and see 14.5.1 NMAC, General Provisions.
 - E. Section 105 - Permits.** Delete this section of the IBC and see 14.5.2 NMAC, Permits.

- F. Section 106 - Floor and Roof Design Loads.** See this section of the IBC.
- G. Section 107 - Construction Documents.** Delete this section of the IBC and see 14.5.2 NMAC, Permits.
- H. Section 108 - Temporary Structures and Uses.** Delete this section of the IBC and see 14.5.2 NMAC, Permits.
- I. Section 109 - Fees.** Delete this section of the IBC and see 14.5.5 NMAC, Fees.
- J. Section 110 - Inspections.** Delete this section of the IBC and see 14.5.3 NMAC, Inspections or 14.5.2 NMAC, Permits.
- K. Section 111 - Certificate of Occupancy.** Delete this section of the IBC and see 14.5.3 NMAC, Permits.
- L. Section 112 - Service Utilities.** Delete this section of the IBC and see 14.5.2 NMAC, Permits.
- M. Section 113 - Means of Appeals.** Delete this section of the IBC and see 14.5.1 NMAC, General Provisions.
- N. Section 114 - Violations.** Delete this section of the IBC and see 14.5.3 NMAC, Inspections.
- O. Section 115 - Stop Work Order.** Delete this section of the IBC and see 14.5.3 NMAC, Inspections.
- P. Section 116 - Unsafe Structures and Equipment.** Delete this section of the IBC and see 14.5.1 NMAC, General Provisions.
[14.7.2.9 NMAC - Rp, 14.7.2.9 NMAC, 7/14/2023]

14.7.2.10 CHAPTER 2 - DEFINITIONS: See this section of the IBC except as provided below.

- A. Section 201 – General.** See this section of the IBC except as provided as provided below.
 - (1) Section 201.1 - Scope.** See this section of the IBC except add the following: If the same term is defined in the New Mexico construction codes and the IBC, it shall have the meaning given it in the New Mexico construction codes.
 - (2) Section 201.3 - Terms defined in other codes.** Delete this section of the IBC and substitute: If a term is not defined in this code and is defined in a New Mexico construction code, the term shall have the meaning given it in the New Mexico construction code.
- B. Section 202 - Definitions.** See this section of the IBC except as provided below.
 - (1) Positive roof drainage.** Delete the definition in the IBC and substitute with the following: The drainage condition in which consideration has been made for all loading deflections of the roof deck, and the additional slope has been provided to ensure drainage of the roof within 48 hours of precipitation. Drainage has occurred when no more than one-half inch of standing water remains after 48 hours of precipitation in normal drying conditions.
 - (2) Primary entrance.** Add this definition to this section of the IBC: The entrance through which most people enter the building or facility. A building or facility may have more than one primary entrance.
 - (3) Roof replacement.** Delete this definition in the IBC and substitute with the following: The process of removing the existing roof covering to the structural roof deck, repairing any substrate, and installing a new roof covering.
 - (4) Standpipe System, Classes of:** See this section of the IBC and add the following: **Exception:** 1.5-inch hoses and hose cabinets shall not be provided, unless required by the New Mexico laws applicable to fire protection for class II and class III standpipe systems.
 - (5) Unbalanced backfill height.** Add this definition to this section of the IBC: The difference in height between the exterior finish ground level and the lower of the top of the concrete footing that supports the foundation wall or the interior finish ground level. Where an interior concrete slab on grade is provided and is in contact with the interior surface of the foundation wall, the unbalanced backfill height is permitted to be measured from the exterior finish ground level to the top of the interior concrete slab.
[14.7.2.10 NMAC - Rp, 14.7.2.10 NMAC, 7/14/2023]

14.7.2.11 CHAPTER 3 - OCCUPANCY CLASSIFICATION AND USE: See this chapter of the IBC except as provided below. **Section 304 - Business Group B.** See this section of the IBC except as provided below. **Section 304.1 - Business group B.** See this section of the IBC and add the following to the list: Fire stations and police stations.

[14.7.2.11 NMAC - Rp, 14.7.2.11 NMAC, 7/14/2023]

14.7.2.12 CHAPTER 4 - SPECIAL DETAILED REQUIREMENTS BASED ON OCCUPANCY AND USE: See this chapter of the IBC with the following exception: For **Sections 404.1 through 404.11**, the definition of the term “ATRIUM”, is amended to substitute the words “floor levels” for the word “stories”.

[14.7.2.12 NMAC - Rp, 14.7.2.12 NMAC, 7/14/2023]

14.7.2.13 CHAPTER 5 - GENERAL BUILDING HEIGHTS AND AREAS: See this chapter of the IBC except as provided below. **Section 504 - Building Height and Number of Stories.** See this section of the IBC except as provided below.

A. Section 504.1 – General. See this section of the IBC except as provided below. Add the following section: **504.1.3 - Stair enclosure pressurization increase.** For Group R-1 and R-2 located in buildings of type VA construction equipped throughout with an approved automatic sprinkler system in accordance with section 903.3.1.1, the maximum number of stories permitted in section 504.4 may be increased by one provided the interior exits stairways and ramps are pressurized in accordance with section 903.6.3 and 909.20. Legally required standby power shall be provided in accordance with section 909.11 and 2702.2.17 for buildings constructed in compliance with this section and shall be connected to stairway shaft pressurization equipment, elevators and lifts used for accessible means of egress (if provided), elevator hoistway pressurization equipment (if provided) and other life safety equipment as determined by the authority having jurisdiction. For the purposes of this section, legally required standby power shall comply with 2020 NEC section 701.12, options A, B, C, D, F, or G.

B. Section 504.4 - Number of stories. Delete this section and substitute with the following: The maximum numbers of stories of a building shall not exceed the limits specified in Table 504.4.

[14.7.2.13 NMAC - Rp, 14.7.2.13 NMAC, 7/14/2023]

14.7.2.14 CHAPTER 6 - TYPES OF CONSTRUCTION: See this chapter of the IBC except as provided below. **Section 603 – Combustible Material in Types I and II Construction.** See this section of the IBC except as provided below. **Section 603.1 - Allowable materials.** Add the following exceptions to subsection 2: **Exception 28.** Stairways within individual dwelling units and stairways serving a single tenant space are permitted to be of fire-retardant wood or heavy-timber construction. In other than Group R occupancies, such stairways shall not serve as a required means of egress. **Exception 29.** Stairways complying with section 510.2, item 4 permitted to be constructed of wood above the horizontal assembly are also permitted to be constructed of wood below the horizontal assembly.

[14.7.2.14 NMAC - Rp, 14.7.2.14 NMAC, 7/14/2023]

14.7.2.15 CHAPTER 7 - FIRE AND SMOKE PROTECTION FEATURES: See this chapter of the IBC except as provided below. **Section 708.4.2 - Fireblocks and draftstops in combustible construction.** See this section of the IBC except delete Exception 2.

[14.7.2.15 NMAC - Rp, 14.7.2.15 NMAC, 7/14/2023]

14.7.2.16 CHAPTER 8 - INTERIOR FINISHES: See this chapter of the IBC.

[14.7.2.16 NMAC - Rp, 14.7.2.16, NMAC, 7/14/2023]

14.7.2.17 CHAPTER 9 - FIRE PROTECTION SYSTEMS: See this chapter of the IBC except as provided below.

A. Section 903 - Automatic Sprinkler Systems. See this section of the IBC except as provided below. **Section 903.2 - Where required.** See this section of the IBC except delete the exception.

B. Section 909 - Smoke Control Systems. See this section of the IBC except as provided below.

(1) Section 909.8 - Exhaust method. See this section of the IBC except as provided below. **Section 909.8.1 - Smoke layer.** Delete this section of the IBC and substitute with the following: The height of the lowest horizontal surface of the accumulating smoke layer shall be maintained at least six feet (1829 mm) above any walking surface which forms a portion of a required egress system within the smoke zone. The required exhaust rate for the zone shall be the largest of the calculated plume mass flow rates for the possible plume configurations. Provisions shall be made for a natural or mechanical supply of air from outside or adjacent smoke zones to make up for the air exhausted. Makeup airflow rates, when measured at the potential fire locations shall

not increase the smoke production rate beyond the capabilities of the smoke control system. The temperature of the makeup air shall be such that it does not expose temperature-sensitive fire protection systems beyond their limits.

(2) **Section 909.9 - Design fire.** Delete this section of the IBC and substitute with the following. The design fire shall be based on a rational analysis performed by a registered design professional and approved by the building official. The design fire shall be based on the analysis in accordance with Section 909.4 and this section.

[14.7.2.17 NMAC - Rp, 14.7.2.17 NMAC, 7/14/2023]

14.7.2.18 CHAPTER 10 - MEANS OF EGRESS: See this chapter of the IBC except as provided below.

A. Section 1004 - Occupant Load. See this section of the IBC except as provided below. **Table 1004.5 - Maximum floor area allowances per occupant.** See this table of the IBC and amend as follows: under the *function of space* column, in the *institutional areas* block, below sleeping areas add: "correctional facilities and detention centers: 60 square feet gross floor area per occupant".

B. Section 1010 - Doors, Gates, and Turnstiles. See this section of the IBC except as provided below.

(1) **Section 1010.1.2 - Egress door types.** See this section of the IBC except delete exception #9.

(2) **Section 1010.1.2.1 - Direction of swing.** See this section of the IBC and add the following to the end: a double-acting door shall be provided with a view panel of not less than 200 square inches (0.129 m²): double-acting doors shall not be used as exits where any of the following conditions exist:

- (a) 1. the occupant load served by the door is 100 or more,
- (b) 2. the door is part of a fire assembly,
- (c) 3. the door is part of a smoke- and draft-control assembly,
- (d) 4. panic hardware is required or provided on the door.

(3) **Section 1010.2.14 - Controlled egress doors in Groups I-1 and I-2.** See this section of the IBC and add the words "when approved by the building official" at the beginning of the section.

(4) **Section 1010.2.13 - Delayed egress.** See this section of the IBC and add the words "when approved by the building official" at the beginning of the section.

C. Section 1019 - Exit Access Stairways and Ramps. See this section of the IBC except as provided below. Add the following to the end of the section: **Section 1019.5 - Occupancies other than H and I.** In other than Group H and I occupancies, the following are required:

(1) A maximum of fifty percent of egress stairways serving one adjacent floor are not required to be enclosed, provided at least two means of egress are provided from both floors served by the unenclosed stairways. Any two such interconnected floors shall not be open to other floors. Unenclosed exit stairways shall be remotely located as required in Section 1015.2 and complies with Section 1017.1 for travel distance locations.

(2) Interior egress stairways serving only the first and second stories of a building equipped throughout with an automatic sprinkler system in accordance with Section 903.3.1.1 are not required to be enclosed, provided at least two means of egress are provided from both floors served by the unenclosed stairways. Such inter-connected stories shall not be open to other stories. Unenclosed exit stairways shall be remotely located as required in Section 1015.2 and complies with Section 1017.1 for travel distance locations.

[14.7.2.18 NMAC - Rp, 14.7.2.18 NMAC, 7/14/2023]

14.7.2.19 CHAPTER 11 - ACCESSIBILITY: See this chapter of the IBC except as provided below.

A. Section 1102 - Compliance. See this section of the IBC except as provided below. **Section 1102.1 Design.** Delete this section of the IBC except and substitute with the following: Building and facilities shall be designed and constructed to be accessible in accordance with this chapter, Appendix E - Supplementary Accessibility Requirements, and the current adopted ICC A117.1.

B. Section 1104 - Accessible Route. See this section of the IBC except as provided below.

Section 1104.4 - Multistory buildings and facilities. See this section of the IBC except as provided below.

Exception: 1. Delete the exception of this section and substitute with the following: An accessible route is not required to stories, mezzanines and occupied roofs that have an area of not more than 3,000 square feet (278.7 m²) per story and are located either above and or below the accessible levels in buildings or facilities that are less than three (3) stories. This exception shall not apply to:

- (1) **Subsection 1.1** - See this section of the IBC.
- (2) **Subsection 1.2** - See this section of the IBC.
- (3) **Subsection 1.3** - See this section of the IBC.
- (4) **Subsection 1.4** - See this section of the IBC.
- (5) **Subsection 1.5** - See this section of the IBC.

C. Section 1105 - Accessible Entrances. See this section of the IBC except as provided below.

(1) **Section 1105.1 - Public Entrances.** Delete this section of the IBC and substitute with the following: In addition to accessible entrances required by Sections 1105.1.1 through 1105.1.7, at least 60 percent of all public entrances, but not less than one primary entrance shall be accessible.

(2) **Section 1105.1.7 - Tenant spaces.** See this section of the IBC except add the following to the exceptions: **Exception 2.** Loading and service entrances that are not the only entrance to a tenant space are not required to be accessible.

D. Section 1106 - Parking and Passenger Loading Facilities. See this section of the IBC except delete table 1106.2 from the IBC and substitute with the following table:

Table 1106.2 Accessible Parking Spaces		
Total Parking Spaces	Total Required Accessible Parking Spaces	Number Required to be Van Accessible
1-25	1	1
26-35	2	1
36-50	3	1
51-100	4	1
101-300	8	2
301-500	12	2
501-800	16	3
801-1000	20	4
1,001 and over	20 spaces plus 1 space for every 100 spaces, or fraction thereof, over 1,000	1 of every 6 accessible parking spaces, or fraction thereof

E. Section 1108 - Dwelling Units and Sleeping Units. See this section of the IBC except as provided below.

(1) **Table 1108.6.1.1 - Accessible dwelling units and sleeping units.** See this table in the IBC and add the following provision after the table. For publicly funded projects, the total number of accessible dwelling units and sleeping units shall be five percent, or fraction thereof. Of these accessible dwelling units and sleeping units, one percent, or fraction thereof, shall be provided with roll-in showers.

(2) **Section 1108.6.2.2 - Apartment houses, monasteries, and convents.** Delete this section of the IBC and substitute with the following: In occupancies group R-2 containing more than 20 dwelling units or sleeping units, at least two percent, but not less than one of the units shall be a type A unit. In type A units, one in five, but not less than one of the units shall be provided with a roll-in shower including a permanently mounted folding shower seat. All Group R-2 units on a site shall be considered to determine the total number of units and the required number of type A units. Type A units shall be dispersed among the various classes of units.

F. Section 1109 - Special Occupancies. See this section of the IBC except as provided below.

(1) **Section 1109.2.5 - Designated aisle seats.** See this section of the IBC and add the following section: **Section 1109.2.5.1 - Location.** At least one of each four required designated aisle seats shall be located not more than two rows from an accessible route serving such seats.

(2) **Section 1109.4.1.4 - Employee work stations.** See this section of the IBC except delete the last sentence without substitution.

G. Section 1110 - Other Features and Facilities. See this section of the IBC except as provided below.

(1) **Section 1110.2 - Toilet and bathing facilities.** See this section of the IBC except as provided below.

(a) Insert the following sentence at the end of the first paragraph: When 20 or more fixtures of any type are installed in an *accessible* toilet room or bathing room, at least two of that type shall be accessible.

(b) Add the following language as a new paragraph: With respect to construction of any new restroom in a place of public accommodation as defined in 14.5.2 NMAC, see 14.7.2.45 NMAC, Baby Changing Facilities.

(c) Add the following to the end of the exceptions. **Exception 10:** Toilet fixtures and bathing facilities that exceed the minimum number of plumbing fixtures pursuant to the New Mexico construction codes and located in private restricted areas in other than government owned or leased facilities.

(2) **Section 1110.8 Elevators.** See this section of the IBC and add the following sentence: Limited-use or limited-application elevators may be used to access spaces or areas that have five occupants or less.

(3) **Section 1110.9 - Lifts:** Delete item 5 without substitution.

H. Section 1111 – Recreational Facilities. See this section except as provided below. **Section 1111.4.13 - Play Areas.** See this section and add the following sentence to the end of the section: Play areas containing play components designed and constructed for children shall be accessible and be located on an accessible route.

I. Section 1112 - Signage. See this section of the IBC except as provided below. **Section 1112.1 - Signs.** See this section of the IBC except as provided below. **Exception:** Delete this exception and substitute with the following: Where the total number of parking spaces provided is four or less, the following provisions are required:

(1) 1.1 Accessible parking spaces shall be identified by a sign centrally located at the head of each parking space.

(2) 1.2 Van accessible parking spaces shall have an additional sign mounted below the International Symbol of Accessibility identifying the space as “van accessible”. **Exception:** Where all the accessible parking spaces comply with the standards for van accessible parking spaces.

(3) 1.3 Accessible parking sign shall state, “Violators will be fined and/or towed”.

(4) 1.4 Accessible parking spaces shall provide pavement markings in compliance with the following sections 1.4.1 to 1.4.3.

(5) 1.4.1 Accessible parking spaces shall be identified by the International Symbol of Accessibility; a clearly visible depiction of the symbol shall be painted in blue on the pavement surface at the rear of the space; except where the total number of parking spaces provided is four or less.

(6) 1.4.2 The access aisle shall be clearly marked by diagonal, blue pavement striping.

(7) 1.4.3 At the rear of striped access aisle state “NO PARKING”. Lettering shall be one-foot-high minimum and two inches wide minimum.

[14.7.2.19 NMAC - Rp, 14.7.2.19 NMAC, 7/14/2023]

14.7.2.20 CHAPTER 12 - INTERIOR ENVIRONMENT: See this chapter of the IBC.

[14.7.2.20 NMAC - Rp, 14.7.2.20 NMAC, 7/14/2023]

14.7.2.21 CHAPTER 13 - ENERGY EFFICIENCY: Delete this chapter of the IBC and see NMAC 14.7.9, New Mexico Commercial Energy Conservation Code.

[14.7.2.21 NMAC - Rp, 14.7.2.21 NMAC, 7/14/2023]

14.7.2.22 CHAPTER 14 - EXTERIOR WALLS: See this chapter of the IBC.

[14.7.2.22 NMAC - Rp, 14.7.2.22 NMAC, 7/14/2023]

14.7.2.23 CHAPTER 15 - ROOF ASSEMBLIES AND ROOFTOP STRUCTURES: See this chapter except as provided below:

A. Section 1503 - Weather Protection. See this section of the IBC except as provided below.

(1) **Section 1503.3 - Parapet walls.** Delete this section and replace with the following: Parapet walls shall be coped or covered in accordance with Sections 1503.3.1, 1503.3.2, and 1503.3.3. The top surface of the parapet wall shall provide positive drainage.

(2) Add the following new section: **1503.3.3 - Plastered Parapets.** Plastered parapets shall require a seamless but permeable waterproof cover or weather barrier, capping the entire parapet and wrapping over each side. The cover shall extend past any break from the vertical a minimum of four inches on the wall side. On the roof side, the cover shall properly lap any rising roof felts or membranes and be properly sealed.

A layer of expanded metal lath shall be installed over the cover before plaster or stucco is applied. The lath shall extend past any break from the vertical on the wall side a minimum of five inches and on the roof side, the same distance as the cover below, allowing for plaster stops or seals. No penetrating fasteners are allowed on the horizontal surface of parapets.

B. Section 1506 - Materials. See this section of the IBC and add the following new sections.

(1) **Section 1506.4 - Loose granular fill.** Pumice and other granular fill type materials are not permitted in roofing assemblies.

(2) **Section 1506.5 - Roof deck transitions.** Where roof sheathing is overlapped to create “crickets” or valleys to canals, taperboard or equivalent shall be used to transition between the two deck levels to create a uniform substrate.

(3) **Section 1506.6 - Canales or scuppers.** All canales and scuppers must have a metal pan lining extending not less than six inches (152 mm) past the inside of the parapet and not less than six inches (152 mm) from each side of the canale or scupper opening. All canales and scuppers must have positive drainage.

C. Section 1512 - Reroofing. See this section of the IBC except as provided below. **Section 1512.3 – Roof recovering.** See this section of the IBC and add the following sentence to the end: New roof coverings shall not be installed without first removing existing roof coverings down to the structural roof deck. Where pumice or other granular fill are present, the material must be removed prior to installing new roof. [14.7.2.23 NMAC - Rp, 14.7.2.23 NMAC, 7/14/2023]

14.7.2.24 CHAPTER 16 - STRUCTURAL DESIGN: See this chapter of the IBC. [14.7.2.24 NMAC - Rp, 14.7.2.24 NMAC, 7/14/2023]

14.7.2.25 CHAPTER 17 - SPECIAL INSPECTIONS AND TESTS: See this chapter of the IBC except as provided below.

A. Section 1705.3 - Concrete Construction. See this section of the IBC except as provided below.

(1) **Subsection 2 -** Delete this section of the IBC and substitute: continuous concrete footings supporting walls of buildings three stories or less in height that are fully supported on earth or rock;

(2) **Subsection 3 -** Delete this section of the IBC and substitute: nonstructural concrete slabs supported directly on the ground, except pre-stressed slabs-on-grade;

(3) **Subsection 4 -** Delete this section of the IBC with no substitution.

B. Section 1705.4 - Masonry Construction. See this section of the IBC except delete Exception 2.

C. Section 1705.18 – Fire-resistant penetrations and joints. Delete this section of the IBC and substitute with the following: In buildings three stories or greater, in buildings to Risk Category III and IV, or in fire areas containing Group R occupancies with an occupant load greater than 200, special inspections for through-penetrations, membrane penetration firestops, fire-resistant joint systems and perimeter fire containment systems that are tested and listed in accordance with Sections 714.4.1.2, 714.5.1.2, 715.3.1 and 715.4 shall be in accordance with Section 1705.18.1 or 1705.18.2. [14.7.2.25 NMAC - Rp, 14.7.2.25 NMAC, 7/14/2023]

14.7.2.26 CHAPTER 18 - SOILS AND FOUNDATIONS: See this chapter of the IBC except as provided below. **Section 1809 - Shallow Foundations.** See this section of the IBC except as provided below.

A. Section 1809.7 - Prescriptive footings for light-frame construction. Delete this section of the IBC and substitute with the following: Where a specific design is not provided, concrete footings supporting walls of light-frame construction shall be permitted to be designed in accordance with Table 1809.7. A turndown footing cast monolithically with the slab-on-grade may be used to support walls of light-frame construction for the number of floors outlined in Table 1809.7, provided the minimum width of the turndown footing is 12 inches and the depth meets the requirements of Sections 1809.4 and 1809.5.

B. Table 1809.7 - Delete this table and substitute with the following table:

TABLE 1809.7 PRESCRIPTIVE FOOTINGS SUPPORTING WALLS OF LIGHT-FRAME CONSTRUCTION ^{a, b, c, d, e}		
NUMBER OF FLOORS SUPPORTED BY THE FOOTING	WIDTH OF FOOTING (inches)	THICKNESS OF FOOTING (inches)

1	16	8
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C. Table 1809.7 Footnotes. See this section of the IBC except delete footnote “g” with no substitution.

D. Section 1809.8 Plain concrete footings. Delete this section of the IBC and substitute with the following: The edge thickness of plain concrete footings supporting walls other than light-frame construction shall be not less than 8 inches (203MM) where placed on soil or rock.

[14.7.2.26 NMAC - Rp, 14.7.2.26 NMAC, 7/14/2023]

14.7.2.27 CHAPTER 19 - CONCRETE: See this chapter of the IBC except as provided below.

A. Section 1906 Footings for Light-Frame Construction. Delete this section of the IBC with no substitution.

B. Section 1907 Minimum Slab Provisions. See this section of the IBC except as provided below. **Section 1907.1 General.** Delete this section and the exception and substitute with the following: The thickness of concrete floor slabs supported directly on the ground shall be not less than 3½ inches (89mm). When required by a geotechnical investigation, design professional, building official or where moisture sensitive flooring is present, a minimum A 6-mil (0.006 inch; 0.15mm) polyethylene vapor retarder with joints lapped not less than 6 inches (152mm) shall be placed between the base course or subgrade and the concrete floor slab, or other approved equivalent methods or materials shall be used to retard vapor transmission through the floor slab.

[14.7.2.27 NMAC - Rp, 14.7.2.27 NMAC, 7/14/2023]

14.7.2.28 CHAPTER 20 - ALUMINUM: See this chapter of the IBC.

[14.7.2.28 NMAC -Rp, 14.7.2.28 NMAC, 7/14/2023]

14.7.2.29 CHAPTER 21 - MASONRY: See this chapter of the IBC except as provided below.

A. Section 2111 - Masonry Fireplaces. See this section of the IBC except as provided below. **Section 2111.5 - Seismic Anchorage.** Delete this section of the IBC and substitute with the following: Two three-sixteenth-inch by one-inch (4.8 mm by 25.4mm) straps shall be embedded a minimum of 12 inches (305 mm) into the chimney with a 180-degree bend with a six-inch (152 mm) extension around the vertical reinforcing bars in the outer face of the chimney. Each strap shall be fastened to the structural framework of the building with two one-half-inch (12.7 mm) diameter bolts per strap. Where the joists do not head into the chimney, the anchor strap shall be connected to two-inch by four-inch (51 mm by 102 mm) ties crossing a minimum of four joists. The ties shall be connected to each joist with two 16d nails. As an alternative to the two-inch by four-inch (51 mm by 102 mm) ties, each anchor strap shall be connected to the structural framework by two one-half-inch (12.7 mm) diameter bolts in an approved manner.

B. Section 2113 - Masonry Chimneys. See this section of the IBC except as provided below. **Section 2113.4 - Anchorage.** Delete this section of the IBC and substitute with the following: Two three-sixteenth-inch by one-inch (4.8 mm by 25.4mm) straps shall be embedded a minimum of 12 inches (305 mm) into the chimney with a 180 degree bend with a six-inch (152 mm) extension around the vertical reinforcing bars in the outer face of the chimney. Each strap shall be fastened to the structural framework of the building with two one-half-inch (12.7 mm) diameter bolts per strap. Where the joists do not head into the chimney, the anchor strap shall be connected to two-inch by four-inch (51 mm by 102 mm) ties crossing a minimum of four joists. The ties shall be connected to each joist with two 16d nails. As an alternative to the two-inch by four-inch (51 mm by 102 mm) ties, each anchor strap shall be connected to the structural framework by two one-half-inch (12.7 mm) diameter bolts in an approved manner.

[14.7.2.29 NMAC - Rp, 14.7.2.29 NMAC, 7/14/2023]

14.7.2.30 CHAPTER 22 - STEEL: See this chapter of the IBC.

[14.7.2.30 NMAC - Rp, 14.7.2.30 NMAC, 7/14/2023]

14.7.2.31 CHAPTER 23 - WOOD: See this chapter of the IBC except as provided below. **Section 2308 - Conventional Light-Frame Construction.** See this section of the IBC except as provided below.

A. Section 2308.4.5 - Joists supporting bearing partitions. See this section of the IBC except delete the first sentence and substitute: bearing partitions parallel to joists shall be supported on beams, girders, built-up joists of sufficient size to carry the load, walls, or other bearing partitions.

B. Section 2308.7.6 - Framing around openings. See this section of the IBC except delete the first sentence and substitute: Trimmer and header joists shall be of sufficient size to support the load. [14.7.2.31 NMAC - Rp, 14.7.2.31 NMAC, 7/14/2023]

14.7.2.32 CHAPTER 24 - GLASS AND GLAZING: See this chapter of the IBC except as provided below. **Section 2403 – General Requirements for Glass.** See this section of the IBC except as provided below.

A. Section 2403.1 - Identification. Delete the first paragraph of this section of the IBC and substitute: Each pane shall bear the manufacturer's label designating the type and thickness of the glass or glazing material. The identification shall not be omitted unless approved by the building official. The building official is authorized to require an affidavit from the glazing contractor certifying that each light is glazed in accordance with approved construction documents that comply with the provisions of this chapter. Safety glazing shall be identified in accordance with Section 2406.3.

B. Section 2403.2 - Glass supports. Delete this section of the IBC and substitute: Where one or more sides of any pane of glass is not firmly supported, or is subject to unusual load conditions, detailed construction documents, detailed shop drawings and analysis or test data assuring safe performance for the specific installation shall be submitted when required by the building official. [14.7.2.32 NMAC - Rp, 14.7.2.32 NMAC, 7/14/2023]

14.7.2.33 CHAPTER 25 - GYPSUM BOARD, GYPSUM PANEL PRODUCTS AND PLASTER: See this chapter of the IBC except as provided below.

A. Section 2510 - Lathing and Furring for Cement Plaster (Stucco). See this section of the IBC except as provided below. **Section 2510.6 - Weather - Resistant Barrier.** Delete this section and substitute with the following: Water-resistive barriers shall be installed as required in sections, 1403.2, 1405.3, and 1503.2 and, where applied over wood-based sheathing, shall comply with section 2510.6.1 or 2510.6.2.

B. Section 2512 – Exterior Plaster. See this section of the IBC except as provided below.

(1) Section 2512.1.1 - On Grade Floor Slab. Delete this section of the IBC and substitute with the following: On wood framed or steel stud construction with an on-grade concrete floor slab system, approved acrylic based exterior plaster systems and acrylic based color coats shall be applied in such a manner as to cover but not to extend below, the lath, paper, and screed. When a cement plaster stucco and cement plaster color coat is installed, and no perimeter insulation is on the exterior of a concrete or masonry foundation, the color coat shall terminate not further than six inches (153 mm) below finished grade. All excess plaster shall be removed from the site and no drip screeds shall comply with ASTM C 1063.

(2) Section 2512.1.2 - Weep Screeds. See this section of the IBC.

(3) Add the following section to the IBC. Section 2512.1.3 - Plaster to Roof

Separation. A reglet and weep screed or equivalent metal flashing shall be applied where all stucco wall surfaces terminate at a roof.

[14.7.2.33 NMAC - Rp, 14.7.2.33 NMAC, 7/14/2023]

14.7.2.34 CHAPTER 26 - PLASTIC: See this chapter of the IBC.

[14.7.2.34 NMAC - Rp, 14.7.2.34 NMAC, 7/14/2023]

14.7.2.35 CHAPTER 27 - ELECTRICAL: Delete this chapter of the IBC and see the NMEC except as provided below.

A. Section 2701 - General. See this section of the IBC except as provided below. **2701.1 - Scope.** Delete this section of the IBC and substitute: Electrical systems, including emergency and standby power systems, and electrical equipment, appliances, fixtures, fittings, and appurtenances thereto, shall be installed, altered, repaired, replaced, maintained, tested, and designed pursuant to the provisions of the NMEC.

B. Section 2702 - Emergency and Standby Power Systems. See this section of the IBC except as provided below.

(1) Section 2702.1 - General. See this section of the IBC except as provided below.

(a) Section 2702.1.1 - Stationary generators. Delete this section of the IBC.

(b) Section 2702.1.3 – Installation. Delete this section of the IBC.

(c) Section 2702.1.4 - Load transfer. Delete this section of the IBC.

(d) Section 2702.1.5 - Load duration. Delete this section of the IBC.

(e) **Section 2702.1.6 - Uninterruptable power source.** Delete this section of the IBC.

(f) **Section 2702.1.7 – Interchangeability.** Delete this section of the IBC.

(2) **Section 2702.2 - Where Required.** See this section of the IBC except as provided below. Section 2702.2.5 Exhaust Systems. Delete this section of the IBC without substitution. [14.7.2.35 NMAC - Rp, 14.7.2.35 NMAC, 7/14/2023]

14.7.2.36 CHAPTER 28 - MECHANICAL SYSTEMS: Delete this chapter of the IBC and see the NMMC. [14.7.2.36 NMAC - Rp, 14.7.2.36 NMAC, 7/14/2023]

14.7.2.37 CHAPTER 29 - PLUMBING SYSTEMS: Delete this chapter of the IBC and see the NMPC except as provided below.

A. Section 2901 - General. See this section of the IBC except as provided below.

(1) **Section 2901.1 Scope.** Delete this section of the IBC and substitute with the following: Plumbing systems, including piping systems, equipment, appliances, fixtures, fittings and appurtenances, and when connected to a water or sewage system, and all aspects of a medical gas system, shall be installed, altered, repaired, replaced, maintained, tested and designed pursuant to the provisions of the NMPC.

(2) **Section 2901.2.** All references in Chapter 29 of the IBC to the International Plumbing Code are deemed references to the NMPC.

B. Section 2902 - Minimum Plumbing Facilities. Section 2902.1 - Minimum Number of Fixtures. See this section of the IBC and add the following language to the end of the first paragraph: urinals may be substituted for up to fifty percent of the maximum number of water closets in other than A or E occupancies; in A and E occupancies, urinals may be substituted for up to sixty-seven percent of the maximum number of water closets.

(1) **Table 2902.1 - Minimum Number of Required Plumbing Facilities.** See this table in the IBC.

(2) **Section 2902.1.1 - Fixture Calculations.** See this section of the IBC. [14.7.2.37 NMAC - Rp, 14.7.2.37 NMAC, 7/14/2023]

14.7.2.38 CHAPTER 30 - ELEVATORS AND CONVEYING SYSTEMS: See this chapter of the IBC. [14.7.2.38 NMAC - Rp, 14.7.2.38 NMAC, 7/14/2023]

14.7.2.39 CHAPTER 31 - SPECIAL CONSTRUCTION: See this chapter of the IBC. [14.7.2.39 NMAC - Rp, 14.7.2.39 NMAC, 7/14/2023]

14.7.2.40 CHAPTER 32 - ENCROACHMENTS INTO THE PUBLIC RIGHT-OF-WAY: See this chapter of the IBC. [14.7.2.40 NMAC - Rp, 14.7.2.40 NMAC, 7/14/2023]

14.7.2.41 CHAPTER 33 - SAFEGUARDS DURING CONSTRUCTION: See this chapter of the IBC. [14.7.2.41 NMAC - Rp, 14.7.2.41 NMAC, 7/14/2023]

14.7.2.42 CHAPTER 34 - EXISTING STRUCTURES: Delete this chapter of the IBC and see 14.7.7 NMAC. [14.7.2.42 NMAC - Rp, 14.7.2.42 NMAC, 7/14/2023]

14.7.2.43 CHAPTER 35 - REFERENCED STANDARDS: See this chapter of the IBC. [14.7.2.43 NMAC - Rp, 14.7.2.43 NMAC, 7/14/2021]

14.7.2.44 APPENDIX E - SUPPLEMENTARY ACCESSIBILITY REQUIREMENTS: See the appendix of the IBC except as provided below.

A. E102 - Definitions. See this section of the IBC and add the following definition: **Children's use** – Children's use are spaces and elements specifically designed for use primarily by occupants 12 years old and

younger.

B. E105 - Other Features and Facilities. See this section of the IBC except delete Subsection E105.1.

C. E107 - Signage. See this section of the IBC except delete Subsection E107.1.

D. E111 - Children's Accessible Elements. Add children's accessibility table as shown below.

TABLE E111 CHILDREN'S ACCESSIBLE ELEMENTS TABLE This is provided as a comprehensive reference guide to children's standards within NMBC-2021 and ANSI A117.1-2017				
Element	Children's Requirements			
Children's use definition	ANSI-2017Section 106. Children's use: Spaces and elements specifically designed for use primarily by people 12 years old and younger.			
Scoping	E112 - Children's Standards. The technical requirements in the main body of the 2021 International Building Code are based on adult dimensions and anthropometrics. This section contains technical requirements based on children's dimensions and anthropometrics in addition to those in ICC ANSI – 2017 and 2010 ADA			
Scoping	E112.1. The predominant use of an element (rather than a building or facility) shall guide the determination of whether to use specifications for adults or children for that element. If children are the primary users of the element, children's specifications shall be applied.			
Scoping	E112.2 - Children's Accessible Elements. When children are the primary users of a building or facility (such as day care centers, schools, children's areas of libraries, etc.), the accessibility standards shall correspond to the children's provisions of this section.			
Element	Details	Ages 3 and 4 Pre-K	Ages 5 through 8 K through 2nd grade	Ages 9 through 12 3rd through 6th grade
Forward or Side Reach Range <i>See 2010 ADA Advisory 308.1 and modify as shown to right</i>	High maximum	36 in (915 mm)	40 in (1015 mm)	44 in (1120 mm)
	Low minimum	20 in (510 mm)	18 in (455 mm)	16 in (405 mm)
Ramps <i>See ANSI 2017 and modify as shown to right</i>	Slope	1 :16	1 :16	1 :16
	Clear Width between handrails for single wheelchair	44" min (118 mm)	44" min (118 mm)	44" min (118 mm)
	Clear Width between handrails for two wheelchairs	88" min. (2236 mm)	88" min. (2236 mm)	88" min. (2236 mm)
	Rise for any ramp run	20 inches maximum.	20 inches maximum.	20 inches maximum.
	Handrails <i>See ANSI-505</i>	"34" – "38" 865 mm – 965 mm)	"34" – "38" 865 mm – 965 mm)	"34" – "38" 865 mm – 965 mm)
Element	Details	Ages 3 and 4 Pre-K	Ages 5 through 8 K through 2nd grade	Ages 9 through 12 3rd through 6th grade

Drinking fountains and water coolers <i>See ANSI - 2017 and modify as shown to right. See IBC-2021 section 1110.5 Exception 2</i>	Spout outlet height for children's wheelchair access. <i>See ANSI 602.2.1 Exception</i>	30 in. - 43 in. (760 mm – 1090 mm)	30" max. (760 mm)	30" max. (760 mm)
	Spout outlet for standing occupant. <i>See ANSI 602.3.2 Exception</i>	30 in. 43 in. (760 mm – 1090 mm)	Same	Same
Water closets for Toilet Rooms, Wheelchair Stalls, and Ambulatory Stalls <i>See ANSI-2017 604.11 and 604.1 See IBC-2021 section 1110.2 Exception 9</i>	Centerline <i>See ANSI 604.11.2</i>	12" max. (305 mm)	12"-15" (305-380 mm)	15"-18" (380-455 mm)
	Clearance <i>See ANSI 604.11.3 and 604.3</i>	60" (1525 mm) wide by 56" (1420 mm) min. deep	60" (1525 mm) wide by 56" (1420 mm) min. deep	60" (1525 mm) wide by 56" (1420 mm) min. deep
	Toilet seat height <i>See ANSI 604.11.4</i>	11"-12" (280-305 mm)	12"-15" (305-380 mm)	15"-17" (380-430 mm)
	Horizontal grab bar height to centerline <i>See ANSI 604.11.5, 604.5 and 609.4.2</i>	18"-20" (455-510 mm)	20"-25" (510-635 mm)	25"-27" (635-685 mm)
	Rear grab bar may be split or shifted. <i>ANSI 604.5.2 Exception 2 and 609.4.2</i>	18"-20" (455-510 mm)	20"-25" (510-635 mm)	25"-27" (635-685 mm)
	Vertical grab bar 18" (455mm) long <i>See ANSI 604.11.5, 604.5.1, and 609.4.2</i>	Vertical grab bar bottom is 21" (533 mm) min. - 30" (760 mm) max. above the floor	Vertical grab bar bottom is 21" (533 mm) min. - 30" (760 mm) max. above the floor	Vertical grab bar bottom is 21" (533 mm) min. - 30" (760 mm) max. above the floor
		Centerline is 34 inches (865 mm) max. - 36" (915 mm) max. from the rear wall	Centerline is 34 inches (865 mm) max. - 36" (915 mm) max. from the rear wall	Centerline is 34 inches (865 mm) max. - 36" (915 mm) max. from the rear wall
	Flush control <i>See ANSI 604.11.6</i>	36" Max. high (915mm)	36" max. high (915 mm)	36" max. high (915 mm)
Dispensers <i>See ANSI-2017 section 604.11.7</i>	See this entire NEW section	Same	Same	Same
Element	Details	Ages 3 and 4 Pre-K	Ages 5 through 8 K through 2nd grade	Ages 9 through 12 3rd through 6th grade
Family or Assisted-Use Toilet Rooms	Family or assisted-use toilet rooms	Same	Same	Same

IBC-2021 section 1110.2.1.2 Exceptions	shall include only one water closet. and only one lavatory. A family or assisted-use bathing room in accordance with section 1110.2.1.3 shall be considered a family or assisted-use toilet room. Exception: The following additional fixtures shall be permitted in a family or assisted use toilet room: 1. A urinal 2. A child height water closet 3. A child height lavatory.			
Wheelchair water closet compartments <i>See ANSI-2017 604.11.8 and modify as shown to right.</i>	Size <i>See ANSI 604.9.2.2</i>	60" (1525 mm) min. wide by 59" (1500 mm) deep min.	60" (1525 mm) min. wide by 59" (1500 mm) deep min.	60" (1525 mm) min. wide by 59" (1500 mm) deep min.
	Toe clearance beneath front partition and one side partition <i>See ANSI 604.9.5.2</i>	12" (305 mm) min high and extend 8" beyond the compartment side face of partition, exclusive of partition supports	Same	Same
	Toe clearance beneath front partition and one side partition. See ANSI 604.9.5.2 Exceptions 1 & 2	Exception 1. Toe clearance at front partition is not required in a wheelchair accessible compartment greater than 67 inches (1700 mm) in depth	Same	Same
		2. Toe Clearance at side partition is not required in a wheelchair accessible compartment greater than 68 inches (1725 mm) in width	Same	Same

Ambulatory water closet compartments <i>See ANSI-2017 604.11.8, 604.10 and modify as shown to right</i>	Stall Size <i>See ANSI 604.10.2</i>	60" (1525 mm) long by 35" (890 mm) wide	60" (1525 mm) long by 35" (890 mm) wide	60" (1525 mm) long by 35" (890 mm) wide
	Horizontal parallel grab bars on both sidewalls 42" (1065 mm) long <i>See ANSI 604.5.1</i>	18"-20" (455-510 mm)	Same	Same
	Vertical grab bars on both sidewalls 18" (455 mm) long <i>See ANSI 604.5.1</i>	Bottom of bar 21" (535 mm) to 30" (760 mm) above floor	Same	Same
		Centerline of bar 34" (865 mm) to 36" (915 mm) from the rear wall	Same	Same
Urinals <i>See ANSI- 2017 and modify as shown to right</i>	Top of rim	14" max. (355 mm)	14" max. (355 mm)	14" max. (355 mm)
Element	Details	Ages 3 and 4 Pre-K	Ages 5 through 8 K through 2nd grade	Ages 9 through 12 3rd through 6th grade
Lavatories and sinks <i>See ANSI - 2017 and modify as shown to right</i>	Sink rim <i>See ANSI 606.2 Exception 3 and 4</i>	22" max. (559 mm)	31" max. (797 mm)	31" max. (797 mm)
	Knee clearance height <i>See ANSI 606.2 Exception 2 and 3</i>	none required with parallel approach	24" min. (610 mm)	24" min. (610 mm)
Mirrors <i>See ANSI – 2017 section 603.3 and modify as shown to right.</i>	Full length mirror 60" (1525 mm) min. tall	Bottom of reflecting surface 12" (455 mm) max. above floor	Same	Same
	Mirrors over sinks	Bottom of reflecting surface 28" (710 mm) max. above floor	Bottom of reflecting surface 37" (940 mm) max. above floor	Bottom of reflecting surface 37" (940 mm) max. above floor
Signage, Braille <i>See ANSI – 2017 section 703.4.5 and modify as shown to right</i>	Centerline	36" (915 mm) min. 44" (1120 mm) max	Same	Same
Dining surfaces and work surfaces <i>See ANSI – 2017 section 902.5 and modify as shown to right</i>	Tops of tables and counters	26" (660 mm) min. 30" (760 mm) max.	Same	Same
Benches <i>See ANSI-2017 903.5 Exception</i>	Top of seat	11"-17" (280-430 mm)	Same	Same

<i>and modify as shown to right</i>				
Tray slides <i>See ANSI-2017 section 904.5.2 and modify as shown to right</i>	Top of tray slide	28" (710 mm) min. 30" (762 mm) max.	Same	Same
Storage <i>See ANSI-2017 section 905 and modify as shown to right</i>	Frontal approach height range	20"-36" (510-915 mm)	20"-40" (510-1015 mm)	20"-44" (510-1120 mm)
	Side approach height range	20"-36" (510-915 mm)	40" max. (1015 mm)	44" max. (1120 mm)

[14.7.2.44 NMAC - Rp, 14.7.2.44 NMAC, 7/14/2023]

14.7.2.45 BABY CHANGING FACILITIES

A. Construction of a new restroom, intended for use in a place of public accommodation, as defined in 14.5.2 NMAC, shall provide for at least one baby changing facility on each floor that has a public toilet facility and shall accommodate any person needing to utilize a baby changing facility, pursuant to Section 60-13-10.3 NMSA 1978.

B. Baby changing facilities shall be included in all required documentation including plans submitted under submittal documents pursuant to Subparagraph (b) of Paragraph (1) of Subsection A of 14.5.2 10 NMAC and shall be subject to plan review pursuant to Subsection A of 14.5.2.11 NMAC - Permits, and inspections pursuant to Subsection A of 14.5.3.8 NMAC.

C. All requirements for baby changing facilities must be complied with in order for a certificate of occupancy to be issued or a final inspection approved, whichever is appropriate.

D. Baby changing facilities shall comply with the American national standards institute (ANSI) A117.1-2017: Section 603.5 diaper changing tables; Section 305 floor space; Section 308.2.1 unobstructed access; Chapter 7 Communication Elements and Features; Chapter 9 built in furnishings and equipment; and Subsection K of 14.7.2.19 NMAC, Section 1111, signage.

[17.7.2.45 NMAC -Rp, 14.7.2.45 NMAC, 7/14/2023]

HISTORY OF 14.7.2 NMAC:

Pre-NMAC History: Material in this part was derived from that previously filed with the commission of public records - state records center and archives as:

GCB-NMBC-83-1, 1982 New Mexico Building Code, filing date, 2/15/1983

CID-GCB-NMBC-85-1, 1985 New Mexico Building Code, filing date, 11/19/1985

CID-GCB-NMBC-88-1, 1988 New Mexico Building Code, filing date, 01/20/1989

CID-GCB-NMBC-91-1, 1991 New Mexico Building Code, filing date, 05/04/1993

History of Repealed Material:

14 NMAC 7.2, New Mexico Building Code, filed 10/30/1998 (with the exception of material incorporated by reference which was also filed 10/30/1998), repealed 12/1/2000.

14.7.2 NMAC, 1997 New Mexico Building Code (filed 10/16/2000), repealed 7/1/2004.

14.7.2 NMAC, 2003 New Mexico Commercial Building Code (filed 5-27-2004) repealed 1/1/2008.

14.7.2 NMAC, 2006 New Mexico Commercial Building Code (filed 08/16/2007) repealed 1/28/2011.

14.7.2 NMAC, 2009 New Mexico Commercial Building Code (filed 12/28/2010) repealed 11/15/2016.

Other History:

CID-GCB-NMBC 91-1, 1991 New Mexico Building Code (filed 5/4/1993) was replaced by 14 NMAC 7.2, Housing and Construction, Building Codes General, 1997 New Mexico Building Code, effective 12/31/1998.

14 NMAC 7.2, Housing and Construction, Building Codes General, 1997 New Mexico Building Code (filed 10/30/1998) replaced by 14.7.2 NMAC, 1997 New Mexico Building Code, effective 12/1/2000.

Those applicable portions of 14.7.2 NMAC, 1997 New Mexico Building Code (filed 10/16/2000) and those applicable portions of 14 NMAC 7.3, 1997 Uniform Building Code (filed 10/30/1998) replaced by 14.7.2 NMAC, 2003 New Mexico Commercial Building Code, effective 7/1/2004.

14.7.2 NMAC, 2003 New Mexico Commercial Building Code (filed 5/27/2004) replaced by 14.7.2 NMAC, 2006 New Mexico Commercial Building Code, effective 1/1/2008.

14.7.2 NMAC, 2006 New Mexico Commercial Building Code (filed 08/16/2007) replaced by 14.7.2 NMAC, 2009 New Mexico Commercial Building Code, effective 1/28/2011.

14.7.2 NMAC, 2009 New Mexico Commercial Building Code (filed 12/28/2010) replaced by 14.7.2 NMAC, 2015 New Mexico Commercial Building Code, effective 11/15/2016.

14.7.2 NMAC, 2015 New Mexico Commercial Building Code (filed 11/15/2016) replaced by 14.7.2 NMAC, 2021 New Mexico Commercial Building Code, effective 7/14/2023.

TITLE 14 HOUSING AND CONSTRUCTION
CHAPTER 10 ELECTRICAL CODES
PART 4 2020 NEW MEXICO ELECTRICAL CODE

14.10.4.1 ISSUING AGENCY: The Construction Industries Division of the Regulation and Licensing Department (CID).

[14.10.4.1 NMAC - Rp, 14.10.4.1 NMAC, 3/28/2023]

14.10.4.2 SCOPE: This rule applies to all contracting work performed in New Mexico on or after March 28, 2023 that is subject to the jurisdiction of CID, unless performed pursuant to a permit for which an application was received by CID before that date.

[14.10.4.2 NMAC - Rp, 14.10.4.2 NMAC, 3/28/2023]

14.10.4.3 STATUTORY AUTHORITY: Section 60-13-9 NMSA 1978.

[14.10.4.3 NMAC - Rp, 14.10.4.3 NMAC, 3/28/2023]

14.10.4.4 DURATION: Permanent.

[14.10.4.4 NMAC - Rp, 14.10.4.4 NMAC, 3/28/2023]

14.10.4.5 EFFECTIVE DATE: March 28, 2023, unless a later date is cited at the end of a section.

[14.10.4.5 NMAC - Rp, 14.10.4.5 NMAC, 14.10.4.5 NMAC - Rp, 3/28/2023]

[From the date of publication of this rule in the New Mexico Register, until September 28, 2023, permits may be issued under either the previously adopted rule, or this rule. After September 28, 2023 permits may be issued only under this rule.]

14.10.4.6 OBJECTIVE: The purpose of this rule is to establish minimum standards for electrical wiring, as defined in CILA Section 60-13-32 NMSA 1978, in New Mexico.

[14.10.4.6 NMAC - Rp, 14.10.4.6 NMAC, 3/28/2023]

14.10.4.7 DEFINITIONS: [RESERVED]

14.10.4.8 ADOPTION OF THE 2020 NATIONAL ELECTRICAL CODE:

A. This rule adopts by reference the 2020 National Electrical Code (NEC), as amended by this rule.

B. In this rule, each provision is numbered to correspond with the numbering of the 2020 National Electrical Code.

C. This rule is to be applied in conjunction with 14.7.6 NMAC, the 2018 New Mexico Residential Energy Conservation Code and 14.7.9 NMAC, the 2018 New Mexico Commercial Energy Conservation Code.

[14.10.4.8 NMAC - Rp, 14.10.4.8 NMAC, 3/28/2023]

14.10.4.9 ADMINISTRATION AND ENFORCEMENT:

A. Inspectors. See 14.6.5 NMAC, Inspectors.

B. Disconnect orders. See CILA Section 60-13-42.

C. Stop orders. See 14.5.3 NMAC, Inspections.

D. Unsafe wiring. See 14.5.1 NMAC, General Provisions.

E. Electrical plan review. See 14.5.2 NMAC, Permits.

F. Electrical permit. See 14.5.2 NMAC, Permits.

G. Electrical inspections.

(1) Inspections required: See 14.5.3 NMAC, Inspections.

(2) Electrical customer-owned distribution system requirements. See 14.5.3

NMAC, Inspections.

[14.10.4.9 NMAC - Rp, 14.10.4.9 NMAC, 3/28/2023]

14.10.4.10 ARTICLE 90 INTRODUCTION: See this article of the NEC.
[14.10.4.10 NMAC - Rp, 14.10.4.10 NMAC, 3/28/2023]

14.10.4.11 CHAPTER 1 GENERAL:

A. Article 100 - Definitions. See this article of the NEC.
B. Article 110 - Requirements for electrical installations. See this article of the NEC except as provided below.

(1) Section 110.2 Approval. See this section of the NEC and add the following:

- (a)** product listing and labeling - electrical wiring, equipment or material approval shall be based on listing and labeling by a nationally recognized testing laboratory recognized by the federal occupational safety and health administration;
- (b)** field evaluation - electrical wiring, equipment or material that is not listed and labeled, but for which a (UL) safety standard exists may be approved upon certification by a nationally recognized testing laboratory recognized by the federal occupational safety and health administration or by a field evaluation body accredited by the international accreditation service, inc.;
- (c)** engineer certification - electrical wiring, equipment or material for which a (UL) safety standard does not exist may be approved upon certification by an electrical engineer licensed to practice in New Mexico; such a certification will not be valid unless based on a verification of the manufacturer's safety and performance test data for the product.
- (d)** engineer certification - electrical equipment assemblies that contain only nationally recognized testing laboratories (NRTL) labeled components that are not NRTL listed as an assembly may be approved upon certification by an electrical engineer licensed to practice in New Mexico; such a certification will not be valid unless based on a verification of the UL standard if applicable, NEC 110.3 and the manufacturer's safety and performance test data for the product.

(2) Section 110.21 Marking. See this section of the NEC except as provided below:
Section 110.21(A) Equipment markings. See this section of the NEC except as provided below. **Section 110.21(A)(1) General.** See this section of the NEC and add the following: all equipment used on circuits over 300 volts between conductors shall have a warning sign either on or adjacent to the equipment. Warning signs shall be made in accordance with ANSI Z535 environmental and safety signs. The language shall read:

- (a)** for voltages over 300 volts but less than 600 volts: "480 VOLTS". (Label dimensions shall be 1" x 4"); and
- (b)** for voltages over 600 volts and there are exposed parts: "DANGER - HIGH VOLTAGE - KEEP OUT".

(3) Section 110.26 Spaces about electrical equipment.

- (a) 110.26 (A) Working space.** See this section of the NEC and add the following exception: Disconnects that do not provide over-current, overload, short circuit, or ground fault protection are not required to maintain the dimensions of 110.26(A)(1), (A)(2) and (A)(3) where adequate space is not readily available and the disconnect is permanently labeled "INADEQUATE WORKING SPACE-DO NOT WORK ON WHILE ENERGIZED". The label shall be readily visible on the exterior of the disconnect.
- (b) 110.26 (A)(3) Height of working space.** See this section of the NEC and add the following exception: Exception No. 4: In underground water well pump enclosures, service equipment or panel boards that do not exceed 200 amperes, operating at 250 volts or less and only feeding equipment associated with the water well enclosure, shall be permitted in spaces where the headroom is less than six and one half feet (6 1/2 ft.) but greater than five feet (5 ft.) provided the enclosure is supplied with a removable lid, that when removed would allow a minimum of six and one half feet (6 1/2 ft.) headroom.

[14.10.4.11 NMAC - Rp, 14.10.4.11 NMAC, 3/28/2023]

14.10.4.12 CHAPTER 2 WIRING AND PROTECTION:

A. Article 210. Branch circuits. See this article of the NEC except as provided below.
(1) Section 210.8 Ground-fault circuit-interrupter protection for personnel. See this section of the NEC except as provided below. **Section 210.8 (F) Outdoor outlets.** See this section of the NEC and add the following exception: Exception No. 2 GFCI protection shall not be required for listed HVAC equipment.

(2) **Section 210.11 Branch circuits required.** See this section of the NEC except as provided below.

(a) **210.11 (A) Number of branch circuits.** See this section of the NEC and add: In dwelling units, branch circuits for 125-volt, 15- and 20- ampere general purpose lighting and receptacles outlets shall be limited to a maximum of ten (10) lighting and/or receptacle outlets per branch circuit. Single and duplex receptacle outlets are considered to be one receptacle outlet. Exception: Branch circuits serving only lighting loads may be calculated per article 220 of the NEC.

(b) **210.11 (C) Dwelling units.** See this section of the NEC except as provided below.

(i) **(1) Small appliance branch circuits.** See this section of the NEC and add: not more than four (4) 20 ampere 125 volt receptacle outlets shall be connected to these circuits. Single and duplex receptacle outlets are considered to be one receptacle outlet. Exception: small appliance circuits that supply only dining area receptacles may serve not more than six (6) receptacle outlets.

(ii) **(2) Laundry branch circuits.** Delete the text of this section of the NEC and substitute: in addition to the number of branch circuits required by other parts of this section, at least one additional 20-ampere branch circuit shall be provided to supply the laundry receptacle outlet. Such circuits shall have no other outlets.

(3) **Section 210.19 Conductors - minimum ampacity and size.** See this section of the NEC except as follows: **(A) Branch circuits not more than 1000 volts:**

(a) **General.** See this section and add: conductors for branch circuits shall be sized to prevent excessive voltage drop.

(b) **Branch circuits with more than one receptacle.** Conductors of general-purpose branch circuits supplying more than one receptacle outlet for cord-and-plug connected portable loads shall have an ampacity of not less than the rating of the branch circuit and shall be not less than 12 AWG CU or 10 AWG CU-CLAD.

(4) **Section 210.52 Dwelling unit receptacle outlets.** See this section of the NEC except as follows:

(a) **Section 210.52 (A)(2) Wall space.** See this section and add: Exception: free-standing cabinets designed to be used as an eating or drinking bar where stools or chairs are pulled up to a counter top which extends at least one (1) foot from the front of the cabinet, shall not be considered as wall space.

(b) **Section 210.52 (C)(2) Island and peninsular countertops and work surfaces.** See this section of the NEC except as follows: **Section 210.52(C)(2) subsection (a)** delete this subsection and replace with the following: Island countertop spaces. At least one (1) receptacle shall be installed at each island countertop space with a long dimension of 600 mm (24 in.) or greater and a short dimension of 300 mm (12in.) or greater.

(c) **Section 210.52 (G) Basement, garages, and accessory buildings.** See this section of the NEC and add: receptacle outlets must be installed a minimum of eighteen (18) inches above finished floor, in attached or detached garages.

(5) **Section 210.70 Lighting outlets required.** See this section of the NEC except as follows: **Section 210.70 (A)(2) Dwelling units.** See this section of the NEC and add a new subsection as follows: (d) on single family dwellings at least one wall switch, located within five (5) feet from each entrance or exit or automatic lighting control such as a motion detector shall be installed to control exterior illumination.

B. Article 215. Feeders. See this article of the NEC except as provided below: **Section 215.1. Scope.** See this section of the NEC and add: approved wiring methods for feeders: nonmetallic-sheathed cable types NM, NMC and NMS (Article 334) , and service entrance cable type SER (Article 338), shall be permitted to be used for feeders in dwelling units providing that the cables shall not pass through or under any other dwelling unit(s). Underground feeder and branch circuit cable type UF cable (Article 340) shall be permitted to be used underground for any occupancy, and indoors only in accordance with nonmetallic-sheathed cable (Article 334) providing that the cable shall not pass through or under any other dwelling unit(s).

C. Article 225. Outside branch circuits and feeders. See this article of the NEC except as follows.

(1) **Section 225.19 Clearance from buildings for conductors of not over 1000 volts, nominal.** See this section of the NEC except as follows: **Section 225.19(A) Above roofs.** See this section of the NEC but delete exception number two (2) in its entirety.

(2) **Section 225.32 Location.** Delete this section of the NEC and replace with the following: The disconnecting means shall be installed either inside or outside of the building or structure served. The disconnecting means shall be a readily accessing location and comply with one of the following: (1) Where the disconnecting means is located outside the building or structure served, the disconnecting means enclosure shall be installed within ten (10) feet from the building or structure and visible, or on the exterior wall of the building or structure served. (2) Where the disconnecting means is installed inside the building or structure served, the disconnecting means enclosure shall be located within forty-eight (48) inches from where the feeder conductor raceway enters the building or structure.

Exception No. 1 – see this section of the NEC.

Exception No. 2 – see this section of the NEC.

Exception No. 3 – see this section of the NEC.

Exception No. 4 – see this section of the NEC.

D. Article 230. Services. See this article of the NEC except as provided below.

(1) **Section 230.24 Clearances.** See this section of the NEC except as provided below:

(A) **Above roofs.** Delete exception no. 2 and exception no. 5 in their entirety.

(2) **Section 230.28. Service masts as supports.** See this section of the NEC and add: where a service mast is used for the support of service drop conductors, it shall be a minimum two inch (2") rigid metal conduit, intermediate metal conduit or must comply with local utility requirements.

(3) **Section 230.31 Size and ampacity.** See this section of the NEC except as provided below: (A) **General.** See this section of the NEC and add: where the underground service lateral is customer owned, the service lateral conductors shall be sized to prevent excessive voltage drop. The maximum voltage drop on the service lateral conductors shall not exceed five percent (5%). For the purpose of this calculation, the ampacity shall be based on the calculated demand load of the building or structure served. Customer owned includes all non-utility owned or operated service lateral conductors.

(4) **Section 230.43. Wiring methods for 1000 volts, nominal, or less.** See this section of the NEC but delete subsection (1) open wiring on insulators, and subsection (6), Electrical nonmetallic tubing (ENT).

(5) **Section 230.54 Overhead service locations.** See this section of the NEC and add a new section as follows: (H) overhead service support shall comply with the serving utility requirements or be at least six inch by six inch (6" x 6") pressure-treated timber or equivalent round poles (minimum 6" diameter crown) installed to a depth not less than four (4) feet below finish grade.

(6) **Section 230.70 Service equipment - disconnecting means.**

(a) **230.70 General. (A) Location.** See this section of the NEC and add: the disconnecting means for each occupant of a multiple occupancy building shall be grouped at a common location.

(b) **230.70 General. (A) Location. (1) Readily accessible location.** Delete the text of this section of the NEC and substitute:

(i) Service disconnects located outside the building or structure.

Where the service disconnect is located outside of the building or structure it shall be located in a readily accessible location within 48 inches of the metering equipment. Remote service disconnects that are located not more than 10 feet from the building or structure shall be considered to be located on the building or structure.

Exception: Where metering equipment is installed at the utility transformer, the disconnecting means on the outside of the building shall be installed within 48 inches from where the service conductors emerge from the earth.

(ii) Service disconnects located inside the building or structure.

Where the service disconnect is located inside of a building or structure it shall be located in a readily accessible location within 48 inches from the metering equipment or the service equipment enclosure shall be installed within 48 inches of where the service conductors penetrate the building or structure.

(7) **Section 230.72 Grouping of disconnects. (A) General.** See this section of the NEC and add: all building or structure disconnects of each service shall be grouped at one location and shall be separated by the least practical distance, within sight of each other and not to exceed an overall distance of fifty (50) feet.

E. Article 250 - Grounding and bonding. See this article of the NEC except as provided below.

(1) **Section 250.50 Grounding electrode system.** See this section of the NEC and add: on new construction, a concrete encased electrode shall be considered available and installed in compliance with NEC 250.52(A) (3). If a concrete encased electrode is not present, then at least 20 feet of 2 AWG bare copper in direct contact with the earth at a depth below the earth's surface of not less than thirty (30) inches shall be installed in a continuous trench that is at least twenty (20) feet in length, augmented with a minimum of two (2), eight (8) foot grounds rods one at each end of the 2 AWG conductor.

(2) **Section 250.52 (A) Grounding electrodes. (5) Rod and pipe electrodes.** See this section of the NEC but delete subsection (a) in its entirety.

(3) **Section 250.53 (A) (2)** See this section of the NEC and add the following exception: Exception No. 2 See this section of the NEC and add: A single grounding electrode consisting of a rod or plate may be utilized on temporary construction services rated 200 amperes or less.

(4) **Section 250.66 Size of alternating-current grounding electrode conductor. (B) Connections to concrete-encased electrodes.** See this section of the NEC and add the following to the end: The grounding electrode conductor shall not be smaller than 4 AWG copper.

(5) **Section 250.104. Bonding of piping systems and exposed structural steel. (B) Other metal piping.** See this section of the NEC and add: CSST gas piping systems shall be bonded to the electrical service grounding electrode system at the point where the gas service enters the building. The bonding jumper shall not be smaller than (6) AWG copper wire.

(6) **Section 250.106. Lightning protection systems.** See this section of the NEC and add: Where a lightning protection system is installed, the bonding of the gas piping system shall be in accordance with NFPA 780, standard for installation of lightning protection systems.

(7) **Section 250.118. Types of equipment grounding conductors.** See this section of the NEC and add the following new subsection: (15) an equipment grounding conductor shall be installed in all branch circuit and feeder raceways on or above a roof. The equipment grounding conductor shall be a wire type sized in accordance with table 250.122.

[14.10.4.12 NMAC – N, 3/28/2023]

14.10.4.13 CHAPTER 3 WIRING METHODS AND MATERIALS:

A. **Article 300. General requirements for wiring methods and materials.** See this article of the NEC except as provided below.

(1) **Section 300.6 Protection against corrosion and deterioration.** See this section of the NEC except as provided below. **Section 300.6 (A) Ferrous metal equipment.** Delete the first sentence of this section and substitute the following language: All ferrous metal raceways, cable trays, cablebus, auxiliary gutters, cable armor, boxes, cable sheathing, cabinets, metal elbows, couplings, nipples, fittings, supports, and support hardware shall be suitably protected against corrosion inside and outside (except threads at joints) by a coating of approved corrosion-resistant material.

(2) **Section 300.11 Securing and supporting.** See this section of the NEC except as provided below.

(a) **Section 300.11(A) Secured in place.** See this section of the NEC and add: independent support wires shall be limited to support of flexible wiring methods from the last means of support or junction box for connections within an accessible ceiling to luminaire(s) or equipment served.

(b) **Section 300.11 (B) (1). Fire rated assemblies.** Delete the text of this section of the NEC and substitute: the ceiling support system shall be permitted to support listed junction boxes and/or support brackets that have been tested as part of a fire-rated assembly.

(c) **Section 300.11 (B) (2). Non-fire rated assemblies.** Delete the text of the exception and substitute: the ceiling support system shall be permitted to support listed junction boxes and/or support brackets where installed in accordance with the ceiling system manufacturer's instructions.

(3) **Section 300.14 Length of free conductors at outlets, junctions, and switch points.** Delete the text of this section of the NEC and substitute: at least six (6) inches of free conductor, measured from the point in the box where it emerges from its raceway or cable sheath, shall be left at each outlet, junction, and switch point for splices or the connection of luminaire (fixtures) or devices. Where the opening of an outlet, junction, or switch point is less than eight (8) inches in any dimension, each conductor shall be long enough to extend at least six (6) inches outside of the opening.

B. Article 310. Conductors for general wiring. See this article of the NEC except as provided below. **Section 310.3 Conductors.** See this section of the NEC except as provided below. **Section 310.3 (B) Conductor material.** See this section of the NEC and add the following subsection 310.3 (B)(1) The use of aluminum current carrying conductors shall be of the AA-8000 series or equivalent and shall be limited to size 8 AWG or larger. Exception: the equipment-grounding conductor shall be limited to size 10 AWG or larger if in a listed cable assembly.

C. Article 314. Outlet, device, pull, and junction boxes; conduit bodies; fittings; and handhole enclosures. See this article of the NEC except as provided below. **Section 314.27 Outlet Boxes.** See this section of the NEC except as provided below. **Section 314.27 (C) Boxes at ceiling-suspended (paddle) fan outlets.** See this section of the NEC except add the following exception to the end of the section:

Exception No. 1 Fan boxes in habitable rooms shall not be required over islands, peninsulas, or above kitchen sinks.

D. Article 340. Underground feeder and branch circuit cable: type UF. See this article of the NEC except as provided below. **Section 340.10 Part II. Installation** See this section of the NEC except as provided below: **Section 340.10 Uses permitted.** See this section of the NEC and add the following new subsections:

(1) (7) type UF cable shall be permitted to be embedded in adobe construction;
 (2) (8) type UF cable, or an approved electrical raceway shall be installed on straw bale residential construction.

E. Article 352 Rigid polyvinyl chloride conduit : Type PVC. See this article of the NEC and add the following to section 352.10 uses permitted. (F) Exposed: PVC conduit, type schedule 40 shall not be used where the raceway is exposed and under eight (8) feet from finished floor or grade.

F. Article 394 Concealed knob and tube wiring. See this article of the NEC and add the following to section 394.12 uses not permitted: concealed knob and tube wiring shall not be permitted to be installed except by special written permission from the electrical bureau.

[14.10.4.13 NMAC – N, 3/28/2023]

14.10.4.14 CHAPTER 4 EQUIPMENT FOR GENERAL USE: Article 422 Appliances. See this article of the NEC and add the following to section 422.19. evaporative cooling units: where an evaporative cooler is installed, a listed raceway shall be installed during rough-in from the control point to the evaporative cooler location. The raceway shall contain a wire-type equipment-grounding conductor from the control point outlet box to the junction box at the unit. The equipment grounding conductor shall be sized in accordance with table 250.122.

[14.10.4.14 NMAC – N, 3/28/2023]

14.10.4.15 CHAPTER 5 SPECIAL OCCUPANCIES:

A. Article 545 Manufactured buildings and relocatable structures. See this article of the NEC except as provided below. Add the following part to the end of the article. Part III. Service and Feeders.

(1) Add the following new section: Section 545.29 For service and feeder calculations for manufactured buildings used as a relocatable structure as defined in this article, for temporary on-site offices and other temporary manufactured buildings other than dwelling units, use the table below for service and feeder calculations:

(2) Add the following new table: **Table 545.29 Service and feeder factors for relocatable structures and manufactured buildings.**

Number of temporary structures	Demand Factor
1	100
2	55
3	44
4	39
5	33
6	29

7-9	28
10-12	27
13-15	26
16-21	25
22-40	24
41-60	23
61 and over	22

B. Article 550. Mobile homes, manufactured homes and mobile home parks. See this article of the NEC except as provided below.

(1) **Section 550.32 Service equipment.** See this section of the NEC except as provided below: **Section 550.32 (A) Mobile home service equipment.** Delete the text of this section of the NEC and substitute the following: the mobile home service equipment shall be located adjacent to the mobile home and not mounted in or on the mobile home. The service equipment shall be located where visible from and not more than one hundred (100) feet from the exterior wall of the mobile home it serves. The service equipment shall be permitted to be located elsewhere on the premises, provided that a disconnecting means marked “suitable for use as service equipment” is located where visible from and not more than thirty (30) feet from the exterior wall of the mobile home it serves. Grounding at the disconnecting means shall be in accordance with 250.32.

(2) **Section 550.32 Service equipment.** See this section of the NEC and add the following new subsection. **(I) Overhead services.** Overhead service support shall comply with the serving utility requirements or be at least six inches by six inches (6” x 6”) pressure-treated timber or equivalent round poles (minimum 6” diameter crown) installed to a depth not less than four (4) feet below finish grade.

[14.10.4.15 NMAC – N, 3/28/2023]

14.10.4.16 CHAPTER 8 COMMUNICATION SYSTEMS: Article 800. Communications circuits.

See this article of the NEC and add the following to Section 800.156: Any exterior wall penetration shall be installed in a listed raceway.

[14.10.4.16 NMAC - N, 3/28/2023]

14.10.4.17 SMOKE DETECTORS: For smoke detectors, refer to the current adopted edition of the New Mexico residential building code. Smoke detectors installed in new single family dwellings shall be served by an individual branch circuit. When two or more smoke detectors are required in a dwelling unit, they shall be interconnected with a multi-conductor cable assembly. Location and power back-up requirement shall be in accordance with the current adopted edition of the New Mexico residential building code.

[14.10.4.17 NMAC - Rp, 14.10.4.12 NMAC, 3/28/2023]

14.10.4.18 ACCESSIBILITY REQUIREMENTS FOR PERSONS WITH DISABILITIES: Electrical device installation shall comply with accessibility codes adopted for New Mexico.

[14.10.4.18 NMAC - Rp, 14.10.4.13 NMAC, 3/28/2023]

14.10.4.19 NIGHT SKY PROTECTION ACT: Outdoor lighting shall comply with the Night Sky Protection Act 74-12-1 through 74-12-11 NMSA 1978.

[14.10.4.19 NMAC – Rp, 14.10.4.14 NMAC, 3/28/2023]

14.10.4.20 RESIDENTIAL ENERGY EFFICIENCY: See 14.7.6 NMAC, the 2018 New Mexico residential energy conservation code.

[14.10.4.20 NMAC - Rp, 14.10.4.15 NMAC, 3/28/2023]

14.10.4.21 COMMERCIAL ENERGY EFFICIENCY: See 14.7.9 NMAC, the 2018 New Mexico commercial energy conservation code.

[14.10.4.21 NMAC - Rp, 14.10.4.16 NMAC, 3/28/2023]

HISTORY OF 14.10.4 NMAC:

Pre-NMAC History: The material in this part was derived from that previously filed with the commission of public records, state records center and archives under:

CIC 71-1, 1971 National Electrical Code, filed 12/1/1971

CIC71-2, 1972 New Mexico Electrical Code, filed 12/1/1971

CID 78-1, 1978 New Mexico Electrical Code, filed 1/31/1978

CID EB 81-3, State of New Mexico Electrical Code Revised to July 24, 1981, Technical Provision based on the 1981 National Electrical Code and Related Codes and Standards, filed 11/24/1981

CID EB 84-1, State of New Mexico Electrical Code, filed 05/11/1984

CID NMEB 93-1, State of New Mexico Electrical Code 1993, filed 2/25/1993.

History of Repealed Material:

14 NMAC 10.4, Housing and Construction, Electrical Codes, State of New Mexico Electric Code (filed 01/15/1997), repealed 07/1/1999.

14 NMAC 10.4, Housing and Construction, Electrical Codes, State of New Mexico Electrical Code (filed 06/01/1999), repealed 12/1/2000.

14.10.4 NMAC, Housing and Construction, Electrical Codes, State of New Mexico Electrical Code (filed 10/16/2000), repealed 7/30/2002.

14.10.4 NMAC, Housing and Construction, Electrical Codes, State of New Mexico Electrical Code (filed 7/30/2002) repealed 7/1/2004.

14.10.4 NMAC, Housing and Construction, Electrical Codes, State of New Mexico Electrical Code (filed 05/27/2004) - part name later changed to 2002 State of New Mexico Electrical Code (filed 10/18/2004) both repealed 07/01/2005.

14.10.4 NMAC, Housing and Construction, Electrical Codes, 2005 New Mexico Electrical Code (filed 5/4/2005) repealed 7/1/2008.

14.10.4 NMAC, Housing and Construction, Electrical Codes, 2008 New Mexico Electrical Code (filed 1/24/2008) repealed 8/1/2011.

14.10.4 NMAC, Housing and Construction, Electrical Codes, 2008 New Mexico Electrical Code (filed 6/15/2011) repealed 11/1/2011.

14.10.4 NMAC, Housing and Construction, Electrical Codes, 2011 New Mexico Electrical Code (filed 9/27/2011) repealed 6/28/2013.

14.10.4 NMAC, Housing and Construction Electrical Codes, 2020 New Mexico Electrical Code (filed 2/16/2023)

Other History:

CID NMEB, State of New Mexico Electric Code (filed 2/25/1993) replaced by 14 NMAC 10.4, Housing and Construction, Electrical Codes, State of New Mexico Electric Code, effective 1/31/1997.

14 NMAC 10.4, Housing and Construction, Electrical Codes, State of New Mexico Electric Code (filed 1/15/1997) replaced by 14 NMAC 10.4, Housing and Construction, Electrical Codes, State of New Mexico Electrical Code, effective 7/1/1999.

14 NMAC 10.4, Housing and Construction, Electrical Codes, State of New Mexico Electrical Code (filed 06/1/1999) replaced by 14.10.4 NMAC, Housing and Construction, Electrical Codes, State of New Mexico Electrical Code, effective 12/1/2000.

14.10.4 NMAC, Housing and Construction, Electrical Codes, State of New Mexico Electrical Code (filed 10/16/2000) replaced by 14.10.4 NMAC, Housing and Construction, Electrical Codes, State of New Mexico Electrical Code, effective 7/30/2002.

14.10.4 NMAC, Housing and Construction, Electrical Codes, State of New Mexico Electrical Code (filed 07/01/2002) replaced by 14.10.4 NMAC, Housing and Construction, Electrical Codes, State of New Mexico Electrical Code, effective 7/1/2004.

14.10.4 NMAC, Housing and Construction, Electrical Codes, State of New Mexico Electrical Code (filed 05/27/2004) and part name later changed to "2002 State of New Mexico Electrical Code" (filed 10/18/2004) replaced by 14.10.4 NMAC, Housing and Construction, Electrical Codes, 2005 New Mexico Electrical Code, effective 7/1/2005.

14.10.4 NMAC, Housing and Construction, Electrical Codes, 2005 New Mexico Electrical Code (filed 5/4/2005) was replaced by 14.10.4 NMAC, Housing and Construction, Electrical Codes, 2008 New Mexico Electrical

Code, effective 7/1/2008.

14.10.4 NMAC, Housing and Construction, Electrical Codes, 2008 New Mexico Electrical Code (filed 1/24/2008) was replaced by 14.10.4 NMAC, Housing and Construction, Electrical Codes, 2008 New Mexico Electrical Code, effective 8/1/2011.

14.10.4 NMAC, Housing and Construction, Electrical Codes, 2008 New Mexico Electrical Code (filed 06/15/2011) was replaced by 14.10.4 NMAC, Housing and Construction, Electrical Codes, 2011 New Mexico Electrical Code, effective 11/1/2011.

14.10.4 NMAC, Housing and Construction, Electrical Codes, 2011 New Mexico Electrical Code (filed 09/27/2011) was replaced by 14.10.4 NMAC, Housing and Construction, Electrical Codes, 2011 New Mexico Electrical Code, effective 6/28/2013.

14.10.4 NMAC, Housing and Construction, Electrical Codes, 2011 New Mexico Electrical Code (filed 05/29/2013) amendment and part name changed to “2014 New Mexico Electrical Code”, effective 8/1/2014.

14.10.4 NMAC, Housing and Construction, Electrical Codes, 2017 New Mexico Electrical Code (filed 6/28/2013) was replaced by 14.10.4 NMAC, Housing and Construction, Electrical Codes, 2020 New Mexico Electrical Code, effective 3/28/2023.

Developments in Fluoropolymer Manufacturing Technology to Remove Intentional Use of PFAS as Polymerization Aids

Bruno Ameduri, Jaime Sales and Michael Schlipf*

Fluoropolymers are heavily impacted by the restriction proposal on per- and polyfluoroalkyl substances (PFAS) that has been recently published under the EU REACH Regulation.¹ While matching the definition of PFAS due to their chemical composition and structure, fluoropolymers are significantly different from other substances in the PFAS family. The only substantial reason for concern associated to fluoropolymers is the use of non-polymeric PFAS as polymerization aids during the manufacturing process. In the past, environmental pollution caused by PFOA and PFOS, which are prominent non-polymer substances in the PFAS family, has attracted regulatory attention. PFOS has been restricted and PFOA has been banned under the EU Regulation on Persistent Organic Pollutants. This article highlights the progress that industry has made over the last years in relation to control of PFAS emissions due to their use in fluoropolymer production. Such a progress is based on the improvement of abatement techniques, but more importantly, on the removal of PFAS polymerization aids, introducing alternative technologies that do not require using such chemicals. It is expected that most of the fluoropolymer production will be developed completely free from PFAS polymerization aids in a relatively short time frame. Thus, it appears reasonable to claim that fluoropolymers that are manufactured without the use of PFAS polymerization aids should be exempted from any regulatory initiative, and that their uses should be allowed without any unjustified restriction.

I. Introduction

The PFAS family of chemicals is currently under strong regulatory scrutiny globally. Some of the substances covered by this group are known for being highly harmful to the environment and human health, due to their persistency, bioaccumulation/mobility and other toxic effects. However, the broad definition that is frequently used to describe PFAS,

which was not originally introduced to be used for regulatory purposes², results in a very large number of substances covered jointly in this family of chemicals, more than 4,700 according to the OECD³ as being present on the global market. There have been significant efforts to group and classify the different substances that can be regarded as meeting the definition of PFAS (Figure 1). One such group is that of fluoropolymers.⁴

* Bruno Ameduri, Senior Researcher at ICGM, University of Montpellier, CNRS, ENSCM, Montpellier, France; Jaime Sales, Managing Director at Chemservice Iberia, Castellón, Spain; Michael Schlipf, Chairman of the Fluoropolymer group at pro-K industrial association for semi-finished and consumer products made of plastic, Frankfurt am Main, Germany. For Correspondence: <j.sales@chemservice-group.com>.

1 ECHA, 'Registry of restriction intentions until outcome - Per- and polyfluoroalkyl substances (PFAS)' (2023).

2 J K Anderson, R W Brecher, I T Cousins, J DeWitt, H Fiedler, K Kannan, C R Kirman, J Lipscomb, B Priestly, R Schoeny, J Seed, M

Verner, S M Hays, 'Grouping of PFAS for human health risk assessment: Findings from an independent panel of experts' (2022) Regulatory Toxicology and Pharmacology, 134.

3 OECD, 'Toward a new comprehensive global database of per- and polyfluoroalkyl substances (PFASs)' (2018) Series on Risk Management No. 39. Organisation for Economic Co-operation and Development.

4 Bruno Ameduri, 'Fluoropolymers: A special class of per- and polyfluoroalkyl substances (PFASs) essential for our daily life' (2023) Journal of Fluorine Chemistry 267, 110117.

One of the key features of fluoropolymers is that they fulfil the conditions set out by the OECD to meet the definition of Polymers of Low Concern (PLC). This has been demonstrated for the vast majority of these substances, accounting for >96% of global production.⁵ This means that fluoropolymers are not toxic, mobile or bioaccumulative. While they are persistent, the lack of degradability during normal conditions of use and at end of life makes fluoropolymers completely inert and not hazardous to human health and the environment.

Due to their intrinsic nature based on the carbon-fluorine bond, fluoropolymers offer a combination of various properties of interest that render them highly valuable products in different industrial sectors such as renewable energy, in applications such as back sheets for photovoltaic panels and lubricants in wind turbines, binders and separators for lithium-ion batteries and proton exchange membranes and frame gaskets for hydrogen production and fuel cells. Fluoropolymers are also valuable in industries such as semiconductors, food and water processing, automotive, aerospace, chemical processing, electrical, electronics, and construction. It is to be noted that the broad applications of fluoropolymers, which are virtually irreplaceable in critical industrial sectors needed by modern society is not in scope of this paper, and significant information on this can be found in literature.⁶

II. Historical Concerns Related to Manufacture of Fluoropolymers

The manufacture of fluoropolymers has been flagged by researchers as a source of environmental damage in different locations in Europe (Italy, France, the Netherlands), the USA and China.⁷ However, it needs to be stressed that this concern is not related to the fluoropolymers as individual substances, but to the use of non-polymeric PFAS that have been frequently used as polymerization aids. These Fluorinated Polymerization Aids (FPAs), also referred to as surfactants, facilitate the development and completion of the polymerization reaction. In the past, this use has led to specific situations of uncontrolled emissions of these surfactants, which are known to pose an environmental hazard.⁸

In terms of global production, fluoropolymers represent a very small share compared to the total amount of plastics, with estimated 320,000 tonnes of fluoropolymers in 2019⁹ in front of 460 million tonnes of total plastics.¹⁰ It is estimated that only 50% of fluoropolymer production requires the use of FPAs, based on standard manufacturing practices by industry to this date;¹¹ while manufacture of fluoropolymers via suspension process normally does not require the use of surfactants, these have traditionally been required to achieve high molecular weight polymer emulsions.¹²

- 5 Barbara J Henry, 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' (2022) 14 Integrated Environmental Assessment and Management 13, 316–334; Stephen H. Korzeniowski, Robert C. Buck, Robin M. Newkold, Ahmed El kassmi, Evan Laganis, Yasuhiko Matsuoka, Bertrand Dinelli, Severine Beauchet, Frank Adamsky, Karl Weilandt, Vijay Kumar Soni, Deepak Kapoor, Priyanga Gunasekar, Marco Malvasi, Giulio Brinati, Stefana Musio, 'A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers' (2022) Integrated Environmental Assessment and Management.
- 6 Bruno Ameduri and Sergey Fomin, *Fascinating Fluoropolymers and Applications* (Elsevier, 2020); Bruno Ameduri, 'The Promising Future of Fluoropolymers' (2020) *Macromol Chem Phys* 221, 1900573; Bruno Ameduri, *Issues, Challenges, Regulations and Applications of Perfluoroalkyl Substances* (Oxford University Press, 2022).
- 7 Wouter A Gebbink, Laura van Asseldonk and Stefan P J van Leeuwen, 'Presence of Emerging Per- and Polyfluoroalkyl Substances (PFASs) in River and Drinking Water near a Fluorochemical Production Plant in the Netherlands' (2017) 51 *Environ Sci Technol* 19, 11057–11065; Rainer Lohmann, Ian T. Cousins, Jamie C. DeWitt, Juliane Glüge, Greta Goldenman, Dorte Herzke, Andrew B. Lindstrom, Mark F. Miller, Carla A. Ng, Sharyle Patton, Martin Scheringer, Xenia Trier, and Zhanyun

Wang, 'Are Fluoropolymers Really of Low Concern for Human and Environmental Health and Separate from Other PFAS?' (2022) *Environ Sci Technol* 54, 12820–12828; Xuan Jia, Hongyan Guan, Zhongbao Guo, Chengjing Qian, Yali Shi and Yaqi Cai, 'Occurrence of Legacy and Emerging Poly- and Perfluoroalkyl Substances in Fluorocarbon Paint and Their Implications for Emissions in China' (2021) 8 *Environ Sci Technol Lett* 11, 968–974.

- 8 Rob Bonta, Superior Court of the State of California, County of Alameda 10 November 2022.
- 9 ETC/WMGE Consortium Partners, 'Fluorinated polymers in a low carbon, circular and toxic-free economy - Technical report' <<https://www.eionet.europa.eu/etcs/etc-wmge/products/etc-wmge-reports/fluorinated-polymers-in-a-low-carbon-circular-and-toxic-free-economy>> accessed 1 May 2023.
- 10 OECD, 2022. Plastic pollution is growing relentlessly as waste management and recycling fall short, says OECD. Available at: <https://www.oecd.org/environment/plastic-pollution-is-growing-relentlessly-as-waste-management-and-recycling-fall-short.htm>. Last access December 2022.
- 11 Jaime Sales, Francisco Hernández, Deepak Kapoor, Marcel van den Noort, 'Fluoropolymers: The Safe Science That Society Needs' (2022) 5 *International Chemical Regulatory and Law Review* 1, 13–23.
- 12 Ebnesajjad, *Fluoroplastics, Volume 1: Non-Melt Processible Fluoropolymers - The Definitive User's Guide and Data Book* (Elsevier, 2014).

Aqueous emulsions are required to produce high performance grades of some fluoropolymers.¹³ Surfactants are highly soluble in water, but the final fluoropolymer substances are not; hence after separation, the residual water contains amounts of dissolved surfactant, which may lead to PFAS emissions when FPAs are used.¹⁴

Another consequence of the use of these surfactants is that sometimes the final fluoropolymer product may carry residuals of such non-polymeric PFAS, which can be also emitted to the environment during the life cycle of fluoropolymers. Again, in this case there is an indirect pollution associated to fluoropolymers, not related to the intrinsic specific properties of these substances.

As a final step in the life cycle of fluoropolymers, disposal and waste treatment has been frequently flagged as a reason for concern of these products. However, recent studies have demonstrated that the waste generation of fluoropolymers is insignificant compared to that of other plastics,¹⁵ and that the most common waste treatment technique for fluoropolymers - incineration - will not result in any PFAS species of concern.¹⁶ In addition to this, fluoropolymers do not degrade during normal use or environmental conditions¹⁷ and do not pose any significant risk if they are landfilled.¹⁸

In summary, it can be established that the only real source of concern for human health or the environment related to fluoropolymers is the use of PFAS as polymerization aids in the manufacture of these

polymers of low concern. Providing efficient solutions that would completely neutralize such concerns would result in completely safe manufacture, use and disposal of fluoropolymers.

III. How to Avoid PFAS Emissions (Polymerization Aids) from the Fluoropolymer Value Chain?

For many years, industry has placed significant efforts to reduce emissions of PFAS from the manufacturing process of fluoropolymers. In order to achieve this goal, there are basically two options available:

1. To improve the abatement techniques and recovery of PFAS surfactants from the manufacture of fluoropolymers.
2. To develop alternative processes that do not require the use of such PFAS polymerization aids for the production of fluoropolymers.

In the case of item 1 above, significant improvements have occurred over the last years that have allowed for reduction of 99% of emissions of fluorinated surfactants since the 1990s.¹⁹ More recent research brings that value as high as 99.99%.²⁰ Extensive literature exists in relation to control and treatment of emitted PFAS from industrial processes.²¹ The strategies of containment involve the recovery, removal, purification, sorption techniques, microbial degradability and recyclability of the polymerization aids

13 Oleg N. Primachenko, Alexey S. Odinko, Elena A. Marinenko, Yuri V. Kulvelis, Valerij G. Barabanov and Svetlana V. Kononova, 'Influence of sulfonyl fluoride monomers on the mechanism of emulsion copolymerization with the preparation of proton-conducting membrane precursors' (2021) *Journal of Fluorine Chemistry* 244, 109736.

14 Ebnesajjad, *Fluoroplastics, Volume 1: Non-Melt Processible Fluoropolymers - The Definitive User's Guide and Data Book* (Elsevier, 2014).

15 Conversio, 'Fluoropolymer waste in Europe 2020 – End-of-life (EOL) analysis of fluoropolymer applications, products and associated waste streams' (2022).

16 Krasimir Aleksandrov, Hans-Joachim Gehrmann, Manuela Hauser, Hartmut Mätzing, Daniel Pigeon, Dieter Stapf and Manuela Wexler, 'Waste incineration of Polytetrafluoroethylene (PTFE) to evaluate potential formation of per- and Poly-Fluorinated Alkyl Substances (PFAS) in flue gas' (2019) 226 *Chemosphere*; RIVM, 'Per- and polyfluorinated substances in waste incinerator flue gases. Rijksinstituut voor Volksgezondheid en Milieu' (2021).

17 Danish EPA, 'Survey of PFOS, PFOA and other perfluoroalkyl and polyfluoroalkyl substances. The Danish Environment Protection Agency' (2013) LOUS Review, Environmental Project No. 1475, 2013.

18 Stephen H. Korzeniowski, Robert C. Buck, Robin M. Newkold, Ahmed El Kassmi, Evan Laganis, Yasuhiko Matsuoka, Bertrand Dinelli, Severine Beauchet, Frank Adamsky, Karl Weilandt, Vijay Kumar Soni, Deepak Kapoor, Priyanga Gunasekar, Marco Malvasi, Giulio Brinati and Stefana Musio, 'A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers' (2022) *Integrated Environmental Assessment and Management*.

19 Daikin Chemicals, 'Measures concerning environment emission of PFAS' (2022) <<https://www.daikinchemicals.com/company/sustainability/pfas.html>> accessed 1 May 2023. Chemours, 'Our Commitment to Responsible Chemistry' <<https://www.chemours.com/en/corporate-responsibility/sustainability-safety/our-commitment-to-pfas-stewardship>> accessed 1 May 2023.

20 Rebecca DiStefano, Tony Feliciano, Richard A. Mimna, Adam M. Redding and John Matthis, 'Thermal destruction of PFAS during full-scale reactivation of PFAS-laden granular activated carbon' (2022) *Remediation* 32, 231–238.

21 ITRC, 'PFAS Technical and Regulatory Guidance Document and Fact Sheets: 12. Treatment Technologies' (2022) Interstate Technology and Regulatory Council; Jinxia Liu and Sandra Mejia Avendaño, 'Microbial degradation of polyfluoroalkyl chemicals in the environment: A review' (2013) *Environment International* 61, 98–114.

from off-gases, waste-water streams, aqueous dispersions, and final products. The recovery/recycling techniques of the polymerization aids depend on the final form of the fluoropolymer product: they can be removed when the aqueous emulsion is dried for sale as a solid (in the case of powder), or they can be thermally destroyed at high temperatures during the curing process (in the case of aqueous dispersion). Such techniques, including ion exchange technology for removal of FPAs from aqueous emulsions, have been applied for more than 20 years, and at present time, they are installed in most of the fluoropolymer manufacturing facilities around the world.

However, it needs to be acknowledged that achieving an absolute zero value of emissions in processes where PFAS are used is technically impossible. Frequently industry operates with the concepts of As Low As Reasonably Practicable/Achievable.²² From that point, developing improved technologies becomes complex and significantly resource intensive for industry. Furthermore, with the development of ever more sophisticated analytical techniques, the possibility that (low) PFAS concentrations in the vicinity of industrial sites where these chemicals are used will be detected will continue to increase as well. This is certainly a positive development, due to the properties of the most dangerous PFAS as persistent, bio-accumulative, mobile and toxic. However, if the goal is to ensure zero emissions, it is highly unlikely that continued improvement of abatement techniques (which is nevertheless a clear necessity) will achieve this target.

Instead, option 2 appears to be the only realistic possibility to ensure that the emission of PFAS surfactants will be completely removed; if no PFAS sur-

factants are used in the manufacturing process of fluoropolymers, then no emissions will occur. Thus, the use of Non-Fluorinated Polymerization Aids (NFPA) can be considered as the most direct path forward to respond to the societal concern related to PFAS pollution associated to fluoropolymers.

However, it needs to be noted that both options are not mutually exclusive. The switch to fluoropolymer manufacture with the use of NFPA will also require the implementation of the most efficient abatement techniques, such as, use of ion exchange resin,²³ filtration²⁴ or foam fractionation.²⁵ This is because the process may still lead to small amounts of residual fluorinated by-products coming from side reactions between chemicals involved, such as monomers or the NFPA. Still, an adequate selection of surfactant and process conditions should allow for a minimisation of fluorinated residuals, particularly if compared to the situation where fluorinated surfactants are used.

Indeed, when comparing manufacturing processes of fluoropolymers that may use either FPAs or NFPA, the whole life-cycle of all the chemicals involved in the process needs to be taken into account. The use of FPAs requires its manufacture, transport, storage and maintenance (e.g., cleaning) of the equipment used in those processes. All these activities will result in potential PFAS emission sources that have to be added to the possible emissions of the FPA (and residuals) that will be generated during the manufacture of the fluoropolymer. In the case of NFPA technology, only the contribution of residuals from the manufacture of fluoropolymer may contribute to emissions. Again, the fact that today such emissions can be adequately controlled via efficient abatement, e.g., by keeping values of fluorinated residuals well below the 250 ppb limit established in the restriction proposal²⁶ clearly results in favour of the transition to manufacturing processes of fluoropolymers involving NFPA technology.

An overview on the current situation about implementation of NFPA technology and expected future developments is provided next.

1. State of the Art Related to NFPA Technology for the Manufacture of Fluoropolymers and Path Forward

Over the past years, the fluoropolymer industry has undertaken significant efforts in continued attempts

22 HSE, 'ALARP at a glance. Health and Safety Executive' (2022) <<https://www.hse.gov.uk/managing/theory/alarpglance.htm>> accessed 1 May 2023.

23 Fuhrar Dixit, Rahul Dutta, Benoit Barbeau, Pierre Berube and Madjid Mohseni, 'PFAS removal by ion exchange resins: A review' (2021) *Chemosphere*, 129777.

24 EPA, 'Reducing PFAS in drinking water with treatment technologies' <<https://www.epa.gov/sciencematters/reducing-pfas-drinking-water-treatment-technologies>> accessed 1 May 2023.

25 Sanne J. Smith, Karin Wiberg, Philip McCleaf and Lutz Ahrens, 'Pilot-Scale Continuous Foam Fractionation for the Removal of Per- and Polyfluoroalkyl Substances (PFAS) from Landfill Leachate' (2022) *ACS EST Water* 5, 841–851.

26 ECHA, 'Registry of restriction intentions until outcome - Per- and polyfluoroalkyl substances (PFAS)' (2023) <<https://echa.europa.eu/es/registry-of-restriction-intentions/-/dislist/details/0b0236e18663449b>> accessed 1 May 2023.

to introduce NFPA technologies in the manufacture of fluoropolymers. An overview on patents that have been filed on technology based on non-fluorinated surfactants demonstrates that this is an effort that the whole industry has taken in parallel, and not limited to the initiative of one or a reduced group of suppliers. Several manufacturers of fluoropolymers have filed multiple patents on NFPA technology over the past 2 decades. This explains a high focus and investment in this direction by the industry. Table 1 (Appendix) provides a list of identified patents related to the use of NFPA technologies for the manufacture of fluoropolymers as published over the last years. While this is not an exhaustive list of initiatives in this field, it provides a good description of efforts developed by the whole fluoropolymer industry.

It should be noted that, even if Table 1 lists patents filed in the XXI Century, initiatives to introduce NFPA technology in the manufacture of fluoropolymers have been on-going since the 1960s.²⁷

2. Commercialization of NFPA Technology and Successful Market Acceptance

As of today, it is assumed that there are technologies available that allow for the manufacture of more than 80% of fluoropolymer global production in volume without the use of FPAs.²⁸ This includes 100% of the three main fluoropolymers by volume: polytetrafluoroethylene (PTFE), polyvinylidene fluoride (PVDF) and fluoroelastomers (FKM). While progress on PVDF was achieved around 15 years ago²⁹, and some grades of PTFE and FKM have been traditionally manufactured without the use of FPAs, success with other PTFE grades (aqueous dispersions and fine powders) and other FKM grades has only been possible in the last months. Progress on smaller volume products such as is poly (TFE-co-perfluoroalkoxyvinylether) copolymers or perfluoro(alkoxyvinylether)s (PFA) have also been recently announced, and it is expected that further developments will be confirmed in the next months that will involve other fluoropolymers.

It needs to be noted that, while such technologies are currently available, it is not expected that all the suppliers will be in a position to integrate them in their manufacturing processes at the same time. This means, for example, that while one supplier may have developed a procedure to manufacture all grades of PTFE without the use of FPAs, this may not

yet be feasible today for all the suppliers. While sub-licensing of rights to a specific technology is possible, full implementation of these procedures by all the suppliers may take some time.

For many years, the fluoropolymer industry has made efforts to develop alternative technologies that do not require the use of FPAs. However, it is in the recent past when different fluoropolymer manufacturers have increased the announcements of different developments to replace technologies based on FPAs, either by introducing NFPA, or by turning to completely alternative processes that simply remove the use of surfactants.³⁰

In order to be considered as a completely viable option for fluoropolymer manufacture, the alternative processes must lead to the production of grades that are accepted by downstream users in terms of quality and performance. This can be confirmed since thousands of metric tonnes of fluoropolymers manufactured without the use of FPAs have already been introduced on the global market and have been well accepted by customers. In recent years, it was only possible to manufacture those fluoropolymers with FPAs, however this situation has changed following recent developments by industry. Furthermore, these grades have to ensure that any water-soluble fluorinated by-products present in the final product are brought to insignificant levels, which can

27 Hoashi Juzaemon, Stabilized, concentrated polytetrafluoroethylene dispersions containing non-ionic surfactants. U.S. Patent No. 3,301,807. 31 Jan. 1967.

28 Jaime Sales, Francisco Hernández, Deepak Kapoor, Marcel van den Noort, 'Fluoropolymers: The Safe Science That Society Needs' (2022) 5 International Chemical Regulatory and Law Review 1, 13-23.

29 PCI, 'Arkema Eliminates Fluorosurfactants from Kynar 500® PVDF' (2008) <<https://www.pcimag.com/articles/88876-arkema-eliminates-fluorosurfactants-from-kynar-500-pvdf>> accessed 1 May 2028.

30 Chemours, 'Chemours Announces Process Innovation with New Viton™ Fluoroelastomers Advanced Polymer Architecture (APA) Offering' (2022) <<https://www.chemours.com/en/news-media-center/all-news/press-releases/2022/chemours-announces-process-innovation-with-new-viton-fluoroelastomers-advanced-polymer-architecture>> accessed 1 May 2022; Solvay, 'Producing new fluoropolymers without fluorosurfactants' (2022) <<https://www.solvay.com/en/article/eliminating-pfas>> accessed 1 May 2023; Gujarat Fluorochemicals, 'Company Announcements' (9 March, 2022) <<https://www.gfl.co.in/upload/pages/ebce5fed9030753d0ee651bf1f48d0a0.pdf>> accessed 1 May 2023; Gujarat Fluorochemicals Limited, 'Company Announcement' (27 August, 2022) <<https://www.gfl.co.in/assets/pdf/Announcement-on-NFPA-technology-FKM-27-Aug-2022.pdf>> accessed 1 May 2023; Gujarat Fluorochemicals Limited, 'Company Announcement' (30 November, 2022) <https://www.gfl.co.in/assets/pdf/GFL%20Announcement%2030.11.22_new.pdf> accessed 1 May 2023.

also be guaranteed by some suppliers using known analytical methods.

In the recent past, and mainly in 2022, various fluoropolymer manufacturers have released statements announcing discontinuation of use of FPAs in the manufacturing of specific fluoropolymers. A summary of latest announcements is given in Table 2 (Appendix).

The fluoropolymer user industry has already witnessed the transition when PFOA was substituted by other PFAS polymerization aids, except in China where PFOA is still in use.³¹ They have now become sensitive to the potentially negative aspects of FPAs currently in use replacing PFOA.³² Hence, the user industry is requesting fluoropolymer manufacturers to switch to NFPA. There is an urgency to qualify new versions of fluoropolymer products produced without the use of fluorinated polymerization aids. The regulatory developments from various authorities are pushing the industry to swiftly move towards sustainable technologies. As a result, fluoropolymers produced with NFPA technology are a commercial success and that further motivates the industry to work harder in this direction.

IV. A Regulatory Proposal for Fluoropolymers

The EU Chemicals Strategy for Sustainability (CSS) towards a Toxic-Free Environment proposes the development of a horizontal essential use concept to apply across chemicals legislation (European Commission, 2020). The CSS commits to “define criteria for essential uses to ensure that the most harmful

chemicals are only allowed if their use is necessary for health, safety or is critical for the functioning of society and if there are no alternatives that are acceptable from the standpoint of environment and health”.

Most harmful substances as defined in the CSS are chemicals that cause cancers, gene mutations, affect the reproductive or the endocrine system, or are persistent and bioaccumulative. It also covers chemicals affecting the immune, neurological or respiratory systems and chemicals toxic to specific organs. It is clear that fluoropolymers as independent substances do not fall into the category of Most Harmful Chemicals as defined in the CSS, based on³³:

- Fluoropolymers are Polymers of Low Concern as per well-established OECD criteria
- Fluoropolymers are insoluble, non-mobile, non-bio accumulative and non-toxic

However, the FPAs that have been traditionally used in the manufacture of fluoropolymers are small non-polymeric PFAS substances of low molecular weight such as perfluorooctanoic acid (PFOA), ammonium salt of hexafluoropropylene oxide dimer acid (HFPO-DA, or GenX), ammonium 4,8-dioxo-3H-perfluorononanoate (ADONA), or perfluorohexanesulfonic acid (PFHxS) might fall into the category of Most Harmful Chemicals and they would therefore require regulatory control. It is important to highlight that, as mentioned above, at present between 50 and 80% of fluoropolymers do not require the use of fluorinated polymerization aids (depending on suppliers and implemented technology).

Any regulatory process on fluoropolymers should start by differentiating if the polymer has been manufactured with the use of FPAs. If this is not the case, then the fluoropolymer substance should be excluded from any legislative action, because there is no justification to regulate a chemical that will not pose any concern to human health or the environment.

If FPAs have been used in the manufacturing process, fluoropolymers should only be used in situations where the use can be considered to be essential. While the concept of essential use is still under development³⁴, this is expected to include situations in which it can be clearly demonstrated that the application is critical to ensure health, safety, and an adequate functioning of society. It is out of the scope of this article to discuss about the conditions under which essential use could be demonstrated. Yet it is

31 Rainer Lohmann, Ian T. Cousins, Jamie C. DeWitt, Juliane Glüge, Gretta Goldenman, Dorte Herzke, Andrew B. Lindstrom, Mark F. Miller, Carla A. Ng, Sharyle Patton, Martin Scheringer, Xenia Trier, and Zhanyun Wang, 'Are Fluoropolymers Really of Low Concern for Human and Environmental Health and Separate from Other PFAS?' (2022) *Environ Sci Technol* 54, 12820–12828.

32 Bruno Ameduri, *Issues, Challenges, Regulations and Applications of Perfluoroalkyl Substances* (Oxford University Press, 2022).

33 (n 5).

34 Cefic, 2022. Regulating Chemicals Based on the Essential Use Concept. Available at: <https://cefic.org/policy-matters/defining-europes-essential-chemical-for-society/>. Last access November 2022; Wood 2022, prepared for European Commission, DG Environment. Supporting the Commission in developing an essential use concept. Workshop report. Available at: <https://environment.ec.europa.eu/system/files/2022-05/Essential%20Use%20Workshop%20Report%20final.pdf>. Last access December 2022.

expected that many applications of fluoropolymers would meet these criteria.³⁵

The essential use concept will be linked to the availability of alternatives. In cases where viable alternatives are proven to be available for a specific use of fluoropolymers, the use should be restricted so that it can be covered by the alternatives. Again, detailed discussions will be required to demonstrate viability of alternatives, particularly in situations where health and safety parameters (or even adequate functioning of society, depending on the case) will be critical. In such cases, equivalent performance to that provided by fluoropolymers will be necessary since downgrades in performance could have extremely negative impacts for the environment or the population. Likewise, the typical parameters of overall reduced risk and economic availability of the alternative (and in sufficient amount) will have to be carefully evaluated. So, availability of alternatives would have to be evaluated with a broad perspective covering items such as performance, accessibility, resource efficiency, waste generation, cost, availability, stability and lifetime. Where viable alternatives are not found for essential uses of fluoropolymers manufactured with FPAs, derogations from the impact of upcoming regulatory restrictions should be granted. Such derogations would need to be based on the introduction of all existing abatement techniques based on the most modern developments, plus the guarantee of a maximum PFAS content in the final product. For example, 250 ppb as has been included in the restriction proposal.³⁶ However, such derogations should be time limited to provide incentives to move suppliers to fully implement manufacturing process involving NFPA technology as soon as possible.

Figure 2 displays a schematic overview of the proposed regulatory path for fluoropolymers. In the absence of a definitive definition of "Essential Use Concept", the term 'Critical Use for Society' is used.

V. Conclusions

The manufacture of certain grades of fluoropolymers had traditionally required the use of FPAs (short-chain PFAS) to ensure an optimal production. This practice has resulted in PFAS emissions and pollution of certain areas around manufacturing and processing sites, which has been a reason of major con-

cern for the society. This has also triggered significant regulatory actions globally against PFAS. Fluoropolymers have been impacted by such actions, due to use of non-polymeric PFAS in the manufacturing process and the fact that they meet the very broad definition of PFAS based on structure.

For many years the fluoropolymer industry has been looking for alternative technologies that would help to remove the use of FPAs while ensuring top quality end-products. For this to be assured, not only commercial acceptance is required, but it also needs to be ensured that the final fluoropolymer will not lead to emissions of undesirable PFAS. The fact that industry has placed substantial efforts in such developments is proven by the relatively large number of patents that have been deposited over the last two decades.

Due to the increased regulatory pressure, and also to a better understanding by industry of the increasing constraints in terms of societal acceptance of chemical risk, significant progress has been achieved over the past years on the development of NFPA technology. In fact, only in the year 2022, up to 5 announcements from 3 different fluoropolymer suppliers have been released describing upcoming implementation of different manufacturing methods that will remove the need to continue using FPAs. Such announcements are not only based on achieved technical progress, but also on successful introduction of new fluoropolymer grades on the market, including customer acceptance. This demonstrates that such NFPA technology is not a vague concept or an aspiration, but a reality that should be developed by industry in a relatively short timeframe.

It is possible that not all suppliers will be ready to introduce such changes at the same pace, for every single fluoropolymer grade. Due to the well-established high value of fluoropolymers to many critical applications for society, it is expected that those uses should be allowed to continue, while likely on a time-limited basis. Nevertheless, efforts should be made by industry to ensure that all feasible abatement techniques are in place to guarantee that PFAS emissions from the manufacture of fluoropolymer is kept as low as possible.

35 Bruno Ameduri, 'The Promising Future of Fluoropolymers' (2020) *Macromol Chem Phys*, 1900573.

36 ECHA, 'Registry of restriction intentions until outcome - Per- and polyfluoroalkyl substances (PFAS)' (2023).

This article also suggests a regulatory frame for fluoropolymers which is based on the need to exclude fluoropolymers that are manufactured with NFPA technology from any future restriction on their use. This is based on the fact that fluoropolymers are substances that pose no hazard to human health or the environment. Removing FPAs from their manufacture takes away the only real concern associated to fluoropolymers. The lack of degradability and the possibility to effectively destroy them during end-of-

life without generating further PFAS emissions supports this principle. The proposal considers the need of other considerations such as uses that are critical for society (pending a final definition of the essential use concept) or the availability of alternatives to provide derogations to continue using fluoropolymers manufactured with FPAs, which should in any case be granted under specific time limits and with the obligation to introduce highly efficient abatement techniques to minimize emissions.

Appendix

Table 1: Summary of identified patents on fluoropolymers and NFPA (in no particular order)

Name of the patent	Company	Application	Reference
Fluoropolymer dispersions containing no or little low molecular weight fluorinated surfactant	3M	United States	Dadalas et al., 2005
Polymerization of Halogen-Containing Monomers Using Siloxane Surfactant and Aqueous Composition	ARKEMA	United States	Wille et al., 2005a
Polymerization of fluoromonomers using 3-allyloxy-2hydroxy-1propanesulfonic acid salt as surfactant	ARKEMA	United States	Wille et al., 2005b
Emulsifier free aqueous emulsion polymerization to produce copolymers of a fluorinated olefin and hydrocarbon olefin	3M	United States	Kaspar et al., 2006
Process for preparing fluoropolymer dispersions	SOLVAY SPECIALTY POLYMERS ITALY	United States	Kapeliouchko et al., 2007
Process for preparing fluoropolymer	DAIKIN	United States	Otsuka et al., 2009
Preparation and Stabilization of Fluoropolymer Dispersions by Aqueous Emulsion Polymerization with Carbosilane Surfactants	3M	United States	Bissinger et al., 2010
Aqueous process for making fluoropolymers	ARKEMA	United States	Amin-Sanayei et al., 2011
Polymerization of Fluoropolymers Using Alkyl Phosphate Surfactants	ARKEMA	United States	Durali et al., 2012
Aqueous Process for Making a Stable Fluoropolymer Dispersion	ARKEMA	United States	Amin-Sanayei et al., 2012a
Aqueous Process for Making Polyvinylidene Fluoride Dispersion	ARKEMA	United States	Amin-Sanayei et al., 2012b
Polymerization of fluoropolymers using polycaprolactone	ARKEMA	European patent specification	Hedhi, 2013
Polymerization of fluoropolymers using non-fluorinated surfactants	ARKEMA	United States	Durali et al., 2014
Synthesis of making 2,3,3,3-tetrafluoropropene containing fluoropolymers	ARKEMA	United States	Amin-Sanayei et al., 2014
Method for producing aqueous fluorinated polymer dispersion, aqueous fluorinated polymer dispersion and fluorinated polymer	AGC	United States	Toyoda et al., 2015

Fluoropolymer Compositions Containing a Polyol Compound as Emulsifier and Methods of Making Them	3M	United States	Zipplies et al., 2015
Method of producing fluoropolymers using alkyl sulfate surfactants	ARKEMA	United States	Amin-Sanayei et al., 2016
Method of Producing Fluoropolymers Using Acid-Functionalized Monomers	ARKEMA	United States	Durali et al., 2016
Aqueous polymerization of fluoromonomer using hydrocarbon surfactant	CHEMOURS	European patent specification	Brothers et al., 2016
Employing polyalkylene oxides for nucleation in aqueous polymerization of fluoromonomer	CHEMOURS	United States	Brothers et al., 2019
Fluoropolymer aqueous dispersion production method and fluoropolymer aqueous dispersion	DAIKIN	United States	Hayashi et al., 2020
Method for stabilizing aqueous dispersions of fluorinated polymers	SOLVAY SPECIALTY POLYMERS ITALY	United States	Carella et al., 2020
Peroxide curable fluoropolymers obtainable by polymerization with non-fluorinated emulsifiers	3M	United States	Jochum et al., 2020
Method for producing modified polytetrafluoroethylene, method for producing modified polytetrafluoroethylene powder, and method for producing stretched porous material	AGC	United States	Higuchi et al., 2020
Process for preparing fluoropolymers and fluoroelastomers in presence of a non fluorinated sulfonate type hydrocarbon containing surfactant thereof	GUJARAT FLUORO-CHEMICALS	European patent specification	Chauhan et al., 2022

Table 2. Summary of recent announcements by fluoropolymer manufacturers on commercial progress to introduce NFPA technology in the manufacture of fluoropolymers that previously required the use of FPA.

Development of NFPA technology by fluoropolymer manufacturers	
PTFE Aqueous dispersions	Gujarat Fluorochemicals (2022a)
PTFE Fine powders	Gujarat Fluorochemicals (2022c)
PVDF	Arkema (PCI, 2008), Solvay (2022), Gujarat Fluorochemicals (2022c)
FKM	Chemours (2022b), Solvay (2022), Gujarat Fluorochemicals (2022b)
PFA	Gujarat Fluorochemicals (2022c)

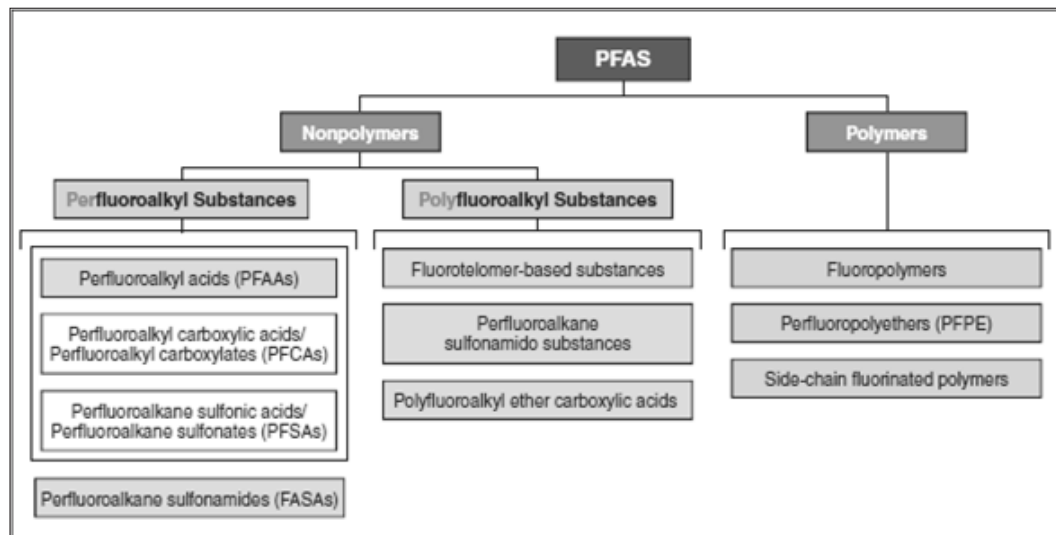


Figure 1: Commonly recognized PFAS groups of substances

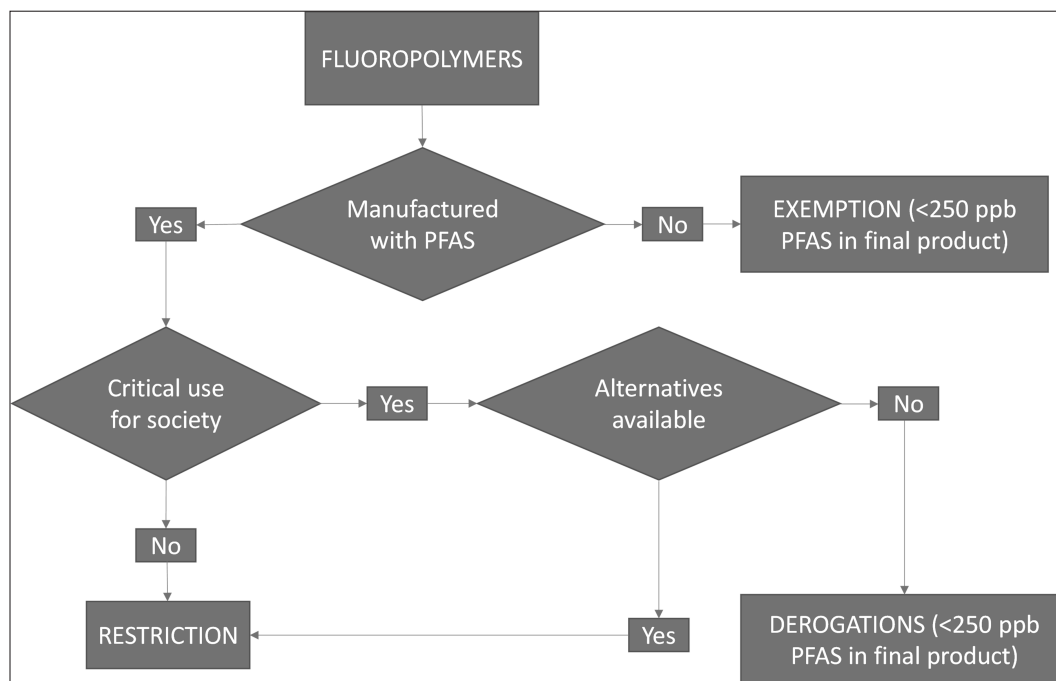


Figure 2: Summary of the regulatory process recommended for fluoropolymers

Critical Review

A Critical Review of the Application of Polymer of Low Concern and Regulatory Criteria to Fluoropolymers

Barbara J Henry,*† Joseph P Carlin,† Jon A Hammerschmidt,† Robert C Buck,‡ L William Buxton,‡
Heidelore Fiedler,§ Jennifer Seed,|| and Oscar Hernandez#

†WL Gore & Associates, Elkton, Maryland, USA

‡Chemours Company, Wilmington, Delaware, USA

§MTM Research Centre School of Science and Technology, Örebro University, Örebro, Sweden

||Risk Assessment Consultant, Alexandria, Virginia, USA

#Bergeson & Campbell, Washington, DC, USA

ABSTRACT

Per- and polyfluoroalkyl substances (PFAS) are a group of fluorinated substances that are in the focus of researchers and regulators due to widespread presence in the environment and biota, including humans, of perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA). Fluoropolymers, high molecular weight polymers, have unique properties that constitute a distinct class within the PFAS group. Fluoropolymers have thermal, chemical, photochemical, hydrolytic, oxidative, and biological stability. They have negligible residual monomer and oligomer content and low to no leachables. Fluoropolymers are practically insoluble in water and not subject to long-range transport. With a molecular weight well over 100 000 Da, fluoropolymers cannot cross the cell membrane. Fluoropolymers are not bioavailable or bioaccumulative, as evidenced by toxicology studies on polytetrafluoroethylene (PTFE): acute and subchronic systemic toxicity, irritation, sensitization, local toxicity on implantation, cytotoxicity, in vitro and in vivo genotoxicity, hemolysis, complement activation, and thrombogenicity. Clinical studies of patients receiving permanently implanted PTFE cardiovascular medical devices demonstrate no chronic toxicity or carcinogenicity and no reproductive, developmental, or endocrine toxicity. This paper brings together fluoropolymer toxicity data, human clinical data, and physical, chemical, thermal, and biological data for review and assessment to show that fluoropolymers satisfy widely accepted assessment criteria to be considered as “polymers of low concern” (PLC). This review concludes that fluoropolymers are distinctly different from other polymeric and nonpolymeric PFAS and should be separated from them for hazard assessment or regulatory purposes. Grouping fluoropolymers with all classes of PFAS for “read across” or structure–activity relationship assessment is not scientifically appropriate. *Integr Environ Assess Manag* 2018;14:316–334. © 2018 The Authors. *Integrated Environmental Assessment and Management* published by Wiley Periodicals, Inc. on behalf of Society of Environmental Toxicology & Chemistry (SETAC)

Keywords: Fluoropolymer International regulation Polytetrafluoroethylene Polymer of low concern PFAS

INTRODUCTION

The carbon–fluorine (C–F) bond is the strongest bond between C and another atom, instilling substances that contain a majority of C–F bonds with stability, inertness, and persistence (Banks et al. 1994). Per- and polyfluoroalkyl substances (PFAS) are a large group of highly fluorinated synthetic substances with diverse properties that have been used in a wide variety of industrial and consumer applications since the 1950s (Buck et al. 2011). Within the group are

distinct substances with different properties: polymers and nonpolymers; solids, liquids, and gases; persistent and nonpersistent substances; highly reactive and inert substances; mobile and insoluble substances; and toxic and nontoxic chemicals.

The PFAS are a large, diverse group of substances that, in some respects, challenge easy distinction for assessment and management. A clearer understanding of the origin of PFAS found in the environment and assessment of their properties is needed to be able to determine which classes of PFAS require management action. Per- and polyfluoroalkyl substances must be assessed taking into account their differences in chemical, physical, thermal, and biological properties. A single, globally harmonized system for PFAS classification has not yet been defined, resulting in a lack of distinction between PFAS. As regulatory frameworks continue to evolve, such as the Regulation (EC) No 1907/2006 of the European

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* Address correspondence to bhenry@wlgore.com

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Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (EC 2006), more work is needed to distinguish classes of PFAS to ensure that regulations are appropriate in scope and proportionality.

Two long-chain nonpolymer perfluoroalkyl acids (PFAAs), perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS) (both PFAS), found widespread in the environment and living systems, led to regulatory assessment and management efforts in several countries (Buck et al. 2011; OECD 2017; USEPA 2017a). Management actions to curtail manufacture of long-chain PFAAs, including PFOS and PFOA, and substances that may degrade to form them (also known as “precursors”) have been taken (EC 2006; ECHA 2015; USEPA 2017a). Both PFOS and PFOA have been determined by regulators to be persistent, bioaccumulative, and toxic (PBT) substances (EC 2006; ECHA 2015). A current concern is the potential for certain side-chain polymer PFAS to degrade in the environment to PFOS and PFOA or lower homologues (Liu and Mejia-Avendaño 2013). In addition, PFOS (a nonpolymeric perfluoroalkyl substance) and related substances have been listed as persistent organic pollutants (POPs) under Annex B of the Stockholm Convention (UNEP 2009), and PFOA and other related substances (UNEP 2011), as well as perfluorohexane sulfonic acid (PFHxS) and related substances are being evaluated for listing (UNEP 2017a). As a result, questions about the health and environmental safety of PFAS as a group have been raised (Scheringer et al. 2014; Blum et al. 2015).

These findings have prompted expanded regulatory interest and concern about PFAS as a group, spurring additional assessment and management actions. The German Environment Agency, Umweltbundesamt (UBA), published a proposal to implement new assessment criteria and procedures for identifying persistent (P), mobile (M), and toxic (T) substances under the European Union REACH chemical registration process (UBA 2017). The UBA has concluded that PM and/or PMT substances constitute “an irreversible threat to sources of drinking water and the quality of drinking water” in Germany. This has prompted the designation of PFAS substances as posing an “equivalent level of concern” under Article 57(f) of REACH and thereby has prompted the need for a new paradigm for chemical assessment and authorization. The Swedish Chemicals Agency, Kemikalieinspektionen (KEMI), announced agreement among 37 government agencies and research institutions in the European Union (EU) to expand cooperation to reduce the risks and increase the knowledge of PFAS, thereby endorsing the UBA view on the hazards posed by all PFAS substances (KEMI Swedish Chemicals Agency 2016). The KEMI announcement indicated that all perfluoroalkyl substances should be considered as extremely persistent in the environment, and many are water soluble, mobile in soil, and likely to contaminate waterways and drinking water supplies. A risk assessment report prepared by KEMI is forthcoming (ChemNews 2016).

The PFAS are divided into 2 primary categories: non-polymers and polymers (Figure 1). Figure 1 shows that these 2 categories are divided into 5 classes of PFAS. The fluoropolymer class of PFAS is the focus of the present

paper. The nonpolymer category includes perfluoroalkyl substances and polyfluoroalkyl substances. The polymer category includes fluoropolymers, perfluoropolyethers, and side-chain fluorinated polymers. Polymers generally have very different physical, chemical, and biological properties than do nonpolymer chemical substances of low molecular weight. Precise criteria that distinguish polymers from nonpolymers have been established (OECD 1993).

There are distinct differences between the 5 classes of PFAS. For example, PFOA, in the class nonpolymer perfluoroalkyl substances, is small, mobile, and persistent; has been assessed and determined to be a PBT chemical (ECHA 2015); and is in the final stage for recommendation of listing as a POP under the Stockholm Convention (UNEP 2017b). Regulatory and industry management actions on PFOA include precursor substances that may degrade to form PFOA (USEPA 2017a). An example in the class of nonpolymer polyfluorinated substances, 8:2 fluorotelomer alcohol, is known to degrade under environmentally relevant conditions to form PFOA (Liu and Mejia-Avendaño 2013). It is therefore a precursor substance to PFOA and subject to regulatory management (Liu and Mejia-Avendaño 2013). Polymers derived from 8:2 fluorotelomer alcohol are examples of the side-chain fluorinated polymers class. These polymers may degrade to form PFOA and therefore are subject to regulatory management. Lastly, perfluoropolyethers class is a complex class of PFAS, which contains O linkages in the polymer backbone.

In the present paper, we address fluoropolymers, a class of PFAS polymers (Figure 1). Fluoropolymers are high molecular weight solid plastics that have been studied extensively.

The present paper brings together fluoropolymer toxicity data, human clinical data, and physical, chemical, thermal, and biological data for review and assessment to show that fluoropolymers satisfy widely accepted assessment criteria to be considered as “polymers of low concern” (PLC) and to show that fluoropolymers are distinctly different enough from other classes of PFAS to not be grouped with them for hazard assessment or regulatory purposes.

PERFORMANCE CHARACTERISTICS AND USES OF FLUOROPOLYMERS

Since the discovery of polytetrafluoroethylene (PTFE) in 1938 (Plunkett 1987), the use of fluoropolymers has grown considerably to take advantage of their unique physical–chemical, thermal, and biological properties. The 4 fluoropolymers addressed in the present paper, polytetrafluoroethylene (PTFE), fluorinated ethylene propylene (FEP), ethylene tetrafluoroethylene (ETFE), and tetrafluoroethylene copolymers with perfluoroalkyl vinyl ethers (e.g., perfluoroalkoxy polymer, PFA), accounted for approximately 70% to 75% of the world fluoropolymer consumption in 2015 (IHS 2016). The representative fluoropolymer discussed in the present paper, PTFE, made up 58% (by weight) of 2015 worldwide fluoropolymer consumption (IHS 2016). Fluoropolymers are high molecular weight plastics with unique properties attributable to the strong C–F bonds, the strongest bond between C and another atom, making

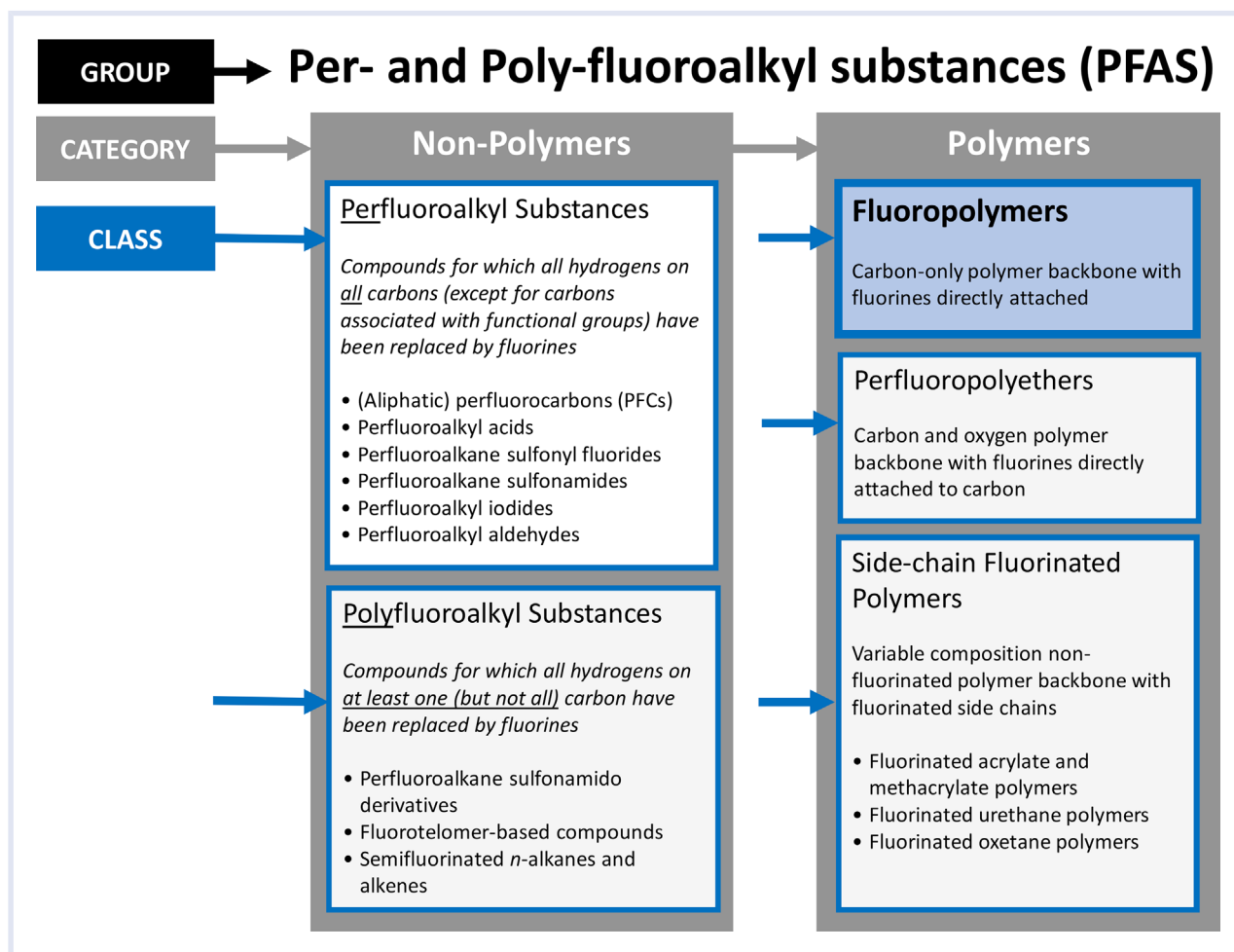


Figure 1. Per- and polyfluoroalkyl substances (PFAS).

them highly stable (Olabisi and Adewale 2015). Carbon atoms alone form the fluoropolymer backbone, each surrounded by an envelope of F atoms. Fluoropolymers are generally very high molecular weight (>100 000 Da); have high thermal, chemical, photochemical, oxidative, hydrolytic, and biological stability; have low flammability, neutral electrical charge, and resistance to degradation; have negligible residual monomers and low molecular weight oligomer content; have limited low molecular weight leachables; and have no reactive functional groups of concern (Gangal and Brothers 2015).

The unique properties of fluoropolymers include durability, mechanical strength, inertness, thermal stability in foreseeable use conditions, and resistance to chemical, biological, and physical degradation (Hougham et al. 1999). Table 1 shows performance characteristics required in various commercial fluoropolymer applications (Gangal and Brothers 2015; Dams and Hintzer 2016). For example, medical devices are successful when they are made from “biocompatible” biomaterials, that is, the material has the ability to perform with an appropriate host response in a specific situation (Williams 1987). The inertness of PTFE allows for its acceptance into the body. Moreover, PTFE flexibility and

durability deliver mechanical integrity for the device’s lifetime. The microstructure of PTFE can be modified to meet specific physiological needs (e.g., porous and open structure to facilitate tissue ingrowth), enhancing its utility in medical devices. In terms of end-use function, PTFE’s inertness, physical properties (Ebnesajjad 2011), and the low level of residual monomer, oligomers, and low molecular weight leachables (Supplemental Data p 32–55) meet the requirements for low levels of contaminants and particulates in manufacturing environments essential for the food and beverage, pharmaceutical, medical, and semiconductor industries (Olabisi and Adewale 2015). Manufacturing applications requiring ultrapure high efficiency particulate air (HEPA) filtration use the finely controlled microporous PTFE membranes. Other components requiring a high degree of contamination control associated with patient care (e.g., dialysis tubing) also find the properties of PTFE essential. Durability in harsh conditions makes PTFE a superior material of choice in aerospace, environmental controls, energy production and storage, and electronics, as well as in technical apparel. The thermal stability of PTFE and FEP fluoropolymers provides improved fire safety risk over other polymers when used in plenums and structural

Table 1. Fluoropolymer functionality and commercial applications

Commercial application	Fluoropolymer characteristics									
	Durable		Inert			Functional			Stable	
	Mechanical strength	Low particulation	Resistance to chemicals	Nontoxic, biocompatible, resistant to biological degradation	Flexibility	Friction resistance	Low dielectric constant	Low leachables	Resistance to photolysis, oxidation, hydrolysis	Stability
Aerospace	X	—	X	—	X	X	X	—	X	X
Automotive industry	X	—	X	—	X	X	X	—	X	x
Medical devices	X	X		X	X	X	—	X	X	X
Pharmaceutical manufacture	X	X	X	X	X	—	—	X	—	X
Consumer outdoor apparel	X	—		X	X	—	—	X	—	—
Technical clothing (military, firefighters, first responders, medical personnel)	X	—	X	X	X	X	—	X	X	X
Consumer electronics	X	—	X	—	X	X	X	—	X	X
Wireless communications	X	—	X	—	X	X	X	—	X	X
Satellite navigation systems	X	—	X	—	X	X	X	—	X	X
Semiconductor industry	—	X	X	—	—	—	X	X	—	—
Building construction	X	—	—	X	X	—	X	—	X	X
Energy production and storage	X	X	—	—	—	—	X	X	X	X
Food and beverage production	X	X	X	X	X	X	—	X	X	—
Food protection and packaging	X	X	X	X	X	—	—	X	—	—
Drinking water filtration	—	X	X	X	—	—	—	X	X	—
Environmental protection	—	X	X	X	—	—	—	X	X	X

geometries in aviation and standard building construction (Olabisi and Adewale 2015). In addition, chemical resistance to acids, bases, solvents, and chemical attack, combined with its unique conformable strength, makes PTFE an ideal coating for chemical process equipment, lining for process piping, sealants for gaskets and hoses, and fabricated parts for pumps, gears, and other mechanical parts that need this extreme resistance for functionality (Olabisi and Adewale 2015). The low dielectric constant of PTFE ensures the integrity of high speed–low signal loss systems as employed in the aerospace industry for flight controls, communication, and protection from extreme cold, moisture, and altitude changes (Dams and Hintzer 2016). These are lifesaving applications that are used in satellite systems for navigation, wireless communications, in-flight navigation, and shielding from electronic interference. Civil and military aviation depends on reliable performance of these systems for long service hours with minimal maintenance down times. In addition, PTFE provides reduced friction of moving parts (e.g., cable chains), preventing particulation during automated manufacturing in cleanroom environments (Dams and Hintzer 2016). This friction reduction is also uniquely beneficial in light load bearings, gears, cams, and other mechanical machine parts as well as in weaving fibers, yarns, and greases (Dams and Hintzer 2016).

ASSESSMENT OF POLYMERS

History

Prior to the mid-20th century, regulation of new chemical substances, mixtures, and polymers in general was very limited. National chemical inventories were created with notification requirements for new chemical substances, mixtures, and polymers. In the United States, new chemicals submitted to the US Environmental Protection Agency (USEPA) under the Toxic Substances Control Act (TSCA) (USC 1976) for addition to the US chemical inventory are reviewed for potential physical, chemical, and biological effects (environmental and mammalian), as well as for potential exposure to the environment and human populations. Over time, the USEPA regulatory scientists gained enough knowledge through the review of the thousands of data packages to develop tools to assist in the identification of physical–chemical properties, potential hazard, and potential exposure to assist in and expedite the chemical review and assessment process (Auer et al. 1990; Wagner et al. 1995; USEPA 2012; USEPA 2017b).

The predictive power and reliability of these approaches were tested and refined (Wagner et al. 1995). Over time, it was recognized that many of the physical–chemical properties, such as molecular weight, limit the ability of the chemical to cross the cell membrane and therefore limit its bioavailability. Further examination of general physical–chemical properties and their relationship to hazard potential of a given chemical led to the development of general principles or criteria for the identification of chemicals, including polymers, with low hazard potential.

These criteria were developed for use by USEPA for its hazard evaluation of new polymers. The USEPA made this methodology available to the public to assist submitters interested in developing low hazard polymers (USEPA 1997a). In 1984, the USEPA published the polymer exemption rule to exempt low hazard polymers from certain notification requirements under the new chemicals program (USFR 1984). The polymer exemption rule incorporated the hazard criteria as part of the criteria to determine eligibility for exemption (USEPA 1997a, 2010).

The hazard criteria that support the PLC concept represent an extension of these principles and practices developed for (nonpolymeric) chemicals and rely heavily on physical–chemical properties that determine a chemical's bioavailability. In 1993, the Organisation for Economic Co-operation and Development (OECD) Expert Group on Polymers found that sufficient data existed to create a consensus document identifying the essential data elements to qualify a polymer as a PLC to human health and the environment (OECD 1993). By 2007, the OECD Expert Group on Polymers agreed that, "Polymers of low concern are those deemed to have insignificant environmental and human health impacts" (OECD 2009). Thus, there was agreement within the OECD that polymeric chemicals meeting these criteria have a low hazard potential. However, the integration of the criteria into a risk management framework may differ from country to country according to their individual regulatory mandate.

In a recent report commissioned by the European Commission (EC) (BIO by Deloitte 2015), the following countries agreed on the polymer properties predictive of adverse human health and environmental hazard: Australia, Canada, China, Japan, South Korea, Philippines, New Zealand, Taiwan, and the United States. Further, the report identified the eligibility criteria to be considered a PLC with respect to potential for adverse impact on health and the environment. The report also compiled existing polymer regulations outside the EU and proposed alternative options for EU polymer registration, including defining a category of a PLC and grouping polymers into families.

The PLC criteria are described in the following section. Note that there are some policy components, such as elemental composition, as well as the physical–chemical attributes, in the PLC criteria.

POLYMER OF LOW CONCERN CRITERIA

Here we describe each of the eligibility criteria for PLC and provide an assessment for the representative fluoropolymer PTFE. We will show that fluoropolymers, including PTFE, satisfy the widely accepted assessment criteria to be considered PLCs (Table 2) and therefore are considered to be of low hazard to human health and the environment.

Polymer composition

The polymer composition criterion requires structure and elemental composition of the polymer be described and identified (e.g., by Chemical Abstracts Service [CAS] number).

Table 2. Fluoropolymers and PLC criteria

Assessment criteria ^a	Fluoropolymers			
	PTFE	ETFE	FEP	PFA
	CAS 9002-84-0	CAS 25038-71-5, 68258-85-5	CAS 25067-11-2	CAS 26655-00-5, 31784-04-0
Structure	$\text{-(CF}_2\text{-CF}_2\text{)}_n$	$\text{-(CH}_2\text{-CH}_2\text{)}_n\text{-(CF}_2\text{-CF}_2\text{)}_m$	$\text{-(CF}_2\text{-CF}_2\text{)}_n\text{-(CF}_2\text{-CF(CF}_3\text{))}_m$	$\text{-(CF}_2\text{-CF}_2\text{)}_n\text{-(CF}_2\text{-CF(R}_f\text{))}_m$
Polymer composition (must have C, H, Si, S, F, Cl, Br, or I covalently bound to C)	Yes	Yes	Yes	Yes
Molecular weight	389 000–8 900 000 ^{bc}	—	—	—
(M _n > 1000 Da and oligomer content < 1%)	520 000–45 000 000 ^{bd}	530 000–1 200 000 ^{ef}	241 000–575 000 ^{eg}	200 000–450 000 ^{eh}
Molecular weight distribution MW ÷ number average M _n (M _n and heterogeneity of MW distribution indicate if majority are >1000 or <1000 Da, which could penetrate the cell)	2.3 ⁱ	1.4–2.7 ^f	1.55–2.09 ^g	1.7 ^j
Wt % oligomer (see Figure 2) (<5% for <1000 Da oligomers, <2% for <500 Da oligomers)	Negligible	Negligible	Negligible	Negligible
Ionic character (cationic polymers associated with aquatic toxicity; polycationic with adverse human health effect)	Neutral	Neutral	Neutral	Neutral
RFGs ^k (some highly reactive functional groups associated with adverse human health and ecotoxicology effects, e.g., acrylates, isocyanates, anhydrides, aziridines)	<1 (see section <i>Reactive functional groups and RFG ratio to MW</i>)	<1 (see section <i>Reactive functional groups and RFG ratio to MW</i>)	<1 (see section <i>Reactive functional groups and RFG ratio to MW</i>)	<1 (see section <i>Reactive functional groups and RFG ratio to MW</i>)
FGEW ^k (typical value) (the lower the FGEW, the more reactive the polymer and the higher the potential for health and environmental impact)	>10 ⁵ –10 ⁷	>10 ⁵ –10 ⁶	>10 ⁵	>10 ⁵
Low molecular weight leachables (MW < 1000 Da able to enter cell)	<1 ppm	No active leachables by USP class VI ^l (121 °C)	No active leachables by USP class VI ^l (121 °C)	No active leachables by USP class VI ^l (121 °C)
Residual monomers (monomers have lower MW than polymers; typically more hazardous than polymers)	<1 ppm	<50 ppb	<50 ppb	<50 ppb
Ratio of residual monomers to molecular weight (typical value) (more low MW monomer content per mole increases bioavailability and hazard potential)	~10 ⁻¹³ to 10 ⁻¹⁵	~10 ⁻¹³ to 10 ⁻¹⁴	~10 ⁻¹³	~10 ⁻¹³
Structural similarities to RFG of concern (increases potential risk of adverse effects)	None	None	None	None
Reference standard see also ISO 1133 (ISO 2011), ISO 12086 (ISO 2006)	ASTM D 4894 (ASTM 2015a), D 4895 (ASTM 2015b)	ASTM D 2116 (ASTM 2016a)	ASTM D 3159 (ASTM 2015c)	ASTM D 3307 (ASTM 2016b)

(Continued)

Table 2. (Continued)

Assessment criteria ^a	Fluoropolymers			
	PTFE	ETFE	FEP	PFA
	CAS 9002-84-0	CAS 25038-71-5, 68258-85-5	CAS 25067-11-2	CAS 26655-00-5, 31784-04-0
Physical–chemical properties				
Water solubility (per USP 2011) (water solubility < 10 mg/L showed generally low health concerns; 10 mL/L to 10000 mg/L had potential health concern)	Practically insoluble or insoluble (1 × 10 ⁻⁵ mg/L)	Practically insoluble or insoluble	Practically insoluble or insoluble	Practically insoluble or insoluble
Octanol–water partition coefficient, <i>K</i> _{OW} (higher <i>K</i> _{OW} associated with lipophilicity and a high potential to bioaccumulate or bioconcentrate)	NA	NA	NA	NA
Particle size (median mass aerodynamic diameter, MMAD, should be >5 μm)	100–500 μm (powders)	50–250 μm (powders)	50–250 μm (powders)	50–250 μm (powders)
	—	2–4 mm (pellets)	2–4 mm (pellets)	2–4 mm (pellets)
Stability				
Hydrolysis (breaking into <i>M</i> _n < 1000 Da increases hazard potential)	Stable	Stable	Stable	Stable
Light (hν) (breaking into <i>M</i> _n < 1000 Da increases hazard potential)	Stable	Stable	Stable	Stable
Oxidation (breaking into <i>M</i> _n < 1000 Da increases hazard potential)	Stable	Stable	Stable	Stable
Biodegradation (aerobic and anaerobic) (breaking into <i>M</i> _n < 1000 Da increases hazard potential)	Stable	Stable	Stable	Stable
Thermal stability at normal foreseeable use maximum continuous temp (°C) (breaking into <i>M</i> _n < 1000 Da increases hazard potential)	260	150	200	260
Meets PLC criteria ^a (Y/N)	Yes	Yes	Yes	Yes

ASTM = American Society for Testing and Materials; CAS = Chemical Abstracts Service; Da = dalton; ETFE = ethylene tetrafluoroethylene; FEP = fluorinated ethylene propylene; FGEW = functional group equivalent weight; ISO = International Organization for Standardization; MMAD = median mass aerodynamic diameter; *M*_n = number average molecular weight; MW = molecular weight; MWD = molecular weight distribution; OECD = Organisation for Economic Co-operation and Development; PFA = perfluoroalkoxy polymer; PFPE = perfluoropolyether; PLC = polymer of low concern; PTFE = polytetrafluoroethylene; PVDF = polyvinylidene fluoride; PVF = polyvinyl fluoride; RFG = reactive functional groups; USEPA = US Environmental Protection Agency; USP = US Pharmacopeia.

^aSee OECD 2009 and BIO by Deloitte 2015 for details on characteristics of a “polymer of low concern.”

^bMolecular weight is number average molecular weight.

^cBerry and Peterson 1951; Doban et al. 1956.

^dSuwa et al. 1973.

^eMolecular weight is weight average molecular weight.

^fTuminello et al. 1993.

^gTuminello 1989.

^hPutnam 1986.

ⁱChu et al. 1989.

^jFrick et al. 2012.

^kFor definition of reactive functional group; lists of low-, moderate-, and high-concern functional groups; and FGEW limits, see USEPA Polymer Exemption Guidance Manual (USEPA 1997b), BIO by Deloitte 2015 (p 191–192), and USEPA 2010. See Supplemental Data.

^lIn the USP<88> testing for “class VI,” 2 g of the plastic (e.g., FEP, ETFE, or PFA) were extracted at 121 °C in: 1) 0.9% sodium chloride solution, 2) sesame oil, NF, 3) alcohol saline, and d) polyethylene glycol. The acute systemic toxicity and intracutaneous reactivity tests were conducted with those extracts. The intramuscular implantation was conducted with the plastic. Passing these 3 tests indicates that any leachables were not released in concentrations capable of causing these adverse effects, but does not result in a quantitative concentration of leachables. (See USP 2018.)

Note: The following are not addressed in this paper: PFPEs, side-chain fluorinated polymers, fluoroelastomers, PVF, and PVDF.

Molecular weight, number average molecular weight, MW distribution, and % oligomer <1000 Da

The number average molecular weight (M_n) and oligomer content are the most commonly used criteria for PLC assessment. The EU assessment report (BIO by Deloitte 2015) states that the “most potential health concern polymers have a number average molecular weight, M_n , < 1000 Da and oligomer content >1%.” The higher the oligomeric content, the more likely a polymer is to be a health or ecotoxicological (OECD 2009, p 9). In fact, when comparing the potential health concern of polymers with varying percent oligomer content, “...the distribution of potential health concern polymers showed an increased incidence of higher oligomer content that began at 5% for <1000 Da and 2% for <500 Da oligomeric content” (OECD 2009, p 24).

Molecular weight (MW) is an important predictor of biological effect because very large molecules (>1000–10 000 Da) are too large to penetrate cell membranes (Supplemental Data in Beyer 1993, p 14). Because large molecular weight polymers cannot enter the cell, they cannot react with “target organs,” such as the reproductive system, and are not bioavailable. “Therefore, as the M_n of a polymer increases, a reduced incidence of potential health concern effects might be expected” (OECD 2009, p 20).

An additional PLC consideration is the weight percent oligomers <1000 Da. Oligomers may be composed of, for example, dimers, trimers, and tetramers, meaning they have 2-, 3-, and 4-monomer units, respectively. The EU report (BIO by Deloitte 2015) concluded that most potential health concern polymers have M_n of <1000 Da and oligomer content of >1%: “...the distribution of potential health concern polymers showed an increased incidence of higher oligomer content that began at 5% for <1000 Da and 2% for <500 Da oligomeric content” (OECD 2009, p 24).

Molecular weight distribution (MWD), also known as “polydispersity index,” measures the heterogeneity of size of polymer molecules in a polymer. The MWD is an important parameter for predicting potential biological effects of polymers because although M_n may be a large value, low MW oligomers <1000 Da may be present, which could penetrate the cell.

Electrical charge (ionic character)

Electrical charge or ionic character can be anionic, cationic, amphoteric, or nonionic. Specifically, cationic polymers have been associated with aquatic toxicity (Auer et al. 1990; USEPA 1997a). Polycationic polymers that are water soluble or dispersible are of concern due to adverse human health (inhalation) effects (NICNAS 2016).

Reactive functional groups and RFG ratio to MW

A “reactive functional group” (RFG) is defined as an atom or associated group of atoms in a chemical substance that is intended or can be reasonably anticipated to undergo facile chemical reaction (USFR 2012). Some highly reactive functional groups (or a high ratio of RFGs per mole) have been associated with adverse human health and ecotoxicology (e.g., acrylates,

methacrylates, isocyanates, anhydrides, aziridines) (USEPA 2010). Methods have been demonstrated to identify the functional end groups on fluoropolymers (Pianca et al. 1999).

The functional group equivalent weight (FGEW) is used to determine if the RFGs in a polymer are substantially diluted by polymeric material to allow the polymer to be a PLC (USEPA 1997b). The FGEW of a polymer is defined as the ratio of the M_n to the number of functional groups in the polymer. It is the weight of a polymer that contains 1 formula weight of the functional group. The FGEW is used as an indication of the degree of reactivity of the polymer; the lower the FGEW, the more reactive the polymer and the higher the potential for health and environmental impact (OECD 2009, p 10).

Low MW leachables

Low MW leachables are chemical molecules, either inorganic or organic, that migrate (i.e., leach) out of the polymer. These could be residual monomers or oligomers resulting from incomplete polymerization processes, surface residues, or other chemicals used in the manufacturing processes (e.g., initiators, catalysts, chain transfer agents, surfactants). Chemical analysis, by techniques such as thermal gravimetric analysis (TGA), gas chromatography mass spectrometry (GC-MS), or liquid chromatography mass spectrometry (LC-MS) are used to identify low MW leachables.

Low MW leachables are critically important to the potential for a polymer to affect health and the environment, given that they may be able to migrate out of the polymer and cross cell membranes to potentially react with biomolecules. In a report to the EU (BIO by Deloitte 2015) the polymer policies for 10 countries around the world, including the EU REACH handling of polymers, were reviewed. The report concluded that “Polymers with <1% MW <1000 Da and low water extractivity are not able to cause systemic effects which are toxicologically or ecotoxicologically relevant.”

Monomers, by nature, are reactive. Unreacted monomer left in a polymer may migrate out of the polymer to react with biomolecules to cause potential adverse effects. Regulatory authorities (BIO by Deloitte 2015) and the OECD Expert Group on Polymers (OECD 2009) agree that the residual monomer content of a polymer is critical to determining if it qualifies to be a PLC.

Particle size

Particle size is also a PLC criterion. Particles that are small enough to reach the deep lung upon inhalation are often associated with adverse health effects. Therefore, to qualify as a PLC, median mass aerodynamic diameter (MMAD) of the polymer particle size should be greater than 5 μm .

Structural and elemental composition

In the United States, Chemical Categories of Concern are the result of the review of new chemicals by the USEPA under the TSCA (see <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/chemical-categories-used-review-new>). New chemicals submitted to the USEPA

under the TSCA for addition to the US chemical inventory are reviewed for potential chemical, physical, and biological effects (environmental and mammalian). The USEPA groups Pre-manufacture Notice (PMN) chemicals with shared chemical and toxicological properties into categories, enabling both PMN submitters and USEPA reviewers to benefit from the accumulated data and past decisional precedents, allowing reviews to be facilitated. The categories describe the molecular structure, boundary conditions such as MW, equivalent weight, the log of the octanol–water partition coefficient, log P, or water solubility, and standard hazard (mammalian and ecological) and (environmental) fate tests to address concerns. The categories include chemicals for which sufficient history has been accumulated so that hazard concerns and testing recommendations vary little from chemical to chemical within the category. (See Supplemental Data, p 30, for details on USEPA's chemical categories.)

Elemental composition

The elemental composition is a factor in the assessment of the eligibility of polymers for reduced notification requirements. The exclusion of polymers under this step is not a conclusion of hazard but a determination that the elemental composition does not fall within the parameters of the polymer set under which this rule was formulated, and consequently, these polymers would have to follow the standard notification and review process. These elemental requirements differ across jurisdictions as covered in the report to the EU on global regulatory approaches to polymer assessment (BIO by Deloitte 2015). For example, in the EU under REACH it is proposed that polymers composed from among these elements, covalently bound to C, have reduced hazard: H, N, O, Si, S, F, Cl, Br, or I (BIO by Deloitte 2015). In contrast, the USEPA Polymer Exemption Rule states that a polymer is eligible for reduced agency review when it has at least 2 of the following elements: C, H, O, N, S, or Si (USFR 1995).

Water and lipid solubility and the octanol–water partition coefficient

Water solubility is the extent to which a compound will dissolve in water. According to the OECD 2009 meeting of the Expert Group on Polymers, polymers with “negligible” water solubility, or those described as “hydrophobic” have been represented with a water solubility of 0.000001 mg/L (1×10^{-6} mg/L; assigned arbitrarily) (OECD 2009). That is equivalent to 1 ppt, a very conservative definition.

Based on the data set studied, the OECD Expert Group on Polymers concluded “A higher proportion of polymers with intermediate water solubility values (10 mL/L–10 000 mg/L) displayed potential health concern. Polymers with water solubility <10 mg/L showed generally low health concerns” (OECD 2009, p 10). Although not a solubility metric, a polymer capable of absorbing its weight in water was associated with increased inhalation cancer risk in rats (OECD 2009).

The octanol–water partition coefficient (K_{OW}) is another criterion to assess chemicals and their environmental and health impact. The K_{OW} is a physical–chemical property at equilibrium to represent the lipophilic or hydrophilic nature

of a chemical, the distribution of a compound in octanol, representing the lipophilic nature, to its solubility in water, representing the aqueous nature. The higher the K_{OW} , the more lipophilic the compound. Typically, a $K_{OW} > 5000$ or a $\log K_{OW} > 5$ means high lipophilicity and, thus, a high potential to bioaccumulate or bioconcentrate. Numerous studies showed that K_{OW} was useful for correlating structural changes of drug chemicals with the change observed in some biological, biochemical, or toxic effect (LaGrega et al. 2010). It has been found to be related to water solubility, soil or sediment adsorption coefficients, and bioconcentration factors for aquatic life. According to the Stockholm Convention, a bioconcentration factor of >5000 and a $\log K_{OW} > 5$ is used as a criterion for bioaccumulation.

Stability

Stability is resistance to physical, chemical, or biological transformation. Loss of stability in the polymer breaks it down into smaller pieces, producing low MW species. As was previously described in the Polymer of Low Concern section under the *Molecular weight, number average molecular weight, MW distribution, and % oligomer < 1000 Da* heading, molecules with $M_n < 1000$ Da are capable of crossing cell membranes, making unstable polymers potentially hazardous to health and the environment.

Abiotic stability

Polymers are stable; monomers are not. Abiotic degradation may involve sunlight, water, or oxygen. Photochemical transformation is a reaction involving the radiation energy of sunlight (ultraviolet radiation) that may break a bond in a molecule to change it to another chemical entity. Hydrolytic degradation of polymers is another potential way to break the polymer bonds, creating smaller oligomers that may be bioavailable. Chemical oxidation is a reaction involving the loss of electrons from 1 atom to another.

Biotic stability: aerobic, anaerobic, and in vivo

Biotic stability is assessed by whether or not the polymer is degraded by microorganisms under oxygenated (aerobic) or anoxic (anaerobic) conditions; in vitro and in vivo stability studies demonstrate this. In vivo biodegradation involves the breaking of the polymer bonds by the action of bacteria, enzymes, and oxidants within the organism.

Thermal stability

Thermal stability of a polymer can be assessed when used as intended under normal, foreseeable use conditions or in extreme temperatures during disposal, such as by incineration. Thermal stability testing may involve Thermal Gravimetric Analysis (TGA), which determines mass loss over time and temperature of a test substance.

ASSESSMENT OF FLUOROPOLYMERS ACCORDING TO PLC CRITERIA

Characteristics of a PLC have been described in the preceding section. These criteria represent the combined

experience and knowledge of global regulatory authorities on factors demonstrated to be predictive of health and environmental hazards of polymers (OECD 2009; BIO by Deloitte 2015). Four fluoropolymers were assessed according to the PLC criteria. The results are summarized in Table 2, and an expanded discussion on specific criteria is provided in the remainder of this section.

Polymer composition

Fluoropolymers satisfy the PLC criterion of polymer composition. Polytetrafluoroethylene is a homopolymer of tetrafluoroethylene (TFE). Polytetrafluoroethylene can be a homopolymer (1 monomer) or it can be a modified homopolymer containing TFE widely and not more than 1% of another fluoromonomer (see ASTM 2015). Polytetrafluoroethylene contains only C and F having a $-\text{CF}_2-$ backbone terminated on both ends of each polymer chain with $-\text{CF}_3$. In unique cases, based on production method and ingredients used, commercial PTFE may have end groups that contain O, H, N, or S, depending on the initiator or chain transfer agent used in polymerization (Pianca et al. 1999). Polytetrafluoroethylene meets the compositional criterion to be a PLC.

Molecular weight, M_n , MWD, and % oligomer < 1000

Fluoropolymers satisfy the PLC criterion of MW, M_n , MWD, and % oligomer < 1000. Fluoropolymers are practically insoluble in water and all organic solvents. Therefore, standard MW methods are not applicable for fluoropolymers like PTFE and have been replaced by standardized indirect methods that use specific gravity and melt flow index to determine MW of PTFE and fluoropolymers (see Supplemental Data, p 27–28). Standard Specific Gravity (SSG) and Melt Flow Rate (MFR) are more conveniently and frequently used with fluoropolymers rather than rheological and dynamic light scattering methods (Chu et al. 1989; Starkweather and Wu 1989; Tuminello 1989; Tuminello et al. 1993). Polytetrafluoroethylene has an M_n of 500 000 to 9 000 000 Da (Berry and Peterson 1951; Doban et al. 1956; Suwa et al. 1973; Putnam 1986; Chu et al. 1989; Tuminello 1989; Tuminello et al. 1993; Frick et al. 2012). Therefore, PTFE, as a very high molecular weight polymer, cannot cross cell membranes, is not bioavailable, and cannot bioaccumulate or be toxic (see Supplemental Data, p 14). High molecular weight fluoropolymers, such as PTFE, therefore meet the PLC criterion for having MW that prevents them from entering the cells. Polytetrafluoroethylene has negligible (<<1%) oligomeric content (Starkweather and Wu 1989), as does FEP (Figure 2.) In summary, fluoropolymers are high molecular weight polymers with narrow MWD and negligible oligomer content.

Reactive functional groups and RFG ratio to MW

Fluoropolymers satisfy the PLC criterion of RFGs and RFG ratio to MW. Polytetrafluoroethylene most typically has a terminal $-\text{CF}_3$ group that is not an RFG. When this is not the case, the most common terminal group is $-\text{COOH}$, which is

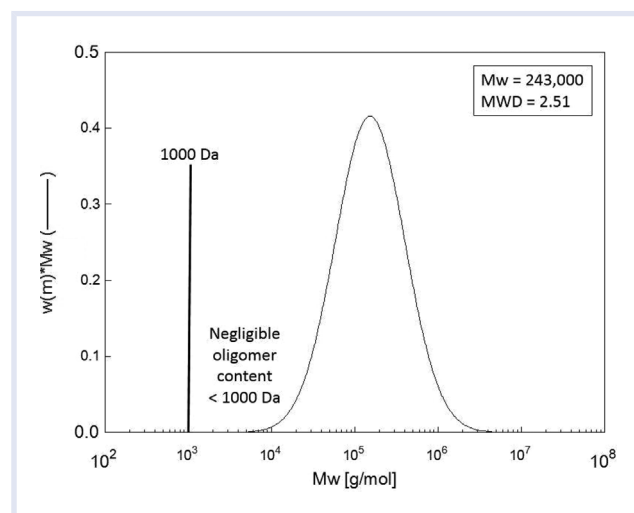


Figure 2. A fluorinated ethylene propylene (FEP) fluoropolymer molecular weight distribution from a rheological study. MW = molecular weight; MWD = molecular weight distribution.

categorized by the USEPA as a low-concern functional group. In unique cases, based on production method and ingredients used, PTFE may have end groups that may contain O, and H, N, or S, depending on the initiator or chain transfer agent used in polymerization. Fluoropolymers have a very high MW, which yields an FGEW on the order of 10^5 or more, well beyond the FGEW threshold of concern.

Low MW leachables

Fluoropolymers satisfy the PLC criterion of low MW leachables. Concentration of leachables from fluoropolymers, particularly PTFE “fine powder” (ASTM [2015] 4895-16 Type I fine powder definition), are typically very low (<1 ppm) (see Supplemental Data). This finding can be explained by the sensitivity of the PTFE polymerization reaction to contamination and is due to the postpolymerization processing steps aggressively exercised to wash out residuals and drive off volatiles. In order to achieve high MW polymerization of TFE, all traces of telogenic H- or Cl-bearing impurities must be removed (Ebnesajjad 2011; Supplemental Data).

In the analysis done on PTFE (see Supplemental Data, p 32), residual TFE monomer was not detected in PTFE resin by headspace GC-MS with a limit of detection of 1 ppm. In addition, publicly available analytical data from independent industry authorities demonstrate that TFE is not detected in finished articles made from fluoropolymers at detection limits down to about 0.01 ppm wt/wt (SPI 2005). Table 3 compares the molecular weight and the 8-h time weighted average (TWA) (American Conference of Governmental Industrial Hygienists [ACGIH], threshold limit value [TLV]), for monomers used to make fluoropolymers (ACGIH 2010). The TWAs are the exposure levels to which a worker could be exposed in an 8-h shift without adverse effects. The monomers have significantly lower MW, have lower TWAs, and are reactive. Note that the fluoropolymers are high MW, have no TWAs, and are inert. Table 3 illustrates that polymers do not have the same health hazards or MWs as their monomers.

Table 3. Fluoropolymer and monomer molecular weight and TLV data

Substance	CAS Nr	Molecular weight	ACGIH TLV 8-h TWA
Monomer: TFE	116-14-3	100	2 ppm
Monomer: Ethylene	74-85-1	28	200 ppm
Monomer: HFP	116-15-4	150	0.1 ppm
Monomer: PPVE	1623-05-8	266	200 ppm (vendor limit)
Polymer: PTFE	9002-84-0	389 000–45 000 000	None
Polymer: ETFE	25038-71-5, 68258-85-5	530 000–1 200 000	None
Polymer: FEP	25067-11-2	241 000–575 000	None
Polymer: PFA	26655-00-5, 31784-04-0	200 000–450 000	None

ACGIH = American Conference of Governmental Industrial Hygienists (ACGIH 2010); CAS = Chemical Abstracts Service; ETFE = ethylene tetrafluoroethylene; FEP = fluorinated ethylene propylene; HFP = hexafluoropropene; PFA = perfluoroalkoxy polymer; PPVE = perfluoropropylvinyl ether; PTFE = polytetrafluoroethylene; TFE = tetrafluoroethylene; TLV = threshold limit value; TWA = time weighted average.

Elemental composition

Fluoropolymers meet the widely accepted elemental composition criterion (BIO by Deloitte 2015). The USEPA, in updating its Polymer Exemption Rule, which applies to new polymers only, changed some review procedures to address certain side-chain fluorinated polymers that may degrade into small, mobile, and persistent substances (USFR 2010). This has contributed to confusion regarding the assessment of fluoropolymers. The exclusion of polymers under this step is not a conclusion of hazard, but a determination that the elemental composition does not fall within the parameters of the polymer set under which this rule was formulated, and consequently, these polymers would have to follow the standard notification and review process.

When USEPA updated the polymer exemption rule in 2010, the agency excluded polymers containing $-\text{CF}_3$ or larger chains that are covalently bound to C. The agency's rationale for the change was "...because the Agency has receiving information which suggests that polymers containing PFAS (perfluoroalkyl sulfonates) or PFAC (perfluoroalkyl carboxylates) may degrade and release fluorochemical residual compounds in the environment. Once released, PFAS or PFAC are expected to persist in the environment, may bioaccumulate, and may be highly toxic..." (USFR 2006).

Although USEPA recognized that PFAS and PFAC chemicals with longer C chain lengths (C7 and longer) may be of greater concern, it stated that there is insufficient evidence at this time, however, to definitively establish a lower C chain length limit to meet the "will not present an unreasonable risk" finding, which is the determination necessary to support an exemption under section 5(h)(4) of TSCA. The USEPA believes that it is possible for polymers containing these other types of perfluoroalkyl moieties to also degrade over time in the environment, thereby releasing the perfluoroalkyl moiety (USFR 2006).

The updated USEPA polymer exemption definition in 2010, summarized in the Objective and Rationale section for the Final Rule, may imply that new fluoropolymers with pendant or terminal $-\text{CF}_3$ groups, such as FEP, do not meet

the polymer exemption eligibility for reduced PMN reporting (USFR 2010). However, the summary definition in USFR (2010) lacks critical context found in the preamble to the Final Rule, which elaborates the conditions that would be necessary to exclude a perfluoro chemical from the polymer exemption:

- The first condition is cited above, "...polymers containing PFAS (perfluoroalkyl sulfonates) or PFAC (perfluoroalkyl carboxylates)..." where the C or S atom is an integral part of the polymer molecule; and
- the second condition notes that, polymers containing fluorotelomers or "...perfluoroalkyl moieties that are covalently bound to either a carbon or sulfur atom where the carbon or sulfur atom is an integral part of the polymer molecule can be attached to the polymers using conventional chemical reactions."

For the PFAS and PFAC as described by USEPA, the agency offers a clarification about the nature of the linkage, stating "How these materials are incorporated into the polymer is immaterial (they may be counter ions, terminal/end capping agents, or part of the polymer backbone)" (USFR 2010). The key characteristic is the presence of a $-\text{CF}_3$ group that is attached to, or forms part of, the polymer backbone and "this link (between the polymer backbone and the $-\text{CF}_3$ group) is susceptible to degradation and cleavage." (USFR 2010). Thus, in USEPA's review, the presence of $-\text{CF}_3$ group is important because it is a structural alert to consider potential degradation products. The USEPA will make a determination whether the potential degradation of the polymer in question presents an unreasonable risk to health and the environment under TSCA. As shown in Table 2, these fluoropolymers are not subject to degradation.

Water and lipid solubility and the octanol–water partition coefficient

Fluoropolymers, such as PTFE, are not soluble in octanol or water. Therefore, it is not possible to measure or calculate a

K_{OW} . Because solubility in octanol is predictive of lipid solubility, PTFE cannot dissolve in cell membrane lipids to gain access to cellular contents, nor is it small enough to enter the cell due to its very high MW. Because PTFE cannot enter the cells, it is not capable of bioaccumulation or bioconcentration in aquatic life.

Stability

Under normal, foreseeable uses, fluoropolymers are stable. Stability is resistance to physical, chemical, or biological transformation. Loss of stability in the polymer breaks it down into smaller pieces, producing low MW species. Molecules with $M_n < 1000$ Da are capable of crossing cell membranes, making unstable polymers potentially hazardous to health and the environment. Fluoropolymers, in general, have exceptional chemical and thermal stability; that is why they are so unique and useful. This is due to very strong C–F bonds that are stable under even extreme conditions (Gangal and Brothers 2015). Polytetrafluoroethylene is inert and chemically resistant to all solvents except molten alkali metals, chlorine trifluoride, and oxygen difluoride. Polytetrafluoroethylene, as a representative fluoropolymer, has the best chemical resistance of all currently known polymers and is insoluble in all known solvents, including water (Drobny 2006).

Abiotic stability

Polymers are stable; monomers are not. Photochemical transformation is a reaction involving the radiation energy of sunlight (ultraviolet radiation) that may break a bond in a molecule to change it to another chemical entity. Although PTFE will rapidly degrade in ionizing radiation (e.g., gamma radiation or high energy electron-beam radiation), it is resistant to photolysis (Drobny 2006). Photoinduced reactions with fluoropolymers do not occur. In addition, hydrolysis is a reaction involving the breaking of a bond in a molecule using water. The fluorine envelope surrounding the C backbone of PTFE is very hydrophobic. Fluoropolymers, such as PTFE, are hydrolytically stable, water resistant, and are not subject to hydrolysis catalyzed degradation (Arkles 1973). Finally, chemical oxidation is a reaction involving the loss of electrons from one atom to another. Because the C–F bond is one of the strongest known, and F is the most electronegative element, the C–F bond is thermodynamically stable, unfavorable to lose electrons (i.e., to oxidize) (Arkles 1973).

Biotic stability: aerobic, anaerobic and in vivo

Fluoropolymers like PTFE are biologically inert and not degraded by microorganisms under oxygenated (aerobic) or anoxic (anaerobic conditions); in vitro and in vivo studies demonstrate this. In vivo degradation involves the breaking of the polymer bonds due to bacteria and other enzymes and oxidants. For example, PTFE hernia patches explanted from patients and examined by scanning electron microscopy, attenuated total reflectance Fourier transform infrared spectroscopy, modulated differential scanning calorimetry, and optical microscope showed no degradation in vivo (King et al. 2013).

Thermal stability

Fluoropolymers, when used as intended under normal, foreseeable use conditions as specified in Table 2 (or “continuous processing temperature”) are thermally stable (Puts et al. 2014). The fluoropolymer industry has provided significant information on appropriate use of fluoropolymers (SPI 2005). Thermal gravimetric analysis determines mass loss over time and temperature of a test substance. Polytetrafluoroethylene is one of the most thermally stable polymers. Polytetrafluoroethylene’s continuous processing temperature is 260 °C (SPI 2005). This means that PTFE could remain for decades at 260 °C and not decompose (SPI 2005 see percent mass lost per hour at maximum continuous processing temperature).

Outside of normal, foreseeable use conditions (also known as “misuse”), when fluoropolymers are held at temperatures above their recommended processing temperatures, they degrade. Upon decomposition, fluoropolymers generate volatile degradation products (SPI 2005). At 450 °C, the decomposition of PTFE “only proceeds at a rate on the order of one percent per hour. It is not until considerably above the polymer first-order transition temperature (329 °C) that substantial decomposition is observed” (Arkles and Bonnett 1974). As the temperatures increase above recommended processing temperatures, the rate of generation rises and may sufficiently degrade the polymer to produce hazardous gaseous byproducts and polymer (particulate) fume fever (SPI 2005). Temperature, availability of O, the physical form of the polymer article, and the residence time at elevated temperature factor into the ultimate nature of the decomposition products (SPI 2005), mainly fluoroalkenes, hydrogen fluoride, oxides of C, and lower molecular weight fluoropolymer particulates. For PTFE, TFE is the principle gaseous product observed at temperatures near 330 °C. See Supplemental Data for additional information regarding overheating PTFE.

PRODUCT-SPECIFIC REGULATORY REQUIREMENTS

Certain product-specific regulations, such as those for medical devices and food contact for the United States and the EU, require the development of additional data beyond what is required to conduct a PLC evaluation. The following text will discuss food contact requirements for the United States and the EU, and medical device requirements.

Data requirements for food, pharmaceutical, and medical device applications

There are country-specific data requirements for fluoropolymer use in food, pharmaceutical, and medical device applications because the intended use of these products has the potential to directly or indirectly introduce the product into the human body. An extensive fluoropolymer data set has been developed by W.L. Gore for these uses. The clinical history of the safe implantation of more than 40 million PTFE medical devices over 40 y, extensive toxicity data, preclinical

data, and chemical extractables and migration testing confirmed that fluoropolymers are not bioavailable. Although the data requirements have evolved over time for contacting food, pharmaceuticals, or use in medical devices, the data (some of which are provided in the present article, the Supplemental Data for the present paper, regulatory submissions, and product literature) confirm the conclusion that fluoropolymers are safe for these intended uses and support the conclusion that fluoropolymers should be considered PLCs.

Polymer of low concern data and US and European Union food contact requirements

In general, the data required to support a PLC determination are helpful, but insufficient to qualify a material for food contact use. Submissions to the US Food and Drug Administration (USFDA) to support new food contact substances require extensive data submissions, including, for example, the nature and amount of nonvolatile extractives (USFDA 2017). Fluoropolymers, however, are not new substances in applications where they come in contact with food and have longstanding acceptance by regulators. In the United States, the USFDA is responsible for regulation of materials that come in contact with food and are considered "indirect food additives," specifically polymers (USFR 2016a). Food storage or food packaging materials, such as the fluoropolymers PTFE, FEP, and PFA, are "perfluorocarbon resins" acceptable for use by application and material type, provided they meet the extractable limits specified in the regulation (USFR 2016b).

Similarly, the European Food Safety Agency (EFSA) provides recommendations to the European Commission (EC) within the EU for the regulation of food contact materials, requirements for their evaluation, and authorization of acceptable uses (EC 2004). Polymer clearance is based in part upon the fact that polymers will not migrate into food due to their high molecular weight. The EU focuses on potential low molecular weight moieties, such as residual monomers and leachables, rather than on the polymer itself. The EU food contact regulation requires that monomers, other starting substances, and additives used to produce food contact polymers should be risk assessed and authorized (EU 2011). The regulation lists authorized substances that are permitted to have food contact (EU 2011). This regulation also sets the specific migration limit (SML), which is the maximum permitted amount of substance in food that has been determined not to pose a risk to human health, specifically for individual chemicals (e.g., monomer) (EU 2011). Note that these limits exist whether or not the substance is present in the food contact material (FCM). The monomers, other starting substances, and additives used to produce fluoropolymers for food contact (e.g., PTFE, FEP, and PFA) have been authorized for food contact uses. Representative SMLs for these monomers, additives, and starting substances relevant for fluoropolymers are given in the Supplemental Data (p 14).

Polymer of low concern data and medical device regulatory requirements

Satisfaction of the PLC criteria is insufficient to satisfy medical device requirements. Formal biocompatibility evaluations are required by the USFDA and other global regulatory authorities to support submissions for approval of medical devices and pharmaceuticals (e.g., combination products, such as drug-eluting stents or prefilled single-dose syringes). The International Organization for Standardization (ISO) 10993 Biocompatibility of Medical Devices standards describe a broad array of biocompatibility tests that require consideration for each new device or significant changes to existing devices (ISO 2009). Over the years, medical devices containing PTFE (or expanded PTFE) have been evaluated using ISO 10993 and US Pharmacopeia (USP) Class VI standards (USP 2011) and have been determined to be biocompatible in their intended uses.

The ISO 10993 standards provide guidance for evaluation of the biological response to a medical device. The USFDA, as well as most international regulatory agencies, recognizes and uses ISO 10993 standards to guide safety evaluations of medical devices submitted for their approval. Requirements to demonstrate the biocompatibility of medical devices are set forth in ISO 10993-1, and regulatory authority-specific requirements (e.g., PMDA 2003; USFDA 2016). In addition, country pharmacopeial organizations also specify testing required for biological reactivity of drugs (e.g., US Pharmacopeia, EU Pharmacopeia, Japan Pharmacopeia). The ISO requirements are categorized by the nature of body contact (e.g., mucosal membrane, circulating blood, tissue, bone, dentin) and duration of contact (<24 h, ≥ 1 d ≤ 30 d, >30 d). Depending on the nature and duration of contact, requirements include cytotoxicity, irritation, sensitization, implantation, acute-subchronic-chronic systemic toxicity, material-mediated pyrogenicity, hemocompatibility (e.g., hemolysis, thrombogenicity, and complement activation), genotoxicity (in vitro and in vivo), carcinogenicity, and developmental toxicity. (See Supplemental Data p 15 for a list of ISO 10993 biocompatibility tests.)

MEETING PLC CRITERIA PRECLUDES A FINDING THAT A CHEMICAL IS OF HIGH CONCERN

Just as regulatory frameworks have mechanisms to identify materials of low concern such as PLCs, they also have mechanisms to identify chemicals of high concern. For example, under REACH, a mechanism exists to identify substances of very high concern (SVHCs). Having demonstrated that fluoropolymers like PTFE should be considered PLCs, we will also demonstrate that these fluoropolymers cannot be SVHCs under REACH, do not meet the PM and PMT criteria proposed by UBA, and do not meet the criteria for listing as a POP under the Stockholm Convention.

Fluoropolymers and EU REACH SVHC, CMR, PBT, vPvB, and endocrine disrupting chemical (EDC) criteria

According to the European Chemicals Agency (ECHA), SVHCs are defined in Article 57 of Regulation (EC) Nr 1907/2006 ("the REACH Regulation") (EC 2006) and include substances that are

- "Carcinogenic, mutagenic or toxic to reproduction (CMR), meeting the criteria for classification in category 1 or 2 in accordance with Directive 67/548/EEC. This directive was replaced in beginning of 2009 by the new EU regulation (EC) No 1272/2008 on classification, labeling and packaging of chemical substances and mixtures, the so-called CLP Regulation. According to the new CLP Regulation these substances shall be classified as 1a or 1b."
- "Persistent, Bioaccumulative and Toxic (PBT) or very Persistent and very Bioaccumulative (vPvB) according to the criteria in Annex XIII of the REACH Regulation."
- "Identified, on a case-by-case basis, from scientific evidence as causing probable serious effects to human health or the environment of an equivalent level of concern as those above (e.g., EDCs)."

Under REACH, polymer substances are not registered, but the monomers they are composed of are registered, and the registration must be supported by data submissions that are tiered on the basis of tonnage (see EC 2006, Annex VII). The REACH definition of polymer includes materials with as few as 3 repeating units. But such a small molecule would not meet common industry standard definitions for fluoropolymers (ASTM 2015). It is highly unlikely that fluoropolymers meeting the PLC criteria would exhibit the criteria of an SVHC under REACH. Fluoropolymer data developed for other regulatory needs support the predictive value of the PLC assessment criteria and demonstrate the low hazard potential of this class of PFAS. Due to their physical-chemical properties, PLCs are not bioavailable to cause toxicity or to bioaccumulate. Toxicity study data on PTFE in the Supplemental Data (p 15–27), for example, demonstrate a lack of toxicity, including genotoxicity. Although fluoropolymers are persistent, they are not bioaccumulative or toxic and therefore do not meet the PBT criteria.

Fluoropolymers and German UBA-proposed PMT criteria

As regulatory frameworks continue to evolve, more work is needed in the area of PFAS classification to ensure that regulations are appropriate in scope and proportionality. Although some well-known PFAS would qualify as PM or PMT substances as proposed by the UBA (2017), fluoropolymers do not possess these characteristics. Although fluoropolymers are highly stable (persistent), they do not meet the criteria to be mobile or toxic. To demonstrate this point, PTFE, a high molecular weight fluoropolymer and a member of the PFAS group, is assessed (in the last 4 paragraphs of this section) according to the proposed UBA criteria (UBA 2017).

Briefly, the changes to PM and/or PMT assessment proposed by UBA address applicability, persistence, mobility, and toxicity. The UBA proposes an initial step involving assessment of the chemical composition of a substance to determine if the substance is within the applicability domain of the proposed new assessment criteria. The UBA notes that currently only identifiable organic and organometallic chemicals are considered, and purely inorganic substances or substances of unknown or variable compositions, complex reaction products, or biological material are excluded (UBA 2017).

With respect to persistence, UBA proposes that the criterion for persistence be the same as in Annex XIII of REACH, which considers degradation half-lives in marine water, fresh- or estuarine water, marine sediment, and soil as part of the PBT/very persistent, very bioaccumulative (vPvB) assessment criteria; these degradation half-life criteria range from 40 to 180 d. The UBA proposes that a substance meets the persistent criterion if the degradation half-life in marine water at pH 6 to 8 and 12 °C is higher than 60 d, the half-life in fresh- or estuarine water at pH 6 to 8 and 12 °C is higher than 40 d, the half-life in marine sediment at pH 6 to 8 and 12 °C is higher than 180 d, the half-life in fresh- or estuarine water sediment at pH 6 to 8 and 12 °C is higher than 120 d, or the half-life in soil at pH 6 to 8 and 12 °C is higher than 120 d.

The UBA proposes that the mobility criterion for a persistent chemical should be determined on the basis of 2 considerations. First, the water solubility of a substance at pH 6 to 8 and 12 °C must be greater than or equal to 150 µg/L, and the log K_{OC} at pH 6 to 8 and 12 °C must be less than or equal to 4.5. The UBA notes that the mobility criterion should be applied only to substances that have fulfilled the criterion for persistence.

Lastly, with respect to toxicity, UBA proposes a 5-part test for involving data to understand if the substance is carcinogenic, germ cell mutagenic, or toxic for reproduction; if there is other evidence of chronic toxicity; and if there is evidence for effects on or via lactation. The derived no adverse effect level (DNEL) must be less than or equal to 9 µg·kg⁻¹·d⁻¹. The UBA notes that the first 2 considerations are the same criteria defined in Annex XIII of REACH as part of the PBT/vPvB assessment criteria regarding human health. The next 2 criteria specifically address concerns for drinking water exposure and are based on Regulation EC No 1272/2008 (EC 2008) and Cramer class II (Cramer et al. 1978) for substances exhibiting moderate or low biological activity, respectively. The DNEL criterion is based on Kalberlah et al. (2014).

Regardless of the arguments concerning the scientific foundation and credibility of the changes proposed by UBA to REACH PM and PMT assessment criteria, the central question with respect to PTFE is whether chemical-specific assessment would lead to an outcome different from that assuming PTFE behaved similarly to other PFAS substances. Polymers, including fluoropolymers, are different from non-polymeric chemicals and may be regulated differently. Because of these differences, it is recognized that some data requirements may not be applicable to polymers (EU 2011) For example, as we have shown, the physical-chemical criteria of PLC are predictive of lack of hazard.

With respect to applicability, PTFE is not a substance currently registered under REACH because it meets the REACH definition of a polymer substance: “a molecule that contains a sequence of at least 3 monomer units, which are covalently bound to at least one other monomer unit or other reactant” (EC 2006). However, because PTFE is an identifiable organic substance, the proposed UBA framework for assessment using the proposed PMT criteria would be applicable. Further, PTFE is highly stable and persistent in the environment. It is resistant to thermal degradation, being stable for decades at temperatures up to 260 °C (SPI 2005); is stable in terms of hydrolysis, oxidation, and light (Brydson 1999); and is stable in terms of anaerobic and aerobic degradation (King et al. 2013). Therefore, PTFE would fulfill the UBA’s proposed persistence criterion.

In contrast, PTFE is practically insoluble in water and, therefore, is not mobile in the environment. Using the descriptive solubility table for the USP (2011), the water solubility of PTFE would be classified as practically insoluble (1×10^{-5} mg/L or 0.01 µg/L) to very slightly soluble (1×10^{-4} mg/L or 0.1 µg/L) (USP 2011). The mobility of PTFE is 1000 to 10000× lower than UBA’s proposed mobility criterion. Therefore, PTFE does not fulfill UBA’s proposed mobility criterion and would not be classified as a PM or PMT substance.

A similar negative finding for PTFE pertains to toxicity. The average molecular weight of PTFE is too large for the polymer to cross a cell membrane, which means it is not bioavailable or toxic. Polytetrafluoroethylene has been tested extensively in the United States and European Union to assess commercial applications for food contact and global medical device regulations (see Supplemental Data for additional details). Results demonstrate the absence of toxicity. Therefore, PTFE does not fulfill UBA’s proposed toxicity criterion and would not be classified as a PM or PMT substance (Table 4).

Fluoropolymers and the Stockholm Convention POP criteria

In addition to country and regional regulations, there are global legally binding instruments, such as the United Nations Environment Programme-administered conventions on chemicals and waste (UNEP 2001), such as the Stockholm Convention on Persistent Organic Pollutants. The Convention aims to eliminate POPs by eliminating their production, reducing their use, or limiting their use through a cradle-to-grave approach. For the listing of new chemicals into the Convention, numeric or other criteria have been set for the screening of proposed compounds. Stockholm Convention Criteria (annex D) are compared to those of the USEPA, EU REACH, and the UBA-proposed PMT (Table 4). Fluoropolymers meet the persistence criterion only, not the bioaccumulative, toxic, or mobile criteria.

Fluoropolymers satisfy widely accepted criteria to be considered PLCs. Their physical-chemical properties prevent bioavailability, bioaccumulation, toxicity, and degradation. They have negligible monomer, oligomer, and leachable content and no reactive functional groups with high toxicity. These comparisons of PLC and various regulatory assessment criteria demonstrate that, in the realm of PFAS, high

molecular weight fluoropolymers like PTFE have vastly different properties than do other PFAS, and therefore, they are truly a separate class of materials that must be assessed on their own merits as has been done here. They also underscore the value of a global regulatory definition of a polymer.

FUTURE WORK

It is important to acknowledge that the manufacture and end-of-life phases of the fluoropolymer life cycle are not the subject of the present paper. The following reflections are provided on how these may be explored in future work. Fluoropolymer manufacture includes fluoromonomers and a wide array of initiators, catalysts, et cetera, including polymer production aids, some of which are fluorosurfactants (non-polymer PFAS) (see Supplemental Data, p 8, for more information about them). Historically, perfluorocarboxylic acids such as PFOA and perfluorononanoic acid (PFNA) were used as polymer production aids in the manufacture of fluoropolymers. They are no longer used by leading global fluoropolymer manufacturers (USEPA 2017a), who are now using alternative substances such as fluorinated polyether carboxylates (see Supplemental Data Table S2). The toxicological and environmental properties (e.g., persistence, bioavailability, and mobility) of these alternatives are very important. Future work should delve into fluoropolymer manufacture and describe the safety, health, and environmental management practices and controls employed; should describe the applicable regulations; and should assess substances used in fluoropolymer manufacture, their human health and environmental attributes, and their mass balance.

At end-of-life when a fluoropolymer has fulfilled its intended use and will be disposed of, the fate of fluoropolymers should be investigated further. Although there are sufficient data to demonstrate that fluoropolymers such as PTFE do not degrade in the environment or release substances of toxicological or environmental concern (Hintzer and Schwertfeger 2014), the downstream, end-of-life process of incineration merits future work. For instance, at temperatures above 450 °C, PTFE begins to degrade, releasing hazardous substances such as hydrofluoric acid. There are published studies on the incineration of fluoropolymers under normal, foreseeable municipal waste incinerator conditions targeting specific analytes (Taylor 2009). Presently, most legislation addresses the release of hydrogen fluoride (HF) as the only critical parameter; limit values are for stack emissions (e.g., EU 2000). Future work should investigate incineration under a range of relevant foreseeable use conditions to determine more comprehensively the substances formed and their amounts. Such an incineration study is underway with results to be published upon completion (W.L. Gore 2017). In addition, the practice of the open burning of fluoropolymers, or for that matter of any polymer, is unacceptable and unsafe. Responsible incineration of fluoropolymers, adhering to regulatory guidelines, at the end of their life cycle is appropriate.

Table 4. Comparison of United States, Stockholm Convention, EU REACH, and German Criteria

Criterion	United States ^a	Stockholm Convention ^b	REACH ^{c,d}	Germany ^{d,e}
Persistence (half-life)				
P	Water, soil, sediment > 60 d	Water >60 d	Marine water > 60 d	Same as REACH
		Soil, sediment >180 d	Estuarine water > 40 d	
			Fresh or estuarine sediment or soil > 120 d	
vP	Water, soil, sediment > 180 d		Marine, fresh, estuarine H ₂ O > 60 d	
			Marine, fresh, or estuarine sediment > 180 d	
			Soil > 180 d	
Bioaccumulation				
B	Aquatic BCF > 1000	Aquatic BCF or BAF > 5000	BCF > 2000	
		Log K _{OW} > 5		
vB	BCF > 5000		BCF > 5000	
Toxicity				
	Fish	Toxic or ecotoxic	Long-term aquatic NOEC or EC10 < 0.01	1) Carcinogenic, germ cell mutagenic, or toxic for reproduction ^d ;
	Low > 10 mg/L	(No numeric criteria)	Classified as carcinogen category 1A or 1B; mutagen 1A or 1B; reproductive toxin 1A, 1B, or 2 ^d	2) other evidence of chronic toxicity ^d ; and
	Moderate 0.1 mg/L–10 mg/L			3) evidence for effects on or via lactation ^d .
	High < 0.1 mg/L			4) DNEL ^f ≤ 9 μg · kg ⁻¹ d ⁻¹
			Specific target organ toxicity (STOT RE 1 or 2) upon repeated (chronic) exposure) ^d	
Long-range transport (potential for)		Long-range transport (potential for): Presence through monitoring or modeled data; t _{1/2} (air): 2 d		
Mobility				Mobility: water solubility at pH 6–8, 12 °C, must be ≥150 μg/L, and the log K _{OC} at pH 6–8, 12 °C must be ≤4.5.

BAF = bioaccumulation factor; BCF = bioconcentration factor; DNEL = derived no adverse effect level; EU = European Union; M = mobile; P = persistent; REACH = Registration, Evaluation, Authorisation and Restriction of Chemicals; STOT RE = specific target organ of toxicity repeat exposure; T = toxic; v = very.

^aUSEPA 1999.

^bUNEP 2001

^cECHA 2014

^dEC 2008

^eUBA 2017

^fBarlow 2005; Kalberlah et al. 2014.

Recycling, reuse, and closed loop systems are alternative options at the end of life. Recent work has shown, on a small scale, the ability to convert fluoropolymers back to their monomers for capture (Schlipf 2014; Invertec 2017).

This approach to a closed loop economy for fluoropolymers merits additional work and discussion, as does the recycling and reuse of melt-processable fluoropolymers, such as FEP.

CONCLUSIONS

The present review has brought together fluoropolymer toxicity data, human clinical data, and physical–chemical characteristics, using PTFE as an example to show that fluoropolymers satisfy the widely accepted regulatory assessment criteria to be considered as PLCs. Fluoropolymers are high molecular weight, have narrow molecular weight distribution, and have negligible oligomer content and organic and inorganic leachables. Data show that fluoropolymers have thermal, chemical, photochemical, hydrolytic, and biological stability. Polytetrafluoroethylene has been extensively tested to comply with US and EU food contact and global medical device regulations (e.g., USFDA, CFDA, Korea MFDS, Japan PMDA), including ISO 10993 biocompatibility testing and preclinical animal testing. Toxicology studies on PTFE demonstrate the absence of acute or subchronic systemic toxicity, irritation, sensitization, local toxicity on implantation, in vitro and in vivo genotoxicity, hemolysis, complement activation, or thrombogenicity. The data presented demonstrate that the fluoropolymer class of PFAS is well defined, meets PLC criteria, and should be considered as distinctly different from other classes of PFAS. The grouping of all PFAS together is not supported by the scientific data.

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Data Accessibility—All data and information used in this manuscript have been made available in tabulated form (Tables 1–4) by the authors and are included in the paper and the Supplemental Data.

SUPPLEMENTAL DATA

The Supplemental Data contains descriptive and more detailed information as highlighted in the paper.

Figure S1. Where does polytetrafluoroethylene (PTFE) come from?

Figure S2. Fluoropolymer primer: polytetrafluoroethylene (PTFE) polymerization scheme.

Figure S3. Fluoropolymer primer: polytetrafluoroethylene (PTFE) finishing scheme.

Figure S2. A fluorinated ethylene propylene (FEP) fluoropolymer molecular weight distribution from a rheological study.

Table S1. Polytetrafluoroethylene (PTFE) polymerization and post polymerization aids

Table S2. Alternative fluoropolymer processing aids: Sources of data

Table S3. Solubility table from USP 34 NF 29 General Notices, Section 5.3.0, p 6

Table S4. European Union (EU) specific migration limits (SMLs) for monomers in representative fluoropolymers

Table S5. Biocompatibility tests, conditions, and acceptance criteria results for expanded polytetrafluoroethylene patch

Table S6. US Environmental Protection Agency's (USEPA's) chemical categories of concern, 2010

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Critical Review

A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers

Stephen H. Korzeniowski,¹ Robert C. Buck,² Robin M. Newkold,² Ahmed El kassmi,³ Evan Laganis,³ Yasuhiko Matsuoka,⁴ Bertrand Dinelli,⁵ Severine Beauchet,⁵ Frank Adamsky,⁶ Karl Weilandt,⁷ Vijay Kumar Soni,⁸ Deepak Kapoor,⁹ Priyanga Gunasekar,⁹ Marco Malvasi,¹⁰ Giulio Brinati,¹⁰ and Stefana Musio¹⁰

¹BeachEdge Consulting LLC, Media, Pennsylvania, USA

²The Chemours Company, Wilmington, Delaware, USA

³AGC Chemicals Americas, Exton, Pennsylvania, USA

⁴AGC Performance Chemicals General Division, Tokyo, Japan

⁵Arkema, Colombes, France

⁶Daikin America Inc., Decatur, Alabama, USA

⁷Advanced Materials Division, 3M Center, 3M Company, St. Paul, Minnesota, USA

⁸Gujarat Fluorochemicals Limited, Noida, Uttar Pradesh, India

⁹Gujarat Fluorochemicals GmbH, Regus Centre Watermark, Hamburg, Germany

¹⁰Solvay Specialty Polymers, V.le Lombardia, Bollate, (MI), Italy

Abstract

Fluoropolymers are a distinct class of per- and polyfluoroalkyl substances (PFAS), high molecular weight (MW) polymers with fluorine attached to their carbon-only backbone. Fluoropolymers possess a unique combination of properties and unmatched functional performance critical to the products and manufacturing processes they enable and are irreplaceable in many uses. Fluoropolymers have documented safety profiles; are thermally, biologically, and chemically stable, negligibly soluble in water, nonmobile, nonbioavailable, nonbioaccumulative, and nontoxic. Although fluoropolymers fit the PFAS structural definition, they have very different physical, chemical, environmental, and toxicological properties when compared with other PFAS. This study describes the composition, uses, performance properties, and functionalities of 14 fluoropolymers, including fluoroplastics and fluoroelastomers, and presents data to demonstrate that they satisfy the widely accepted polymer hazard assessment criteria to be considered polymers of low concern (PLC). The PLC criteria include physicochemical properties, such as molecular weight, which determine bioavailability and warn of potential hazard. Fluoropolymers are insoluble (e.g., water, octanol) solids too large to migrate into the cell membrane making them nonbioavailable, and therefore, of low concern from a human and environmental health standpoint. Further, the study results demonstrate that fluoropolymers are a distinct and different group of PFAS and should not be grouped with other PFAS for hazard assessment or regulatory purposes. When combined with an earlier publication by Henry et al., this study demonstrates that commercial fluoropolymers are available from the seven participating companies that meet the criteria to be considered PLC, which represent approximately 96% of the global commercial fluoropolymer market. *Integr Environ Assess Manag* 2023;19:326–354. © 2022 The Authors. *Integrated Environmental Assessment and Management* published by Wiley Periodicals LLC on behalf of Society of Environmental Toxicology & Chemistry (SETAC).

KEYWORDS: Applications, Fluoropolymers, Low concern, PFAS, Property Combinations

This article contains online-only Supporting Information.

Correspondence Stephen H. Korzeniowski, BeachEdge Consulting LLC, Media, PA, USA.

Email: shkorzo@gmail.com

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INTRODUCTION

“Fluoropolymers are high MW polymers with fluorine atoms directly attached to their carbon-only backbone” (Ebnesajjad, 2017). The carbon–fluorine (C–F) bond is the strongest bond between carbon and another atom and imparts unique, outstanding, and beneficial properties and extraordinary functional performance to fluoropolymers (Ameduri, 2020; Ameduri & Sawada, 2017a, 2017b; Banks et al., 1994; Fluoropolymer Products Group of Plastics Europe [FPG], 2021a; Scheirs, 2007). These properties

include chemical, biological, and thermal stability, heat and chemical resistance, unique dielectric properties, and durability. Additional fluoropolymer properties include fire resistance, weather resistance, nonwetting, and nonstick. Fluoropolymers are regarded as irreplaceable in many applications because their unique combination of specific properties, which are critical to ensure optimal performance in many applications, cannot be achieved or guaranteed by alternative materials (FPG, 2021a, 2017; Henry et al., 2018; Performance Fluoropolymer Partnership of the American Chemistry Council [PPF], 2020).

Per- and polyfluoroalkyl substances (PFAS), a universe of substances with widely diverse properties that have been used in industrial and consumer applications since the 1950s, include fluoropolymers as a distinct class (Buck et al., 2011; Henry et al., 2018). A single, globally harmonized definition for PFAS has not yet been agreed upon. PFAS have been defined differently based on their structure and atomic composition (Buck et al., 2021; Wallington et al., 2021). For example, the USEPA's working PFAS structure definition is "a structure that contains the unit $R-CF_2-CF(R')(R'')$, where R, R', and R'' do not equal "H" and the carbon-carbon bond is saturated (note: branching, heteroatoms, and cyclic structures are included)" (USEPA, 2021a). The European Chemicals Agency (ECHA) employed a much broader PFAS structural definition (ECHA, 2020). A recent Organisation for Economic Cooperation and Development (OECD) report, which defined PFAS as fluorinated substances that contain in their structure at least one fully fluorinated methyl or methylene carbon atom (without any H/Cl/Br/I atom attached to it), that is, with a few noted exceptions, any chemical with at least a perfluorinated methyl group ($-CF_3$) or a perfluorinated methylene group ($-CF_2-$; OECD, 2021). This report acknowledges that the term "PFAS" is broad, general, and nonspecific, which does not inform whether a compound presents risk or not, but only communicates that the compounds under this term share the same structural trait of having a fully fluorinated methyl or methylene carbon moiety. Further, the report highlights that, among the substances defined as PFAS, there are distinct substances with very different properties: polymers and nonpolymers; solids, liquids and gases; persistent and nonpersistent substances; highly reactive and inert substances; mobile and insoluble (immobile) substances; and (eco) toxic and nontoxic chemicals. In addition, the report recognizes that PFAS have diverse molecular structures (e.g., neutral, anionic, cationic, or zwitterionic; with or without aromatic rings; nonpolymers or polymers; low or high molecular weight (MW), and thus diverse physical, chemical, and biological properties (e.g., involatile or volatile; water soluble or water insoluble; reactive vs. inert; bioaccumulative or nonbioaccumulative) and as such highly recommends that such diversity be properly recognized and communicated in a clear, specific, and descriptive manner when communicating about PFAS.

There is considerable media and public confusion and misunderstanding regarding PFAS, as the many different chemicals and groups are often not clearly differentiated under the broad term PFAS. Per- and polyfluoroalkyl substances, a large, diverse group of substances with vastly different properties, is too broad to allow effective, science-based assessment and regulation of chemical compounds as an entire group. This point has been raised in recent publications that suggest approaches to effectively group PFAS for regulatory assessment (American Chamber of Commerce in Europe [Amcham], 2020a; Buck et al., 2021; Bundesverband der Deutschen Industrie e.V. [BDI], 2021; Fiedler et al., 2020; Miller et al., 2020; Orgalim, 2021; Royal Society of Chemistry [RSC], 2021; Sha et al., 2019; Wallington et al., 2021). A clear understanding of the origin of PFAS found in the environment, the PFAS that are commercially relevant (Buck et al., 2021), and assessment of their properties are needed to be able to determine which classes of PFAS require management action. PFAS must be assessed based on their chemical, physical, thermal, and biological property differences and uses (Amcham, 2020a; BDI, 2021; Buck et al., 2021; RSC, 2021; Wallington et al., 2021). As regulatory frameworks, such as the EU REACH regulation, continue to evolve, more work is needed to distinguish clearly among PFAS based on their properties to assure that regulations are appropriate in scope, proportionate, and are science-based.

Per- and polyfluoroalkyl substances are divided into two primary categories: nonpolymers and polymers (Buck et al., 2011). Polymeric PFAS, generally known as "fluorinated polymers," include fluoropolymers (discussed here), perfluoropolyethers (PFPE), and side-chain fluorinated polymers (SCFP; Buck et al., 2011; Henry et al., 2018 and Supporting Information: Figure 6.1). This article deals strictly with fluoropolymers. Neither PFPE nor SCFP are discussed here.

The nonpolymer category includes perfluoroalkyl substances and polyfluoroalkyl substances. Certain nonpolymer PFAS substances, for example, short- and long-chain per- and polyfluoroalkyl carboxylic acids and sulfonic acids, received regulatory scrutiny recently due to their toxicity, as well as their persistence, potential to bioaccumulate, and/or mobility in the environment. Regulatory processes have been launched worldwide to address these concerns related to specific nonpolymer PFAS. These targeted regulatory measures have evolved increasingly into restrictions on the entire family of PFAS. For example, five Member States of the European Economic Area have initiated a procedure to prepare a joint restriction proposal under the EU REACH Regulation to limit the risks to human health and the environment from the manufacture and use of all substances in the PFAS family based on structure alone (ECHA, 2020). Although fluoropolymers fit the PFAS structural definition, they have vastly different physicochemical, environmental, and toxicological properties than other PFAS in addition to substantial societal benefits and importance (Fluoropolymer Products Group of Plastics Europe [FPG], 2017, 2021a). For

these reasons, fluoropolymers should be considered separately and not aggregated with all other PFAS for regulatory action. Concurrently, the USEPA prepared a PFAS Strategic Roadmap laying out how it plans to evaluate and potentially regulate PFAS (USEPA, 2021a). Recognizing that there are many PFAS very diverse in their physical form, chemical structure and composition, functional characteristics, and toxicity profiles, USEPA “is conducting new research to better understand the similar and different characteristics of specific PFAS and whether and how to address groups and categories of PFAS.”

Fluoropolymers have documented safety profiles, are thermally, biologically, and chemically stable, negligibly soluble in water, nonmobile, nonbioavailable, non-bioaccumulative, and nontoxic (Henry et al., 2018). Some fluoropolymers have been demonstrated to meet the “polymers of low concern” (PLC) criteria, and as such do not present notable concern for human health or the environment (Henry et al., 2018). PLC criteria were developed over time within regulatory frameworks around the world as an outcome of chemical hazard assessment processes, which identified physical–chemical properties of polymers that determine polymer bioavailability and thereby report a polymer's potential hazard. For example, many of the physicochemical properties, such as MW, limit the ability of a polymer to cross the cell membrane and therefore limit its bioavailability (Kostal, 2016; Lipinski et al., 2001; USEPA, 2012). The USEPA built on this knowledge to adopt a polymer exemption rule to exempt low-hazard polymers from certain regulatory notification requirements under the Toxic Substances Control Act's (TSCA) new chemicals program (United States Federal Register [USFR], 1984). An OECD expert group on polymers reached consensus on these criteria and their respective metrics, documenting the data required for a polymer to qualify as a PLC to human health and the environment (OECD, 1993). Subsequently, an additional OECD work group concurred that PLC have “insignificant environmental health and human health impacts” (OECD, 2009). In addition, the European Commission commissioned a report (BIO by Deloitte, 2015) wherein several member countries agreed on the polymer properties predictive of adverse human health and environmental hazard. The report outlined eligibility criteria for a polymer to be considered a PLC. In 2019, the industry-led European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC) developed a “Conceptual Framework for Polymer Risk Assessment” (“CF4Polymers”; ECETOC, 2019). CF4Polymers provides guiding elements to be considered in assessing potential ecological and human health hazards and risks posed by polymer substances. CF4Polymers also considers specific life-cycle stages of polymer products and their associated routes of exposure. The authors of the CF4Polymers framework support the PLC approach as a means to accomplish polymer risk assessments. They specifically support the findings of Henry et al. (2018) and state that they are “...unaware of scientific evidence to justify generally assigning fluoropolymers the same level of

regulatory concern as other PFAS” (ECETOC, 2019). In 2020, the European Commission contracted a study to propose criteria for the identification of polymers requiring registration (PRR) under REACH (Wood, 2020a). The Wood report states that the authors consider that fluoropolymers meet the criteria to be considered PLC, “following the recommendations of Henry et al.” Considerable debate and comment on proposals have been put forward as the process and discussion advances (American Chamber of Commerce in Europe [Amcham], 2020b; FPG, 2021a; Hafer, 2021).

Four major fluoropolymers have previously been demonstrated to meet the criteria as PLC (Henry et al., 2018). This 2018 study raised interest in gathering similar data for additional commercial fluoropolymer products, both in scope and polymer type. In this study, seven global fluoropolymer manufacturers from the USA, Europe, and Asia collaborated to gather and present data for 14 additional fluoropolymers. In addition to information describing chemical composition, uses, performance properties, and functionalities of the 14 fluoropolymers, author company data for each of the PLC criteria are presented and discussed. The results demonstrate that each of the 14 commercially manufactured fluoropolymers in this study satisfy the widely accepted assessment criteria to be considered PLC and merit such designation. The study results add further evidence to demonstrate that fluoropolymers are demonstrably different and should not be grouped with other PFAS for hazard assessment or regulatory purposes.

USES, PERFORMANCE PROPERTIES, AND FUNCTIONALITY OF FLUOROPLASTICS AND FLUOROELASTOMERS IN THIS STUDY

The fluoropolymers described and evaluated in this study are high-performance materials used in commercial and industrial applications. Described herein are the industries and sectors (Table 1) and the performance properties and functionalities (Table 2) of the study fluoropolymers. The unparalleled combination of properties makes fluoropolymers critical materials for a broad range of applications and industrial sectors including automotive, aerospace, energy production and storage, and electronics (Table 1). Fluoropolymers are an important driver of the European Green Deal (FPG, 2021a) and UN Sustainability Development Goals (United Nations [UN], 2021), supporting smart mobility, clean energy, and sustainable industry. They are used in various components of renewable energy installations, such as hydrogen and photovoltaic panels and facilitate advanced energy storage and conversion technologies such as lithium-ion batteries (FPG, 2021a). 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

TABLE 1 Fluoropolymer end uses and industries

Industries End uses	Transportation		Health care		Chemical		Consumer		Telecommunications		Infra-structure		Renewable energy			
	Automotive	Aerospace	Pharma- ceuticals	Medical devices	Oil and gas industry (CPI)	Chemical process industry (CPI)	Production of goods	Protection and packaging	Electronics and semicon- ductors	Internet and wireless communica- tions	Textiles Technical textiles	Construc- tion and archi- tecture	Energy production	Hydrogen production	Energy storage	
Fluoroplastics																
PVDF homopolymer	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
PVDF copolymer	•	•	•	•		•	•	•	•	•	•	•	•	•	•	•
ECTFE copolymer	•	•	•		•	•			•	•		•				
ECTFE terpolymer			•		•	•										
PCTFE		•	•						•							
FEVE	•	•							•			•				
EFEP	•			•		•			•							
CPT	•								•							
THV	•	•	•	•		•	•	•	•			•	•	•	•	•
Fluoroelastomers																
FEPM	•	•	•	•	•	•	•		•			•	•	•		
FKM	•	•	•	•	•	•	•	•	•		•	•	•	•	•	•
FFKM		•	•	•	•	•	•		•							
Specialty																
Amorphous		•	•	•		•			•	•				•	•	•
Ionomer	•			•		•			•				•	•	•	•

Note: See also Chapter 5 in the Supporting Information.
Abbreviations: CPT, chlorotrifluoroethylene-tetrafluoroethylene; ECTFE, ethylene-chlorotrifluoroethylene; EFEP, ethylene-tetrafluoroethylene-hexafluoropropylene; FEPM, trifluoroethylene-propylene copolymer; FEVE, fluoroethylene-vinyl ether; FKM, HFP-VF2 polymer and HFP-VF2 TFE polymers; FFKM, TFE-PMVE perfluoroelastomer; PCTFE, polychlorotrifluoroethylene; PVDF, polyvinylidene fluoride; THV, TFE-HFP-VF2.

TABLE 2 Fluoropolymer properties and functionality

See Supporting Information: Chapter 2 for property descriptions	Durable				Inert—Stable				
	Mechanical strength	Wear resistance	Flexibility	Low coefficient of friction	Resistance to chemicals	Weatherability	Cryogenic properties (lower than −50 °C)	High operating temperature range	High limiting oxygen index
Fluoroplastics									
PVDF Homopolymer	•	•		•	•	•		•	•
PVDF Copolymer	•	•		•	•	•		•	•
ECTFE Copolymer	•	•		•	•	•	•	•	•
ECTFE Terpolymer		•		•	•	•		•	•
PCTFE	•	•		•	•	•	•	•	•
FEVE	•	•	•	•	•	•		•	•
EFEP	•	•		•	•	•	•	•	•
CPT				•	•	•	•	•	•
THV			•		•	•		•	•
Fluoroelastomers									
FEPM	•	•	•		•	•		•	•
FKM	•	•	•		•	•		•	•
FFKM	•	•	•		•			•	•
Specialty									
Amorphous			•	•	•			•	•
Ionomer			•		•			•	•
Functional									
See Supporting Information: Chapter 2 for property descriptions	Electrical insulator—high data transmission rate	Ionic conductivity	Piezo-electrical properties	Barrier properties	Nonstick properties	Ultra high purity grades for clean applications	Optical clarity	Low refractive index—used for optical effects	Polymer processing additive (PPA) ^a
Fluoroplastics									
PVDF Homopolymer			•	•		•		•	•
PVDF Copolymer			•	•				•	•
(Continued)									

(Continued)

TABLE 2 (Continued)

See Supporting Information: Chapter 2 for property descriptions	Functional							
	Electrical insulator—high data transmission rate	Ionic conductivity	Piezo-electrical properties	Barrier properties	Nonstick properties	Ultra high purity grades for clean applications	Optical clarity	Low refractive index—used for optical effects
ECTFE Copolymer	•			•				
ECTFE Terpolymer				•				
PCTFE				•	•	•	•	•
FEVE				•			•	
EFEP				•	•		•	•
CPT				•	•	•	•	•
THV				•			•	•
Fluoroelastomers								
FEPM	•			•				
FKM				•	•			•
FFKM	•			•		•		
Specialty								
Amorphous	•	•		•	•	•	•	•
Ionomer	•	•		•			•	

Note: See Chapter 5 in the Supporting Information.

Abbreviations: CPT, chlorotrifluoroethylene-tetrafluoroethylene; ECTFE, ethylene-chlorotrifluoroethylene; EFEP, ethylene-tetrafluoroethylene-hexafluoropropylene; FEPM, trifluoroethylene-propylene copolymer; FEVE, fluoroethylene-vinyl ether; FKM, HFP-VF2 polymer and HFP-VF2-TFE polymers; FFKM, TFE-PMVE perfluoroelastomer; PCTFE, polychlorotrifluoroethylene; PVDF, polyvinylidene fluoride; THV, TFE-HFP-VF2.

^aPolymer Processing Additives (PPA); also known as Polymer Processing Aid, Extrusion Process Aids or Polymer Processing and Recycling Aids.

temperature, fire, and weather (Table 2). 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. As a result, fluoropolymers have become a critical mainstay for our society providing vital, reliable functionality to a broad range of industrial and consumer products.

Three fluoropolymer types are included in this study: fluoroplastics, fluoroelastomers, and specialty fluoroplastics. Here, we describe briefly each included in this study. Additional details about each polymer are provided in the Supporting Information: Chapter 5.

Fluoroplastics

The fluoroplastics included in this study are: polyvinylidene fluoride (PVDF) homopolymer, PVDF copolymer, ethylene-chlorotrifluoroethylene (ECTFE) copolymer, ECTFE terpolymer, polychlorotrifluoroethylene (PCTFE), fluoroethylene-vinyl ether (FEVE), ethylene-tetrafluoroethylene-hexafluoropropylene (EFEP) terpolymer, chlorotrifluoroethylene-tetrafluoroethylene (CPT) terpolymer, and tetrafluoroethylene, hexafluoropropylene, vinylidene fluoride (TFE-HFP-VF2 [THV]) terpolymer as well as the specialty fluoroplastics, amorphous fluoropolymers, and fluorinated ionomers. Typical monomers used in the manufacture of fluoroplastics include tetrafluoroethylene (TFE), hexafluoropropylene (HFP), vinylidene fluoride (VDF or VF2), chlorotrifluoroethylene (CTFE), vinyl fluoride (VF), trifluoroethylene (TrFE), and perfluoroalkyl vinyl ethers (PAVEs), which include trifluoromethyl trifluorovinyl ether (PMVE), pentafluoroethyl trifluorovinyl ether (PEVE), and heptafluoropropyl trifluorovinyl ether (PPVE). In some copolymers, monomers that do not contain fluorine attached to the olefinic carbons may be used. These include ethylene, propylene, perfluoroalkyl-substituted ethylenes, and others (Ebnesajjad, 2000, 2003; Grot, 2011).

Fluoroelastomers

The fluoroelastomers included in this study are: trifluoroethylene-propylene copolymer (FEP), HFP-VF2 polymer and HFP-VF2-TFE polymers (FKM), and TFE-PMVE perfluoroelastomer (FFKM). Typical monomers used in the manufacture of fluoroelastomers include VDF, HFP, TFE, CTFE, PAVEs, as well as propylene, 1-hydropentafluoropropene (HPFP), and 2,3,3,3-tetrafluoropropene (HFO-1234yf; FPG, 2021a). Although fluoroelastomers are based on many of the monomers that are also used for the synthesis of fluoroplastics, they are different because of the specific composition, flexibility with subambient glass transition temperatures, as well as their elastomeric properties, resulting from the cross-linking process. Cross-linking, known as curing or vulcanizing, is a hardening process to form chemical bonds between polymer chains that gives polymers their elasticity (Améduri et al., 2001; Drobny, 2016).

PVDF homo- and copolymers

Polyvinylidene fluoride fluoropolymers are specified by end users across the world for their outstanding combination of properties. Because they have high temperature resistance, low permeability, and high mechanical strength, and provide chemical resistance to a wide range of aggressive chemicals, PVDF fluoropolymers are used as a contact surface for the production, storage, and transfer of corrosive fluids (chemically resistant to halogens and acids) in the chemical processing industry, oil and gas transportation, and cables industry (Arkema, 2021a; Gujarat Fluorochemicals Limited, 2018, 2022; Solvay, 2021a). The outstanding resistance to sunlight/UV exposure make PVDF suitable for architectural coatings. The outdoor aging and weathering properties of PVDF resin led to its use in long-lasting paints for coating metal sheet for the past 50 years. PVDF resins can also be used to protect thermoplastics through coextrusion or film lamination techniques to obtain antigraffiti surfaces with exceptional weathering properties. PVDF fluoropolymers also exhibit radiation resistance, desirable burn characteristics, flame, and smoke properties, easy processing on industry-standard equipment, and easy postprocessing steps, such as welding and fabrication. PVDF is used as a binder in lithium-ion batteries as well as PVDF film for solar power panels because of its high thermal and electrochemical stability, its stability under harsh environmental conditions, and its strong adhesion properties are critical to achieving environmental goals.

ECTFE (co- and terpolymers)

Ethylene chlorotrifluoroethylene (ECTFE) is a semicrystalline and melt-processable fluoropolymer obtained by the copolymerization of the two monomers, ethylene and chlorotrifluoroethylene, with an essentially 1:1 alternating structure (Ebnesajjad, 2017). Due to its chemical structure, ECTFE offers a unique combination of properties including chemical resistance, high thermal rating, and very good mechanical properties (Solvay, 2021b). ECTFE terpolymer with added hexafluoroisobutylene monomer displays enhanced stress-cracking performances resulting from chain-structure modifications of the polymer. ECTFE is used widely in anticorrosion applications such as coatings or in self-supporting construction (pipes) and architectural films (Solvay, 2021c). One of the principal advantages of ECTFE fluoropolymer is the ease with which it can be processed. It is a true thermoplastic that can be handled by conventional techniques of extrusion as well as by blow, compression, injection, rotational, and transfer molding. Powder coating methods are also applicable. ECTFE embodies an exemplary trade-off among general properties, offering high chemical and mechanical resistance combined with easy processing of the resin.

PCTFE

Polychlorotrifluoroethylene is a homopolymer of chlorotrifluoroethylene. PCTFE is melt processable and can be

extruded or molded (Satokawa, 1990). PCTFE has outstanding mechanical properties, especially hardness, and chemical resistance compared with PTFE and PFA, although it is slightly inferior to PFA and FEP in heat resistance and chemical resistance (Daikin, 2021a; Satokawa, 1990). PCTFE has been applied widely in the semiconductor industries and aerospace industries (Curbell, 2021; Daikin, 2021a). In addition to distinguished thermal and chemical stability, it has very low moisture absorption and permeation; therefore, PCTFE is used in pharmaceutical packaging (Honeywell, 2021).

FEVE

Fluoroethylene-vinyl ether fluoropolymer resins are manufactured by copolymerization of fluoroethylene monomer and a vinyl ether monomer and consist of alternating fluoroethylene and alkyl vinyl ether segments (AGC Chemicals Company, 2021a; Parker & Blankenship, 2015). They were developed in 1982 as the first solvent-soluble fluoropolymers in the world (Darden & Parker, 2021; Kojima & Yamabe, 1984; Munekata, 1988; Yamabe et al., 1984). The alternating fluorinated segments provide outstanding UV stability, weather resistance, and chemical resistance, while the vinyl ether segments provide solvent compatibility and cross-linking sites (Parker & Blankenship, 2015; Scheirs, 2007). FEVE resins are used to make ultra-weatherable coatings for architectural, aerospace, automotive, bridge, and industrial maintenance markets (Hoshino & Morizawa, 2017).

EFEP

Ethylene-tetrafluoroethylene-hexafluoropropylene is a terpolymer of ethylene, tetrafluoroethylene, and hexafluoropropylene. It was designed to have many of the properties of ETFE. It has a lower processing temperature, which allows it to be coextruded with conventional thermoplastic polymers such as polyamide, ethylene vinyl alcohol (EVOH), and modified polyethylene. EFEP can be extruded, injection molded, and blow molded, and it is used in many applications such as those identified in Supporting Information: Chapter 4.7 (Daikin, 2011a). EFEP is a melt-processable resin with good processability because of its low melting point. It also has excellent mechanical properties, provides chemical resistance, low permeability, exceptional weatherability, and good heat resistance. Other prominent features include inherent flame retardancy as well as good optical properties given that EFEP is highly transparent and has both a low dielectric constant and loss tangent.

CPT

Chlorotrifluoroethylene-tetrafluoroethylene is a terpolymer of chlorotrifluoroethylene, tetrafluoroethylene, and perfluoroalkyl-vinyl-ether. It is a melt-processable polymer and resin, which is readily processed because of its lower melting point. It can be melt-molded as a thermoplastic resin by extrusion, injection, and compression molding. CPT

is a modified perfluoroalkoxy fluoropolymer (PFA), which utilizes chlorotrifluoroethylene to provide low permeability to PFA, and it has many outstanding properties as a hybrid polymer of PFA and PCTFE as shown below. It has demonstrated permeation resistance to organic solvent, chemicals, water vapor, and gasoline (Daikin, 2011b). CPT offers superior permeation resistance against gasoline and flexible fuel and can be part of construction meeting the LEV III requirements (US environmental protection regulations in this automotive application). CPT also has notable barrier properties against many kinds of organic solvents and strong acids, especially HF, HCl, and HNO₃. This is very useful for semiconductor applications (Daikin, 2021b). In addition to the features noted above, CPT also provides heat resistance, excellent weatherability, flame retardancy, and good optical properties owing to its high transparency.

THV

THV fluoropolymers are a group of fluorinated thermoplastic polymers composed mainly of tetrafluoroethylene (TFE), hexafluoropropylene (HFP), and vinylidene fluoride (VDF; Dominghaus, 1998; Hintzer & Schwertfeger, 2014; Hull et al., 1997). The melting point of the different grades ranges from approximately 100 °C to nearly 250 °C. THV fluoropolymers are easy to process due to their broad processing windows. Different THV grades exhibit high flexibility, high transparency, bondability to fluorinated and nonfluorinated materials, and very good permeation resistance against fuels and other chemicals. The polymers are used as a barrier layer in fuel hoses, for transparent films and tubing, as matrix materials in composites, and the bonding layer in multilayer construction (Dams & Hintzer, 2017; Hull et al., 1997). The high transparency of the special film makes it an ideal adhesive film for laminated glass and the optimal protective film for surfaces. THV grades compete against other fluorothermoplastic materials for applications that require transparency and low refractive index as well as with fuel barrier materials. Commercial nonfluorinated materials cannot be used as substitutes for THV because of the unique combination of properties. Polymethylmethacrylate (PMMA) is used in conjunction with THV to provide differences in refractive index to create the total reflection needed for polymer optical fibers (Park et al., 2008). Transparent polymers, such as PMMA or polycarbonate, do not have the same chemical resistance or UV resistance to compete directly with THV.

FEPM

Trifluoroethylene-propylene copolymer elastomers, ASTM D1418, are high MW fluoropolymers with alternating tetrafluoroethylene and propylene segments (Kojima et al., 1977). They are also known as TFE-P copolymers. Various articles can be produced by means of compression molding, extrusion, injection molding, and calendaring. FEPM elastomers are compounded and cured (cross-linked) to deliver unique and valuable properties by providing exceptional heat resistance with a continuous service temperature higher than

200 °C, outstanding chemical resistance with little or no deterioration even in contact with strong acids, bases, and oxidants at high temperatures, steam resistance, and high electrical resistivity on the order of 10^{15} – 10^{16} Ω /cm (bulk resistivity). Formulated FEPM components are now used worldwide in many critical industrial applications where they must function safely in harsh environments, thereby extending the life of critical components and reducing downtime and costly repairs. FEPM elastomers are used in a range of applications including thermal power plants, oil and gas industry, ocean development, chemical and nuclear plants, automotive, aerospace, heavy-duty diesel, electronics, machinery, renewable energy, food processing, and medical. Their noted heat and chemical resistance make them especially valuable in oil and gas extraction (downhole) applications, where reliability is essential to cost effective and environmentally responsible production (Hull, 1983). FEPM elastomers are also used in high-performance wire and cable applications as insulating materials with the highest heat resistance, for example, lightweight, high-voltage automotive cables and motor cables for Japanese high-speed bullet trains (AGC Chemicals Company, 2021b).

Fluoroelastomers (FKM)

FKM are a family of fluoroelastomer materials defined by ASTM international standard D1418 (ASTM, 2021). FKM fluoroelastomers contain vinylidene fluoride (VDF) as a monomer combined with a variety of other fluoromonomers to create a palette of polymers with properties tailored for specific uses (Dams & Hintzer, 2017; Drobny, 2016; Van Cleeff, 1997; Worm & Grootaert, 2001). Cross-linked FKM fluoroelastomers are amorphous polymers designed for demanding service applications in hostile environments characterized by broad operating temperature ranges in contact with industrial chemicals, oils, or fuels (Worm & Grootaert, 2001). FKM fluoroelastomers are used mainly in fabricated parts (e.g., o-rings, gaskets, seals) to provide barriers against a wide range of fluids under severe service conditions (Drobny, 2016). Their design allows stable extrusion and molding processes and fitting in a wide range of processing constraints, reducing the risk of failure and increasing productivity. FKM fluoroelastomers provide high temperature and aggressive fluids resistance and retention of properties over a wide and demanding range of operating use conditions (high and low temperatures) for sealing and fluid transport applications, offering far superior performance than hydrocarbon elastomers. Applications include aerospace, automotive, oil and gas, chemical processing, electrical, office equipment, food, pharmaceuticals, and consumer wearables. Additionally, uncured FKM fluoroelastomers are used as a polymer processing additive (PPA) or polymer extrusion aids in small amounts (50–2000 ppm) dispersed in polyolefins such as high-density polyethylene (HDPE) and linear low-density polyethylene (LLDPE), significantly improving their film extrusion characteristics, reducing melt fracture and die build-up, as well as increasing productivity, minimizing energy and

water footprint, and enabling the extrusion of thin films (Lavallée, 2020; Shell, 2020).

FFKM

Perfluoroelastomers, designated by ASTM D1418 as FFKM, are a fully fluorinated class of elastomers that are typically made up of tetrafluoroethylene (TFE), a perfluoro (alkyl vinyl ether; PAVE), and a cure site monomer(s) (Ohkura & Morizawa, 2017). FFKM elastomers offer superior chemical and temperature resistance, excellent resistance to gas and liquid permeation, and resistance to weather and ozone with operating temperatures ranging from -40 °C to 325 °C (Drobny, 2016; Greene-Tweed, 2021a, 2021b). These polymers can also be compounded to meet the special requirements of upstream, midstream, and downstream oil and gas exploration due to their superior properties (Barnwell, 2021; Daemar, 2021). Because of these properties, FFKM elastomers are used in a wide variety of applications such as critical sealing solutions for the aerospace, pharmaceutical, medical, chemical processing, semiconductor, and oilfield industries (Atkinson, 2018; Marshall, 2017).

Amorphous fluoropolymers

Amorphous fluoropolymers are copolymers of TFE and specialty monomers that yield linear, high molar mass non-crystalline polymers (AGC Chemicals Company, 2021c; Gangal & Brothers, 2010; Hintzer et al., 2013; Korinek, 1994; Resnick & Buck, 1997, 1999). Amorphous fluoropolymers have the outstanding chemical and thermal stability and surface properties of semicrystalline perfluoropolymers as well as the unique properties associated with amorphous materials such as optical clarity and high gas permeability. The optical properties are outstanding, with more than 90% transmission, and thereby low dissipation, over a wide range of wavelengths (e.g., 200–2000 nm). TFE/PDD (2,2-bis(trifluoromethyl)-4,5-difluoro-1,3-dioxole) copolymers have the lowest refractive index known for a solid organic polymer (Groh & Zimmermann, 1991). This unique combination of properties makes amorphous fluoropolymers unmatched for uses in degassing, fiber optics, photolithography, antireflective coatings, passivation and protective coatings for medical, military, and aerospace devices, as well as electronic applications (Gangal & Brothers, 2010; Hintzer et al., 2013).

Fluorinated ionomers

Fluorinated ionomers are copolymers of TFE and a perfluorovinylether monomer containing an ionic group, typically a sulfonic acid or carboxylic acid (Grot, 2011, 2013). Fluorinated ionomers can be extruded or cast into film and converted into ion exchange materials (IXMs). IXMs come in a variety of useful forms offering a broad range of solutions for different applications (AGC Chemicals Company, 2021d; Asahi-Kasei, 2021; Chemours, 2021a). These forms include ion exchange membranes (IEMs), dispersions, and resins. IEMs must possess the required ion transport properties for the electrochemical cell in which they reside to perform well

and work effectively. Some of these properties include high ionic conductivity, chemical resistance, high operating temperature range, low permeability, and balanced durability and performance (Chemours, 2021b).

Ion exchange membranes (IEMs) stand to play a noteworthy role in today's modern world (Chemours, 2021b) and as such, are utilized in a wide range of applications and end-use industries including electrochemical processing, energy production, and hydrogen production. IEMs revolutionized the chlor-alkali industry (Grot, 2013), the manufacture of primarily caustic soda and chlorine, by eliminating the use of hazardous materials such as mercury and asbestos (Asahi-Kasei, 2021) and, in doing so, reducing energy consumption. Water electrolysis, the process of converting water into hydrogen and oxygen, relies on IEM technology. Although this process requires electricity, renewable energy sources such as solar or wind power can be utilized, allowing the potential for hydrogen to be a “clean” energy source (Science Center, 2021). Hydrogen fuel cells, some of which use a type of IEM known as a proton exchange membrane, can then convert hydrogen to electricity, a crucial technology to reach the stated target of the EU New Green Deal (EC, 2021).

STUDY METHODOLOGY AND DATA

Seven global fluoropolymer manufacturers (AGC Chemicals Americas, Arkema, The Chemours Company, Daikin Industries, Gujarat Fluorochemicals Limited, Solvay Specialty Polymers, and 3M Company) participated in this study and contributed data, writing, critique, and analysis. The companies noted above are members of the US-based Performance Fluoropolymer Partnership (PFP) and/or EU-based Fluoropolymer Product Group (FPG).

This study provides data on 14 fluoropolymers, building on a prior study (Henry et al., 2018). The study was characterized within two global industry groups. Participants put forward candidate fluoropolymers of notable commercial importance for the study and provided company and published data that address the PLC criteria. Thirteen PLC criteria that relate to the polymer structure and properties, including three to physicochemical properties and five to

stability, set forth in BIO by Deloitte (2015) and presented in prior work on four fluoropolymers (Henry et al., 2018), are addressed in this study (Figure 1). These criteria are briefly described in Table 3 with further description provided in Supporting Information: Chapter 3 and in the prior work (Henry et al., 2018). Participants provided company and published data and a description of methods and/or public references to demonstrate the origin of the data provided. These methods and references are provided in detail in Supporting Information: Chapter 4. The PLC criteria data were compiled and are presented in Tables 4 and 5.

The data assessment was done in two ways: Companies could self-assess the PLC data if they had the technical resources to do so or they could submit their PLC data to a third-party contractor for an independent technical review. The third-party consultant hired by PFP was GSI Environmental Inc. The objective was to be able to publish the references and methods behind the PLC data provided for each fluoropolymer in the study. In cases where the data and/or methods contained confidential business information, the third-party consultant independently evaluated the information supplied before it was shared in a blinded, aggregate form with the participating project companies. In several cases—FKM, PVDF, and ionomers—several companies submitted data for the same fluoropolymer. The data were combined and are presented in Tables 4 and 5. There is no intentional company attribution for the data presented.

The following describes further how the study data were generated and compiled.

- A third-party consulting company (GSI) was engaged to comment independently on data, methods, and references initially supplied by study participants for their respective fluoropolymers. Several study participants used this third-party consultant.
- Following the initial third-party assessment and assembly of the master data Tables 4 and 5 as well as the FKM data in Supporting Information: Table 4.11, a series of subsequent assessments were conducted (within PFP)

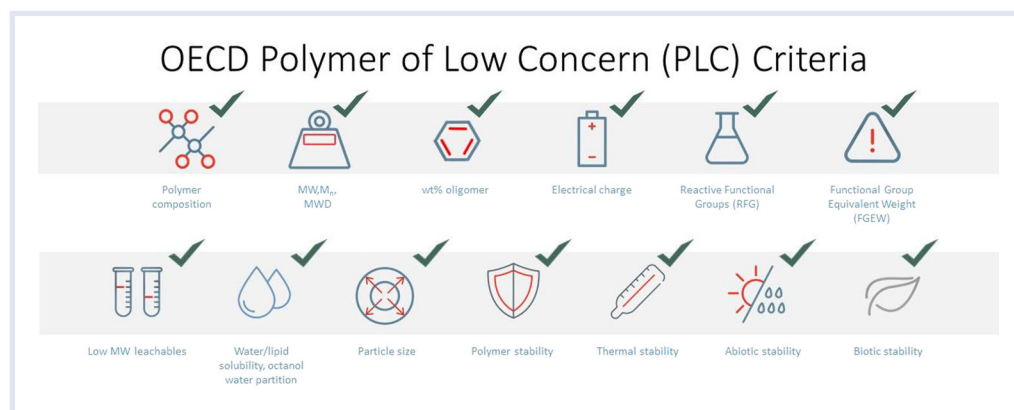


FIGURE 1 OECD polymer of low concern (PLC) criteria add (C) 2021 W.L.Gore & Associates

TABLE 3 Polymer of low concern (PLC) criteria descriptions

(See Supporting Information: Chapter 3 for additional details) Criterion	Description
Polymer composition	The polymer composition criterion requires structure and elemental composition of the polymer be described and identified (e.g., by Chemical Abstracts Service [CAS] number).
Molecular weight, number average molecular weight, MW distribution, and % oligomer <1000 Da	The number average molecular weight (Mn) and oligomer content are the most commonly used criteria for PLC assessment. The EU assessment report (BIO by Deloitte, 2015) states that the “most potential health concern polymers have a number average molecular weight, Mn, <1000 Da and oligomer content >1%.” The higher the oligomeric content, the more likely a polymer is to be a health or ecotoxicological (OECD, 2009, p. 9). Molecular weight (MW) is an important predictor of biological effect because large molecules (>1000–10 000 Da) are too large to penetrate cell membranes (Supporting Information: in Beyer, 1993, p. 14). Because large molecular weight polymers cannot enter the cell, they cannot react with “target organs,” such as the reproductive system, and are not bioavailable. “Therefore, as the Mn of a polymer increases, a reduced incidence of potential health concern effects might be expected” (OECD, 2009, p. 20). An additional PLC consideration is the weight percentage of oligomers that are <1000 Da. Oligomers may be composed of, for example, dimers, trimers, and tetramers, meaning they have 2- monomer, 3- monomer, and 4-monomer units, respectively. The EU report (BIO by Deloitte, 2015) concluded that most potential health concern polymers have Mn of <1000 Da and oligomer content of >1%: “...the distribution of potential health concern polymers exhibited an increased incidence of higher oligomer content that began at 5% for <1000 Da and 2% for <500 Da oligomeric content” (OECD, 2009, p. 24). Molecular weight distribution (MWD), also known as “polydispersity index,” measures the heterogeneity of size of polymer molecules in a polymer. The MWD is an important parameter for predicting potential biological effects of polymers because, although Mn may be a large value, low MW oligomers <1000 Da may be present, which could penetrate the cell.
Ionic character	Electrical charge or ionic character can be anionic, cationic, amphoteric, or nonionic. Specifically, cationic polymers have been associated with aquatic toxicity (Auer et al., 1990; USEPA, 1997a).
Reactive functional groups and RFG ratio to MW	A “reactive functional group” (RFG) is defined as an atom or associated group of atoms in a chemical substance that is intended or can be reasonably expected to undergo facile chemical reaction (USFR, 2012). Some highly reactive functional groups (or a high ratio of RFGs per mole) have been associated with adverse human health and ecotoxicology (e.g., acrylates, methacrylates, isocyanates, anhydrides, aziridines; USEPA, 2010). The functional group equivalent weight (FGEW) is used to determine if the RFGs in a polymer are substantially diluted by polymeric material to allow the polymer to be a PLC (USEPA, 1997). The FGEW of a polymer is defined as the ratio of the Mn to the number of functional groups in the polymer. The FGEW is used as an indication of the degree of reactivity of the polymer; the lower the FGEW, the more reactive the polymer and the greater the potential for health and environmental impact (OECD, 2009, p. 10).
Low MW leachables	Low MW leachables are chemical molecules, either inorganic or organic, that migrate (i.e., leach) out of the polymer. These could be residual monomers or oligomers resulting from incomplete polymerization processes, surface residues, or other chemicals used in the manufacturing processes (e.g., initiators, catalysts, chain transfer agents, surfactants). Low MW leachables are critically important to the potential for a polymer to affect health and the environment, given that they may be able to migrate out of the polymer and cross cell membranes to potentially react with biomolecules. A report to the EU (BIO by Deloitte, 2015) concluded that “Polymers with <1% MW < 1000 Da and low water extractability are not able to cause systemic effects which are toxicologically or ecotoxicologically relevant.” Monomers, by nature, are reactive. Unreacted monomers left in a polymer may migrate out of the polymer to react with biomolecules to cause potential adverse effects. Regulatory authorities (BIO by Deloitte, 2015) and the OECD Expert Group on Polymers (OECD, 2009) agree that the residual monomer content of a polymer is critical to determining if it qualifies as a PLC.

(Continued)

TABLE 3 (Continued)

(See Supporting Information: Chapter 3 for additional details) Criterion	Description
Particle size	Particle size is also a PLC criterion. Particles that are small enough to reach the deep lung upon inhalation are often associated with adverse health effects. Therefore, to qualify as a PLC, median mass aerodynamic diameter (MMAD) of the polymer particle size should be >5 µm.
Structural and elemental composition	In the US, Chemical Categories of Concern are the result of the review of new chemicals by the USEPA under the TSCA (see https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/chemical-categories-used-review-new). The categories describe the molecular structure, boundary conditions such as MW, equivalent weight, the log of the octanol–water partition coefficient, log <i>P</i> , or water solubility, and standard hazard (mammalian and ecological) and (environmental) fate tests to address concerns.
Elemental composition	The elemental composition is a factor in the assessment of the eligibility of polymers for reduced notification requirements. The exclusion of polymers under this step is not a conclusion of hazard but a determination that the elemental composition does not fall within the parameters of the polymer set under which this rule was formulated, and consequently, these polymers would have to follow the standard notification and review process. These elemental requirements differ across jurisdictions as covered in the report to the EU on global regulatory approaches to polymer assessment (BIO by Deloitte, 2015). For example, in the EU under REACH it is proposed that polymers composed from among these elements, covalently bound to C, have reduced hazard: H, N, O, Si, S, F, Cl, Br, or I (BIO by Deloitte, 2015). In contrast, the USEPA Polymer Exemption Rule states that a polymer is eligible for reduced agency review when it has at least two of the following elements: C, H, O, N, S, or Si (USFR, 1995).
Water and lipid solubility and the octanol–water partition coefficient	Water solubility is the extent to which a compound will dissolve in water. According to the OECD (2009) meeting of the Expert Group on Polymers, polymers with “negligible” water solubility, or those described as “hydrophobic” have been represented with a water solubility of 0.000001 mg/L (1×10^{-6} mg/L; assigned arbitrarily; OECD, 2009). That is equivalent to 1 ppt, a very conservative definition.
	Polymers with water solubility <10 mg/L showed generally low health concerns.
	The octanol–water partition coefficient (K_{ow}) is another criterion to assess chemicals and their environmental and health impact. The K_{ow} is a physical–chemical property at equilibrium to represent the lipophilic or hydrophilic nature of a chemical, the distribution of a compound in octanol, representing the lipophilic nature, to its solubility in water, representing the aqueous nature. The higher the K_{ow} , the more lipophilic the compound. Typically, a $K_{ow} > 5000$ or a log $K_{ow} > 5$ means high lipophilicity and, thus, a high potential to bioaccumulate or bioconcentrate. According to the Stockholm Convention, a bioconcentration factor of >5000 and a log $K_{ow} > 5$ is used as a criterion for bioaccumulation.
Stability	Stability is resistance to physical, chemical, or biological transformation. Loss of stability in the polymer breaks it down into smaller pieces, producing low MW species. As was previously described in the Polymer of Low Concern section under the molecular weight, number average molecular weight, MW distribution, and % oligomer <1000 Da heading, molecules with Mn <1000 Da are capable of crossing cell membranes, making unstable polymers potentially hazardous to health and the environment.
Abiotic stability	Polymers are stable; monomers are not. Abiotic degradation may involve sunlight, water, or oxygen. Photochemical transformation is a reaction involving the radiation energy of sunlight (ultraviolet radiation) that may break a bond in a molecule to change it to another chemical entity. Hydrolytic degradation of polymers is another potential way to break the polymer bonds, creating smaller oligomers that may be bioavailable. Chemical oxidation is a reaction involving the loss of electrons from one atom to another.
Biotic stability: aerobic, anaerobic, and in vivo	Biotic stability is assessed by whether the polymer is degraded by microorganisms under oxygenated (aerobic) or anoxic (anaerobic) conditions; in vitro and in vivo stability studies demonstrate this. In vivo biodegradation involves the breaking of the polymer bonds by the action of bacteria, enzymes, and oxidants within the organism.
Thermal stability	Thermal stability of a polymer can be assessed when used as intended under normal, foreseeable use conditions or in extreme temperatures during disposal, such as by incineration. Thermal stability testing may involve Thermogravimetric Analysis (TGA), which determines mass loss over time and temperature of a test substance.

TABLE 4 Fluoroplastics and PLC criteria

Supporting Information Data: Chapter	Fluoroplastics				
	4.1 PVDF	4.2 PVDF-HFP copolymer	4.3 ECTFE	4.4 ECTFE	4.5 PCTFE
	Polyvinylidene fluoride	Vinylidene fluoride, hexafluoropropene copolymer	Ethylene, chlorotrifluoroethylene copolymer	Ethylene, chlorotrifluoroethylene, hexafluoroisobutylene terpolymer	Polychlorotrifluoroethylene
PLC assessment criterion ^a	CAS 24937-79-9	CAS 9011-17-0	CAS 25101-45-5	CAS 54302-04-04	CAS 9002-83-9
Structure	$-(CF_2-CH_2)_n-$	$-(CF_2-CH_2)_n-[CF(CF_3)-CF_2]_m-$	$-(CF_2-CFCl-CH_2-CH_2)_n-$	$-(C_4H_2F_6)_n-(C_2H_4)_m-(C_2ClF_3)_l-$	$-(CF_2-CFCl)_n-$
Polymer composition (must have C, H, Si, S, F, Cl, Br, or I covalently bound to carbon)	Yes	Yes	Yes	Yes	Yes
Molecular weight (Mn) ^b (Mn > 1000 Da and oligomer content <1%)	70 000–300 000	80 000–300 000	Mn >50 000	Mn >50 000	70 000–400 000 average based on grade type
Molecular weight distribution $M_w^c \div$ number average M_n	2–3	2–3	1.1	1.7	3
Wt% oligomer (<5% for <1000 Da oligomers, <2% for <500 Da oligomers)	Negligible	Negligible	Negligible	Negligible	Negligible
Ionic character	Neutral	Neutral	Neutral	Neutral	Neutral
Reactive functional groups (RFGs) ^d and functional group equivalent weight (FGEW)	None and N/A	None and N/A	None and N/A	None and N/A	None and N/A
Low molecular weight leachables	No active leachables by USP class VI (121 °C)	No active leachables by USP class VI (121 °C)	No active leachables by USP class VI (121 °C)	No active leachables by USP class VI (121 °C)	Negligible
Residual monomers	<50 ppb	<50 ppb	<50 ppb	<50 ppb	<0.1 wt%
Ratio of residual monomers to molecular weight (typical value)	$\sim 10^{-12}$ – $\sim 10^{-13}$	$\sim 10^{-12}$ – $\sim 10^{-14}$	$\sim 10^{-13}$	$\sim 10^{-13}$	<10 ⁻⁵
Structural similarities to RFG of concern	None	None	None	None	None
Reference standard	ASTM D3222-18a	ASTM D5575-18	ASTM D3275-81	ASTM D3275-81	

(Continued)

TABLE 4 (Continued)

Fluoroplastics		4.1	4.2	4.3	4.4	4.5
Supporting Information Data: Chapter	PVDF	PVDF-HFP copolymer	ECTFE	ECTFE	PCTFE	
Physical-chemical properties						
Water solubility and octanol/water partition coefficient, K_{ow}	Insoluble/practically insoluble and N/A	Insoluble/practically insoluble and N/A	Insoluble/practically insoluble and N/A	Insoluble/practically insoluble and N/A	Insoluble/practically insoluble and N/A	
Particle size (median mass aerodynamic diameter, MMAD, should be $>5\ \mu\text{m}$)	Powders: 5–300 μm pellets: 2–4 mm	Powders: 5–300 μm pellets: 2–4 mm	D50%: 50–70 μm (typical)	D50%: 50–70 μm (typical)	Pellet: 2–4 μm , flake: 0.54 mm powder: 5–300 micron	
Stability						
Hydrolysis, light ($h\nu$), Oxidation, biodegradation (aerobic and anaerobic)	Stable	Stable	Stable	Stable	Stable	
Thermal stability at normal foreseeable use maximum continuous temp. ($^{\circ}\text{C}$)	150 $^{\circ}\text{C}$	150 $^{\circ}\text{C}$	150 $^{\circ}\text{C}$	150 $^{\circ}\text{C}$	120 $^{\circ}\text{C}$	
Meets ^a PLC criteria (Yes or No)	Yes	Yes	Yes	Yes	Yes	
Fluorinated polymerization aid (PA) used? (Yes or No)	No	No	No	No	No	
Recommended processing/application (use) temperature ($^{\circ}\text{C}$)	Processing: 200 $^{\circ}\text{C}$ –250 $^{\circ}\text{C}$ Use max temp: 150 $^{\circ}\text{C}$	Processing: 180 $^{\circ}\text{C}$ –250 $^{\circ}\text{C}$ Use max temp: 100 $^{\circ}\text{C}$ –140 $^{\circ}\text{C}$ depending on HFP content	Processing: 250 $^{\circ}\text{C}$ –280 $^{\circ}\text{C}$ Use max. Temp: 150 $^{\circ}\text{C}$	Processing: 250 $^{\circ}\text{C}$ –280 $^{\circ}\text{C}$ Use max. Temp: 150 $^{\circ}\text{C}$	Molding: 230 $^{\circ}\text{C}$ –330 $^{\circ}\text{C}$ Use Max same as above at 120 $^{\circ}\text{C}$	
Fluoroplastics						
Supporting Information Data: Chapter	4.6 FEVE	4.7 EFEP	4.8 CPT	4.9 THV		
Fluoroethylene-vinyl ether copolymer	1-Propene, 1,1,2,3,3,3-hexafluoro-, polymer with ethylene and 1,1,2,2-tetrafluoroethylene	1-Propene, 1,1,2,3,3,3-hexafluoro-, polymer with ethylene and 1,1,2,2-tetrafluoroethylene	1,1,1,2,2,3,3-Heptafluoro-3-[(trifluoroethenoxy)oxy]propane polymer with chlorotrifluoroethylene and tetrafluoroethylene	1-Propene, 1,1,2,3,3,3-hexafluoro-polymer with 1,1-difluoroethylene and tetrafluoroethylene		
PLC assessment criterion ^a	cbi	35560-16-8	116018-07-6	25190-89-0		(Continued)

TABLE 4 (Continued)

Supporting Information Data:		Fluoroplastics		
Chapter	4.6 FEVE	4.7 EFEP	4.8 CPT	4.9 THV
Structure	cbi	$-(CH_2-CH_2)_n-(CF_2-CF_2)_m-(CF_2-CF(CF_3))_l-$	$-(CF_2-CF_2)_n-(CFCl-CF_2)_m-(CF_2-CF(OR))_l-$	$-(CF_2CH_2)_x-(CF_2-CF-CF_3)_y-(CF_2-CF_2)_z$
Polymer composition (must have C, H, Si, S, F, Cl, Br, or I covalently bound to carbon)	Yes	Yes	Yes	Yes
Molecular weight (Mn) ^b (Mn > 1000 Da and oligomer content < 1%)	7000–46 000	130 000	200 000–300 000	131 000
Molecular weight distribution Mw ^c ÷ number average M _n	2.0–4.0	4	2–5	1.8
Wt% oligomer (< 5% for < 1000 Da oligomers, < 2% for < 500 Da oligomers)	Mn < 1000 range of < 3.5% and Mn < 500 is < 0.7%	Negligible; < 0.1 wt% oligomer content	Negligible; < 0.1 wt% oligomer content	wt.% < 1000: None
Ionic character	Neutral	Neutral	Neutral	Neutral
Reactive functional groups (RFGs) ^d and functional group equivalent weight (FGEW)	None and N/A	None and N/A	None and N/A	None and N/A
Low molecular weight leachables	Negligible; cross-linked as final product	Negligible	Negligible	No active leachables by USP class VI (121 °C)
Residual monomers	0.12%–1.43% non-fluorinated	Negligible	Negligible	None detected
Ratio of residual monomers to molecular weight (typical value)	10^{-7} – 10^{-8}	< 10^{-5}	< 10^{-5}	$\sim 10^{-13}$
Structural similarities to RFG of concern	None	None	None	None
Reference standard		ASTM D7472	ASTM D7471	

(Continued)

TABLE 4 (Continued)

Supporting Information Data: Chapter	Fluoroplastics			Physical-chemical properties
	4.6 FEVE	4.7 EFEP	4.8 CPT	4.9 THV
Water solubility and octanol/ water partition coefficient, K_{ow}	Insoluble/practically insoluble and N/A	Insoluble/practically insoluble and N/A	Insoluble/practically insoluble and N/A	Insoluble/practically insoluble and N/A
Particle size (median mass aerodynamic diameter, MMAD, should be >5 μm)	Solution or flake 150 nm for emulsion	2–4 mm (pellets)	2–4 mm (pellets)	Pellets ~400–750 μm
Stability				
Hydrolysis, light (h ν), oxidation, biodegradation (aerobic and anaerobic)	Stable	Stable	Stable	Stable
Thermal stability at normal foreseeable use maximum continuous temp. ($^{\circ}\text{C}$)	220 $^{\circ}\text{C}$	130 $^{\circ}\text{C}$; low melting point 160 $^{\circ}\text{C}$ –190 $^{\circ}\text{C}$ and high decomposition temperature of 357 $^{\circ}\text{C}$ –380 $^{\circ}\text{C}$	200 $^{\circ}\text{C}$; low melting point 239 $^{\circ}\text{C}$ –251 $^{\circ}\text{C}$ and high decomposition temperature of >400 $^{\circ}\text{C}$	Continuous use is expected ~room T. (<100 $^{\circ}\text{C}$ as host resin melts at 120 $^{\circ}\text{C}$); No expected degradation; fluoropolymer degrades >350 $^{\circ}\text{C}$ by TGA
Meets ^a PLC criteria (Yes or No)	Yes	Yes	Yes	Yes
Fluorinated polymerization aid (PA) used? (Yes or No)	No	No	No	Yes and No
Recommended processing/ application (use) temperature ($^{\circ}\text{C}$)	180 $^{\circ}\text{C}$ –200 $^{\circ}\text{C}$	Molding temperature: 200 $^{\circ}\text{C}$ –280 $^{\circ}\text{C}$; Use max as noted above	Molding temperature: 310 $^{\circ}\text{C}$ –330 $^{\circ}\text{C}$; Use max as noted above	Melt processing: <350 $^{\circ}\text{C}$ Application: <100 $^{\circ}\text{C}$ (in LLDPE)

Abbreviations: ECTFE, ethylene-chlorotrifluoroethylene; HFP, hexafluoropropylene; PCTFE, polychlorotrifluoroethylene; PLC, polymer of low concern; PVDF, polyvinylidene fluoride.

^aSee OECD (2009) and BIO by Deloitte (2015) for details on characteristics of a “Polymer of Low Concern” and Supporting Information: Chapter 3.

^bMolecular Weight is number average molecular weight which is defined as the total weight of the polymer divided by the total number of molecules. It is the mole fraction of molecules in a polymer sample.

^cMolecular weight is weight average molecular weight which is determined by summing the weights of all the chains and then dividing by the total number of chains. It is the weight fraction of molecules in a polymer sample.

^dFor definition of reactive functional group, lists of low-, moderate-, and high-concern functional groups and FGEW limits, see USEPA polymer exemption guidance manual, BIO by Deloitte (2015, pp. 191–192), and USEPA (2010). See Supporting Information.

TABLE 5 Fluoroelastomers and specialty fluoroplastics—PLC criteria

Supporting Information Data: Chapter	Specialty fluoroplastics		Fluoroelastomers		
	4.13 Amorphous	4.14 Ionomer	4.10 FEPM	4.11 FKM	4.12 FFKM
	Perfluoro(alkenyl vinyl) ether polymer	Sodium or potassium salts of perfluorosulfonic acid/TFE copolymer or perfluorocarboxylic acid/TFE copolymer	Tetrafluoroethylene-propylene copolymer	1-Propene, 1,1,2,3,3,3-hexafluoro-polymer with 1,1-difluoroethylene copolymer and terpolymers	Tetrafluoroethylene-trifluoromethyl trifluorovinyl ether copolymer
PLC assessment criterion ^a	37626-13-4	9002-84-0, 1314-23-4, 409-21-2, 111173-25-2	27029-05-6	9011-17-0, 26425-79-6, 25190-89-0	26425-79-6
Structure	See Supporting Information	See Supporting Information	See Supporting Information	Supporting Information	-(CF ₂ CF ₂) _x -[CF ₂ -CF(OCF ₃)] _y -(Cure Site Monomer) _z
Polymer composition (must have C, H, Si, S, F, Cl, Br, or I covalently bound to carbon)	Yes	Yes	Yes	Yes	Yes
Molecular weight ^b (M _n > 1000 Da and oligomer content <1%)	150 000–300 000	>100 000	Various grades vary between 146 000–275 000	30 000–340 000	10 000–1 000 000
Molecular weight distribution Mw ^c ÷ number average M _n	1.4–2.5	1.0–2.4	Various grades give various ratios from 1.4 to 3.3	1.2–2.4	1.2–3.5
Wt% oligomer (Figure MWD) (<5% for <1000 Da oligomers, <2% for <500 Da oligomers)	Negligible	Negligible	<0.01%	Negligible to <1%	Negligible
Ionic character	Neutral	Neutral	Neutral	Neutral	Neutral
Reactive functional groups (RFGs) ^d	None and N/A	None and N/A	None and N/A	None and N/A	None and N/A
Functional group equivalent weight (FGEW; typical value)	>10 ⁵	>10 ⁵	>10 ⁵	>10 ⁴ –10 ⁵	>10 ⁴

(Continued)

TABLE 5 (Continued)

Supporting Information Data: Chapter	Specialty fluoroplastics		Fluoroelastomers		
	4.13 Amorphous	4.14 Ionomer	4.10 FEPM	4.11 FKM	4.12 FFKM
Low molecular weight leachables	<1 ppm	<1 ppm	No active leachables	<0.4 ppm to <1 ppm	No active leachables
Residual monomers	<1 ppm	<1 ppm	No residual monomers Only cross-linking agent at <1 ppm	<50 ppt to <5 ppm	<50 ppb
Ratio of residual monomers to molecular weight (typical value)	>10 ⁻⁵	>10 ⁻⁵	10 ⁻¹¹ –10 ⁻¹²	>10 ⁻¹⁰ –10 ⁻¹³	0.25 ppt as Mn = 10 ⁵ (for representative FKM)
Structural similarities to RFG of concern	None	None	None	None	None
Reference standard	ASTM D 1418				
Physical–chemical properties					
Water solubility and octanol/water partition coefficient, K _{ow}	Insoluble/practically insoluble and N/A	Insoluble/practically insoluble and N/A	Insoluble/practically insoluble and N/A	Insoluble/practically insoluble and N/A	Insoluble/practically insoluble and N/A
Particle size (median mass aerodynamic diameter, aerodynamic diameter, MMAD, should be >5µm)	Solution, sheet or pellets	(1) Aqueous dispersion casting (as a film) followed by annealing or (2) Melt extrusion as a membrane (reinforced)	Sheet or crumb	Sheet or block; powders 300–350 µm stability increased/enhanced when cross-linked	Sheet or block; or “crumb”
Stability					
Hydrolysis, light (hν), oxidation, biodegradation (aerobic and anaerobic)	Stable	Stable	Stable	Stable	Stable

(Continued)

(Continued)

TABLE 5 (Continued)

Supporting Information Data: Chapter	Specialty fluoroplastics		Fluoroelastomers		
	4.13 Amorphous	4.14 Ionomer	4.10 FEPM	4.11 FKM	4.12 FFKM
Thermal stability at normal foreseeable use maximum continuous Temp (°C)	>250 °C	Sulfonic acid polymer: maximum operating temperature of 175 °C under anhydrous conditions, 220 °C –240 °C in aqueous systems carboxylic acid polymer: use below 120 °C	200 °C	180 °C	200 °C–300 °C
Meets ^a PLC criteria (Yes or No)	Yes	Yes	Yes	Yes	Yes
Fluorinated polymerization aid (PA) used? (Yes or No)	Yes and No	Yes and No	No	Yes and No	Yes and No
Recommended processing/ application (use) temperature (T °C)	<280 °C	Sulfonic acid polymer: maximum operating temperature of 175 °C under anhydrous conditions, 220 °C–240 °C in aqueous systems carboxylic acid polymer: use below 120 °C	–60 °C–204 °C (AFLAS Technical Document)	Melt processing: <300 °C 160 °C–320 °C (cross- linking temperature)	160 °C–320 °C (cross-linking temperature)

Abbreviations: FEPM, trifluoroethylene-propylene copolymer; FKM, HFP-VF2 polymer and HFP-VF2-TFE polymers; FFKM, TFE-PMVE perfluoroelastomer; PLC, polymer of low concern.

^aSee OECD (2009) and BIO by Deloitte (2015) for details on characteristics of a “Polymer of Low Concern.”

^bMolecular weight is number average molecular weight.

^cMolecular weight is weight average molecular weight.

^dFor definition of reactive functional group, lists of low-, moderate-, and high-concern functional groups and FGEW limits, see USEPA polymer exemption guidance manual, BIO by Deloitte (2015, pp. 191–192), and USEPA (2010). See Supporting Information.

until all data cells in the tables cited above were backed up with a narrative, a testing method, and/or references where publicly available.

- Where several companies have provided data on the same fluoropolymers, the table data presented provide a multicompany compilation and assessment along with appropriate methods and references.
- Individual companies supplying data are identified as authors, but there is no direct attribution regarding which company supplied which data for this study.

PLC ASSESSMENT RESULTS

This study was conducted on commercial fluoropolymer products using the PLC criteria to characterize their potential hazard. Figure 1 illustrates the PLC criteria used (BIO by Deloitte, 2015; Henry et al., 2018). The pictured criteria encompass structure, physicochemical property, and stability criteria evaluated in the study. Data informing structure criteria, MW, Mn, and MW distribution (MWD), physicochemical property criteria, water and lipid solubility and K_{ow} , and stability criteria are presented in Tables 4 and 5. The study also gathered structural data on (a) residual monomers, (b) ratio of residual monomers to MW, (c) structural similarities to reactive functional groups (RFGs) of concern, and (d) thermal stability at normal foreseeable maximum continuous use temperatures. Brief descriptions of PLC criteria are provided in Table 3 with additional details, including references for each criterion in Supporting Information: Chapter 3. An additional data point gathered was whether the fluoropolymer(s) presented utilized a fluorinated polymerization aid (PA) during manufacture. The study results are presented in Tables 4 and 5 and summarized below.

Polymer composition: Each of the fluoroplastics, specialty fluoroplastics, and fluoroelastomers assessed in this study met the criterion of polymer composition whereby either fluorine (F) and/or chlorine (Cl) must be covalently bound to the carbon-only polymer backbone.

MW and MWD: All fluoroplastics, specialty fluoroplastics, and fluoroelastomers in the study met the criteria for MW ($M_n > 1000$ Da) and MWD (1–3). The data demonstrate the fluoroplastics, specialty fluoroplastics, and fluoroelastomers in the study are high-MW solid polymers with fairly narrow MWD and negligible to low wt% oligomer content. The MW for fluoroplastics in Table 4 and specialty fluoroplastics in Table 5 ranged from 50 000 to 300 000, and the MWD ranged from approximately 1.4 to 3. We note that FEVE was measured in its uncured state and that, upon curing, its MW increased significantly. The MW and MWD were determined in a variety of ways depending on the fluoropolymer and its solubility (or insolubility) in various solvents. The MW and MWD data for fluoroelastomers and specialty fluoroplastics in the study are presented in Table 5. The MW and MWD varied because of the various grades of fluoroelastomers ranging from 100 000 to 250 000 with some less than (down to 10 000) and greater than (up to 500 000). MWD was on

the order of 1.4 to 3.5. Fluoroelastomer MW is lower for uncured fluoroelastomer versus cured fluoroelastomer. Cured fluoroelastomer is the form used in many formed-use applications (e.g., gaskets and o-rings). The methods and references for MW and MWD data are presented in the Supporting Information: Chapter 4 with the specific chapter noted in Tables 4 and 5. Methods included size exclusion chromatography (SEC), gel permeation chromatography (GPC) along with osmotic pressure, and parallel plate rheometry methods.

Weight % oligomer: The criteria for wt% oligomer are less than 5% oligomer content for M_n less than 1000 Da, and less than 2% oligomer content for M_n less than 500 Da (BIO by Deloitte, 2015; Henry et al., 2018; see also the Supporting Information). All fluoroplastics, specialty fluoroplastics, and fluoroelastomers in the study met the wt% oligomer criteria. Many polymers in the study were reported as “negligible” for oligomers based on analyses conducted. Polymers in the study not cited as negligible have reported numerical data presented in Tables 4 and 5. In addition to SEC and GPC, analytical methods employed included a weight loss upon heating method and the FDA 21 CFR 177.1380 method. The methods and references for wt% oligomer are presented in the Supporting Information: Chapter 4 with the specific chapter noted in Tables 4 and 5.

Ionic character: The fluoroplastics, specialty fluoroplastics, and fluoroelastomers in the study are neutral polymers, either containing no ionic groups or may contain anionic at the terminus of their high MW polymer chains as noted in the prior study of fluoropolymers (Henry et al., 2018). Notably different are fluorinated ionomers, which have neutralized (salts) sulfonic acid or carboxylic acid groups pendant to the polymer backbone and as such are neutral and not ionically charged in their polymeric solid form and are low in toxicity and not dermally irritating on skin contact (USEPA, 1997). None of the evaluated polymers in the study have cationic nature. The methods and references for ionic character are presented in the Supporting Information: Chapter 4 with the specific subchapter noted in Tables 4 and 5.

RFG, functional group equivalent weight (FGEW) and structural similarities to RFG of concern: All fluoroplastics, specialty fluoroplastics, and fluoroelastomers in the study met the RFG and FGEW criteria. The polymers in this study do not contain the reactive functional groups set forth in the PLC criteria (e.g., acrylates, alkoxysilanes, amines, aziridines, carbodiimides, and so forth; see Supporting Information: Chapter 3). Given that the polymers in this study have no RFGs, the FGEW values in Tables 4 and 5 are very large numbers (such as $>10^4$ – 10^5) or the value given is not applicable due to the lack of RFGs altogether. Even the polymers with some functional groups present (e.g., fluorinated ionomers) are not reactive. For example, the FEVE polymerization process leads by design to a polymer with neutral and/or anionic end groups. FEVE resins do contain a small amount of hydroxyl and carboxyl functional groups. These functional groups are classified as low concern RFG

by the USEPA (1997) and OECD (2009). There are no RFG structural similarities across the polymers in this study.

Low MW leachables (MW < 1000 Da): All fluoroplastics, specialty fluoroplastics, and fluoroelastomers in the study met the low MW leachable PLC criteria, which has been widely discussed (see Supporting Information: Chapter 3 for references). Many of the study polymers report no active leachables, whereas the rest cite values less than 1 ppm (Tables 4 and 5). For FEVE, it is reported that some non-fluorinated polymer PA may well remain in the uncured polymer resin. The methods and references for low MW leachables are presented in the Supporting Information: Chapter 4 with the specific chapter noted in Tables 4 and 5. The data presented in Tables 4 and 5 were determined for each of the respective polymers in this study using techniques such as SEC and GPC as the predominant analytical methods along with the use of USP Class VI testing. Additional methods included 21 CFR 177.2600 (USCFR, 2022) and the USEPA's toxicity characteristic leaching procedure (TCLP; SW-846 Test Method 1311; USEPA, 1992).

Residual monomers and ratio of residual monomers to typical MW: PLC criteria of equal interest to the low MW leachables are the residual monomers and the ratio of residual monomers to typical MW (see Supporting Information: Chapter 3 for references). All fluoroplastics, specialty fluoroplastics, and fluoroelastomers in the study met the residual monomers and ratio of residual monomers to typical MW PLC criteria. The study data presented in Tables 4 and 5 show the polymers in this study have residual monomers ranging from less than 50 ppb for several fluoropolymers and up to less than 0.1% for PCTFE based on the methods utilized. Fluoroelastomers in this study have residual monomers ranging from less than 50 ppb up to less than 5 ppm. Residual monomers were determined in several ways including dynamic and static headspace gas chromatography/mass spectrometry (GC/MS) at 150 °C. The monomers used in most cases have very low boiling points and are thus readily volatilized (and captured or destroyed) during polymer manufacture processing and drying steps. The methods and references for residual monomer determination are presented in the Supporting Information: Chapter 4 with the specific chapter noted in Tables 4 and 5. Given the very low residual monomer levels reported, the ratio of residual monomers to polymer MW range from 10^{-11} to 10^{-13} for the study polymers.

Water solubility and octanol/water partition coefficient (K_{ow}): The fluoroplastics, specialty fluoroplastics, and fluoroelastomers in this study are solids that are hydro- and oleophobic, practically insoluble in both water and n-octanol. Therefore, a K_{ow} cannot be computed and is not applicable to these substances. It is worth noting that the practical lack of solubility in water (<10 mg/L) and n-octanol indicate the inability for the study fluoropolymers to actively or passively cross cell membranes. This does mean there is no indication that these polymers can bioaccumulate or bioconcentrate in biota (Henry et al., 2018 and this study). The methods and references for solubility are presented in the

Supporting Information: Chapter 4 with the specific chapter noted in Tables 4 and 5.

Particle size: To meet the PLC assessment criteria for particle size, a powder must be 5 μ m or greater in size (median mass aerodynamic diameter [MMAD]). All fluoroplastics, specialty fluoroplastics, and fluoroelastomers in the study met the particle size PLC criterion. As shown in Tables 4 and 5, the fluoroelastomers in this study are provided in sheets, blocks, pellets, or “crumb,” and the fluoroplastics and specialty fluoropolymers in this study are provided in the form of powders, pellets, sheets, flake, or in dispersions. References and additional information regarding the form of the study polymers is provided in the Supporting Information: Chapter 4.

Stability: All fluoroplastics, specialty fluoroplastics, and fluoroelastomers in the study met the PLC criteria for hydrolysis, light stability, oxidative stability, and aerobic and anaerobic biodegradability (e.g., breakdown into species with Mn <1000 Da). Public literature has abundant thermal, chemical, and biological stability data for the polymers in this study as stability is a hallmark property for these polymers (Ebnesajjad, 2017). For biodegradation, the assessments were largely made based on property data of the study polymers demonstrating they are insoluble and stable in environmental media and thus are not expected to be bioavailable and therefore not biodegrade.

Additionally, published literature reports (Drobny, 2016; Ebnesajjad, 2017; Grot, 2013; Henry et al., 2018; Polymer Industry Association [PIA], 2019) that the study polymers are stable at foreseeable maximum continuous use temperatures presented in Tables 4 and 5. All polymers, including fluoropolymers can degrade when misused or when heated above their recommended use temperatures (Fluoropolymer Products Group of Plastics Europe [FPG], 2012; PIA, 2019). Of course, users are expected to follow guidance for use provided by manufacturers. Hence, the recommended temperatures for reasonably foreseeable use for the study substances are presented in Tables 4 and 5. References and additional information regarding the stability of the study polymers is provided in the Supporting Information: Chapter 4.

Fluorinated PA: If a fluorinated PA was used in the manufacture of the polymer, it was reported for each fluoropolymer in this study. Nine of the 14 fluoropolymers in the study were reported not to have used a fluorinated PA in their manufacture. It is industry practice to use fluorinated PAs when it is necessary to obtain specific end-use property or performance requirements generally related to very high-polymer MWs (see also Supporting Information: Chapter 7). For five study polymers, THV, FKM, FFKM, fluorinated ionomers, and amorphous fluoropolymers, a response of “Yes and No” was provided indicating that for some polymer grades a fluorinated PA is used, but not for others. See Supporting Information: Chapter 4 for additional information.

Results summary: This study examined three fluoroelastomers, nine fluoroplastics, and two specialty fluoroplastics:

ionomers and amorphous. Data for each were gathered from the author companies and assessed by the PLC criteria applicable to the polymer itself “in use” (BIO by Deloitte, 2015; Henry et al., 2018; OECD, 2009). All fluoroplastics, specialty fluoroplastics, and fluoroelastomers in the study met the PLC criteria based on the data presented in Tables 4 and 5 with additional details provided describing methods and references in the Supporting Information: Chapter 4.

Including the four fluoroplastics in the prior study (Henry et al., 2018), data for 18 fluoropolymers have been provided for PLC assessment. These polymers have a wide range of compositions and structures and represent most of the global commercial fluoropolymer market (see additional text in the Discussion). These 18 fluoropolymers represent the major fluoropolymers manufactured and are used worldwide in innumerable critical end-use products and applications. Tables 1 and 2 highlight examples of the end-use markets as well as critical functionality and benefits these polymers provide.

Each of the assessed polymers in this study are insoluble in both water and n-octanol, and thus K_{ow} is not applicable. This lack of solubility in water and octanol confirms that fluoropolymers are not mobile in the environment and are not bioaccumulative and not able to bioconcentrate. The stability studies reported here on each of the study fluoropolymers reveal their stability in terms of light, hydrolysis, heat, oxidation, and biodegradation. When coupled with the lack of solubility, these fluoropolymers are most often characterized as relatively inert materials in the environment. Like any other chemical material or product, it is important to follow the fluoropolymer manufacturer's recommended use and temperature conditions. Tables 4 and 5 describe these recommendations for each fluoropolymer. As reported, the physical forms of the fluoropolymers are largely pellets, blocks, crumb, sheets, some powders (all with MMAD >5 μ m). The solid fluoropolymers are not nanoparticles, and concerns related to nanoparticles do not apply during normal product use. Due to the properties described above for the assessed fluoropolymers—large molecules with no water solubility—the fluoropolymers are biologically inert without the practical ability to cross cell membranes.

During the evaluation of the study fluoropolymers, there was a conscious focus on several core PLC parameters: MW, low MW leachables, % oligomers, and residual monomers, which are direct outcomes related to fluoropolymer manufacturing. In addition to what is reported here in Tables 4 and 5 for the fluoropolymers themselves, industry efforts to manage emissions during manufacturing are discussed below.

DISCUSSION

Fluoropolymers have substantial, unique societal value: Fluoropolymers possess a remarkable combination of properties and functional characteristics, as shown in Tables 1 and 2, that make them valued materials of choice in a broad range of industries and applications critical to life

and a sustainable environment in the 21st century. Their unparalleled combination of properties and performance characteristics deliver functionality to a wide variety of products and systems critical to achieving important societal goals (Amcham, 2020c; FPG, 2021a; Wood, 2020b). They are strategically important to innovation in vital sectors of the global economy requiring high-speed, high-volume data transmission, miniaturization, or operations in extreme temperatures. Moreover, they are crucial to achieving important societal goals such as decarbonization, renewable energies, and/or competitiveness in the digital transition (FPG, 2021a). Fluoropolymers are indispensable for critical applications in the chemical, electronic, semiconductor, healthcare, and transport sectors and the deployment of 5G networks (FPG, 2021a). For many critical applications, fluoropolymers are the material of choice because alternatives are unable to provide the full complement of performance and functionality required. As such, there are currently no viable commercial alternatives to fluoropolymers in virtually every critical application in which they are used (FPG, 2021a, 2017; PFP, 2020).

Commercial fluoropolymers in this study meet the PLC criteria: Widely used by regulators, PLC criteria have been established around the world and documented by OECD expert groups as an appropriate hazard assessment methodology for polymers in-use and can effectively identify low risk fluoropolymers to help prioritize regulatory action (BIO by Deloitte, 2015; OECD, 1993, 2009). Here, we present PLC data, for hazard assessment, that define a group of fluoropolymers' “in-use” properties. PLC is not a comprehensive life-cycle assessment tool. Full life-cycle assessments consider all phases of product “life” including creation (manufacturing) and end-of-life (disposal). Information on manufacture and end-of-life is provided later in this study. Recently, polymers have been under increased regulatory scrutiny. In 2019, the industry-led European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC) developed a Conceptual Framework for Polymer Risk Assessment (“CF4Polymers”; ECETOC, 2019). CF4Polymers provides guiding elements to be considered in assessing potential ecological and human health hazards and risks posed by polymer substances. CF4Polymers also considers specific life-cycle stages of polymer products and their associated routes of exposure. The authors of the CF4Polymers framework support the PLC approach as a means to accomplish polymer risk assessment. They specifically support the findings of Henry et al. (2018) and state that they are “unaware of scientific evidence to justify generally assigning fluoropolymers the same level of regulatory concern as other PFAS” (ECETOC, 2019). In 2020, the European Commission contracted a study to propose criteria to identify PRR under REACH (Wood, 2020a). The report states that the authors consider fluoropolymers meeting the criteria to be considered PLC, “following the recommendations of Henry et al. (2018).”

The properties and characteristics of fluoropolymers are anchored in the strength of the carbon–fluorine bond, which

render them highly stable (thermally, chemically, and biologically), inert, and durable—long lasting in use—under exacting and high-performance conditions. Physical, chemical, thermal, and biological stability are important criteria for a polymer to be considered a PLC. The data presented in Tables 4 and 5 demonstrate that commercial fluoropolymers from the author companies meet the criteria to be considered PLC. The PLC criteria for physicochemical properties reflect the state of the polymers in this study, solids, as well as their inertness and stability. None of the fluoropolymers assessed in this study were soluble in water or octanol. They are biologically inert, insoluble in water and octanol, and not expected to move in or between environmental media. Fluoropolymers are also twice as dense as water. These properties and water insolubility mean fluoropolymers are not mobile in the environment and therefore would not be expected to be found in sources of drinking water. Fluoropolymers are neither bioavailable nor bioaccumulative. These solid polymers cannot be absorbed through a cell membrane via passive or active transport and do not bind or interact with the cell surface (see also Supporting Information: Chapter 8). In addition, whereas aquatic and mammalian toxicology studies of fluoropolymers may be desirable for some, they are technically difficult for insoluble, solid, high-MW polymers. The OECD test guidelines reiterate this in many cases. This is confirmed for example in REACH Annex VII guidance, which repeatedly states toxicity is unlikely to occur “if a substance is highly insoluble in water or the substance is unlikely to cross biological membranes” (see Supporting Information: Chapter 9).

Finally, structure criteria including MW, MWD, residual monomer(s), oligomers, and other synthesis by-products, as represented by low MW extractables and leachables have been determined for the fluoropolymers presented and meet values established for the PLC criteria and regulated uses (e.g., USP). The concentrations in the fluoropolymer that have been evaluated are extremely low, reflective of effective manufacturing processes that minimize these compounds complemented by capture and/or destruction systems for such materials. For additional information, see the section below discussing responsible manufacturing. This study and prior work (Henry et al., 2018) provide a guide for other global fluoropolymer manufacturers to gather and present data on additional commercial fluoropolymers to determine if they too meet the PLC criteria.

Fluoropolymer stability, aka persistence, is not an intrinsic hazard: Fluoropolymers are stable, inert, solid materials. Fluoropolymers resist degradation by acids, bases, oxidants, reductants, photolytic processes, microbes, and metabolic processes; for this reason, they are thermally, chemically, and biologically highly inert. Fluoropolymer stability was presented in the introduction and is further considered in the Supporting Information: Chapters 4 and 5. Fluoropolymers are not expected to degrade under environmental conditions or normal use and processing conditions (Wood, 2020a). They are stable and remarkably durable and are

therefore persistent. However, persistence alone does not imply that there is a present or future risk to human health or the environment (Rüdel et al., 2020). Persistence itself is not an intrinsic hazard, as it does not in itself imply or inform the potential for an adverse effect (aka toxicity). There is no language in REACH supporting the notion that persistence alone justifies risk-management measures. REACH has regulated persistence in combination with other properties that do inform potential hazards. In fact, REACH combines persistence with bioaccumulation and toxicity (or “very persistent” with “very bioaccumulative/very mobile” vPvB/vPvM) to justify designation as a substance of very high concern (SVHC) and consideration of potential risk-management measures for uses associated with unacceptable risk. Therefore, persistence on its own does not justify the need for specific risk-management measures. Fluoropolymers themselves are persistent, but they are not bioaccumulative, not mobile, and not toxic and therefore not SVHCs from a regulatory perspective (Ruwona and Henry, 2021).

PFAS grouping and segmentation—Scope of regulatory measures: The OECD definition of PFAS is based only on chemical structure (OECD, 2021). It describes a universe of fluorinated organic substances with vastly different physical, chemical, and biological properties, including polymers and nonpolymers; solids, liquids, and gases; highly reactive and inert substances; soluble and insoluble substances; and volatile and involatile substances and is too broad to allow effective, science-based assessment and regulation of chemical compounds as an entire group (Amcham 2020a; BDI, 2021; Buck et al., 2021; Orgalim, 2021; Wallington et al., 2021). A 2021 OECD report states: “it is highly recommended that such diversity be properly recognized and communicated in a clear, specific and descriptive manner” and “the term ‘PFASs’ does not inform whether a compound is harmful or not, but only communicates that the compounds under this term share the same trait for having a fully fluorinated methyl or methylene aliphatic carbon moiety” (OECD, 2021).

In this context, the available property data (Tables 4 and 5) reveal that fluoropolymers have distinctly different properties from nonpolymeric PFAS and from SCFPs that have a polymeric backbone that does not contain C–F bonds directly attached to it. The perfluoroalkyl moiety in SCFPs is found in a side-chain connected via a functional group to the polymer backbone and “can potentially lead to the formation of non-polymer PFAS as a result of degradation” (Fluoropolymer Products Group of Plastics Europe [FPG], 2021b; Wood, 2020a; see Supporting Information: Chapter 6). Segmentation that clearly differentiates the broad PFAS family according to their properties, rather than using a structure-based classification alone (OECD, 2021), is needed for a scientifically sound, risk-based regulatory approach. Regulating all PFAS as one homogenous group (ECHA, 2020) absent consideration of their properties, particularly when the properties are so demonstrably different, neglects basic scientific consideration of these properties, which are the foundation of substance differentiation. The USEPA does not consider all PFAS to have

similar risk profiles and therefore they are following a categorical grouping approach based on information about similarities in structure, physicochemical properties, and existing test data on the toxicity of PFAS (USEPA, 2021b). Therefore, segmentation based on properties should be conducted before performing any grouping-based risk assessment, placing stable, nonhazardous fluoropolymers that meet the criteria to be considered PLC in a separate category (see also Supporting Information: Chapter 6).

Fluoropolymer market perspective: The commercial fluoropolymer global market sales have been reported to be approximately 230 000 MT (Dams & Hintzer, 2017). Given the expected fluoropolymer market growth, ranging from approximately 4%–5% to 7%–8% (Allied Market Research [AMR], 2022; Future Market Insights [FMI], 2022; FPG, 2021a; Globe Newswire, 2021), a pro forma market table was created for 2021 using a 5% growth rate. Adding ionomers as well as updated amorphous market information (company data) to the above, the total commercial fluoropolymer market sales is estimated to be approximately 330 000 MT in 2021 (see Supporting Information: Chapter 10). Four fluoropolymers: PTFE, FEP, PFA, and ETFE, were the focus of the first fluoropolymer PLC paper (Henry et al., 2018) and account for approximately 64% of fluoropolymers sold globally in 2021 (pro forma basis). The sales volume of these four fluoropolymers is represented by the first four bars in Figure 10.1 in Supporting Information: Chapter 10. This study discusses 14 fluoropolymers representing an additional 32% (pro forma basis) of the global fluoropolymer market. Therefore, this study, in combination with Henry et al. (2018), presents PLC data from the cited manufacturers of commercial fluoropolymers representing approximately 96% of the global commercial fluoropolymer market that meet the criteria to be considered PLC. The projected 2021 sales volume of the major types of commercial fluoropolymers covered in this study (PVDF, FKM, FEP, amorphous, ionomers, THV, ECTFE, PCTFE, and FFKM, EFEP, CTP, and FEVE) are also represented in Figure 10.1 in Supporting Information: Chapter 10. As noted, estimated market volumes were provided for the sum of FEP, CPT, EFEP, and FEVE as well as a small “others” category. The fluoropolymer polyvinyl fluoride (PVF) was not covered by these two papers but is also shown in Figure 10.1 in Supporting Information: Chapter 10. Other fluorinated polymers, perfluoropolyethers, and SCFPs are not addressed in this study (see Supporting Information: Chapter 6).

FLUOROPOLYMER LIFE-CYCLE CONSIDERATIONS

This study focuses on the properties of the 14 selected commercial fluoropolymers themselves in-use providing data that demonstrate they meet the criteria to be considered PLC. Additionally, the life-cycle stages of fluoropolymer creation (manufacturing) and disposal at the end of industrial or consumer use (end-of-life) are important to consider. The primary focus in these life-cycle stages is generally nonpolymer PFAS from the manufacturing process or fluoropolymer

degradation in end-of-life disposal (ECHA, 2020; FPG, 2021a; Guelfo et al., 2021; Lohmann et al., 2020).

The long-established life-cycle assessment approach to environmental protection and risk management first considers the extent of emissions, their toxicity, and their exposure potential (Guinee et al., 2011). When emissions are sufficiently large in scope, toxicity, and exposure potential, emission-management methods are then considered, including process input changes and emission controls to reduce or eliminate the risk of the emissions. Fluoropolymer manufacturing and disposal life-cycle stages were discussed in the paper that first presented fluoropolymer PLC data (Henry et al., 2018). Here we provide an update and current perspective.

Responsible manufacturing: As corroborated by the data presented here and in prior work (Henry et al., 2018), a large volume percentage and number of commercial fluoropolymers are manufactured that meet the criteria to be considered PLC. Emissions from fluoropolymer manufacture are a key product life-cycle focus. The main focus during the manufacturing phase is not directly related to fluoropolymers but from emissions. Emissions of concern may include nonpolymer PFAS such as fluorinated PAs, unreacted monomers, oligomers, or other unintended by-products formed during manufacturing. It is important to note that, although some high-MW fluoropolymers require use of a fluorinated PA in manufacturing (see also Supporting Information: Chapter 10), it has been reported that at least 50% of commercial fluoropolymers are made without one (Pro-K Fluoropolymer Group, 2021).

Recently, a group of fluoropolymer member companies of FPG voluntarily committed to responsible manufacturing principles through the commissioning of a Regulatory Management Option Analysis, developed by independent consulting firm Chemservices (FPG, 2021a). Member companies of this group are working on individual projects and joint projects at the trade association level with third-party experts. Specifically, companies have committed to continuously improving and/or developing the best available techniques in the manufacturing process, managing environmental emissions, developing R&D programs for the advancement of technologies allowing for the replacement of nonpolymer PFAS PAs and/or working with downstream users to increase the recyclability and reuse of its products in line with the objectives of circular economy (FPG, 2021a). Implementation of this voluntary industry initiative to address concerns relating to fluoropolymers will strengthen already ongoing efforts performed by the fluoropolymer industry promoting responsible manufacturing practices. In addition, member companies are committed to working with EU authorities to establish and implement technical actions to guarantee adequate control of the risks derived from the manufacture and use of fluoropolymers to mitigate such risks wherever possible. This will be done following transparency principles and agreements to monitor progress. For example, important emission reduction has been demonstrated by major fluoropolymer manufacturers including fluorinated PA recovery for reuse, 99% removal of fluorinated PA in wastewater treatment, and

99.99% capture and destruction efficiency of gaseous emissions routed to a thermal oxidizer (Chemours, 2021c), as well as 99–99.9 plant emission reductions (Daikin, 2021c, 2022). Four other companies have reported replacement of fluorinated PAs with nonfluorinated PAs (Arkema, 2008, 2021b; Chemours, 2022; Gujarat Fluorochemicals Limited, 2022; Solvay, 2022). These are substantial efforts toward mitigating emissions associated with fluoropolymer manufacturing being worked on by fluoropolymer manufacturers. This study and the prior study (Henry et al., 2018) provide a guide for other global fluoropolymer manufacturers to gather and present data on their commercial fluoropolymers in-use demonstrating that they meet the PLC criteria.

End-of-use: At the end of industrial or consumer use, fluoropolymers may be disposed via the following routes: landfill, incineration (e.g., waste-to-energy [WTE] facilities), or reuse/recycling. There is considerable data demonstrating that fluoropolymers such as PTFE do not degrade in the environment or release substances of toxicological or environmental concern (FPG, 2021a; Hintzer & Schwertfeger, 2014). FPG member companies are working with the industry and end users on this subject and are engaged in a research project aimed at identifying conditions required for proper disposal (incineration) of fluoropolymers (FPG, 2021a).

Fluoropolymers are chemically, thermally, and biologically stable (Henry et al., 2018; this study) and therefore are not expected to transform to dispersive nonpolymeric PFAS when disposed of in a landfill. A recent study presented results from OECD guideline biodegradation studies demonstrating that PTFE is stable and does not degrade under environmentally relevant conditions (Ruwna and Henry, 2021). Further, fluoropolymers that meet the criteria to be considered PLC, such as those in this study and prior work (Henry et al., 2018), have negligible leachables, unreacted monomers, and oligomers most likely destroyed in fluoropolymer use processing and would therefore not be expected to significantly contribute to landfill leachate (Ruwna and Henry, 2021).

Available data reveal that fluoropolymers are mineralized (i.e., all C–F bonds broken, hydrofluoric acid generated, and scrubbed to calcium fluoride) under commercial WTE incineration operating conditions (Aleksandrov et al., 2019; Bakker et al., 2021; DEC, 2021; Giraud et al., 2021a, 2021b). In recent pilot scale studies representative of full-scale WTE facilities, the most common form of end-of-life destruction conducted on PTFE found that combustion converted the fluorine into controllable hydrogen fluoride gas and that, of the 31 PFAS studied, no fluorine-containing products of incomplete combustion were produced above background levels (Aleksandrov et al., 2019). Further, a recent study investigating the presence of PFAS in waste incinerator flue gas stated: “based on a literature review, RIVM expects that most of the PFASs will largely degrade during the incineration process and then be removed when the flue gases are cleaned. The remaining PFASs are expected to be removed during the recovery of the carbon dioxide” (Bakker et al., 2021). The RIVM report affirmed that PTFE is the most stable fluorine-containing polymer. For PTFE, the RIVM report

concluded that complete thermal decomposition is achieved at a temperature of approximately 800 °C. It was therefore assumed that other fluorine-containing polymers also thermally decompose completely at a temperature of 800 °C. Temperatures at the pyrolysis front and the combustion front in the waste-burning bed range from 900 °C to 1100 °C (As-thana et al., 2006; Ménard et al., 2006), which is well above 800 °C, the temperature at which the complete thermal decomposition of PTFE is achieved (Bakker et al., 2021). Studies for additional fluoropolymers and those with additional pilot and/or full-scale fluoropolymer studies would contribute to this body of data and further affirm their results. The PFP and FPG currently have joint projects working on these potential contributions.

Recycling of fluoropolymer products and articles containing fluoropolymers is difficult because separation of the fluoropolymer from the end products is not always possible (FPG, 2021a; Hintzer & Schwertfeger, 2014; Pro-K Fluoropolymer Group, 2018). This is because fluoropolymers are used predominantly in small components of larger finished articles involving a wide variety of materials. There are several options to recycle fluoropolymer products. In primary recycling, solid fluoropolymer waste is ground and later fed back into the manufacturing cycle of some fluoropolymer products. Recycled fluoropolymers may be used in high-end applications when correctly collected, cleaned, and reprocessed. In secondary recycling, solid fluoropolymer waste is ground, followed by degradation to approximately 1% of the original degree of polymerization by using electron beams, gamma rays, or thermomechanical degradation. The recovered material can be used in the manufacturing of new fluoropolymer products. Lastly, in tertiary recycling or upcycling, solid fluoropolymer is ground, then decomposed into the starting monomers at temperatures higher than 600 °C (pyrolysis) to obtain the same chemical components from which the fluoropolymer was manufactured; monomers, such as tetrafluoroethylene, are purified by distillation, and can then be reused to manufacture new fluoropolymer (3M, 2021; Schlipf & Schwalm, 2014). For the primary and secondary schemes, recycling treatments can be undertaken by the manufacturers of fluoropolymers themselves (onsite), or at a larger scale, mainly by specialist recycling companies. The upcycling needs to be colocated to a fluoropolymer manufacturing plant that can use tetrafluoroethylene.

Primary and secondary recycling is limited because of the presence of fillers, colorants, and other materials in the composition of their final articles. Further, recycling might not work for all end-of-life components, as they are used predominantly in small components of larger finished articles involving a wide variety of materials. Therefore, collecting and dismantling for recycling might not be feasible for all products (FPG, 2021a; Hintzer & Schwertfeger, 2014; Pro-K Fluoropolymer Group, 2018). However, it should be noted that upcycling treatment is applicable to some articles containing fluoropolymers, such as pipe liners in chemical plants, as well as other plant components such as pumps, tank liners, seals, hoses, compensators, and many other fluoropolymer

components and systems. These are the products for which the high quantities of fluoropolymers are used offering significant recycling potential.

SUMMARY

This study has described the composition, uses, performance properties, and functionalities of 14 commercially available fluoropolymers, including fluoroplastics and fluoroelastomers. Fluoropolymers are the preferred material of choice because of their unique combination of properties, which are not achievable from other materials or via other functions. As a result, fluoropolymers have become a critical mainstay for society and are useful to modern living, as they provide vital, reliable functionality to a broad range of industrial and consumer products. Further, the study has presented data demonstrating the subject fluoropolymers satisfy the widely accepted polymer hazard assessment criteria to be considered PLC. The data presented demonstrate the fluoropolymers in the study are thermally, biologically, and chemically stable, negligibly soluble in water, nonmobile, nonbioavailable, nonbioaccumulative, and nontoxic, and contain low levels of impurities. These results further demonstrate that the fluoropolymer class should be considered distinctly different and should not be grouped with other PFAS for hazard assessment or regulatory purposes. When combined with earlier work (Henry et al., 2018), the study demonstrates that commercial fluoropolymers are available that meet the criteria to be considered PLC, which represent approximately 96% of the global fluoropolymer market. Lastly, emissions from fluoropolymer manufacture and disposal at end-of-use are a product life-cycle focus. Emissions may include nonpolymer PFAS such as fluorinated PAs, unreacted monomers, oligomers, or other unintended by-products formed during manufacturing. Fluoropolymer manufacturers recently committed voluntarily to responsible manufacturing principles by continuously improving and/or developing the best available techniques in the manufacturing process, managing environmental emissions, developing R&D programs for the advancement of technologies allowing for the replacement of fluorinated PAs, and/or increasing recyclability and reusing fluoropolymers in line with the objectives of circular economy.

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CONFLICT OF INTEREST

The authors are employed by companies that commercially manufacture fluoropolymers. SHK is an independent fluorotechnology consultant working on behalf of AGC Chemicals Americas Inc. and principal of BeachEdge Consulting LLC.

DATA AVAILABILITY STATEMENT

Data gathered for this paper is presented in the paper itself and the Supporting Information: Data file provided. Additional data are available upon request from the corresponding author Stephen Korzeniowski (shkorzo@gmail.com).

SUPPORTING INFORMATION

The Supplement contains a glossary of terms as well as additional information on the study of fluoropolymers properties and functionalities, polymer of low concern (PLC) background and criteria, references and methods for the PLC data for the study of fluoropolymers, benefits, features and alternatives assessment for the study of fluoropolymers, the differences between fluoropolymers and side-chain fluorinated polymers, fluoropolymer bioavailability and toxicity studies, fluoropolymer global market information, fluoropolymer socioeconomic analyses and risk-management options analysis (RMOA).

ORCID

Robert C. Buck  <http://orcid.org/0000-0002-2604-8905>

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Thermal decomposition of fluoropolymers: Stability, decomposition products, and possible PFAS release

Alireza Arhami Dolatabad^{a,*}, Xuejia Zhang^a, Jiamin Mai^a, Alena Kubátová^b, Jiefei Cao^a, Feng Xiao^{a,c,**}

^a Department of Civil and Environmental Engineering, University of Missouri, Columbia, MO 65211, United States

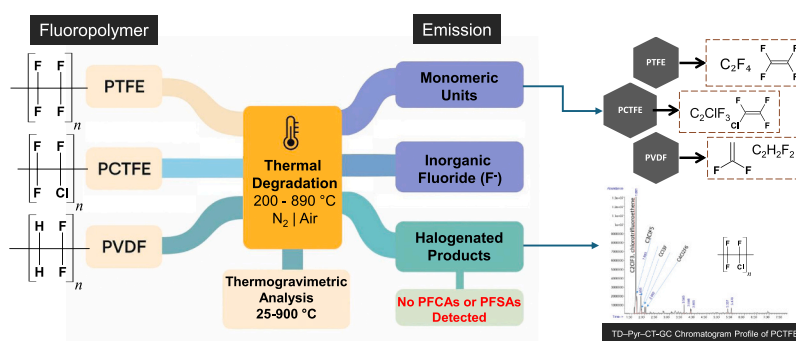
^b Department of Chemical Engineering, University of North Dakota, Grand Forks, ND 58202, United States

^c Missouri Water Center, University of Missouri, Columbia, MO 65211, United States

HIGHLIGHTS

- PFASs or PFCAs such as PFOA and PFBA was not observed from heated fluoropolymers.
- The absence of weaker C–H or C–Cl bonds give PTFE enhanced thermal resilience.
- PCTFE and PVDF generated diverse halogenated byproducts upon heating.
- All polymers exhibited elevated fluorine release beyond their evaporation points.

GRAPHICAL ABSTRACT



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ABSTRACT

The thermal degradation of fluoropolymers poses potential environmental and regulatory challenges due to their emissions of fluorinated byproducts. This study investigates the thermal stability and degradation products of polytetrafluoroethylene (PTFE), polychlorotrifluoroethylene (PCTFE), and polyvinylidene fluoride (PVDF) across temperatures ranging from 200 to 890 °C. Different from previous studies, no short- or long-chain per- and polyfluoroalkyl substances (PFAS) were detected under any tested condition. Among the investigated polymers, PTFE has shown highest stability, remaining intact until ≥ 550 °C and then mainly depolymerizing to tetrafluoroethylene (C_2F_4). In contrast, PCTFE and PVDF degrade at lower temperatures (400–500 °C), generating halogenated byproducts such as chlorotrifluoroethene (C_2ClF_3), chloropentafluoro-1-propene (C_3ClF_5), fluorobenzenes ($C_6H_3F_3$, $C_6H_4F_2$), and dichlorohexafluorobutene ($C_4Cl_2F_6$) that was detected for the first time. This study reports the first-time yields of fluorine (F) release varied across the different fluoropolymers, with PTFE exhibiting the highest F yield, releasing up to 0.8 g fluorine/g PTFE at 600 °C, whereas PCTFE and PVDF peaked at ~ 0.4 and 0.5 g/g, respectively, near 500 °C.

* Corresponding author.

** Corresponding author at: Department of Civil and Environmental Engineering, University of Missouri, Columbia, MO 65211, United States.

E-mail addresses: a.arhamidolatabad@missouri.edu (A.A. Dolatabad), fxiaoee@gmail.com, Feng.Xiao@Missouri.edu (F. Xiao).

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1. Introduction

Per- and polyfluoroalkyl substances (PFAS) represent a class of synthetic chemicals widely recognized for their exceptional thermal and chemical stability, largely attributed to the strength of the carbon–fluorine (C–F) bond [1–6]. Fluoropolymers, an important subset of the PFAS family, are widely used in industrial and consumer applications [7, 8]. Among these, polytetrafluoroethylene (PTFE), polyvinylidene fluoride (PVDF) and polychlorotrifluoroethylene (PCTFE) account for over 250 kt per year of global polymer demand [9]. PTFE, widely marketed under the trade name Teflon, leads global fluoropolymer production at 170–210 kilotons per year as the largest segment in fluoropolymer production [10,11]. Its non-stick surface, exceptional chemical resistance, and proven biocompatibility underpin its widespread application in the chemical-processing, semiconductor, automotive, and pharmaceutical industries [12–14]. PVDF ranks second, with global capacity approaching 50–70 kilotons per year [10]; consumption is projected to expand by about seven percent annually, driven chiefly by its use as a binder in lithium-ion batteries. Its piezoelectricity and robust mechanical properties also support extensive use in sensors, membranes, and medical devices [15,16]. Global production of PCTFE is comparatively modest at 7–10 kt yr^{−1} [10]; however, its mixed C–Cl and C–F backbone is expected to generate transformation products distinct from those of fully fluorinated polymers, giving it an environmental profile that merits investigation. These structural features, coupled with exceptional gas- and solvent-barrier performance, highlight its use in cryogenic valve seats, aerospace components, and high-barrier pharmaceutical blister films [14,17,18].

However, the widespread use and extensive demand for fluoropolymers come with significant environmental challenges. Due to the strong carbon–fluorine (C–F) bond, fluoropolymers exhibit exceptional resistance to natural degradation in the environment, persisting for prolonged periods without breaking down. This durability, while advantageous for their applications, poses difficulties in managing their lifecycle and disposal. As a result, the fate of these materials requires careful consideration to mitigate their environmental impact.

The end-of-life management of fluoropolymers typically involves landfilling or thermal treatments (e.g., pyrolysis and incineration). One particular concern during thermal treatments of fluoropolymers is the possible formation of PFAS as byproducts. PFAS are known for their persistence, bioaccumulation potential, and association with adverse effects on ecosystems and human health [19–25]. Major economies around the world are actively issuing regulations that pertain to PFAS substances under various federal laws [26]. For instance, in April 2024, the United States Environmental Protection Agency announced several rules including the Comprehensive Environmental Response, Compensation, and Liability Act [27] and the first legally enforceable drinking water standard for PFAS [28–30]. European Chemicals Agency have also implemented stringent restrictions on perfluorooctanoic acid (PFOA) and other PFAS [31,32].

Previous studies have shown that when PTFE is heated above 400 °C, the C–F bonds begin to cleave, releasing tetrafluoroethylene and other fluorinated radicals, which can further react in the presence of oxygen or moisture through oxidative and chain-scission reactions to form perfluoroalkyl carboxylic acids (PFCAs). One study [33] demonstrated that thermolysis of PTFE at temperatures exceeding 500 °C produces measurable quantities of PFOA and trifluoroacetic acid (TFA), with yields increasing under oxidative conditions, while another study linked PTFE thermolysis to TFA accumulation in environmental media, underscoring its contribution to broader PFAS contamination [34]. Similarly, Schlummer et al. demonstrated that PTFE-coated consumer products emit PFCAs (e.g., PFOA) when heated, with emissions escalating from trace levels (4.75 ng/h) at normal use temperatures (<230 °C) to significant amounts (up to 12,190 ng/h) at 370 °C during overheating, suggesting thermolysis begins below the commonly cited 300 °C threshold [35].

However, these observations are not supported by recent findings on the thermal degradation of PFOA [36–41], which suggest that PFOA can decompose rapidly under conditions (e.g., 500 °C) where PTFE begins to degrade, casting doubt on its persistence as a byproduct. As shown in our investigation below, we determined that the minimal temperature for PTFE to degrade is approximately 500 °C. At 500 °C, the thermal degradation half-life of PFOA is anticipated to be less than 30 sec, as Xiao and coworkers previously reported near-complete degradation of PFOA after heating at this temperature for just under 1 min [38,40], indicating that the thermal degradation of PTFE occurring at a minimum temperature of 500 °C may not likely be a significant source of PFOA. Similarly, Taylor et al. concluded that incineration of fluorotelomer-based polymers is unlikely to release PFOA [42], and Gehrmann et al. reported non-detectable or negligible PFAS emissions from fluoropolymers (including PTFE) under typical European municipal and hazardous waste incineration conditions [43].

Therefore, the literature remains incomplete, revealing a knowledge gap regarding the precise role of the thermolysis of three major fluoropolymers (PTFE, PCTFE, PVDF) in PFOA and other PFAS contamination pathways. To address this uncertainty, this study was conducted a detailed study using a combination of tools: thermogravimetric Analysis (TGA)–differential scanning calorimetry (DSC) to assess the temperatures at which these fluoropolymers undergo phase changes (e.g., melting) and possible degradation, fluorine (F) released from fluoropolymers, thermal desorption/pyrolysis–gas chromatography–electron ionization–quadrupole mass spectrometry (TD/Pyr–GC–EI–QMS) to analyze degradation products in real time, and offline high-performance liquid chromatography–triple quadrupole mass spectrometry (HPLC–MS/MS) analysis. Due to PFOA's relatively low boiling point (~190 °C) [44] compared to other PFAS, any released PFOA can also be detected by the TD/Pyr–GC–EI–QMS system [41] (Figure S1). Emphasis is placed on capturing the full spectrum of degradation products, including inorganic F, as well as potential polar and non-polar organofluorine byproducts, to provide a comprehensive understanding of PFAS formation potential from PTFE, PVDF, and PCTFE.

2. Materials and methods

2.1. TGA–DSC

Three fluoropolymer substances, PCTFE (CAS: 9002–83–9), PVDF (CAS: 24937–79–9), and PTFE (CAS: 9002–84–0) were purchased from Sigma–Aldrich. To assess the thermal stability and decomposition behavior of the selected polymers, TGA–DSC experiments were performed, which were previously used to study PFAS thermal behaviors in various atmospheres [41,44]. A TA Instruments SDT Q600 thermogravimetric analyzer was used under a controlled nitrogen or oxygen atmosphere to establish pyrolytic conditions. The instrument was calibrated for weight and heat flow using standard calibration procedures. For each test, 15–20 mg of polymer sample was placed in an alumina pan and subjected to a controlled heating program. The temperature increased from 25 °C to 900 °C at a heating rate of 10 °C/min, with a nitrogen or oxygen purge flow of 100 mL/min. Upon reaching the final temperature, the system was held isothermally for 5 min to ensure the complete degradation of volatile components. The purge gas flow rate was maintained at 100 mL/min, with no secondary gas flow. Data were collected at a sampling rate of 0.5 sec per point to ensure high-resolution thermal analysis.

2.2. Analysis of volatile thermal degradation products

Thermal desorption–pyrolysis (TD–Pyr) (Frontier 3030D, Frontier Labs Inc., Japan) was employed in conjunction with a cryogenic trapping (CT)–GC–MS system (Agilent GC 7890 and 5975 C MS; Santa Clara, CA) to detect pyrolysis products of fluoropolymers as described previously [45,46]. This system is capable of detecting volatiles released from

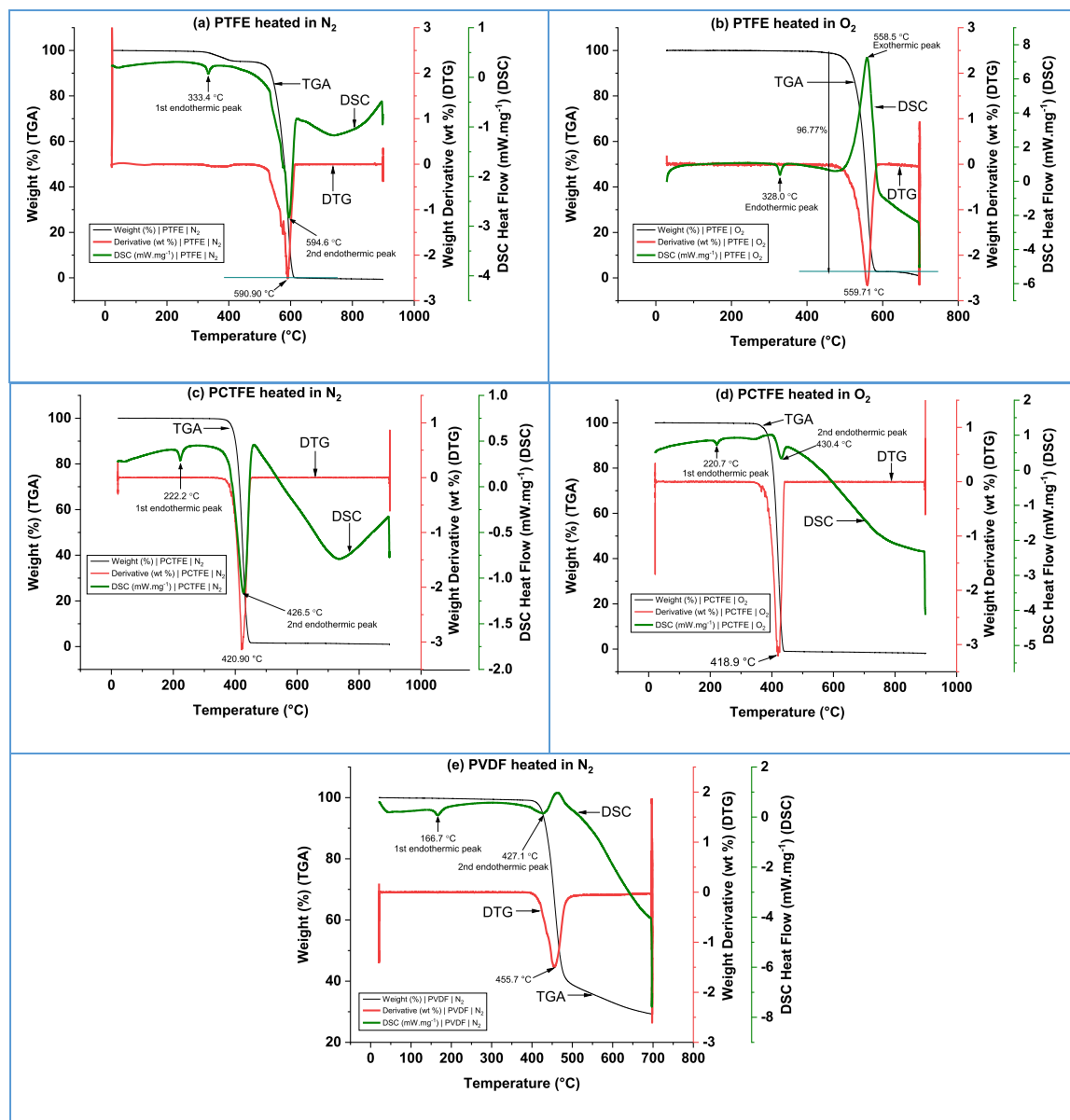


Fig. 1. TGA, DTG, and DSC profiles of PTFE, PCTFE, and PVDF collected under nitrogen flow, and of PTFE and PCTFE under oxygen flow.

substances heated in the TD-Pyr section. Briefly, a multistep heating strategy was applied, with TD at temperatures up to 300 °C facilitating the evolution of low-molecular-weight compounds, and Pyr at higher temperatures enabled the breakdown of thermally stable polymers or high-molecular-weight species. Following thermal processing, gaseous products were cryogenically concentrated in the CT before GC-EI-MS analysis. A 30-m Ultra Alloy capillary column (Frontier Labs Inc., Japan) with an inner diameter of 0.25 mm and a 5 % diphenyldimethyl polysiloxane stationary phase of 0.25 μ m film thickness was used.

Identification of pyrolysis products was primarily based on mass spectral data. Data processing involved evaluating MS fragmentation patterns against the National Institute of Standards and Technology (NIST) 2005 mass spectral library, which contains 190,825 spectra. Unlike HPLC-MS/MS systems, which lack universal library matching, EI-MS mass spectra exhibit uniformity and specificity for organic compounds at a standard EI energy of 70 eV. A previously established strategy was applied [46]:

(1) Each peak was manually evaluated using mass spectral data, and spectral library comparisons were conducted with the instrument's built-in software to assess statistically significant ions.

(2) A minimum of three structure-specific or diagnostic fragments was required for compound identification.

(3) A compound was considered identified if its EI-MS spectrum achieved a high library match quality of ≥ 80 %, as determined by the instrument's built-in software using Agilent's Probability-Based Matching Algorithm to compare statistically significant ions.

2.3. Non-volatile decomposition products of fluoropolymers

To investigate non-volatile decomposition products of fluoropolymers, we conducted a series of batch fluoropolymer thermal degradation experiments in air using borosilicate reactors [37,40,45]. A predetermined mass of fluoropolymer samples, ranging from 5 to 25 mg, was introduced into each reactor. To prevent atmospheric interference, the reactors were sealed using ground-glass stoppers, ensuring no gas exchange occurred during the experiments.

The fluoropolymer samples were subjected to controlled heating in air within a muffle furnace (Neytech, Vulcan 3–550, USA). The temperature gradually increased from ambient conditions (22 °C) to a designated target temperature (200 °C, 300 °C, 400 °C, 450 °C, 500 °C,

or 600 °C) at a constant heating rate of 25 °C/min. Upon reaching the specified temperature, the samples were maintained inside the furnace for one hour to allow for complete thermal exposure. Following the heating process, the reactors were removed from the furnace and left to cool naturally to room temperature.

Following heat treatment and cooling, the reactor was rinsed with methanol containing 100 mmol/L ammonium acetate to extract non-volatile byproducts [37,38]. The methanol extract was subsequently analyzed to identify the thermal decomposition products of PFAS using a HPLC–MS/MS system (Infinity 1290 II HPLC and Ultivo MS/MS, Agilent Inc.) as described previously [47]. The targeted group of PFAS compounds included both short- and long-chain perfluoroalkyl carboxylic acids such as perfluoropropanoic acid (PFPrA), perfluorobutanoic acid (PFBA), perfluoropentanoic acid (PFPeA), PFOA, perfluorononanoic acid (PFNA), perfluorodecanoic acid (PFDA), and perfluoroundecanoic acid (PFUnDA), as well as perfluoroalkane sulfonic acids including perfluorobutane sulfonic acid (PFBS), perfluorohexane sulfonic acid (PFHxS), and perfluorooctane sulfonic acid (PFOS). Chromatographic separation was performed on an Agilent ZORBAX RRHD Eclipse Plus C18 column (100 × 2.1 mm; 95 Å; 1.8 µm; 1200 bar) with a corresponding UHPLC guard column (Agilent ZORBAX RRHD Eclipse Plus C18 UHPLC guard column; 5 × 2.1 mm; 95 Å; 1.8 µm; 1200 bar). The mobile phase consisted of Optima™ water with 0.1 % formic acid (solvent A) and Optima™ methanol with 0.1 % formic acid (solvent B). Analytes were eluted using an Agilent Binary Pump (1290 Infinity II) with a well-plate autosampler at a 0.4 mL/min flow rate, with the column maintained at 55 °C.

Mass spectrometric analysis was conducted in negative ion mode using the Agilent Ultivo TQ with an AJS-ESI source. Operating conditions included a nebulizer pressure of 15 psi, a capillary voltage of 2.5 kV, a capillary current of 3208 nA, and a chamber current of 0.17 µA. The drying N₂ flow rate was 5 L/min at 230 °C, while the sheath gas flow rate was 11 L/min at 350 °C. Leucine enkephalin (400 pg/µL) was infused at 10 µL/min for mass correction. Instrument control, data acquisition, and analysis were managed using Agilent MassHunter Workstation software (Acquisition 12.0, Qualitative Analysis 10.0, and Quantitative Analysis 12.0). Quality control measures included solvent blanks, non-heated sample controls, blank-heated Controls, instrument sensitivity checks, and calibration verification.

2.4. Yield of inorganic F released from fluoropolymers

The above batch thermal experiments were repeated to measure inorganic F released from the polymers upon heating. In brief, 10 mL of distilled water was added to each reactor, and the mixture was allowed to stand for 30 min. The concentration of F[−] ions was then measured using a METTLER TOLEDO™ F meter equipped with a perfection™ comb F ion-selective electrode (ISE). Prior to each measurement session, the ISE was calibrated with standard sodium F solutions prepared in deionized water. To enhance measurement accuracy, each sample was treated with a total ionic strength adjustment buffer (TISAB II), where 10 mL of the sample was mixed with an equal volume of TISAB before analysis.

2.5. Quality assurance and quality control (QA/QC)

To ensure analytical reliability, quality assurance and control (QA/QC) procedures were implemented for analytical tools used in this study. For PFAS detection by LC-MS/MS, method performance was evaluated through matrix controls, solvent blanks, and calibration curves for PFAS quantification in case of their presence in the system. Calibration curves were prepared for each analyte using a nine-point standard series, with linearity confirmed prior to each analytical batch ($R^2 > 0.99$). The extraction efficiency of the methanol-based method had been previously validated using spiked samples, yielding recoveries ranging from 80.4 % to 111.8 % for most PFAS compounds [41,48]. Each batch included two

method blanks consisting of methanol only to assess potential background contamination. Two non-heated samples containing fluoropolymers and two non-heated samples without fluoropolymers were used as matrix blanks to verify the absence of PFAS contamination introduced during the extraction process.

Fluoride ion concentrations were measured using a calibrated ion-selective electrode (ISE). Blank samples containing only deionized water and total ionic strength adjustment buffer (TISAB) were included to ensure the absence of fluoride contamination from reagents or labware. Additionally, two non-heated samples were analyzed to assess any background fluoride released independently of thermal processing. All samples were extracted and analyzed using the same protocols to minimize procedural variability, and replicate measurements were performed where applicable to ensure consistency and reproducibility.

3. Results and discussion

3.1. Thermogravimetric analysis of fluoropolymers

Fig. 1 presents the thermal behaviors of three fluoropolymers, PTFE, PCTFE, and PVDF, investigated using TGA, DTG, and DSC under N₂ and O₂ atmospheres. The TGA curves provide insight into weight loss as a function of temperature, the DTG curves highlight the rate of weight loss, and the DSC curves reveal the thermal transitions, including melting and volatilization.

The TGA curve of PTFE heated in N₂ (Fig. 1a) shows a 95.1 % weight loss between 465.6–618.4 °C, with the DTG curve peaking at 590.9 °C, indicating the maximum rate of decomposition. The DSC curve reveals two distinct endothermic peaks: the 1st endothermic peak at 333.4 °C corresponds to the melting of PTFE, consistent with its crystalline structure, while the 2nd endothermic peak at 590.9 °C aligns with the DTG peak, marking the empirical evaporation point where the evaporation rate of the melted PTFE reaches its maximum. The final weight at 624.0 °C is approximately 0 %, suggesting complete evaporation of melted PTFE or thermal decomposition under N₂. These results are consistent with previous studies, which have reported PTFE decomposition peaking between 550–600 °C, with nearly complete weight loss by approximately 620 °C under both inert and oxidative atmospheres [34,49,50]. For example, Odochian et al. observed a melting transition in the range of 340–345 °C and reported a maximum degradation rate at approximately 590 °C under pyrolytic conditions [50], further supporting the thermal behavior observed in our study.

When heated in O₂, PTFE exhibits a different thermal profile, especially the DSC surface as shown in Fig. 1.b. An endothermic peak at 328.0 °C is characteristic of melting. The DSC curve shows an upward, exothermic peak at 558.5 °C, indicating combustion-type reactions, releasing heating to the system. The DTG curve also peaks at 558.6 °C, reflecting the maximum rate of oxidative decomposition. The corresponding TGA curve reveals a rapid and sharp mass loss beginning just below 500 °C and continuing through approximately 600 °C, suggesting intense degradation facilitated by oxygen. The onset of thermal events occurred at lower temperatures under oxidative conditions compared to pyrolysis. This trend is consistent with prior studies [34,49], which have demonstrated that the presence of oxygen facilitates earlier decomposition by promoting exothermic oxidation reactions during polymer degradation. In both N₂ and O₂ atmospheres, the temperatures of the 2nd endothermic peak (in N₂) and the exothermic peak (in O₂) align well with the DTG peak temperatures where the maximum weight loss was observed.

The TGA curve of PCTFE in N₂, as shown in Fig. 1c, demonstrates thermal stability up to 400 °C, with negligible weight loss below this temperature. Beyond 400 °C, however, a sharp and rapid mass loss occurs. The DTG curve shows a sharp peak at 426.5 °C, marking the maximum rate of weight loss. The DSC curve reveals two endothermic peaks: the 1st at 222.2 °C, corresponding to the melting of PCTFE, and the 2nd at 426.5 °C, which aligns with the DTG peak and represents the

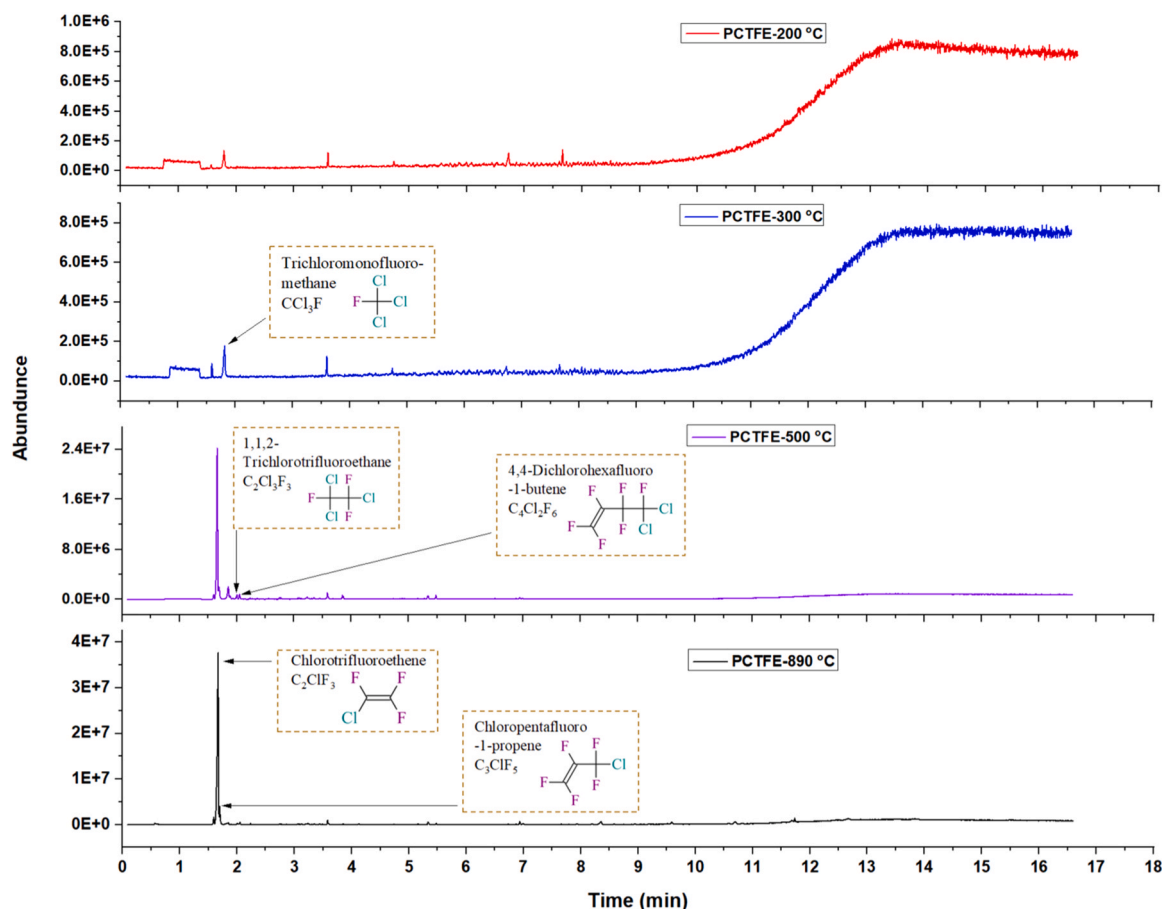


Fig. 2. TD-Pyr-CT-GC-MS chromatograms of PCTFE at 200 °C, 300 °C, 500 °C, and 890 °C.

evaporation/degradation rate of the melted PCTFE is maximized. When PCTFE is heated in O₂, the temperatures of the two endothermic DSC peaks and the DTG peak closely match those observed in N₂.

The TGA curve of PCTFE in O₂ (Fig. 1d) shows that the polymer remains thermally stable up to approximately 390 °C, with minimal mass loss prior to this point. A sharp and substantial weight loss begins just after 400 °C, consistent with the onset of oxidative decomposition. The DTG curve reveals a prominent peak at 418. °C, close to that observed under N₂, indicating that the maximum rate of mass loss remains unchanged despite the presence of oxygen. The DSC profile also displays two distinct endothermic features: the first at 220.7 °C corresponds to the melting of PCTFE, while the second peak, at 430.4 °C, aligns with the DTG maximum and reflects rapid decomposition of the molten polymer. Unlike the N₂ condition, however, the final residue mass in O₂ remains relatively high, suggesting that combustion of certain intermediates is incomplete under the experimental conditions. This retained mass may reflect the formation of thermally stable oxidized species or partial cross-linking during oxidative degradation. Overall, the similarities in decomposition onset and DTG/DSC peaks between N₂ and O₂ suggest that initial degradation mechanisms are thermally driven, although downstream oxidation products may differ significantly.

Fig. 1e presents the TGA curve of PVDF in N₂, highlighting thermal stability up to ~395 °C, with minimal weight loss prior to this point. The DTG curve peaks at 455.7 °C, indicating the maximum rate of weight loss. The DSC curve reveals two endothermic peaks: the 1st at 166.7 °C, corresponding to the melting of PVDF, which is consistent with its semi-crystalline nature, and the 2nd at 427.1 °C, which represents the evaporation/degradation rate of the melted PCTFE is maximized.

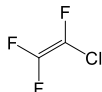
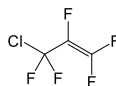
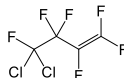
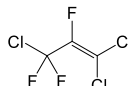
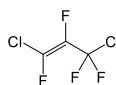
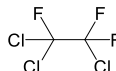
The thermal behavior of PTFE, PCTFE, and PVDF varies significantly due to differences in their chemical structures and the influence of the

heating atmosphere. PTFE (Fig. 1a) exhibits the highest thermal stability in N₂, with a DTG peak of 590.9 °C, followed by PVDF (Fig. 1d) at 455.7 °C and PCTFE (Fig. 1e) at 426.5 °C. This trend reflects the relative strength of the C-F bonds in PTFE, which are stronger than the C-Cl bonds in PCTFE and the C-H bonds in PVDF, making PTFE more resistant to thermal degradation. The melting points (1st endothermic peaks) follow the order PTFE (333.4 °C) > PCTFE (222.2 °C) > PVDF (166.7 °C), consistent with their crystallinity.

In contrast to PTFE under N₂ (which showed essentially complete volatilization with ~0 % residual mass at ~620 °C), neither PCTFE nor PVDF exhibited fully complete evaporation under the tested conditions. For PCTFE, the inert atmosphere (N₂) TGA indicates that while nearly all mass is lost in the 400–450 °C range (Fig. 1c), a small non-zero residue remains by the end of the run, suggesting that PCTFE does not fully evaporate to the extent PTFE does. Under oxidative conditions (O₂), PCTFE's final residue is even more pronounced as a significant fraction of mass remains unburned, implying incomplete combustion or the formation of thermally stable oxidized species (e.g., carbonaceous or chlorine-containing char) that persist at the final temperature. PVDF shows an even greater tendency to retain solid residue: under N₂ it undergoes dehydrofluorination and char formation, leaving a substantial carbon-rich residue (on the order of a few tens of percent of the original mass) instead of volatilizing completely. This comparative behavior highlights the influence of polymer structure on decomposition: PTFE's fully fluorinated backbone cleaves and volatilizes cleanly (yielding complete weight loss in inert conditions), whereas PCTFE (with a weaker C-Cl bond) and especially PVDF (with C-H bonds) form less volatile decomposition products.

Table 1

Thermal degradation products of PCTFE observed from present and previous studies.

CAS	MF	NAME	Chemical structure	Detection (temperature)	
				In this study	Previous Studies
Haloalkenes					
79–38–9	C ₂ ClF ₃	Chlorotrifluoroethene		Pyrolysis: 500–890 °C	Air: 500 °C [33] Pyrolysis: 350, 500, and 700 °C [53]
79–47–0	C ₃ ClF ₅	Chloropentafluoro–1-propene		Pyrolysis: 500–890 °C	Air: 500 °C [33] Pyrolysis: 350, 500, and 700 °C [53]
357–24–4 ^a	C ₄ Cl ₂ F ₆	4,4-Dichlorohexafluoro–1-butene		Pyrolysis: 500–890 °C	
684–06–0	C ₃ Cl ₃ F ₃	1,1,3-Trichloro–2,3,3-trifluoro–1-propene		No	Air: 500 °C [33]
No CAS number	C ₃ Cl ₂ F ₄	1,3-Dichlorotetrafluoropropene		No	Air: 500 °C [33]
Haloalkanes					
76–13–1	C ₂ Cl ₃ F ₃	1,1,2-Trichlorotrifluoroethane		Pyrolysis: 500–890 °C	Air: 500 °C [33]
75–69–4 ^a	CCl ₃ F	Trichloromonofluoromethane		Pyrolysis: 500	
356–18–3	C ₄ Cl ₂ F ₆	1,2-Dichlorohexafluorocyclobutane		No	Air: 500 °C [33]
Halogenated acids					
	C ₄ HCl ₂ F ₅ O ₂	Dichloroperfluorobutanoic acid		No	Air: 500 °C [33]

^a: newly identified in this study.

^a: newly identified in this study.

3.2. Investigation of the possible release of PFAS from fluoropolymer when heated in air

To evaluate the potential formation of short- and long-chain perfluoroalkyl sulfonic acids (PFASs) and PFCAs, including PFOA and PFOS, the thermal treatment of PTFE, PCTFE, and PVDF was conducted in air at 300 °C, 400 °C, 500 °C, and 600 °C. The selection of air as the reaction medium ensured an oxidative environment with sufficient oxygen availability to facilitate potential PFCA formation through radical-driven mechanisms.

Contrary to prior studies that reported the generation of halogenated acids, including PFOA, during the heating of fluoropolymers [33–35, 51], our analysis did not reveal any significant or meaningful peaks across all tested polymers and temperatures, relative to control and blank samples. The method targeted a panel of both short- and long-chain PFCAs and PFASs, including PFPrA, PFBA, PFPeA, PFOA, PFNA, PFDA, PFUnDA, PFBS, PFHxS, and PFOS, none of which were detected in the treated samples. The sensitivity of our HPLC-MS/MS method enabled detection of PFAS compounds at sub-μg/L levels, with limits of quantifications (LOQs) ranging from 0.0067×10^{-9} mol/L for PFHxS to 3.2×10^{-9} mol/L for PFOA. The corresponding PFAS, if released from these fluoropolymers, would range from $< 0.0013 - 0.6625 \times 10^{-6}$ g/g_{fluoropolymer}. These estimates represent upper-bound values; if any PFAS were present above these levels, they would have been detected by the analytical method. This absence

suggests non-detectable or negligible formation of PFCAs and PFASs from these three fluoropolymers, including PTFE, on heating in air. This conclusion is consistent with observations from two previous studies [42,43].

3.3. Non-polar products from PCTFE when heated in N₂

PCTFE [(C₂ClF₃)_n] and PVDF [(C₂H₂F₂)_n] have Cl or H directly attached to the fluorinated chain. The TD–Pyr–CT–GC total ion chromatograms (TICs) chromatograms showed several peaks in the *t_R* range of 1.5–2.5 min (Fig. 2). The MS spectrum at the GC retention time (*t_R*) of 1.7 min indicates a compound with *m/z* 116 and its fragment ions (·Cl, *m/z* 35; ·CF⁺, *m/z* 31; ·CClF⁺, *m/z* 66; ·C₂ClF₂, *m/z* 97), which was identified as chlorotrifluoroethene (C₂ClF₃) based on the NIST library MS data [52]. The cleavage of the C–C bond yielded the biradical :CF⁺ (*m/z* 31). The compound at the *t_R* of 1.7 min was found to be chloropentafluoro-1-propene; the fragmentation pattern and major fragments (·CF⁺, *m/z* 31; ·CF₃, *m/z* 69; ·C₂F₃, *m/z* 81; ·C₃F₅, *m/z* 131; ·C₃ClF₄, *m/z* 147) fit well with the NIST library MS spectrum. All five pyrolyzates of PCTFE, including three haloalkenes and two haloalkanes, were formed at 500 °C and above (Table 1).

Of haloalkenes, 4,4-dichlorohexafluoro-1-butene was reported for the first time, whereas chlorotrifluoroethene and chloropentafluoro-1-propene were observed as PCTFE–air combustion products at 500 °C as reported by Ellis et al. [33]. Furthermore, the study by Ellis et al. also

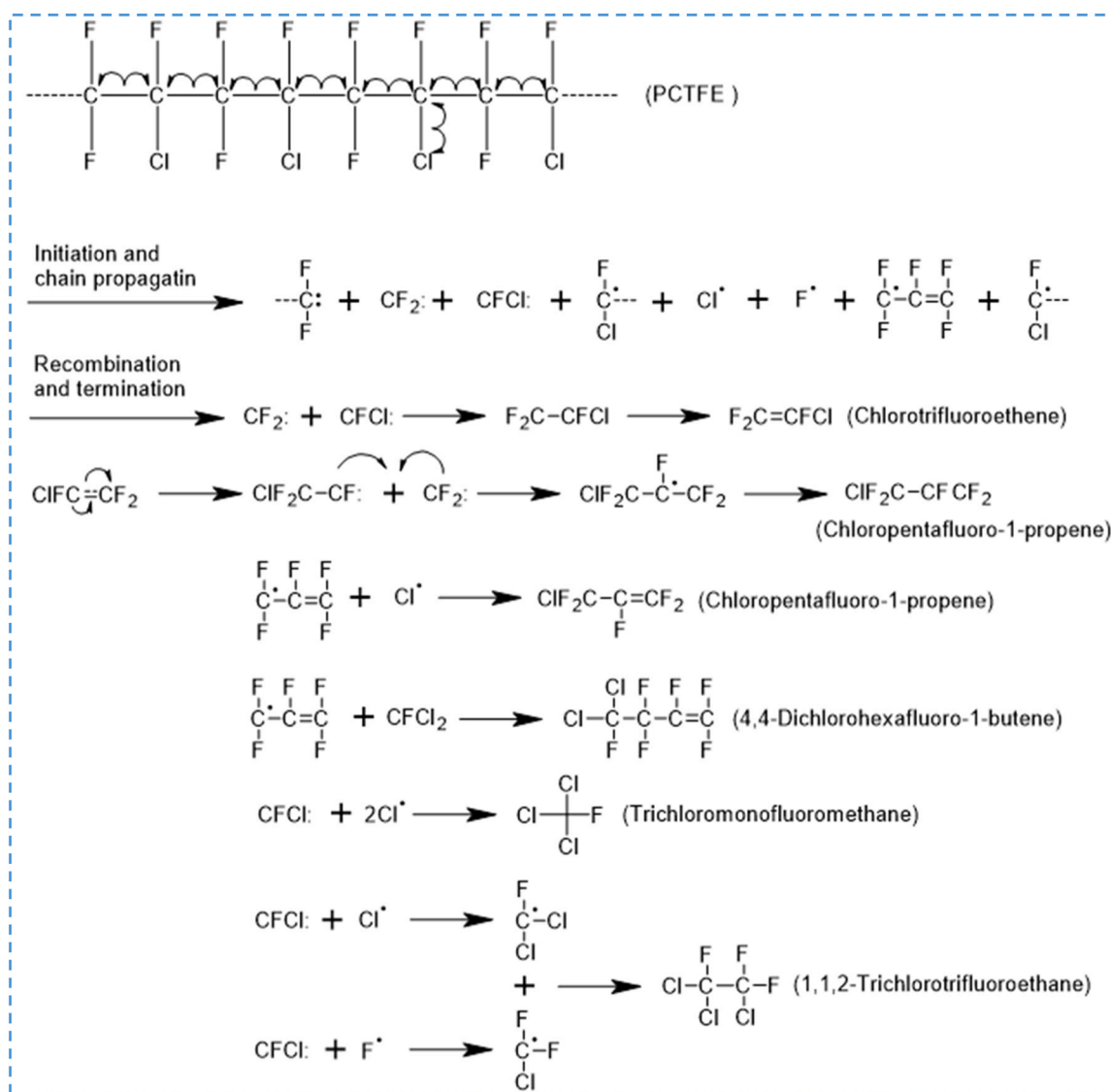


Fig. 3. A possible radical-chain reaction mechanism for the pyrolysis of PCTFE.

identified 1,1,3-trichloro-2,3,3-trifluoro-1-propene and 1,3-dichlorotrifluoropropene, which were not found in PCTFE pyrolysis (Table 1).

Of haloalkanes, the compound at the t_R of 1.9 min had an m/z of 138 that was not reported previously. The MS fragments included $\cdot\text{Cl}$ (m/z 35), $\cdot\text{CClF}^+$ (m/z 66), $\cdot\text{CCl}_2\text{F}^+$ (m/z 101), and $\cdot\text{CCl}_3$ (m/z 117), assigned to trichloromonofluoromethane, a principal chlorofluorocarbon (CFC) that is both a greenhouse gas and an ozone-depleting substance. Another CFC, 1,1,2-trichlorotrifluoroethane, also have been observed, which was also reported by Ellis and co-workers during PCTFE combustion [33]. However, the sterically strained 1,1,2-trichlorotrifluoroethane reported by Ellis et al. [33] was not detected in PCTFE pyrolysis. The MS spectra are provided in [Supporting Information \(Figures S2 to S10\)](#).

A postulated formation mechanism of pyrolyzates from PCTFE is illustrated in Fig. 3. Based on F yields (see below) and the identified species in pyrolyzates obtained at different temperatures, multistep radical chain reactions are likely involved in the degradation process. The thermal cleavage of the PCTFE chain is initiated by random chain scission, leading to the breaking of C—C bonds at various locations along the polymer backbone. This results in the formation of radically terminated chains, generating haloalkyl radicals, chlorine radicals ($\cdot\text{Cl}$), and F radicals ($\cdot\text{F}$). The haloalkyl radicals undergo further cleavage, progressively shortening the polymer chain until the termination of chain

propagation reactions produces short-chain pyrolytic products. The recombination of $\cdot\text{CF}_2$ and $\cdot\text{CFCI}$ forms biradicaloids, which subsequently stabilize to yield chlorotrifluoroethene. Additionally, trichloromonofluoromethane and chloropentafluoro-1-propene may form through recombination reactions involving $\cdot\text{CF}_2$ and $\cdot\text{Cl}$.

3.4. Non-polar products from PVDF when heated in N_2

PVDF ($[\text{C}_2\text{H}_2\text{F}_2]_n$), with a fluorinated carbon backbone and attached hydrogen atoms, undergoes distinct thermal degradation when heated in N_2 . Fig. 4 displays TICs chromatograms from PVDF pyrolysis at various temperatures, showing progressive decomposition. Minimal thermal degradation products are detected between 200–300 °C, highlighting its stability. However, at 500 °C, numerous distinct peaks appeared, confirming the formation of various fluorinated byproducts, with peak intensity notably increasing at 890 °C due to substantial thermal decomposition.

Detected pyrolysis products include 1,3,5-trifluorobenzene ($\text{C}_6\text{H}_3\text{F}_3$), 1,1-difluoroethene ($\text{C}_2\text{H}_2\text{F}_2$), and 1,3-difluorobenzene ($\text{C}_6\text{H}_4\text{F}_2$). 1,3,5-Trifluorobenzene was detected at both 500 °C and 890 °C with a t_{R} of 2.4 min. 1,1-Difluoroethene appeared at the same temperatures with a t_{R} of 1.6 min. 1,3-Difluorobenzene, solely detected at

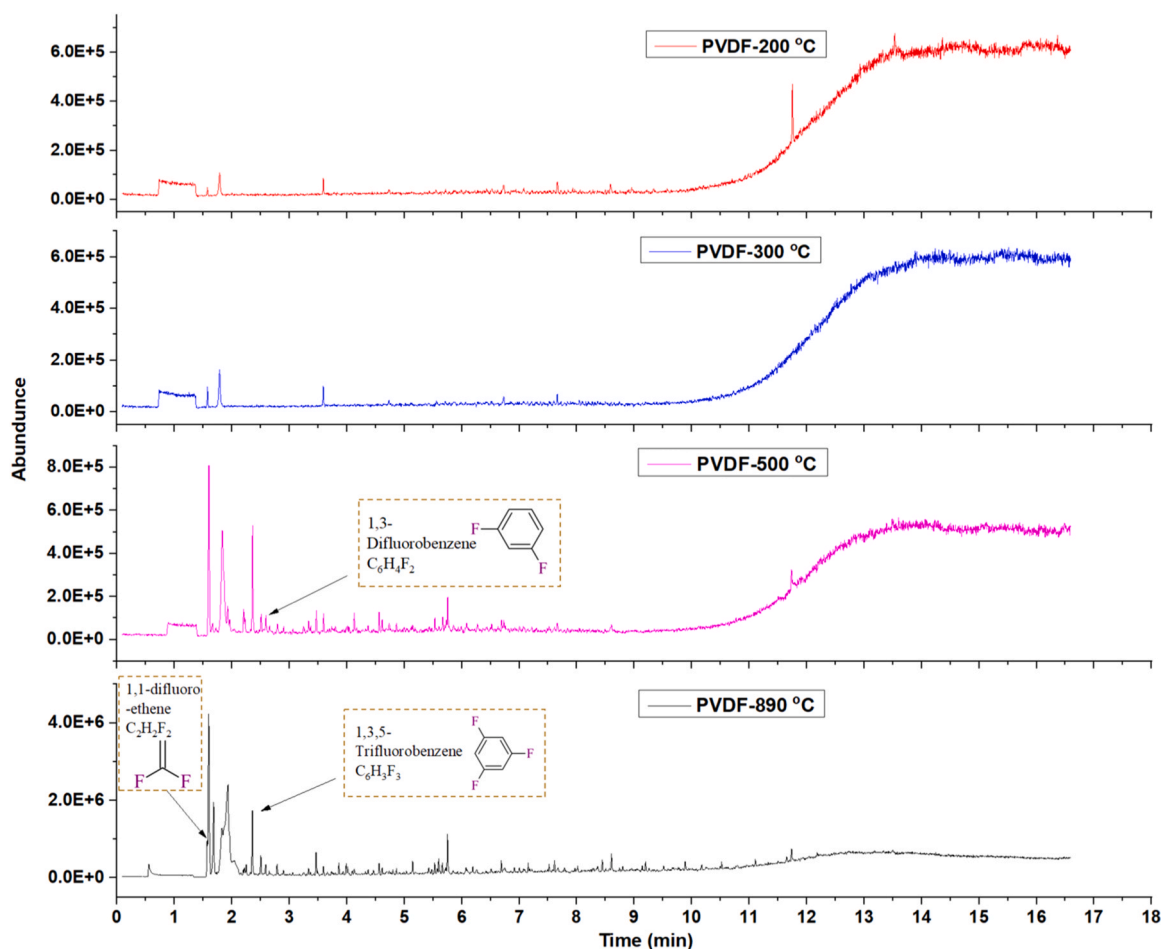


Fig. 4. TD-Pyr-CT-GC-MS chromatograms of PVDF at 200 °C, 300 °C, 500 °C, and 890 °C.

500 °C, had a t_R of 2.6 min. The emergence of these fluorinated aromatic and aliphatic compounds indicates that PVDF undergoes dehydrofluorination and subsequent fragmentation during pyrolysis, forming fluoroalkenes and fluoroaromatic species.

Mass spectral interpretation corroborates these identifications. The spectrum at 1.6 min for 1,1-difluoroethene shows a molecular ion peak at m/z 64, with fragment ions at m/z 45 ($-C_2H_2F$) and m/z 31 ($:CF^+$), indicating stepwise cleavage of fluorine-containing moieties (Figures S11 and S12). The peak for 1,3,5-trifluorobenzene at 2.4 min exhibits a molecular ion at m/z 132 (M), with fragments at m/z 112 (M-F-H) and m/z 81 (M-CF₂-H) (Figures S13 and S14). The peak for 1,3-difluorobenzene at 2.6 min shows a molecular ion at m/z 114 (M), with fragments at m/z 88 (M-C₂H₂) and m/z 63 (M-CF₂-H) (Figure S15).

The appearance of difluoroethene at intermediate temperatures suggests random scission [37,40] of PVDF into monomeric units, while the formation of fluorobenzenes indicates aromatic stabilization plays a role in PVDF pyrolysis, particularly at higher temperatures. Table 2 lists these pyrolysis products, aligning with previous findings [53,54]. Notably, 1,3,5-trifluorobenzene was identified in both past studies, while (C₆H₄F₂) and a hydrofluorocarbon, 1,1-difluoro-ethene (C₂H₂F₂), were unique to current observations. Further details and MS spectra are provided in the supplementary information (Figures S11–S15).

Our analysis focused on compounds for which we had high confidence in identification based on mass spectral library matches, relevant structural patterns, and, when available, retention time comparisons with reference standards. Peaks with low match scores or ambiguous fragmentation patterns were left unassigned to avoid speculative identification. These additional peaks likely represent trace-level pyrolysis

byproducts, structural isomers, or secondary decomposition products. As noted in similar studies [33,34,55], even with comprehensive spectral libraries, a substantial portion of the TIC signal often remains unattributed due to the presence of novel, low-abundance, or co-eluting compounds.

3.5. Non-polar products from PTFE when heated in N₂

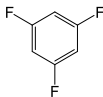
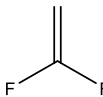
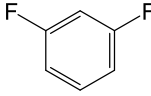
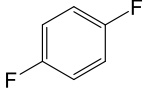
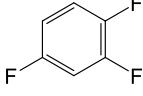
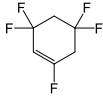
Non-polar products from PTFE when heated in N₂ illustrate the influence of its fully fluorinated carbon backbone on thermal degradation. The TICs (Figure S16) show minimal degradation products between 200–300 °C, underscoring PTFE's notable thermal stability. However, the initial formation of small amounts of tetrafluoroethylene (C₂F₄) at 500 °C and 600 °C signals the onset of thermal degradation, though it remains limited at these temperatures (Table 3). A marked increase in pyrolysis products is observed at 890 °C, indicating significant thermal decomposition.

At elevated temperatures, tetrafluoroethylene (C₂F₄) emerges as the primary pyrolyzate from PTFE, with a notable peak at a t_R of 1.6 min. The corresponding mass spectrum (Figures S17 and S18) reveals a molecular ion at m/z 100 and key fragment ions ($-CF_2$, m/z 50; C₂F₃⁺, m/z 81). This predominance of tetrafluoroethylene suggests a primary depolymerization mechanism, characterized by random chain scission breaking PTFE down into monomeric units. Previous studies corroborate this, showing PTFE's stability up to approximately 550–600 °C, beyond which it undergoes rapid degradation and releases perfluoroalkenes as major volatile products [56–59].

Unlike PCTFE and PVDF, which yield a variety of halogenated alkenes and alkanes upon pyrolysis, PTFE's degradation pathway is more

Table 2

Fluorinated species emitted from PVDF samples used in thermal conditions.

CAS	MF	NAME	Chemical structure	Identification (temperature)	
				In this study	Previous Studies
372–38–3	C ₆ H ₃ F ₃	1,3,5-Trifluorobenzene		Pyrolysis: 500–890 °C	Pyrolysis: 700–900 °C [54]
75–38–7	C ₂ H ₂ F ₂	1,1-Difluoroethene		Pyrolysis: 500–890 °C	Pyrolysis: 350, 500, and 700 °C [53]
372–18–9 ^a	C ₆ H ₄ F ₂	1,3-Difluorobenzene		Pyrolysis: 500–890 °C	
540–36–3	C ₆ H ₄ F ₂	1,4-Difluorobenzene		No	Pyrolysis: 700–900 °C [54]
367–23–7	C ₆ H ₃ F ₃	1,2,4-Trifluorobenzene		No	Pyrolysis: 700–900 °C [54]
	C ₆ H ₅ F ₅	1,3,3,5,5-Pentafluoro cyclohexene		No	Pyrolysis: 700–900 °C [54]

^a: newly identified in this study.

specific, primarily producing C₂F₄. This specificity results from the absence of hydrogen or chlorine in its structure, limiting secondary degradation products. PTFE's thermal degradation follows a radical-driven unzipping mechanism that predominantly generates tetrafluoroethylene as a major volatile species at high temperatures, aligning with its well-documented high-temperature behavior. This detailed analysis helps in understanding the decomposition dynamics of PTFE compared to other fluoropolymers, providing insights into its unique thermal resistance and breakdown products.

While this study identified C₂F₄ as the dominant degradation product, other investigations have reported additional species such as hexafluoropropene (C₃F₆), perfluoroalkanes (e.g., C₂F₆, C₄F₈), and halogenated acids including trifluoroacetic acid and perfluorooctanoic acid (Table 3). These differences can be attributed to several factors, including the type and formulation of PTFE used, reaction atmosphere (air vs. inert gas), heating rate, residence time and analytical approach. It is important to note that majority of these studies relied on off-line sampling and analysis approaches, where intermediate cooling, collection, and transfer steps can promote secondary reactions or condensation of labile species, potentially altering the final composition of captured products.

3.6. Inorganic fluorine yield of fluoropolymers

The thermal degradation of PTFE, PCTFE, and PVDF in air, as illustrated in Fig. 5, displays distinct defluorination behaviors with rising temperatures. For PTFE (Fig. 5a), F release was negligible from 200 °C to 500 °C, which highlights its robust thermal stability (Fig. 1). However, at 600 °C, F release escalates sharply to approximately 0.8 g/g_{PTFE}, indicating a rapid thermal breakdown above this critical temperature. This significant increase correlates with TGA findings (Fig. 1) that demonstrate substantial weight loss and phase transition within the 550–600 °C range, suggesting PTFE remains virtually undegraded under moderate thermal conditions (≤500 °C) but becomes susceptible to high

heat. Although limited information exists on the thermal defluorination of polymers, Knight and Wright reported a similarly abrupt increase in fluoride release from PTFE above 500 °C, supporting our observed defluorination threshold [61].

In contrast, PCTFE (Fig. 5b) and PVDF (Fig. 5c) begin degrading at lower temperatures. F yield from PCTFE starts to rise at 400 °C (~0.2 g/g_{PCTFE}), increases through 450 °C (~0.3 g/g_{PCTFE}), and reaches 500 °C (~0.4 g/g_{PCTFE}), before slightly decreasing at 600 °C. This reduction might be due to secondary reactions of mineralized F species under high temperatures. Similarly, PVDF's F yield climbs steeply at 450 °C (~0.4 g/g_{PVDF}), peaks at 500 °C (~0.5 g/g_{PVDF}), and then slightly declines at 600 °C, potentially from secondary reactions forming stable inorganic fluorides such as silicon tetrafluoride (SiF₄) in the presence of reactive species. To the best of our knowledge, this is the first study to quantify fluoride yield from the thermal degradation of PCTFE and PVDF, providing new insight into their defluorination behavior under oxidative conditions.

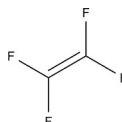
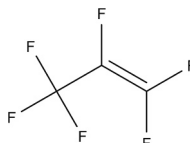
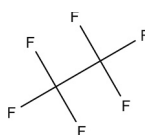
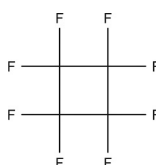
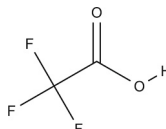
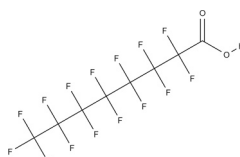
The earlier onset of degradation in PCTFE and PVDF compared to PTFE is attributed to their chemical structures, with PCTFE's C–Cl bonds and PVDF's C–H bonds making their polymer backbones more susceptible to thermal decomposition. This comparative analysis underscores the influence of chemical structure on the thermal stability and degradation patterns of fluoropolymers.

The results on F yield at high temperatures indicate the mineralization of fluoropolymers, suggesting that F is released in an inorganic form. While this phenomenon is favorable in terms of preventing the formation of harmful organofluorine emissions, the release of F into the exhaust gas poses potential risks. F can react with H to form HF, a highly toxic and corrosive gas.

To address this issue, air pollution control devices such as wet scrubbers and adsorption systems using lime (CaO or Ca(OH)₂) can be employed to capture F emissions and convert them into calcium fluoride (CaF₂), a stable and non-hazardous compound. Previous studies have demonstrated that alkali and alkaline-earth metal additives [62–66]

Table 3

Fluorinated species emitted from PTFE samples used in thermal conditions.

CAS	MF	NAME	Chemical structure	Identification (temperature)	
				In this study	Previous Studies
Haloalkenes					
116–14–3	C ₂ F ₄	Tetrafluoroethylene		Pyrolysis: 500–890 °C	Air: 500 °C [33] Pyrolysis: 850 °C [56], 600–800 °C [57,58], 550–790 °C [59], 450–600 °C [60]
116–15–4	C ₃ F ₆	Hexafluoropropene		No	Air: 500 °C [33], 850 °C [56] Pyrolysis: 850 °C [56], 600–800 °C [57,58], 550–790 °C [59], and 450–600 °C [60]
Haloalkanes					
76–16–4	C ₂ F ₆	Hexafluoroethane		No	Air: 850–1050 °C [56] Pyrolysis: 600–800 °C [57,58], and 760–790 °C [59]
115–25–3	C ₄ F ₈	Octafluorocyclobutane		No	Pyrolysis: 600–800 °C [57,58], 550–790 °C [59], and 450–600 °C [60]
-	C _n F _{2n+2}	Other Perfluoroalkanes	-	No	Air: 850–1050 °C [56] Pyrolysis: 600–800 °C [57,58], and 550–790 °C [59]
Halogenated acids					
76–05–1	C ₂ HF ₃ O ₂	Trifluoroacetic Acid		No	Air: 500 °C [33], 500–700 °C [34]
335–67–1	C ₈ HF ₁₅ O ₂	Perfluorooctanoic Acid		No	Air: 500 °C [33]
-	CF ₃ (CF ₂) _n COOH	Other Perfluoroalkyl Carboxylic Acids	-	No	Air: 500 °C [33], 500–700 °C [34]

enhance the thermal degradation of PFAS, while simultaneously reducing the formation of intermediates and capturing emitted F species as compounds like CaF₂.

4. Conclusion

This study provides a comprehensive investigation into the thermal degradation byproducts of three widely used fluoropolymers—PTFE, PCTFE, and PVDF—under various temperature conditions. The results highlight significant differences in the thermal stability and decomposition pathways of these polymers, driven by their distinct chemical structures. PTFE exhibited the highest thermal resistance, undergoing significant degradation only at temperatures above 550 °C, primarily yielding tetrafluoroethylene as the dominant volatile product. In contrast, PCTFE and PVDF, which contain chlorine and hydrogen atoms, respectively, degraded at lower temperatures, producing a more diverse array of halogenated and fluorinated byproducts, including chlorotrifluoroethylene, chloropentafluoro-1-propene, and fluorobenzenes. The strong C-F bonds present in these polymers typically favor

depolymerization as the dominant pathway. In contrast, weaker C-H and C-Cl bonds facilitate degradation through chain transfer reactions.

The F yield findings further confirm the high stability of PTFE as it remains stable under moderate thermal conditions, with minimal F release until temperatures exceed 500 °C. Conversely, PCTFE and PVDF show earlier onset of degradation, with F release beginning at 400 °C and 450 °C, respectively. Coupling TGA and F yield data highlights the fact that the major defluorination occurred after the phase transition of the polymers, indicating that the breakdown of the polymer backbone and subsequent release of F are closely linked to structural changes at elevated temperatures.

Finally, this study indicates that the thermal degradation of PTFE, PCTFE, and PVDF does not significantly contribute to PFAS release as shown by the absence of PFCAs, and PFSAs in thermally treated samples in oxidative atmosphere. Instead, the primary concern in this context lies in the generation of non-volatile organofluorines, which include potent greenhouse gases such as tetrafluoroethylene and inorganic F species, such as HF, poses environmental and health risks, necessitating the implementation of effective air pollution control measures. The

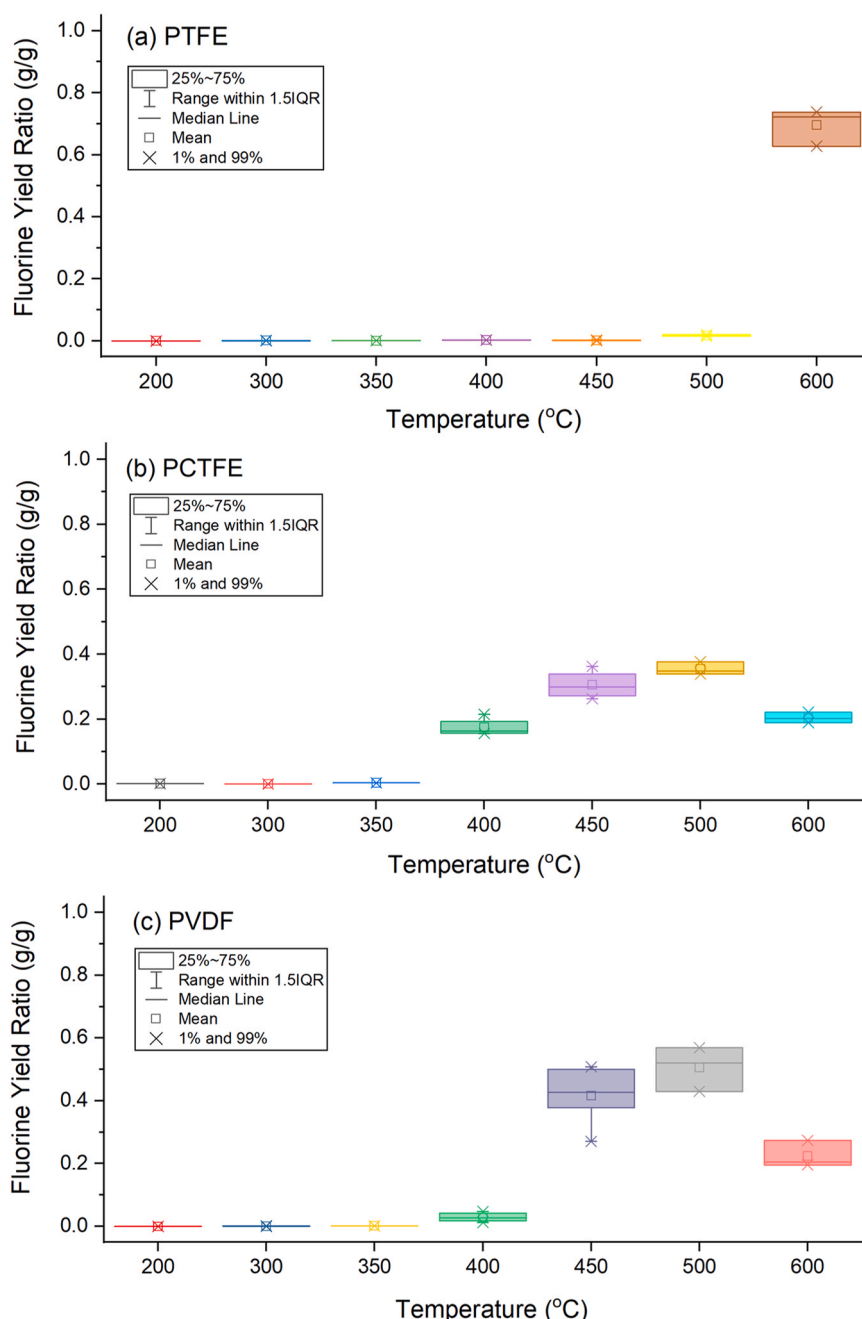


Fig. 5. F yield ($\text{g/g}_{\text{fluoropolymer}}$) as a function of temperature for the thermal degradation of (a) PTFE, (b) PCTFE, and (c) PVDF in air.

findings can provide valuable insights for developing more sustainable waste management strategies, particularly in the context of increasing regulatory scrutiny of PFAS.

Environmental implication

Fluoropolymers are increasingly exposed to high temperatures during use and disposal, yet their potential to form persistent PFAS remains uncertain. This study shows that PTFE, PCTFE, and PVDF did not form detectable PFCAs and PFSA's under pyrolytic and oxidative conditions (200–890 °C), suggesting limited PFAS formation. Instead, concerns center on volatile fluorinated gases and inorganic fluorine, which may form corrosive HF. These findings link polymer structure to degradation behavior and support safer, more sustainable thermal treatment of fluoropolymer-containing wastes.

CRediT authorship contribution statement

Xuejia Zhang: Writing – original draft. **Jiamin Mai:** Writing – original draft. **Alireza Arhami Dolatabad:** Writing – review & editing, Writing – original draft, Visualization, Methodology, Investigation, Formal analysis, Data curation. **Jiefei Cao:** Writing – original draft, Methodology, Formal analysis, Data curation. **Feng Xiao:** Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Conceptualization. **Alena Kubátová:** Writing – review & editing, Writing – original draft, Visualization, Validation, Methodology, Formal analysis.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at [doi:10.1016/j.jhazmat.2025.139322](https://doi.org/10.1016/j.jhazmat.2025.139322).

Data availability

Data will be made available on request.

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On this page:

- Adhesives, Coatings, and Inks
- Aerosols
- Cleaning Solvents
- Fire Suppression and Explosion Protection
- Foam Blowing Agents
- Refrigeration and Air Conditioning
- Sterilants
- Tobacco Expansion

Adhesives, Coatings, and Inks

Adhesives <<https://epa.gov/snap/substitutes-adhesives>>

Adhesives are formulations of sticky solids used to adhere pieces of material together. Common uses are laminate adhesives, flexible foam adhesives, and hardwood floor adhesives.

Coatings <<https://epa.gov/snap/substitutes-coatings>>

Coatings are durable and decorative coatings such as paints, wood stains, and aerospace coatings that contain solids distributed through a carrier solvent.

Inks <<https://epa.gov/snap/substitutes-inks>>

Inks are pigments distributed through a carrier solvent including flexographic and rotogravure printing inks.

Aerosols

Propellants <<https://epa.gov/snap/substitutes-propellants>>

Propellants propel out the pressurized contents of a container.

Solvents <<https://epa.gov/snap/substitutes-solvents>>

Solvents are used to dissolve liquids or solids, particularly for cleaning.

Cleaning Solvents

Metals Cleaning <<https://epa.gov/snap/substitutes-metals-cleaning>>

Metals cleaning is removing contaminants such as cutting oils, grease, or metal filings from metal parts.

Electronics Cleaning <<https://epa.gov/snap/substitutes-electronics-cleaning>>

Electronics cleaning is removing contaminants, primarily solder flux residues, from electronics or circuit boards.

Precision Cleaning <<https://epa.gov/snap/substitutes-precision-cleaning>>

Precision cleaning is cleaning to a specific grade of cleanliness in order for products to maintain their value.

Fire Suppression and Explosion Protection

Total Flooding Agents <<https://epa.gov/snap/substitutes-total-flooding-agents>>

Total flooding systems, which historically used halon 1301, are designed to automatically discharge an extinguishing agent and achieve a specified minimum agent concentration throughout a confined space.

Streaming Agents <<https://epa.gov/snap/substitutes-streaming-agents>>

Streaming fire extinguishers, which historically used halon 1211, are portable and can be manually manipulated to discharge in a specific direction and release a specific quantity of extinguishing agent at the time of a fire.

Foam Blowing Agents

Rigid Polyurethane: Appliance <<https://epa.gov/snap/substitutes-rigid-polyurethane-appliance>>

Appliance foam includes insulation foam in domestic refrigerators and freezers.

Rigid Polyurethane: Spray <<https://epa.gov/snap/substitutes-rigid-polyurethane-spray>>

Spray foam includes insulation for roofing and walls.

Rigid Polyurethane: Commercial Refrigeration <<https://epa.gov/snap/substitutes-rigid-polyurethane-commercial-refrigeration>>

Commercial refrigeration foam includes insulation for pipes, walls and metal doors in commercial refrigeration equipment, vending machines, coolers, buoyancy, and refrigerated transport vehicles.

Rigid Polyurethane: Marine Flotation Foam <<https://epa.gov/snap/substitutes-rigid-polyurethane-marine-flotation-foam>>

Marine flotation foam is used in boat manufacturing for both structural and flotation purposes.

Rigid Polyurethane: Sandwich Panels <<https://epa.gov/snap/substitutes-rigid-polyurethane-sandwich-panels>>

Sandwich panels include insulation for walls and metal doors.

Flexible Polyurethane <<https://epa.gov/snap/substitutes-flexible-polyurethane>>

Flexible polyurethane includes foam furniture, bedding, chair cushions, and shoe soles.

Integral Skin Polyurethane <<https://epa.gov/snap/substitutes-integral-skin-polyurethane>>

Integral skin polyurethane includes car steering wheels, dashboards, and shoe soles.

Polystyrene: Extruded Sheet <<https://epa.gov/snap/substitutes-polystyrene-extruded-sheet>>

Extruded sheet includes foam for packaging and buoyancy or floatation.

Polyolefin <<https://epa.gov/snap/substitutes-polyolefin>>

Polyolefin includes foam sheets and tubes.

Rigid Polyurethane: Slabstock and Other <<https://epa.gov/snap/substitutes-rigid-polyurethane-slabstock-and-other>>

Slabstock includes insulation for panels and pipes.

Polystyrene: Extruded Boardstock & Billet <<https://epa.gov/snap/substitutes-polystyrene-extruded-boardstock-and-billet>>

Extruded boardstock and billet includes insulation for roofing, walls, flooring, and pipes.

Rigid Polyurethane & Polyisocyanurate Laminated Boardstock

<<https://epa.gov/snap/substitutes-rigid-polyurethane-and-polyisocyanurate-laminated-boardstock>>

Rigid polyurethane and polyisocyanurate laminated boardstock includes insulation for roofing and walls.

Phenolic Insulation Board & Bunstock <<https://epa.gov/snap/substitutes-phenolic-insulation-board-and-bunstock>>

Phenolic insulation board and bunstock includes insulation for roofing and walls.

Refrigeration and Air Conditioning

Chillers <<https://epa.gov/snap/substitutes-chillers>>

Chillers typically cool water, which is then circulated to provide comfort cooling throughout a building or other location. Chillers can be classified by compressor type, including centrifugal and positive displacement. Chillers used to cool industrial processes are discussed under Industrial Process Refrigeration.

Cold Storage Warehouses <<https://epa.gov/snap/substitutes-cold-storage-warehouses>>

Cold storage warehouses store meat, produce, dairy products, and other perishable goods. The majority of cold storage warehouses in the United States use ammonia as the refrigerant in a vapor compression cycle, although some rely on other refrigerants.

Commercial Ice Machines <<https://epa.gov/snap/substitutes-commercial-ice-machines>>

Commercial ice machines are used in commercial establishments (e.g., hotels, restaurants, convenience stores) to produce ice for consumer use. Ice machines

produce ice in various sizes and shapes, and with different retrieval mechanisms (e.g., dispensers or self-retrieval from bins).

Household Refrigerators and Freezers <<https://epa.gov/snap/substitutes-household-refrigerators-and-freezers>>

Household refrigerators and freezers are intended primarily for residential use, although they may be used outside the home. Household freezers only offer storage space at freezing temperatures. Products with both a refrigerator and freezer in a single unit are most common. Small refrigerated household appliances may also include chilled kitchen drawers, wine coolers, mini fridges, household beverage centers, ice makers that are part of a household refrigerator-freezer, and stand-alone ice makers for household use.

Ice Skating Rinks <<https://epa.gov/snap/substitutes-ice-skating-rinks>>

Ice skating rinks are used by the general public for recreational purposes and also include professional rinks. These systems frequently use secondary loop refrigeration systems.

Industrial Process Air Conditioning <<https://epa.gov/snap/substitutes-industrial-process-air-conditioning>>

Industrial process air-conditioning units, which are distinct from commercial and residential air conditioning, provide comfort cooling for operators and protect process equipment. This end-use is often used when ambient temperatures approach 200°F (93°C) and corrosive conditions exist.

Industrial Process Refrigeration <<https://epa.gov/snap/substitutes-industrial-process-refrigeration>>

Industrial process refrigeration systems cool process streams in industrial applications. The choice of substitute for specific applications depends on ambient and required operating temperatures and pressures.

Motor Vehicle Air Conditioning <<https://epa.gov/snap/substitutes-motor-vehicle-air-conditioning>>

Motor vehicle air-conditioning systems (MVACs) provide comfort cooling for passengers in light-duty cars and trucks, buses, trains, and other forms of transportation.

Non-Mechanical Heat Transfer Systems <<https://epa.gov/snap/substitutes-non-mechanical-heat-transfer-systems>>

Non-mechanical heat transfer systems include cooling systems that do not rely on a

vapor compression cycle, such as those using convection to remove heat from an area. Two types of such systems are recirculating coolers, i.e., systems with fluid pumps, and thermosiphons, i.e., those that rely on natural convection currents. This end-use also includes Organic Rankine Cycle (ORC) devices that typically pump refrigerant to recover and utilize energy from lower-temperature heat rejected from other processes.

Residential and Light Commercial Air Conditioning and Heat Pumps

<<https://epa.gov/snap/substitutes-residential-and-light-commercial-air-conditioning-and-heat-pumps>>

This end-use includes equipment that cools enclosed spaces in households and commercial industries, but excludes chillers—which include room air conditioning such as window units, packaged terminal air conditioners (PTAC) and heat pumps (PTHP), and portable air conditioners; central air conditioners (i.e., ducted); non-ducted systems (both mini and multi splits); packaged rooftop units; water-source and ground-source heat pumps; and other products. Residential and light commercial air conditioning and heat pumps are often distinguished from chillers by the fact that they condition the air directly, rather than cool (or heat) water that is then used to condition air.

Residential Dehumidifiers <<https://epa.gov/snap/substitutes-residential-dehumidifiers>>

Residential dehumidifiers are primarily used to remove water vapor from ambient air or directly from indoor air for comfort or material preservation purposes. While air-conditioning systems often combine cooling and dehumidification, this application serves only the latter purpose.

Refrigerated Transport <<https://epa.gov/snap/substitutes-refrigerated-transport>>

Refrigerated transport moves products (e.g., perishable goods) from one place to another by various modes of transportation while maintaining necessary temperatures, including refrigerated ship holds, truck trailers, railway freight cars, ships, and other shipping containers.

Retail Food Refrigeration <<https://epa.gov/snap/retail-food-refrigeration>>

Retail food refrigeration, or commercial refrigeration, includes equipment designed to store, display, process, or dispense chilled or frozen goods for commercial sale. This end-use includes these categories of equipment: stand-alone equipment, remote condensing units, supermarket systems, and refrigerated food processing and dispensing equipment.

Refrigerated Transport <<https://epa.gov/snap/substitutes-refrigerated-transport>>

Refrigerated transport moves products (e.g., perishable goods) from one place to another by various modes of transportation while maintaining necessary temperatures, including refrigerated ship holds, truck trailers, railway freight cars, ships, and other shipping containers.

Vending Machines <<https://epa.gov/snap/substitutes-vending-machines>>

Vending machines are self-contained units that dispense goods that must be kept cold or frozen.

Very Low Temperature Refrigeration <<https://epa.gov/snap/substitutes-very-low-temperature-refrigeration>>

Very low temperature refrigeration systems require maintaining temperatures at approximately -80 degrees Fahrenheit (-62 degrees Celsius) or lower. Examples include medical freezers and freeze-dryers, which generally require extremely reliable refrigeration cycles to maintain low temperatures and must meet stringent technical standards that do not normally apply to refrigeration systems.

Water Coolers <<https://epa.gov/snap/substitutes-water-coolers>>

Water coolers are self-contained units providing chilled water, and possibly heated water, for drinking. They may or may not feature detachable containers of water.

Sterilants

Are used to kill micro-organisms on medical equipment and devices. Visit Substitutes in Sterilants <<https://epa.gov/snap/substitutes-sterilants>>.

Tobacco Expansion

Is the process of puffing leaves of tobacco to decrease the volume of tobacco used in cigarette production. Visit Substitutes in Tobacco Expansion <<https://epa.gov/snap/substitutes-tobacco-expansion>>.

Last updated on August 26, 2026

Syllabus

GEIER ET AL. *v.* AMERICAN HONDA MOTOR CO., INC.,
ET AL.CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR
THE DISTRICT OF COLUMBIA CIRCUIT

No. 98–1811. Argued December 7, 1999—Decided May 22, 2000

Pursuant to its authority under the National Traffic and Motor Vehicle Safety Act of 1966, the Department of Transportation (DOT) promulgated Federal Motor Vehicle Safety Standard (FMVSS) 208, which required auto manufacturers to equip some but not all of their 1987 vehicles with passive restraints. Petitioner Alexis Geier was injured in an accident while driving a 1987 Honda Accord that did not have such restraints. She and her parents, also petitioners, sought damages under District of Columbia tort law, claiming, *inter alia*, that respondents (hereinafter American Honda) were negligent in not equipping the Accord with a driver's side airbag. Ruling that their claims were expressly pre-empted by the Act, the District Court granted American Honda summary judgment. In affirming, the Court of Appeals concluded that, because petitioners' state tort claims posed an obstacle to the accomplishment of the objectives of FMVSS 208, those claims conflicted with that standard and that, under ordinary pre-emption principles, the Act consequently pre-empted the lawsuit.

Held: Petitioners' "no airbag" lawsuit conflicts with the objectives of FMVSS 208 and is therefore pre-empted by the Act. Pp. 867–886.

(a) The Act's pre-emption provision, 15 U. S. C. § 1392(d), does not expressly pre-empt this lawsuit. The presence of a saving clause, which says that "[c]ompliance with" a federal safety standard "does not exempt any person from any liability under common law," § 1397(k), requires that the pre-emption provision be read narrowly to pre-empt only state statutes and regulations. The saving clause assumes that there are a significant number of common-law liability cases to save. And reading the express pre-emption provision to exclude common-law tort actions gives actual meaning to the saving clause's literal language, while leaving adequate room for state tort law to operate where, for example, federal law creates only a minimum safety standard. Pp. 867–868.

(b) However, the saving clause does *not* bar the ordinary working of conflict pre-emption principles. Nothing in that clause suggests an intent to save state tort actions that conflict with federal regulations. The words "[c]ompliance" and "does not exempt" sound as if they simply

Syllabus

bar a defense that compliance with a federal standard automatically exempts a defendant from state law, whether the Federal Government meant that standard to be an absolute, or a minimum, requirement. This interpretation does not conflict with the purpose of the saving provision, for it preserves actions that seek to establish greater safety than the minimum safety achieved by a federal regulation intended to provide a floor. Moreover, this Court has repeatedly declined to give broad effect to saving clauses where doing so would upset the careful regulatory scheme established by federal law, a concern applicable here. The pre-emption provision and the saving provision, read together, reflect a neutral policy, not a specially favorable or unfavorable one, toward the application of ordinary conflict pre-emption. The pre-emption provision itself favors pre-emption of state tort suits, while the saving clause disfavors pre-emption at least some of the time. However, there is nothing in any natural reading of the two provisions that would favor one policy over the other where a jury-imposed safety standard actually conflicts with a federal safety standard. Pp. 869–874.

(c) This lawsuit actually conflicts with FMVSS 208 and the Act itself. DOT saw FMVSS 208 not as a minimum standard, but as a way to provide a manufacturer with a range of choices among different passive restraint systems that would be gradually introduced, thereby lowering costs, overcoming technical safety problems, encouraging technological development, and winning widespread consumer acceptance—all of which would promote FMVSS 208's safety objectives. The standard's history helps explain why and how DOT sought these objectives. DOT began instituting passive restraint requirements in 1970, but it always permitted passive restraint options. Public resistance to an ignition interlock device that in effect forced occupants to buckle up their manual belts influenced DOT's subsequent initiatives. The 1984 version of FMVSS 208 reflected several significant considerations regarding the effectiveness of manual seatbelts and the likelihood that passengers would leave their manual seatbelts unbuckled, the advantages and disadvantages of passive restraints, and the public's resistance to the installation or use of then-available passive restraint devices. Most importantly, it deliberately sought variety, rejecting an "all airbag" standard because perceived or real safety concerns threatened a backlash more easily overcome with a mix of several different devices. A mix would also help develop data on comparative effectiveness, allow the industry time to overcome safety problems and high production costs associated with airbags, and facilitate the development of alternative, cheaper, and safer passive restraint systems, thereby building public confidence necessary to avoid an interlock-type fiasco. The 1984 standard also deliberately sought to gradually phase in passive

Syllabus

restraints, starting with a 10% requirement in 1987 vehicles. The requirement was also conditional and would stay in effect only if two-thirds of the States did not adopt mandatory buckle-up laws. A rule of state tort law imposing a duty to install airbags in cars such as petitioners' would have presented an obstacle to the variety and mix of devices that the federal regulation sought and to the phase-in that the federal regulation deliberately imposed. It would also have made adoption of state mandatory seatbelt laws less likely. This Court's pre-emption cases assume compliance with the state law duty in question, and do not turn on such compliance-related considerations as whether a private party would ignore state legal obligations or how likely it is that state law actually would be enforced. Finally, some weight is placed upon DOT's interpretation of FMVSS 208's objectives and its conclusion that a tort suit such as this one would stand as an obstacle to the accomplishment and execution of those objectives. DOT is likely to have a thorough understanding of its own regulation and its objectives and is uniquely qualified to comprehend the likely impact of state requirements. Because there is no reason to suspect that the Solicitor General's representation of these views reflects anything other than the agency's fair and considered judgment on the matter, DOT's failure in promulgating FMVSS 208 to address pre-emption explicitly is not determinative. Nor do the agency's views, as presented here, lack coherence. Pp. 874–886.

166 F. 3d 1236, affirmed.

BREYER, J., delivered the opinion of the Court, in which REHNQUIST, C. J., and O'CONNOR, SCALIA, and KENNEDY, JJ., joined. STEVENS, J., filed a dissenting opinion, in which SOUTER, THOMAS, and GINSBURG, JJ., joined, *post*, p. 886.

Arthur H. Bryant argued the cause for petitioners. With him on the briefs were *Leslie A. Brueckner* and *Robert M. N. Palmer*.

Malcolm E. Wheeler argued the cause for respondents. With him on the brief were *Benjamin S. Boyd*, *Mark A. Brooks*, and *Brad J. Safon*.

Deputy Solicitor General Wallace argued the cause for the United States as *amicus curiae* urging affirmance. With him on the brief were *Solicitor General Waxman*, *Acting Assistant Attorney General Ogden*, *Matthew D. Roberts*,

Opinion of the Court

*Douglas N. Letter, Kathleen Moriarty Mueller, Nancy E. McFadden, Paul M. Geier, and Frank Seales, Jr.**

JUSTICE BREYER delivered the opinion of the Court.

This case focuses on the 1984 version of a Federal Motor Vehicle Safety Standard promulgated by the Department of Transportation under the authority of the National Traffic and Motor Vehicle Safety Act of 1966, 80 Stat. 718, 15 U. S. C. § 1381 *et seq.* (1988 ed.). The standard, FMVSS 208, required auto manufacturers to equip some but not all of their

*Briefs of *amici curiae* urging reversal were filed for the State of Missouri et al. by *Jeremiah W. (Jay) Nixon*, Attorney General of Missouri, *James R. Layton*, State Solicitor, *Charles Hatfield*, and *Barbara McDonnell*, Chief Deputy Attorney General of Colorado, and by the Attorneys General for their respective States as follows: *Janet Napolitano* of Arizona, *Bill Lockyer* of California, *M. Jane Brady* of Delaware, *Thomas J. Miller* of Iowa, *Carla J. Stovall* of Kansas, *Joseph P. Mazurek* of Montana, *Philip T. McLaughlin* of New Hampshire, *Eliot Spitzer* of New York, *W. A. Drew Edmondson* of Oklahoma, *Hardy Myers* of Oregon, *D. Michael Fisher* of Pennsylvania, *Sheldon Whitehouse* of Rhode Island, *William H. Sorrell* of Vermont, and *Christine O. Gregoire* of Washington; for the Association of Trial Lawyers of America by *Jeffrey Robert White*; for the Attorneys Information Exchange Group by *Larry E. Coben*; for the National Conference of State Legislatures et al. by *Richard Ruda* and *James I. Crowley*; and for Robert B Leflar et al. by *Mr. Leflar, pro se*.

Briefs of *amici curiae* urging affirmance were filed for the Chamber of Commerce of the United States by *Theodore B. Olson*, *Theodore J. Boutsous, Jr.*, *Thomas G. Hungar*, and *Robin S. Conrad*; for the Alliance of Automobile Manufacturers et al. by *Thomas W. Merrill*, *Gene C. Schaerr*, *Brett M. Kavanaugh*, and *Richard A. Cordray*; for the Blue Cross Blue Shield Association by *Anthony F. Shelley* and *Alan I. Horowitz*; for the Defense Research Institute by *Kevin M. Reynolds*, *Robert L. Fanter*, *Richard J. Kirschman*, *Lloyd H. Milliken, Jr.*, *Randall R. Riggs*, and *T. Joseph Wendt*; for General Motors Corp. by *David M. Heilbron* and *Leslie G. Landau*; for the Product Liability Advisory Council, Inc., by *Kenneth S. Geller*, *Erika Z. Jones*, and *John J. Sullivan*; and for the Washington Legal Foundation by *Lawrence S. Ebner*, *Daniel J. Popeo*, and *Richard A. Samp*.

David Overlock Stewart and *Thomas M. Susman* filed a brief for the Business Roundtable as *amicus curiae*.

Opinion of the Court

1987 vehicles with passive restraints. We ask whether the Act pre-empts a state common-law tort action in which the plaintiff claims that the defendant auto manufacturer, who was in compliance with the standard, should nonetheless have equipped a 1987 automobile with airbags. We conclude that the Act, taken together with FMVSS 208, pre-empts the lawsuit.

I

In 1992, petitioner Alexis Geier, driving a 1987 Honda Accord, collided with a tree and was seriously injured. The car was equipped with manual shoulder and lap belts which Geier had buckled up at the time. The car was not equipped with airbags or other passive restraint devices.

Geier and her parents, also petitioners, sued the car's manufacturer, American Honda Motor Company, Inc., and its affiliates (hereinafter American Honda), under District of Columbia tort law. They claimed, among other things, that American Honda had designed its car negligently and defectively because it lacked a driver's side airbag. App. 3. The District Court dismissed the lawsuit. The court noted that FMVSS 208 gave car manufacturers a choice as to whether to install airbags. And the court concluded that petitioners' lawsuit, because it sought to establish a different safety standard—*i. e.*, an airbag requirement—was expressly pre-empted by a provision of the Act which pre-empts “any safety standard” that is not identical to a federal safety standard applicable to the same aspect of performance, 15 U. S. C. § 1392(d) (1988 ed.); Civ. No. 95–CV–0064 (D. D. C., Dec. 9, 1997), App. 17. (We, like the courts below and the parties, refer to the pre-1994 version of the statute throughout the opinion; it has been recodified at 49 U. S. C. § 30101 *et seq.*)

The Court of Appeals agreed with the District Court's conclusion but on somewhat different reasoning. It had doubts, given the existence of the Act's “saving” clause, 15 U. S. C. § 1397(k) (1988 ed.), that petitioners' lawsuit involved the po-

Opinion of the Court

tential creation of the kind of “safety standard” to which the Safety Act’s express pre-emption provision refers. But it declined to resolve that question because it found that petitioners’ state-law tort claims posed an obstacle to the accomplishment of FMVSS 208’s objectives. For that reason, it found that those claims conflicted with FMVSS 208, and that, under ordinary pre-emption principles, the Act consequently pre-empted the lawsuit. The Court of Appeals thus affirmed the District Court’s dismissal. 166 F. 3d 1236, 1238–1243 (CA DC 1999).

Several state courts have held to the contrary, namely, that neither the Act’s express pre-emption nor FMVSS 208 pre-empts a “no airbag” tort suit. See, e.g., *Drattel v. Toyota Motor Corp.*, 92 N. Y. 2d 35, 43–53, 699 N. E. 2d 376, 379–386 (1998); *Minton v. Honda of America Mfg., Inc.*, 80 Ohio St. 3d 62, 70–79, 684 N. E. 2d 648, 655–661 (1997); *Munroe v. Galati*, 189 Ariz. 113, 115–119, 938 P. 2d 1114, 1116–1120 (1997); *Wilson v. Pleasant*, 660 N. E. 2d 327, 330–339 (Ind. 1995); *Tebbetts v. Ford Motor Co.*, 140 N. H. 203, 206–207, 665 A. 2d 345, 347–348 (1995). All of the Federal Circuit Courts that have considered the question, however, have found pre-emption. One rested its conclusion on the Act’s express pre-emption provision. See, e.g., *Harris v. Ford Motor Co.*, 110 F. 3d 1410, 1413–1415 (CA9 1997). Others, such as the Court of Appeals below, have instead found pre-emption under ordinary pre-emption principles by virtue of the conflict such suits pose to FMVSS 208’s objectives, and thus to the Act itself. See, e.g., *Montag v. Honda Motor Co.*, 75 F. 3d 1414, 1417 (CA10 1996); *Pokorny v. Ford Motor Co.*, 902 F. 2d 1116, 1121–1125 (CA3 1990); *Taylor v. General Motors Corp.*, 875 F. 2d 816, 825–827 (CA11 1989); *Wood v. General Motors Corp.*, 865 F. 2d 395, 412–414 (CA1 1988). We granted certiorari to resolve these differences. We now hold that this kind of “no airbag” lawsuit conflicts with the objectives of FMVSS 208, a standard authorized by the Act, and is therefore pre-empted by the Act.

Opinion of the Court

In reaching our conclusion, we consider three subsidiary questions. First, does the Act's express pre-emption provision pre-empt this lawsuit? We think not. Second, do ordinary pre-emption principles nonetheless apply? We hold that they do. Third, does this lawsuit actually conflict with FMVSS 208, hence with the Act itself? We hold that it does.

II

We first ask whether the Safety Act's express pre-emption provision pre-empts this tort action. The provision reads as follows:

"Whenever a Federal motor vehicle safety standard established under this subchapter is in effect, no State or political subdivision of a State shall have any authority either to establish, or to continue in effect, with respect to any motor vehicle or item of motor vehicle equipment[,] any safety standard applicable to the same aspect of performance of such vehicle or item of equipment which is not identical to the Federal standard." 15 U. S. C. § 1392(d) (1988 ed.).

American Honda points out that a majority of this Court has said that a somewhat similar statutory provision in a different federal statute—a provision that uses the word "requirements"—may well expressly pre-empt similar tort actions. See, e. g., *Medtronic, Inc. v. Lohr*, 518 U. S. 470, 502–504 (1996) (plurality opinion); *id.*, at 503–505 (BREYER, J., concurring in part and concurring in judgment); *id.*, at 509–512 (O'CONNOR, J., concurring in part and dissenting in part). Petitioners reply that this statute speaks of pre-empting a state-law "safety *standard*," not a "requirement," and that a tort action does not involve a safety *standard*. Hence, they conclude, the express pre-emption provision does not apply.

We need not determine the precise significance of the use of the word "standard," rather than "requirement," however, for the Act contains another provision, which resolves the

Opinion of the Court

disagreement. That provision, a “saving” clause, says that “[c]ompliance with” a federal safety standard “does not exempt any person from any liability under common law.” 15 U. S. C. § 1397(k) (1988 ed.). The saving clause assumes that there are some significant number of common-law liability cases to save. And a reading of the express pre-emption provision that excludes common-law tort actions gives actual meaning to the saving clause’s literal language, while leaving adequate room for state tort law to operate—for example, where federal law creates only a floor, *i. e.*, a minimum safety standard. See, *e. g.*, Brief for United States as *Amicus Curiae* 21 (explaining that common-law claim that a vehicle is defectively designed because it lacks antilock brakes would not be pre-empted by 49 CFR § 571.105 (1999), a safety standard establishing minimum requirements for brake performance). Without the saving clause, a broad reading of the express pre-emption provision arguably might pre-empt those actions, for, as we have just mentioned, it is possible to read the pre-emption provision, standing alone, as applying to standards imposed in common-law tort actions, as well as standards contained in state legislation or regulations. And if so, it would pre-empt all nonidentical state standards established in tort actions covering the same aspect of performance as an applicable federal standard, even if the federal standard merely established a minimum standard. On that broad reading of the pre-emption clause little, if any, potential “liability at common law” would remain. And few, if any, state tort actions would remain for the saving clause to save. We have found no convincing indication that Congress wanted to pre-empt, not only state statutes and regulations, but also common-law tort actions, in such circumstances. Hence the broad reading cannot be correct. The language of the pre-emption provision permits a narrow reading that excludes common-law actions. Given the presence of the saving clause, we conclude that the pre-emption clause must be so read.

Opinion of the Court

III

We have just said that the saving clause *at least* removes tort actions from the scope of the express pre-emption clause. Does it do more? In particular, does it foreclose or limit the operation of ordinary pre-emption principles insofar as those principles instruct us to read statutes as pre-empting state laws (including common-law rules) that “actually conflict” with the statute or federal standards promulgated thereunder? *Fidelity Fed. Sav. & Loan Assn. v. De la Cuesta*, 458 U. S. 141, 153 (1982). Petitioners concede, as they must in light of *Freightliner Corp. v. Myrick*, 514 U. S. 280 (1995), that the pre-emption provision, by itself, does not foreclose (through negative implication) “any possibility of implied [conflict] pre-emption,” *id.*, at 288 (discussing *Cipollone v. Liggett Group, Inc.*, 505 U. S. 504, 517–518 (1992)). But they argue that the saving clause has that very effect.

We recognize that, when this Court previously considered the pre-emptive effect of the statute’s language, it appeared to leave open the question of how, or the extent to which, the saving clause saves state-law tort actions that conflict with federal regulations promulgated under the Act. See *Freightliner*, *supra*, at 287, n. 3 (declining to address whether the saving clause prevents a manufacturer from “us[ing] a federal safety standard to immunize itself from state common-law liability”). We now conclude that the saving clause (like the express pre-emption provision) does *not* bar the ordinary working of conflict pre-emption principles.

Nothing in the language of the saving clause suggests an intent to save state-law tort actions that conflict with federal regulations. The words “[c]ompliance” and “does not exempt,” 15 U. S. C. § 1397(k) (1988 ed.), sound as if they simply bar a special kind of defense, namely, a defense that compliance with a federal standard automatically exempts a defendant from state law, whether the Federal Government meant that standard to be an absolute requirement or only a minimum one. See Restatement (Third) of Torts: Products

Opinion of the Court

Liability §4(b), Comment *e* (1997) (distinguishing between state-law compliance defense and a federal claim of pre-emption). It is difficult to understand why Congress would have insisted on a compliance-with-federal-regulation precondition to the provision's applicability had it wished the Act to "save" all state-law tort actions, regardless of their potential threat to the objectives of federal safety standards promulgated under that Act. Nor does our interpretation conflict with the purpose of the saving provision, say, by rendering it ineffectual. As we have previously explained, the saving provision still makes clear that the express pre-emption provision does not of its own force pre-empt common-law tort actions. And it thereby preserves those actions that seek to establish greater safety than the minimum safety achieved by a federal regulation intended to provide a floor. See *supra*, at 867–868.

Moreover, this Court has repeatedly "decline[d] to give broad effect to saving clauses where doing so would upset the careful regulatory scheme established by federal law." *United States v. Locke*, *ante*, at 106–107; see *American Telephone & Telegraph Co. v. Central Office Telephone, Inc.*, 524 U. S. 214, 227–228 (1998) (*AT&T*); *Texas & Pacific R. Co. v. Abilene Cotton Oil Co.*, 204 U. S. 426, 446 (1907). We find this concern applicable in the present case. And we conclude that the saving clause foresees—it does not foreclose—the possibility that a federal safety standard will pre-empt a state common-law tort action with which it conflicts. We do not understand the dissent to disagree, for it acknowledges that ordinary pre-emption principles apply, at least sometimes. *Post*, at 899–900 (opinion of STEVENS, J.).

Neither do we believe that the pre-emption provision, the saving provision, or both together, create some kind of "special burden" beyond that inherent in ordinary pre-emption principles—which "special burden" would specially disfavor pre-emption here. Cf. *post*, at 898–899. The two provisions, read together, reflect a neutral policy, not a specially

Opinion of the Court

favorable or unfavorable policy, toward the application of ordinary conflict pre-emption principles. On the one hand, the pre-emption provision itself reflects a desire to subject the industry to a single, uniform set of federal safety standards. Its pre-emption of *all* state standards, even those that might stand in harmony with federal law, suggests an intent to avoid the conflict, uncertainty, cost, and occasional risk to safety itself that too many different safety-standard cooks might otherwise create. See H. R. Rep. No. 1776, 89th Cong., 2d Sess., 17 (1966) (“Basically, this preemption subsection is intended to result in uniformity of standards so that the public as well as industry will be guided by one set of criteria rather than by a multiplicity of diverse standards”); S. Rep. No. 1301, 89th Cong., 2d Sess., 12 (1966). This policy by itself favors pre-emption of state tort suits, for the rules of law that judges and juries create or apply in such suits may themselves similarly create uncertainty and even conflict, say, when different juries in different States reach different decisions on similar facts.

On the other hand, the saving clause reflects a congressional determination that occasional nonuniformity is a small price to pay for a system in which juries not only create, but also enforce, safety standards, while simultaneously providing necessary compensation to victims. That policy by itself disfavors pre-emption, at least some of the time. But we can find nothing in any natural reading of the two provisions that would favor one set of policies over the other where a jury-imposed safety standard actually conflicts with a federal safety standard.

Why, in any event, would Congress not have wanted ordinary pre-emption principles to apply where an actual conflict with a federal objective is at stake? Some such principle is needed. In its absence, state law could impose legal duties that would conflict directly with federal regulatory mandates, say, by premising liability upon the presence of the very windshield retention requirements that federal law re-

Opinion of the Court

quires. See, *e. g.*, 49 CFR § 571.212 (1999). Insofar as petitioners' argument would permit common-law actions that "actually conflict" with federal regulations, it would take from those who would enforce a federal law the very ability to achieve the law's congressionally mandated objectives that the Constitution, through the operation of ordinary pre-emption principles, seeks to protect. To the extent that such an interpretation of the saving provision reads into a particular federal law toleration of a conflict that those principles would otherwise forbid, it permits that law to defeat its own objectives, or potentially, as the Court has put it before, to "'destroy itself.'" *AT&T, supra*, at 228 (quoting *Abilene Cotton, supra*, at 446). We do not claim that Congress lacks the constitutional power to write a statute that mandates such a complex type of state/federal relationship. Cf. *post*, at 900, n. 16. But there is no reason to believe Congress has done so here.

The dissent, as we have said, contends nonetheless that the express pre-emption and saving provisions here, taken together, create a "special burden," which a court must impose "on a party" who claims conflict pre-emption under those principles. *Post*, at 898. But nothing in the Safety Act's language refers to any "special burden." Nor can one find the basis for a "special burden" in this Court's precedents. It is true that, in *Freightliner Corp. v. Myrick*, 514 U. S. 280 (1995), the Court said, in the context of interpreting the Safety Act, that "[a]t best" there is an "inference that an express pre-emption clause forecloses implied pre-emption." *Id.*, at 289 (emphasis added). But the Court made this statement in the course of *rejecting* the more absolute argument that the presence of the express pre-emption provision entirely foreclosed the possibility of conflict pre-emption. *Id.*, at 288. The statement, headed with the qualifier "[a]t best," and made in a case where, without any need for inferences or "special burdens," state law obviously would survive, see *id.*, at 289–290, simply preserves a legal possibility. This

Opinion of the Court

Court did not hold that the Safety Act *does* create a “special burden,” or still less that such a burden necessarily arises from the limits of an express pre-emption provision. And considerations of language, purpose, and administrative workability, together with the principles underlying this Court’s pre-emption doctrine discussed above, make clear that the express pre-emption provision imposes no unusual, “special burden” against pre-emption. For similar reasons, we do not see the basis for interpreting the saving clause to impose any such burden.

A “special burden” would also promise practical difficulty by further complicating well-established pre-emption principles that already are difficult to apply. The dissent does not contend that this “special burden” would apply in a case in which state law penalizes what federal law requires—*i. e.*, a case of impossibility. See *post*, at 892–893, n. 6, 900, n. 16. But if it would not apply in such a case, then how, or when, would it apply? This Court, when describing conflict pre-emption, has spoken of pre-empting state law that “under the circumstances of th[e] particular case . . . stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress”—whether that “obstacle” goes by the name of “conflicting; contrary to; . . . repugnance; difference; irreconcilability; inconsistency; violation; curtailment; . . . interference,” or the like. *Hines v. Davidowitz*, 312 U. S. 52, 67 (1941); see *Jones v. Rath Packing Co.*, 430 U. S. 519, 526 (1977). The Court has not previously driven a legal wedge—only a terminological one—between “conflicts” that prevent or frustrate the accomplishment of a federal objective and “conflicts” that make it “impossible” for private parties to comply with both state and federal law. Rather, it has said that both forms of conflicting state law are “nullified” by the Supremacy Clause, *De la Cuesta*, 458 U. S., at 152–153; see *Locke, ante*, at 109; *English v. General Elec. Co.*, 496 U. S. 72, 78–79 (1990), and it has assumed that Congress would not want either kind of conflict. The Court

Opinion of the Court

has thus refused to read general “saving” provisions to tolerate actual conflict *both* in cases involving impossibility, see, *e. g.*, *AT&T*, 524 U. S., at 228, *and* in “frustration-of-purpose” cases, see, *e. g.*, *Locke*, *ante*, at 103–112; *International Paper Co. v. Ouellette*, 479 U. S. 481, 493–494 (1987); see also *Chicago & North Western Transp. Co. v. Kalo Brick & Tile Co.*, 450 U. S. 311, 328–331 (1981). We see no grounds, then, for attempting to distinguish among types of federal-state conflict for purposes of analyzing whether such a conflict warrants pre-emption in a particular case. That kind of analysis, moreover, would engender legal uncertainty with its inevitable systemwide costs (*e. g.*, conflicts, delay, and expense) as courts tried sensibly to distinguish among varieties of “conflict” (which often shade, one into the other) when applying this complicated rule to the many federal statutes that contain some form of an express pre-emption provision, a saving provision, or as here, both. Nothing in the statute suggests Congress wanted to complicate ordinary experience-proved principles of conflict pre-emption with an added “special burden.” Indeed, the dissent’s willingness to impose a “special burden” here stems ultimately from its view that “frustration-of-purpos[e]” conflict pre-emption is a freewheeling, “inadequately considered” doctrine that might well be “eliminate[d].” *Post*, at 907–908, and n. 22. In a word, ordinary pre-emption principles, grounded in long-standing precedent, *Hines*, *supra*, at 67, apply. We would not further complicate the law with complex new doctrine.

IV

The basic question, then, is whether a common-law “no airbag” action like the one before us actually conflicts with FMVSS 208. We hold that it does.

In petitioners’ and the dissent’s view, FMVSS 208 sets a minimum airbag standard. As far as FMVSS 208 is concerned, the more airbags, and the sooner, the better. But that was not the Secretary’s view. The Department of

Opinion of the Court

Transportation's (DOT's) comments, which accompanied the promulgation of FMVSS 208, make clear that the standard deliberately provided the manufacturer with a range of choices among different passive restraint devices. Those choices would bring about a mix of different devices introduced gradually over time; and FMVSS 208 would thereby lower costs, overcome technical safety problems, encourage technological development, and win widespread consumer acceptance—all of which would promote FMVSS 208's safety objectives. See generally 49 Fed. Reg. 28962 (1984).

A

The history of FMVSS 208 helps explain why and how DOT sought these objectives. See generally *Motor Vehicle Mfrs. Assn. of United States, Inc. v. State Farm Mut. Automobile Ins. Co.*, 463 U. S. 29, 34–38 (1983). In 1967, DOT, understanding that seatbelts would save many lives, required manufacturers to install manual seatbelts in all automobiles. 32 Fed. Reg. 2408, 2415. It became apparent, however, that most occupants simply would not buckle up their belts. See 34 Fed. Reg. 11148 (1969). DOT then began to investigate the feasibility of requiring “passive restraints,” such as airbags and automatic seatbelts. *Ibid.* In 1970, it amended FMVSS 208 to include some passive protection requirements, 35 Fed. Reg. 16927, while making clear that airbags were one of several “equally acceptable” devices and that it neither “‘favored’ [n]or expected the introduction of airbag systems.” *Ibid.* In 1971, it added an express provision permitting compliance through the use of nondetachable passive belts, 36 Fed. Reg. 12858, 12859, and in 1972, it mandated full passive protection for all front seat occupants for vehicles manufactured after August 15, 1975, 37 Fed. Reg. 3911. Although the agency's focus was originally on airbags, 34 Fed. Reg. 11148 (1969) (notice of proposed rule-making); *State Farm*, 463 U. S., at 35, n. 4; see also *id.*, at 46, n. 11 (noting view of commentators that, as of 1970, FMVSS

Opinion of the Court

208 was “‘a de facto airbag mandate’” because of the state of passive restraint technology), at no point did FMVSS 208 formally require the use of airbags. From the start, as in 1984, it permitted passive restraint options.

DOT gave manufacturers a further choice for new vehicles manufactured between 1972 and August 1975. Manufacturers could either install a passive restraint device such as automatic seatbelts or airbags or retain manual belts and add an “ignition interlock” device that in effect forced occupants to buckle up by preventing the ignition otherwise from turning on. 37 Fed. Reg. 3911 (1972). The interlock soon became popular with manufacturers. And in 1974, when the agency approved the use of detachable automatic seatbelts, it conditioned that approval by providing that such systems must include an interlock system *and* a continuous warning buzzer to encourage reattachment of the belt. 39 Fed. Reg. 14593. But the interlock and buzzer devices were most unpopular with the public. And Congress, responding to public pressure, passed a law that forbade DOT from requiring, or permitting compliance by means of, such devices. Motor Vehicle and Schoolbus Safety Amendments of 1974, § 109, 88 Stat. 1482 (previously codified at 15 U. S. C. § 1410b(b) (1988 ed.)).

That experience influenced DOT’s subsequent passive restraint initiatives. In 1976, DOT Secretary William T. Coleman, Jr., fearing continued public resistance, suspended the passive restraint requirements. He sought to win public acceptance for a variety of passive restraint devices through a demonstration project that would involve about half a million new automobiles. *State Farm, supra*, at 37. But his successor, Brock Adams, canceled the project, instead amending FMVSS 208 to require passive restraints, principally either airbags or passive seatbelts. 42 Fed. Reg. 34289 (1977).

Andrew Lewis, a new DOT Secretary in a new administration, rescinded the Adams requirements, primarily because DOT learned that the industry planned to satisfy those

Opinion of the Court

requirements almost exclusively through the installation of detachable automatic seatbelts. 46 Fed. Reg. 53419–53420 (1981). This Court held the rescission unlawful. *State Farm, supra*, at 34, 46. And the stage was set for then-DOT Secretary, Elizabeth Dole, to amend FMVSS 208 once again, promulgating the version that is now before us. 49 Fed. Reg. 28962 (1984).

B

Read in light of this history, DOT's own contemporaneous explanation of FMVSS 208 makes clear that the 1984 version of FMVSS 208 reflected the following significant considerations. First, buckled up seatbelts are a vital ingredient of automobile safety. *Id.*, at 29003; *State Farm, supra*, at 52 (“We start with the accepted ground that if used, seatbelts unquestionably would save many thousands of lives and would prevent tens of thousands of crippling injuries”). Second, despite the enormous and unnecessary risks that a passenger runs by not buckling up manual lap and shoulder belts, more than 80% of front seat passengers would leave their manual seatbelts unbuckled. 49 Fed. Reg. 28983 (1984) (estimating that only 12.5% of front seat passengers buckled up manual belts). Third, airbags could make up for the dangers caused by unbuckled manual belts, but they could not make up for them entirely. *Id.*, at 28986 (concluding that, although an airbag plus a lap and shoulder belt was the most “effective” system, airbags alone were *less* effective than buckled up manual lap and shoulder belts).

Fourth, passive restraint systems had their own disadvantages, for example, the dangers associated with, intrusiveness of, and corresponding public dislike for, nondetachable automatic belts. *Id.*, at 28992–28993. Fifth, airbags brought with them their own special risks to safety, such as the risk of danger to out-of-position occupants (usually children) in small cars. *Id.*, at 28992, 29001; see also 65 Fed. Reg. 30680, 30681–30682 (2000) (finding 158 confirmed airbag-induced fatalities as of April 2000, and amending rule

Opinion of the Court

to add new requirements, test procedures, and injury criteria to ensure that “future air bags be designed to create less risk of serious airbag-induced injuries than current air bags, particularly for small women and young children”); U.S. Dept. of Transportation, National Highway Traffic Safety Administration, National Accident Sampling System Crashworthiness Data System 1991–1993, p. viii (Aug. 1995) (finding that airbags caused approximately 54,000 injuries between 1991 and 1993).

Sixth, airbags were expected to be significantly more expensive than other passive restraint devices, raising the average cost of a vehicle price \$320 for full frontal airbags over the cost of a car with manual lap and shoulder seatbelts (and potentially much more if production volumes were low). 49 Fed. Reg. 28990 (1984). And the agency worried that the high replacement cost—estimated to be \$800—could lead car owners to refuse to replace them after deployment. *Id.*, at 28990, 29000–29001; see also *id.*, at 28990 (estimating total investment costs for mandatory airbag requirement at \$1.3 billion compared to \$500 million for automatic seatbelts). Seventh, the public, for reasons of cost, fear, or physical intrusiveness, might resist installation or use of any of the then-available passive restraint devices, *id.*, at 28987–28989—a particular concern with respect to airbags, *id.*, at 29001 (noting that “[a]irbags engendered the largest quantity of, and most vociferously worded, comments”).

FMVSS 208 reflected these considerations in several ways. Most importantly, that standard deliberately sought variety—a mix of several different passive restraint systems. It did so by setting a performance requirement for passive restraint devices and allowing manufacturers to choose among different passive restraint mechanisms, such as airbags, automatic belts, or other passive restraint technologies to satisfy that requirement. *Id.*, at 28996. And DOT explained why FMVSS 208 sought the mix of devices that it expected its performance standard to produce. *Id.*, at

Opinion of the Court

28997. DOT wrote that it had *rejected* a proposed FMVSS 208 “all airbag” standard because of safety concerns (perceived or real) associated with airbags, which concerns threatened a “backlash” more easily overcome “if airbags” were “not the only way of complying.” *Id.*, at 29001. It added that a mix of devices would help develop data on comparative effectiveness, would allow the industry time to overcome the safety problems and the high production costs associated with airbags, and would facilitate the development of alternative, cheaper, and safer passive restraint systems. *Id.*, at 29001–29002. And it would thereby build public confidence, *id.*, at 29001–29002, necessary to avoid another interlock-type fiasco.

The 1984 FMVSS 208 standard also deliberately sought a *gradual* phase-in of passive restraints. *Id.*, at 28999–29000. It required the manufacturers to equip only 10% of their car fleet manufactured after September 1, 1986, with passive restraints. *Id.*, at 28999. It then increased the percentage in three annual stages, up to 100% of the new car fleet for cars manufactured after September 1, 1989. *Ibid.* And it explained that the phased-in requirement would allow more time for manufacturers to develop airbags or other, better, safer passive restraint systems. It would help develop information about the comparative effectiveness of different systems, would lead to a mix in which airbags and other non-seatbelt passive restraint systems played a more prominent role than would otherwise result, and would promote public acceptance. *Id.*, at 29000–29001.

Of course, as the dissent points out, *post*, at 903, FMVSS 208 did not guarantee the mix by setting a ceiling for each different passive restraint device. In fact, it provided a form of extra credit for airbag installation (and other nonbelt passive restraint devices) under which each airbag-installed vehicle counted as 1.5 vehicles for purposes of meeting FMVSS 208’s passive restraint requirement. 49 CFR § 571.208, S4.1.3.4(a)(1) (1999); 49 Fed. Reg. 29000 (1984).

Opinion of the Court

But why should DOT have bothered to impose an airbag ceiling when the practical threat to the mix it desired arose from the likelihood that manufacturers would install, not too many airbags too quickly, but too few or none at all? After all, only a few years earlier, Secretary Dole's predecessor had discovered that manufacturers intended to meet the then-current passive restraint requirement almost entirely (more than 99%) through the installation of more affordable automatic belt systems. 46 Fed. Reg. 53421 (1981); *State Farm*, 463 U. S., at 38. The extra credit, as DOT explained, was designed to "encourage manufacturers to equip *at least some* of their cars with airbags." 49 Fed. Reg. 29001 (1984) (emphasis added) (responding to comment that failure to mandate airbags might mean the "end of . . . airbag technology"); see also *id.*, at 29000 (explaining that the extra credit for airbags "should promote the development of what may be better alternatives to automatic belts *than would otherwise be developed*" (emphasis added)). The credit provision *reinforces* the point that FMVSS 208 sought a gradually developing mix of passive restraint devices; it does not show the contrary.

Finally, FMVSS 208's passive restraint requirement was conditional. DOT believed that ordinary manual lap and shoulder belts would produce about the same amount of safety as passive restraints, and at significantly lower costs—if only auto occupants would buckle up. See *id.*, at 28997–28998. Thus, FMVSS 208 provided for rescission of its passive restraint requirement if, by September 1, 1989, two-thirds of the States had laws in place that, like those of many other nations, required auto occupants to buckle up (and which met other requirements specified in the standard). *Id.*, at 28963, 28993–28994, 28997–28999. The Secretary wrote that "coverage of a large percentage of the American people by seatbelt laws that are enforced would largely negate the incremental increase in safety to be expected from an automatic protection requirement." *Id.*, at 28997.

Opinion of the Court

In the end, two-thirds of the States did not enact mandatory buckle-up laws, and the passive restraint requirement remained in effect.

In sum, as DOT now tells us through the Solicitor General, the 1984 version of FMVSS 208 “embodies the Secretary’s policy judgment that safety would best be promoted if manufacturers installed *alternative* protection systems in their fleets rather than one particular system in every car.” Brief for United States as *Amicus Curiae* 25; see 49 Fed. Reg. 28997 (1984). Petitioners’ tort suit claims that the manufacturers of the 1987 Honda Accord “had a duty to design, manufacture, distribute and sell a motor vehicle with an effective and safe passive restraint system, including, but not limited to, airbags.” App. 3 (Complaint, ¶ 11).

In effect, petitioners’ tort action depends upon its claim that manufacturers had a duty to install an airbag when they manufactured the 1987 Honda Accord. Such a state law—*i. e.*, a rule of state tort law imposing such a duty—by its terms would have required manufacturers of all similar cars to install airbags rather than other passive restraint systems, such as automatic belts or passive interiors. It thereby would have presented an obstacle to the variety and mix of devices that the federal regulation sought. It would have required all manufacturers to have installed airbags in respect to the entire District-of-Columbia-related portion of their 1987 new car fleet, even though FMVSS 208 at that time required only that 10% of a manufacturer’s nationwide fleet be equipped with any passive restraint device at all. It thereby also would have stood as an obstacle to the gradual passive restraint phase-in that the federal regulation deliberately imposed. In addition, it could have made less likely the adoption of a state mandatory buckle-up law. Because the rule of law for which petitioners contend would have stood “as an obstacle to the accomplishment and execution of” the important means-related federal objectives that we have just discussed, it is pre-empted. *Hines*, 312 U. S., at

Opinion of the Court

67; see also *Ouellette*, 479 U. S., at 493; *De la Cuesta*, 458 U. S., at 156 (finding conflict and pre-emption where state law limited the availability of an option that the federal agency considered essential to ensure its ultimate objectives).

Petitioners ask this Court to calculate the precise size of the “obstacle,” with the aim of minimizing it, by considering the risk of tort liability and a successful tort action’s incentive-related or timing-related compliance effects. See Brief for Petitioners 45–50. The dissent agrees. *Post*, at 900–905. But this Court’s pre-emption cases do not ordinarily turn on such compliance-related considerations as whether a private party in practice would ignore state legal obligations—paying, say, a fine instead—or how likely it is that state law actually would be enforced. Rather, this Court’s pre-emption cases ordinarily *assume* compliance with the state-law duty in question. The Court has on occasion suggested that tort law may be somewhat different, and that related considerations—for example, the ability to pay damages instead of modifying one’s behavior—may be relevant for pre-emption purposes. See *Goodyear Atomic Corp. v. Miller*, 486 U. S. 174, 185 (1988); *Cipollone*, 505 U. S., at 536–539 (Blackmun, J., concurring in part, concurring in judgment in part, and dissenting in part); see also *English*, 496 U. S., at 86; *Silkwood v. Kerr-McGee Corp.*, 464 U. S. 238, 256 (1984). In other cases, the Court has found tort law to conflict with federal law without engaging in that kind of an analysis. See, *e. g.*, *Ouellette*, *supra*, at 494–497; *Kalo Brick*, 450 U. S., at 324–332. We need not try to resolve these differences here, however, for the incentive or compliance considerations upon which the dissent relies cannot, by themselves, change the legal result. Some of those considerations rest on speculation, see, *e. g.*, *post*, at 901 (predicting risk of “no airbag” liability and manufacturers’ likely response to such liability); some rest in critical part upon the dissenters’ own view of FMVSS 208’s basic purposes—a view

Opinion of the Court

which we reject, see, *e. g.*, *post*, at 901–904 (suggesting that pre-existing risk of “no airbag” liability would have made FMVSS 208 unnecessary); and others, if we understand them correctly, seem less than persuasive, see, *e. g.*, *post*, at 902 (suggesting that manufacturers could have complied with a mandatory state airbag duty by installing a *different* kind of passive restraint device). And in so concluding, we do not “put the burden” of proving pre-emption on petitioners. *Post*, at 907. We simply find unpersuasive their arguments attempting to undermine the Government’s demonstration of actual conflict.

One final point: We place some weight upon DOT’s interpretation of FMVSS 208’s objectives and its conclusion, as set forth in the Government’s brief, that a tort suit such as this one would “‘stan[d] as an obstacle to the accomplishment and execution’” of those objectives. Brief for United States as *Amicus Curiae* 25–26 (quoting *Hines, supra*, at 67). Congress has delegated to DOT authority to implement the statute; the subject matter is technical; and the relevant history and background are complex and extensive. The agency is likely to have a thorough understanding of its own regulation and its objectives and is “uniquely qualified” to comprehend the likely impact of state requirements. *Medtronic*, 518 U. S., at 496; see *id.*, at 506 (BREYER, J., concurring in part and concurring in judgment). And DOT has explained FMVSS 208’s objectives, and the interference that “no airbag” suits pose thereto, consistently over time. Brief for United States as *Amicus Curiae* in *Freightliner Corp. v. Myrick*, O. T. 1994, No. 94–286, pp. 28–29; Brief for United States as *Amicus Curiae* in *Wood v. General Motors Corp.*, O. T. 1989, No. 89–46, pp. 7, 11–16. In these circumstances, the agency’s own views should make a difference. See *City of New York v. FCC*, 486 U. S. 57, 64 (1988); *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U. S. 707, 714, 721 (1985); *De la Cuesta, supra*, at 158; *Blum v. Bacon*, 457 U. S. 132, 141 (1982); *Kalo Brick, supra*, at 321.

Opinion of the Court

We have no reason to suspect that the Solicitor General's representation of DOT's views reflects anything other than "the agency's fair and considered judgment on the matter." *Auer v. Robbins*, 519 U. S. 452, 461–462 (1997); cf. *Hillsborough County, supra*, at 721 (expressing reluctance, in the absence of strong evidence, to find an actual conflict between state law and federal regulation where agency that promulgated the regulation had not, at the time the regulation was promulgated or subsequently, concluded that such a conflict existed). The failure of the Federal Register to address pre-emption explicitly is thus not determinative.

The dissent would require a formal agency statement of pre-emptive intent as a prerequisite to concluding that a conflict exists. It relies on cases, or portions thereof, that did not involve conflict pre-emption. See *post*, at 908–909; *California Coastal Comm'n v. Granite Rock Co.*, 480 U. S. 572, 583 (1987); *Hillsborough, supra*, at 718. And conflict pre-emption is different in that it turns on the identification of "actual conflict," and not on an express statement of pre-emptive intent. *English, supra*, at 78–79; see *Hillsborough, supra*, at 720–721; *Jones*, 430 U. S., at 540–543. While "[p]re-emption fundamentally is a question of congressional intent," *English, supra*, at 78, this Court traditionally distinguishes between "express" and "implied" pre-emptive intent, and treats "conflict" pre-emption as an instance of the latter. See, e. g., *Freightliner*, 514 U. S., at 287; *English, supra*, at 78–79; see also *Cipollone, supra*, at 545, 547–548 (SCALIA, J., concurring in judgment in part and dissenting in part). And though the Court has looked for a specific statement of pre-emptive intent where it is claimed that the mere "volume and complexity" of agency regulations demonstrate an implicit intent to displace *all* state law in a particular area, *Hillsborough, supra*, at 717; see *post*, at 908–909, n. 23—so-called "field pre-emption"—the Court has never before required a specific, formal agency statement identifying conflict in order to conclude that such a conflict in fact exists.

Opinion of the Court

Indeed, one can assume that Congress or an agency ordinarily would not intend to permit a significant conflict. While we certainly accept the dissent's basic position that a court should not find pre-emption too readily in the absence of clear evidence of a conflict, *English, supra*, at 90, for the reasons set out above we find such evidence here. To insist on a specific expression of agency intent to pre-empt, made after notice-and-comment rulemaking, would be in certain cases to tolerate conflicts that an agency, and therefore Congress, is most unlikely to have intended. The dissent, as we have said, apparently welcomes that result, at least where "frustration-of-purpos[e]" pre-emption by agency regulation is at issue. *Post*, at 907–908, and n. 22. We do not.

Nor do we agree with the dissent that the agency's views, as presented here, lack coherence. *Post*, at 904–905. The dissent points, *ibid.*, to language in the Government's brief stating that

“a claim that a manufacturer should have chosen to install airbags rather than another type of passive restraint in a certain model of car *because of other design features particular to that car* . . . would not necessarily frustrate Standard 208's purposes.” Brief for United States as *Amicus Curiae* 26, n. 23 (emphasis added).

And the dissent says that these words amount to a concession that there is no conflict in this very case. *Post*, at 905. But that is not what the words say. Rather, as the italicized phrase emphasizes, they simply leave open the question whether FMVSS 208 would pre-empt a different kind of tort case—one *not* at issue here. It is possible that some special design-related circumstance concerning a particular kind of car might require airbags, rather than automatic belts, and that a suit seeking to impose that requirement could escape pre-emption—say, because it would affect so few cars that its rule of law would not create a legal “obstacle” to 208's mixed-fleet, gradual objective. But that is not what peti-

STEVENS, J., dissenting

tioners claimed. They have argued generally that, to be safe, a car must have an airbag. See App. 4.

Regardless, the language of FMVSS 208 and the contemporaneous 1984 DOT explanation is clear enough—even without giving DOT’s own view special weight. FMVSS 208 sought a gradually developing mix of alternative passive restraint devices for safety-related reasons. The rule of state tort law for which petitioners argue would stand as an “obstacle” to the accomplishment of that objective. And the statute foresees the application of ordinary principles of pre-emption in cases of actual conflict. Hence, the tort action is pre-empted.

The judgment of the Court of Appeals is affirmed.

It is so ordered.

JUSTICE STEVENS, with whom JUSTICE SOUTER, JUSTICE THOMAS, and JUSTICE GINSBURG join, dissenting.

Airbag technology has been available to automobile manufacturers for over 30 years. There is now general agreement on the proposition “that, to be safe, a car must have an airbag.” *Ante* this page. Indeed, current federal law imposes that requirement on all automobile manufacturers. See 49 U.S.C. §30127; 49 CFR §571.208, S4.1.5.3 (1998). The question raised by petitioners’ common-law tort action is whether that proposition was sufficiently obvious when Honda’s 1987 Accord was manufactured to make the failure to install such a safety feature actionable under theories of negligence or defective design. The Court holds that an interim regulation motivated by the Secretary of Transportation’s desire to foster gradual development of a variety of passive restraint devices deprives state courts of jurisdiction to answer that question. I respectfully dissent from that holding, and especially from the Court’s unprecedented extension of the doctrine of pre-emption. As a preface to an explanation of my understanding of the statute and the regulation, these preliminary observations seem appropriate.

STEVENS, J., dissenting

“This is a case about federalism,” *Coleman v. Thompson*, 501 U. S. 722, 726 (1991), that is, about respect for “the constitutional role of the States as sovereign entities.” *Alden v. Maine*, 527 U. S. 706, 713 (1999). It raises important questions concerning the way in which the Federal Government may exercise its undoubted power to oust state courts of their traditional jurisdiction over common-law tort actions. The rule the Court enforces today was not enacted by Congress and is not to be found in the text of any Executive Order or regulation. It has a unique origin: It is the product of the Court’s interpretation of the final commentary accompanying an interim administrative regulation and the history of airbag regulation generally. Like many other judge-made rules, its contours are not precisely defined. I believe, however, that it is fair to state that if it had been expressly adopted by the Secretary of Transportation, it would have read as follows:

“No state court shall entertain a common-law tort action based on a claim that an automobile was negligently or defectively designed because it was not equipped with an airbag;

“Provided, however, that this rule shall not apply to cars manufactured before September 1, 1986, or after such time as the Secretary may require the installation of airbags in all new cars; and

“Provided further, that this rule shall not preclude a claim by a driver who was not wearing her seatbelt that an automobile was negligently or defectively designed because it was not equipped with any passive restraint whatsoever, or a claim that an automobile with particular design features was negligently or defectively designed because it was equipped with one type of passive restraint instead of another.”

Perhaps such a rule would be a wise component of a legislative reform of our tort system. I express no opinion about

STEVENS, J., dissenting

that possibility. It is, however, quite clear to me that Congress neither enacted any such rule itself nor authorized the Secretary of Transportation to do so. It is equally clear to me that the objectives that the Secretary intended to achieve through the adoption of Federal Motor Vehicle Safety Standard 208 would not be frustrated one whit by allowing state courts to determine whether in 1987 the lifesaving advantages of airbags had become sufficiently obvious that their omission might constitute a design defect in some new cars. Finally, I submit that the Court is quite wrong to characterize its rejection of the presumption against pre-emption, and its reliance on history and regulatory commentary rather than either statutory or regulatory text, as “ordinary experience-proved principles of conflict pre-emption.” *Ante*, at 874.

I

The question presented is whether either the National Traffic and Motor Vehicle Safety Act of 1966 (Safety Act or Act), 80 Stat. 718, 15 U.S.C. §1381 *et seq.* (1988 ed.),¹ or the version of Standard 208 promulgated by the Secretary of Transportation in 1984, 49 CFR §571.208, S4.1.3–S4.1.4 (1998), pre-empts common-law tort claims that an automobile manufactured in 1987 was negligently and defectively designed because it lacked “an effective and safe passive restraint system, including, but not limited to, airbags.” App. 3. In *Motor Vehicle Mfrs. Assn. of United States, Inc. v. State Farm Mut. Automobile Ins. Co.*, 463 U.S. 29, 34–38 (1983), we reviewed the first chapters of the “complex and convoluted history” of Standard 208. It was the “unacceptably high” rate of deaths and injuries caused by automobile accidents that led to the enactment of the Safety Act in 1966. *Id.*, at 33. The purpose of the Act, as stated by Congress,

¹ In 1994, the Safety Act was recodified at 49 U.S.C. §30101 *et seq.* Because the changes made to the Act as part of the recodification process were not intended to be substantive, throughout this opinion I shall refer to the pre-1994 version of the statute, as did the Court of Appeals.

STEVENS, J., dissenting

was “to reduce traffic accidents and deaths and injuries to persons resulting from traffic accidents.” 15 U. S. C. § 1381. The Act directed the Secretary of Transportation or his delegate to issue motor vehicle safety standards that “shall be practicable, shall meet the need for motor vehicle safety, and shall be stated in objective terms.” § 1392(a). The Act defines the term “safety standard” as a “minimum standard for motor vehicle performance, or motor vehicle equipment performance.” § 1391(2).

Standard 208 covers “[o]ccupant crash protection.” Its purpose “is to reduce the number of deaths of vehicle occupants, and the severity of injuries, by specifying vehicle crashworthiness requirements . . . [and] equipment requirements for active and passive restraint systems.” 49 CFR § 571.208, S2 (1998). The first version of that standard, issued in 1967, simply required the installation of manual seatbelts in all automobiles. Two years later the Secretary formally proposed a revision that would require the installation of “passive occupant restraint systems,” that is to say, devices that do not depend for their effectiveness on any action by the vehicle occupant. The airbag is one such system.² The Secretary’s proposal led to a series of amendments to Standard 208 that imposed various passive restraint requirements, culminating in a 1977 regulation that mandated such restraints in all cars by the model year 1984. The two commercially available restraints that could satisfy this mandate

²“The airbag is an inflatable device concealed in the dashboard and steering column. It automatically inflates when a sensor indicates that deceleration forces from an accident have exceeded a preset minimum, then rapidly deflates to dissipate those forces. The lifesaving potential of these devices was immediately recognized, and in 1977, after substantial on-the-road experience with both devices, it was estimated by [the National Highway Traffic Safety Administration (NHTSA)] that passive restraints could prevent approximately 12,000 deaths and over 100,000 serious injuries annually. 42 Fed. Reg. 34298.” *Motor Vehicle Mfrs. Assn. of United States, Inc. v. State Farm Mut. Automobile Ins. Co.*, 463 U. S. 29, 35 (1983).

STEVENS, J., dissenting

were airbags and automatic seatbelts; the regulation allowed each vehicle manufacturer to choose which restraint to install. In 1981, however, following a change of administration, the new Secretary first extended the deadline for compliance and then rescinded the passive restraint requirement altogether. In *Motor Vehicle Mfrs. Assn.*, we affirmed a decision by the Court of Appeals holding that this rescission was arbitrary. On remand, Secretary Elizabeth Dole promulgated the version of Standard 208 that is at issue in this case.

The 1984 standard provided for a phase-in of passive restraint requirements beginning with the 1987 model year. In that year, vehicle manufacturers were required to equip a minimum of 10% of their new passenger cars with such restraints. While the 1987 Honda Accord driven by Ms. Geier was not so equipped, it is undisputed that Honda complied with the 10% minimum by installing passive restraints in certain other 1987 models. This minimum passive restraint requirement increased to 25% of 1988 models and 40% of 1989 models; the standard also mandated that “after September 1, 1989, all new cars must have automatic occupant crash protection.” 49 Fed. Reg. 28999 (1984); see 49 CFR § 571.208, S4.1.3–S4.1.4 (1998). In response to a 1991 amendment to the Safety Act, the Secretary amended the standard to require that, beginning in the 1998 model year, all new cars have an airbag at both the driver’s and right front passenger’s positions.³

Given that Secretary Dole promulgated the 1984 standard in response to our opinion invalidating her predecessor’s rescission of the 1977 passive restraint requirement, she provided a full explanation for her decision not to require air-

³ See 49 U. S. C. § 30127; 49 CFR § 571.208, S4.1.5.3 (1998). Congress stated that it did not intend its amendment or the Secretary’s consequent alteration of Standard 208 to affect the potential liability of vehicle manufacturers under applicable law related to vehicles with or without airbags. 49 U. S. C. § 30127(f)(2).

STEVENS, J., dissenting

bags in all cars and to phase in the new requirements. The initial 3-year delay was designed to give vehicle manufacturers adequate time for compliance. The decision to give manufacturers a choice between airbags and a different form of passive restraint, such as an automatic seatbelt, was motivated in part by safety concerns and in part by a desire not to retard the development of more effective systems. 49 Fed. Reg. 29000–29001 (1984). An important safety concern was the fear of a “public backlash” to an airbag mandate that consumers might not fully understand. The Secretary believed, however, that the use of airbags would avoid possible public objections to automatic seatbelts and that many of the public concerns regarding airbags were unfounded. *Id.*, at 28991.

Although the standard did not require airbags in all cars, it is clear that the Secretary did intend to encourage wider use of airbags. One of her basic conclusions was that “[a]utomatic occupant protection systems that do not totally rely upon belts, such as airbags . . . , offer significant additional potential for preventing fatalities and injuries, at least in part because the American public is likely to find them less intrusive; their development and availability should be encouraged through appropriate incentives.” *Id.*, at 28963; see also *id.*, at 28966, 28986 (noting conclusion of both Secretary and manufacturers that airbags used in conjunction with manual lap and shoulder belts would be “the most effective system of all” for preventing fatalities and injuries). The Secretary therefore included a phase-in period in order to encourage manufacturers to comply with the standard by installing airbags and other (perhaps more effective) nonbelt technologies that they might develop, rather than by installing less expensive automatic seatbelts.⁴ As a further incen-

⁴“If the Department had required full compliance by September 1, 1987, it is very likely all of the manufacturers would have had to comply through the use of automatic belts. Thus, by phasing-in the requirement, the Department makes it easier for manufacturers to use other, perhaps better,

STEVENS, J., dissenting

tive for the use of such technologies, the standard provided that a vehicle equipped with an airbag or other nonbelt system would count as 1.5 vehicles for the purpose of determining compliance with the required 10, 25, or 40% minimum passive restraint requirement during the phase-in period. 49 CFR § 571.208, S4.1.3.4(a)(1) (1998). With one oblique exception,⁵ there is no mention, either in the text of the final standard or in the accompanying comments, of the possibility that the risk of potential tort liability would provide an incentive for manufacturers to install airbags. Nor is there any other specific evidence of an intent to preclude common-law tort actions.

II

Before discussing the pre-emption issue, it is appropriate to note that there is a vast difference between a rejection of Honda's threshold arguments in favor of federal pre-emption and a conclusion that petitioners ultimately would prevail on their common-law tort claims. I express no opinion on the possible merit, or lack of merit, of those claims. I do observe, however, that even though good-faith compliance with the minimum requirements of Standard 208 would not provide Honda with a complete defense on the merits,⁶ I as-

systems such as airbags and passive interiors." 49 Fed. Reg. 29000 (1984).

⁵ In response to a comment that the manufacturers were likely to use the cheapest system to comply with the new standard, the Secretary stated that she believed "that competition, potential liability for any deficient systems[,] and pride in one's product would prevent this." *Ibid.*

⁶ *Wood v. General Motors Corp.*, 865 F. 2d 395, 417 (CA1 1988) (collecting cases). The result would be different, of course, if petitioners had brought common-law tort claims challenging Honda's compliance with a mandatory minimum federal standard—*e. g.*, claims that a 1999 Honda was negligently and defectively designed *because* it was equipped with airbags as required by the current version of Standard 208. Restatement (Third) of Torts: General Principles § 14(b), and Comment *g* (Discussion Draft, Apr. 5, 1999) ("If the actor's adoption [or rejection] of a precaution would require the actor to violate a statute, the actor cannot be found negligent for failing to adopt [or reject] that precaution"); cf. *ante*, at 871–872 (dis-

STEVENS, J., dissenting

sume that such compliance would be admissible evidence tending to negate charges of negligent and defective design.⁷ In addition, if Honda were ultimately found liable, such compliance would presumably weigh against an award of punitive damages. *Silkwood v. Kerr-McGee Corp.*, 485 F. Supp. 566, 583–584 (WD Okla. 1979) (concluding that substantial compliance with regulatory scheme did not bar award of punitive damages, but noting that “[g]ood faith belief in, and efforts to comply with, all government regulations would be evidence of conduct inconsistent with the mental state requisite for punitive damages” under state law).⁸

The parties have not called our attention to any appellate court opinions discussing the merits of similar no-airbag claims despite the fact that airbag technology was available for many years before the promulgation of the 1984 standard—a standard that is not applicable to any automobiles manufactured before September 1, 1986. Given that an arguable basis for a pre-emption defense did not exist until that standard was promulgated, it is reasonable to infer that the manufacturers’ assessment of their potential liability for compensatory and punitive damages on such claims—even

cussing problem of basing state tort liability upon compliance with mandatory federal regulatory requirement as question of pre-emption rather than of liability on the merits); *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U. S. 132, 142–143 (1963) (“A holding of federal exclusion of state law is inescapable and requires no inquiry into congressional design where compliance with both federal [regulations and state tort law] is a physical impossibility . . .”).

⁷ Restatement (Third) of Torts: Products Liability § 4(b), and Comment *e* (1997); *Contini v. Hyundai Motor Co.*, 840 F. Supp. 22, 23–24 (SDNY 1993). See also Restatement (Second) of Torts § 288C, and Comment *a* (1964) (negligence); *McNeil Pharmaceutical v. Hawkins*, 686 A. 2d 567, 577–579 (D. C. 1996) (strict liability).

⁸ The subsequent history of *Silkwood* does not cast doubt on this premise. See *Silkwood v. Kerr-McGee Corp.*, 667 F. 2d 908, 921–923 (CA10 1981) (reversing on ground that federal law pre-empts award of punitive damages), rev’d and remanded, 464 U. S. 238 (1984), on remand, 769 F. 2d 1451, 1457–1458 (CA10 1985).

STEVENS, J., dissenting

without any pre-emption defense—did not provide them with a sufficient incentive to engage in widespread installation of airbags.

Turning to the subject of pre-emption, Honda contends that the Safety Act's pre-emption provision, 15 U.S.C. §1392(d), expressly pre-empts petitioners' common-law no-airbag claims. It also argues that the claims are in any event impliedly pre-empted because the imposition of liability in cases such as this would frustrate the purposes of Standard 208. I discuss these alternative arguments in turn.

III

When a state statute, administrative rule, or common-law cause of action conflicts with a federal statute, it is axiomatic that the state law is without effect. U.S. Const., Art. VI, cl. 2; *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992). On the other hand, it is equally clear that the Supremacy Clause does not give unelected federal judges *carte blanche* to use federal law as a means of imposing their own ideas of tort reform on the States.⁹ Because of the role of States as separate sovereigns in our federal system, we have long presumed that state laws—particularly those, such as the provision of tort remedies to compensate for personal injuries, that are within the scope of the States' historic police powers—are not to be pre-empted by a federal statute unless it is the clear and manifest purpose of Congress to do so. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996); *Gade v. National Solid Wastes Management Assn.*, 505 U.S. 88, 116–117 (1992) (SOUTER, J., dissenting) (“If the [federal] statute's terms can be read sensibly not to have a pre-emptive effect, the presumption controls and no pre-emption may be inferred”).

⁹Regrettably, the Court has not always honored the latter proposition as scrupulously as the former. See, e.g., *Boyle v. United Technologies Corp.*, 487 U.S. 500 (1988).

STEVENS, J., dissenting

When a federal statute contains an express pre-emption provision, “the task of statutory construction must in the first instance focus on the plain wording of [that provision], which necessarily contains the best evidence of Congress’ pre-emptive intent.” *CSX Transp., Inc. v. Easterwood*, 507 U. S. 658, 664 (1993). The Safety Act contains both an express pre-emption provision, 15 U.S.C. § 1392(d), and a saving clause that expressly preserves common-law claims, § 1397(k). The relevant part of the former provides:

“Whenever a Federal motor vehicle safety standard established under this subchapter is in effect, no State or political subdivision of a State shall have any authority either to establish, or to continue in effect, with respect to any motor vehicle or item of motor vehicle equipment[,] any safety standard applicable to the same aspect of performance of such vehicle or item of equipment which is not identical to the Federal standard.”¹⁰

The latter states:

“Compliance with any Federal motor vehicle safety standard issued under this subchapter does not exempt any person from any liability under common law.”¹¹

¹⁰This provision is now codified at 49 U.S.C. § 30103(b)(1). Because both federal and state opinions construing this provision have consistently referred to it as “§ 1392(d),” I shall follow that practice. Section 1392(d) contains these additional sentences: “Nothing in this section shall be construed as preventing any State from enforcing any safety standard which is identical to a Federal safety standard. Nothing in this section shall be construed to prevent the Federal Government or the government of any State or political subdivision thereof from establishing a safety requirement applicable to motor vehicles or motor vehicle equipment procured for its own use if such requirement imposes a higher standard of performance than that required to comply with the otherwise applicable Federal standard.”

¹¹This provision is now codified at 49 U.S.C. § 30103(e). See nn. 1 and 10, *supra*.

STEVENS, J., dissenting

Relying on § 1392(d) and legislative history discussing Congress' desire for uniform national safety standards,¹² Honda argues that petitioners' common-law no-airbag claims are expressly pre-empted because success on those claims would necessarily establish a state "safety standard" not identical to Standard 208. It is perfectly clear, however, that the term "safety standard" as used in these two sections refers to an objective rule prescribed by a legislature or an administrative agency and does not encompass case-specific decisions by judges and juries that resolve common-law claims. That term is used three times in these sections; presumably it is used consistently. *Gustafson v. Alloyd Co.*, 513 U. S. 561, 570 (1995). The two references to a federal safety standard are necessarily describing an objective administrative rule. 15 U. S. C. § 1392(a). When the pre-emption provision refers to a safety standard established by a "State or political subdivision of a State," therefore, it is most naturally read to convey a similar meaning. In addition, when the two sections are read together, they provide compelling evidence of an intent to distinguish between legislative and administrative rulemaking, on the one hand, and common-law liability, on the other. This distinction was certainly a rational one for Congress to draw in the Safety Act given that common-law liability—unlike most legislative or administrative rulemaking—necessarily performs an important remedial role in compensating accident victims. Cf. *Silkwood v. Kerr-McGee Corp.*, 464 U. S. 238, 251, 256 (1984).

It is true that in three recent cases we concluded that broadly phrased pre-emptive commands encompassed common-law claims. In *Cipollone v. Liggett Group, Inc.*, while we thought it clear that the pre-emption provision in the 1965 Federal Cigarette Labeling and Advertising Act applied only to "rulemaking bodies," 505 U. S., at 518, we concluded that the broad command in the subsequent 1969

¹² S. Rep. No. 1301, 89th Cong., 2d Sess., 2 (1966); H. R. Rep. No. 1776, 89th Cong., 2d Sess., 17 (1966).

STEVENS, J., dissenting

amendment that “[n]o requirement or prohibition . . . shall be imposed under State law” did include certain common-law claims. *Id.*, at 548–549 (SCALIA, J., concurring in judgment in part and dissenting in part).¹³ In *CSX Transp., Inc. v. Easterwood*, where the pre-emption clause of the Federal Railroad Safety Act of 1970 expressly provided that federal railroad safety regulations would pre-empt any incompatible state “‘law, rule, regulation, order, or standard relating to railroad safety,’”¹⁴ we held that a federal regulation governing maximum train speed pre-empted a negligence claim that a speed under the federal maximum was excessive. And in *Medtronic, Inc. v. Lohr*, we recognized that the statutory reference to “any requirement” imposed by a State or its political subdivisions may include common-law duties. 518 U. S., at 502–503 (plurality opinion); *id.*, at 503–505 (BREYER, J., concurring in part and concurring in judgment); *id.*, at 509–512 (O’CONNOR, J., concurring in part and dissenting in part).

The statutes construed in those cases differed from the Safety Act in two significant respects. First, the language in each of those pre-emption provisions was significantly broader than the text of § 1392(d). Unlike the broader language of those provisions, the ordinary meaning of the term “safety standard” includes positive enactments, but does not include judicial decisions in common-law tort cases.

Second, the statutes at issue in *Cipollone*, *CSX*, and *Medtronic* did not contain a saving clause expressly preserving common-law remedies. The saving clause in the Safety Act

¹³ The full text of the 1969 provision read: “‘No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.’” 505 U. S., at 515 (quoting Public Health Cigarette Smoking Act of 1969, 84 Stat. 88).

¹⁴ 507 U. S., at 664 (quoting § 205, 84 Stat. 972, as amended, 45 U. S. C. § 434 (1988 ed. and Supp. II)).

STEVENS, J., dissenting

unambiguously expresses a decision by Congress that compliance with a federal safety standard does not exempt a manufacturer from *any* common-law liability. In light of this reference to common-law liability in the saving clause, Congress surely would have included a similar reference in § 1392(d) if it had intended to pre-empt such liability. *Chicago v. Environmental Defense Fund*, 511 U. S. 328, 338 (1994) (noting presumption that Congress acts intentionally when it includes particular language in one section of a statute but omits it in another).

The Court does not disagree with this interpretation of the term “safety standard” in § 1392(d). Because the meaning of that term as used by Congress in this statute is clear, the text of § 1392(d) is itself sufficient to establish that the Safety Act does not expressly pre-empt common-law claims. In order to avoid the conclusion that the saving clause is superfluous, therefore, it must follow that it has a different purpose: to limit, or possibly to foreclose entirely, the possible pre-emptive effect of safety standards promulgated by the Secretary. The Court’s approach to the case has the practical effect of reading the saving clause out of the statute altogether.¹⁵

Given the cumulative force of the fact that § 1392(d) does not expressly pre-empt common-law claims and the fact that § 1397(k) was obviously intended to limit the pre-emptive effect of the Secretary’s safety standards, it is quite wrong for the Court to assume that a possible implicit conflict with the purposes to be achieved by such a standard should have the same pre-emptive effect “‘as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.’” *Ante*, at 873. Properly construed, the Safety Act imposes a special burden on a party relying on an arguable, implicit conflict with a temporary regulatory policy—

¹⁵ The Court surely cannot believe that Congress included that clause in the statute just to avoid the danger that we would otherwise fail to give the term “safety standard” its ordinary meaning.

STEVENS, J., dissenting

rather than a conflict with congressional policy or with the text of any regulation—to demonstrate that a common-law claim has been pre-empted.

IV

Even though the Safety Act does not expressly pre-empt common-law claims, Honda contends that Standard 208—of its own force—implicitly pre-empts the claims in this case.

“We have recognized that a federal statute implicitly overrides state law either when the scope of a statute indicates that Congress intended federal law to occupy a field exclusively, *English v. General Elec. Co.*, 496 U. S. 72, 78–79 (1990), or when state law is in actual conflict with federal law. We have found implied conflict pre-emption where it is ‘impossible for a private party to comply with both state and federal requirements,’ *id.*, at 79, or where state law ‘stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.’ *Hines v. Davidowitz*, 312 U. S. 52, 67 (1941).” *Freightliner Corp. v. Myrick*, 514 U. S. 280, 287 (1995).

In addition, we have concluded that regulations “intended to pre-empt state law” that are promulgated by an agency acting nonarbitrarily and within its congressionally delegated authority may also have pre-emptive force. *Fidelity Fed. Sav. & Loan Assn. v. De la Cuesta*, 458 U. S. 141, 153–154 (1982). In this case, Honda relies on the last of the implied pre-emption principles stated in *Freightliner*, arguing that the imposition of common-law liability for failure to install an airbag would frustrate the purposes and objectives of Standard 208.

Both the text of the statute and the text of the standard provide persuasive reasons for rejecting this argument. The saving clause of the Safety Act arguably denies the Secretary the authority to promulgate standards that would

STEVENS, J., dissenting

pre-empt common-law remedies.¹⁶ Moreover, the text of Standard 208 says nothing about pre-emption, and I am not persuaded that Honda has overcome our traditional presumption that it lacks any implicit pre-emptive effect.

Honda argues, and the Court now agrees, that the risk of liability presented by common-law claims that vehicles without airbags are negligently and defectively designed would frustrate the policy decision that the Secretary made in promulgating Standard 208. This decision, in their view, was that safety—including a desire to encourage “public acceptance of the airbag technology and experimentation with better passive restraint systems”¹⁷—would best be promoted

¹⁶The Court contends, in essence, that a saving clause cannot foreclose implied conflict pre-emption. *Ante*, at 873–874. The cases it cites to support that point, however, merely interpreted the language of the particular saving clauses at issue and concluded that those clauses did not foreclose implied pre-emption; they do not establish that a saving clause in a given statute cannot foreclose implied pre-emption based on frustration of that statute’s purposes, or even (more importantly for our present purposes) that a saving clause in a given statute cannot deprive a *regulation* issued pursuant to that statute of any implicit pre-emptive effect. See *United States v. Locke*, *ante*, at 104–107; *International Paper Co. v. Ouellette*, 479 U.S. 481, 493 (1987) (“Given that the Act itself does not speak directly to the issue, the Court must be guided by the goals and policies of the Act in determining whether it in fact pre-empts an action”); *Chicago & North Western Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 328, 331 (1981). As stated in the text, I believe the language of this particular saving clause unquestionably limits, and possibly forecloses entirely, the pre-emptive effect that safety standards promulgated by the Secretary have on common-law remedies. See *Louisiana Pub. Serv. Comm’n v. FCC*, 476 U.S. 355, 374 (1986). Under that interpretation, there is by definition no frustration of federal purposes—that is, no “toler[ance of] actual conflict,” *ante*, at 874—when tort suits are allowed to go forward. Thus, because there is a textual basis for concluding that Congress intended to preserve the state law at issue, I think it entirely appropriate for the party favoring pre-emption to bear a special burden in attempting to show that valid federal purposes would be frustrated if that state law were not pre-empted.

¹⁷166 F. 3d 1236, 1243 (CADC 1999).

STEVENS, J., dissenting

through gradual implementation of a passive restraint requirement making airbags only one of a variety of systems that a manufacturer could install in order to comply, rather than through a requirement mandating the use of one particular system in every vehicle. In its brief supporting Honda, the United States agreed with this submission. It argued that if the manufacturers had known in 1984 that they might later be held liable for failure to install airbags, that risk “would likely have led them to install airbags in all cars,” thereby frustrating the Secretary’s safety goals and interfering with the methods designed to achieve them. Brief for United States as *Amicus Curiae* 25.

There are at least three flaws in this argument that provide sufficient grounds for rejecting it. First, the entire argument is based on an unrealistic factual predicate. Whatever the risk of liability on a no-airbag claim may have been prior to the promulgation of the 1984 version of Standard 208, that risk did not lead any manufacturer to install airbags in even a substantial portion of its cars. If there had been a realistic likelihood that the risk of tort liability would have that consequence, there would have been no need for Standard 208. The promulgation of that standard certainly did not *increase* the pre-existing risk of liability. Even if the standard did not create a previously unavailable pre-emption defense, it likely *reduced* the manufacturers’ risk of liability by enabling them to point to the regulation and their compliance therewith as evidence tending to negate charges of negligent and defective design. See Part II, *supra*. Given that the pre-1984 risk of liability did not lead to widespread airbag installation, this reduced risk of liability was hardly likely to compel manufacturers to install airbags in all cars—or even to compel them to comply with Standard 208 during the phase-in period by installing airbags exclusively.

Second, even if the manufacturers’ assessment of their risk of liability ultimately proved to be wrong, the purposes of Standard 208 would not be frustrated. In light of the inevi-

STEVENS, J., dissenting

table time interval between the eventual filing of a tort action alleging that the failure to install an airbag is a design defect and the possible resolution of such a claim against a manufacturer, as well as the additional interval between such a resolution (if any) and manufacturers' "compliance with the state-law duty in question," *ante*, at 882, by modifying their designs to avoid such liability in the future, it is obvious that the phase-in period would have ended long before its purposes could have been frustrated by the specter of tort liability. Thus, even without pre-emption, the public would have been given the time that the Secretary deemed necessary to gradually adjust to the increasing use of airbag technology and allay their unfounded concerns about it. Moreover, even if any no-airbag suits were ultimately resolved against manufacturers, the resulting incentive to modify their designs would have been quite different from a decision by the Secretary to mandate the use of airbags in every vehicle. For example, if the extra credit provided for the use of nonbelt passive restraint technologies during the phase-in period had (as the Secretary hoped) ultimately encouraged manufacturers to develop a nonbelt system more effective than the airbag, manufacturers held liable for failing to install passive restraints would have been free to respond by modifying their designs to include such a system *instead of* an airbag.¹⁸ It seems clear, therefore, that any

¹⁸ The Court's failure to "understand [this point] correctly," *ante*, at 883, is directly attributable to its fundamental misconception of the nature of duties imposed by tort law. A general verdict of liability in a case seeking damages for negligent and defective design of a vehicle that (like Ms. Geier's) lacked any passive restraints does not amount to an immutable, mandatory "rule of state tort law imposing . . . a duty [to install an airbag]." *Ante*, at 881; see also *ante*, at 871 (referring to verdict in common-law tort suit as a "jury-imposed safety standard"). Rather, that verdict merely reflects the jury's judgment that the manufacturer of a vehicle without any passive restraint system breached its duty of due care by designing a product that was not reasonably safe because a reasonable alternative design—"including, but not limited to, airbags," App. 3—could

STEVENS, J., dissenting

potential tort liability would not frustrate the Secretary's desire to encourage both experimentation with better passive restraint systems and public acceptance of airbags.

Third, despite its acknowledgment that the saving clause “preserves those actions that seek to establish greater safety than the minimum safety achieved by a federal regulation intended to provide a floor,” *ante*, at 870, the Court completely ignores the important fact that by definition all of the standards established under the Safety Act—like the British regulations that governed the number and capacity of lifeboats aboard the *Titanic*¹⁹—impose minimum, rather than fixed or maximum, requirements. 15 U. S. C. § 1391(2); see *Norfolk Southern R. Co. v. Shanklin*, *ante*, at 359 (BREYER, J., concurring) (“[F]ederal *minimum* safety standards should not pre-empt a state tort action”); *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U. S. 707, 721 (1985). The phase-in program authorized by Standard 208 thus set minimum percentage requirements for the installation of passive restraints, increasing in annual stages of 10, 25, 40, and 100%. Those requirements were not ceilings, and it is obvious that the Secretary favored a more rapid increase. The possibility that exposure to potential tort lia-

have reduced the foreseeable risks of harm posed by the product. See Restatement (Third) of Torts: Products Liability § 2(b), and Comment *d* (1997); *id.*, § 1, Comment *a* (noting that § 2(b) is rooted in concepts of both negligence and strict liability). Such a verdict obviously does not foreclose the possibility that more than one alternative design exists the use of which would render the vehicle reasonably safe and satisfy the manufacturer's duty of due care. Thus, the Court is quite wrong to suggest that, as a consequence of such a verdict, only the installation of airbags would enable manufacturers to avoid liability in the future.

¹⁹ Statutory Rules and Orders 1018–1021, 1033 (1908). See Nader & Page, *Automobile-Design Liability and Compliance with Federal Standards*, 64 Geo. Wash. L. Rev. 415, 459 (1996) (noting that the *Titanic* “complied with British governmental regulations setting minimum requirements for lifeboats when it left port on its final, fateful voyage with boats capable of carrying only about [half] of the people on board”); W. Wade, *The Titanic: End of a Dream* 68 (1986).

STEVENS, J., dissenting

bility might accelerate the rate of increase would actually further the only goal explicitly mentioned in the standard itself: reducing the number of deaths and severity of injuries of vehicle occupants. Had gradualism been independently important as a method of achieving the Secretary's safety goals, presumably the Secretary would have put a ceiling as well as a floor on each annual increase in the required percentage of new passive restraint installations. For similar reasons, it is evident that variety was not a matter of independent importance to the Secretary. Although the standard allowed manufacturers to comply with the minimum percentage requirements by installing passive restraint systems other than airbags (such as automatic seatbelts), it encouraged them to install airbags and other nonbelt systems that might be developed in the future. The Secretary did not act to ensure the use of a variety of passive restraints by placing ceilings on the number of airbags that could be used in complying with the minimum requirements.²⁰ Moreover, even if variety and gradualism had been independently important to the Secretary, there is nothing in the standard, the accompanying commentary, or the history of airbag regulation to support the notion that the Secretary intended to advance those purposes at all costs, without regard to the detrimental consequences that pre-emption of tort liability could have for the achievement of her avowed purpose of reducing vehicular injuries. See *Silkwood v. Kerr-McGee Corp.*, 464 U. S., at 257.

My disagreement with Honda and the Government runs deeper than these flaws, however. In its brief, the Government concedes that "[a] claim that a manufacturer should have chosen to install airbags rather than another type of

²⁰ Of course, allowing a suit like petitioners' to proceed against a manufacturer that had installed no passive restraint system in a particular vehicle would not even arguably pose an "obstacle" to the auto manufacturers' freedom to choose among several different passive restraint device options. Cf. *ante*, at 878, 881.

STEVENS, J., dissenting

passive restraint in a certain model of car because of other design features particular to that car . . . would not necessarily frustrate Standard 208's purposes." Brief for United States as *Amicus Curiae* 26, n. 23.²¹ Petitioners' claims here are quite similar to the claim described by the Government: their complaint discusses other design features particular to the 1987 Accord (such as the driver's seat) that allegedly rendered it unreasonably dangerous to operate without an airbag. App. 4–5. The only distinction is that in this case, the particular 1987 Accord driven by Ms. Geier included no passive restraint of any kind because Honda chose to comply with Standard 208's 10% minimum requirement by installing passive restraints in other 1987 models. I fail to see how this distinction makes a difference to the purposes of Standard 208, however. If anything, the type of claim favored by the Government—*e. g.*, that a particular model of car should have contained an airbag instead of an automatic seatbelt—would seem to trench even more severely upon the purposes that the Government and Honda contend were behind the promulgation of Standard 208: that having a variety of passive restraints, rather than only airbags, was necessary to promote safety. Thus, I conclude that the Government, on the Secretary's behalf, has failed to articulate a coherent view of the policies behind Standard 208 that would be frustrated by petitioners' claims.

V

For these reasons, it is evident that Honda has not crossed the high threshold established by our decisions regarding

²¹ Compare *ante*, at 881 (disagreeing with Government's view by concluding that tort-law duty "requir[ing] manufacturers of all similar cars to install airbags rather than other passive restraint systems . . . would [present] an obstacle to the variety and mix of devices that the federal regulation sought"), with *ante*, at 883, 885 (noting that "the agency's own views should make a difference," but contending that the above-quoted Government view is "*not* at issue here").

STEVENS, J., dissenting

pre-emption of state laws that allegedly frustrate federal purposes: it has not demonstrated that allowing a common-law no-airbag claim to go forward would impose an obligation on manufacturers that directly and irreconcilably contradicts any primary objective that the Secretary set forth with clarity in Standard 208. *Gade v. National Solid Wastes Management Assn.*, 505 U. S., at 110 (KENNEDY, J., concurring in part and concurring in judgment); *id.*, at 111 (“A freewheeling judicial inquiry into whether [state law] is in tension with federal objectives would undercut the principle that it is Congress [and federal agencies,] rather than the courts[,] that pre-emp[t] state law”). Furthermore, it is important to note that the text of Standard 208 (which the Court does not even bother to quote in its opinion), unlike the regulation we reviewed in *Fidelity Fed. Sav. & Loan Assn. v. De la Cuesta*, 458 U. S., at 158, does not contain any expression of an intent to displace state law. Given our repeated emphasis on the importance of the presumption against pre-emption, see, *e. g.*, *CSX Transp., Inc. v. Easterwood*, 507 U. S., at 663–664; *Rice v. Santa Fe Elevator Corp.*, 331 U. S. 218, 230 (1947), this silence lends additional support to the conclusion that the continuation of whatever common-law liability may exist in a case like this poses no danger of frustrating any of the Secretary’s primary purposes in promulgating Standard 208. See *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U. S., at 721; *Silkwood v. Kerr-McGee Corp.*, 464 U. S., at 251 (“It is difficult to believe that [the Secretary] would, without comment, remove all means of judicial recourse for those injured by illegal conduct”).

The Court apparently views the question of pre-emption in this case as a close one. *Ante*, at 883 (relying on Secretary’s interpretation of Standard 208’s objectives to bolster its finding of pre-emption). Under “ordinary experience-proved principles of conflict pre-emption,” *ante*, at 874, therefore, the presumption against pre-emption should control. Instead, the Court simply ignores the presumption,

STEVENS, J., dissenting

preferring instead to put the burden on petitioners to show that their tort claim would not frustrate the Secretary's purposes. *Ante*, at 882 (noting that petitioners' arguments "cannot, by themselves, change the legal result"). In view of the important principles upon which the presumption is founded, however, rejecting it in this manner is profoundly unwise.

Our presumption against pre-emption is rooted in the concept of federalism. It recognizes that when Congress legislates "in a field which the States have traditionally occupied . . . [,] we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Rice v. Santa Fe Elevator Corp.*, 331 U. S., at 230; see *Jones v. Rath Packing Co.*, 430 U. S. 519, 525 (1977). The signal virtues of this presumption are its placement of the power of pre-emption squarely in the hands of Congress, which is far more suited than the Judiciary to strike the appropriate state/federal balance (particularly in areas of traditional state regulation), and its requirement that Congress speak clearly when exercising that power. In this way, the structural safeguards inherent in the normal operation of the legislative process operate to defend state interests from undue infringement. *Garcia v. San Antonio Metropolitan Transit Authority*, 469 U. S. 528, 552 (1985); see *United States v. Morrison*, *ante*, at 660–663 (BREYER, J., dissenting); *Kimel v. Florida Bd. of Regents*, 528 U. S. 62, 93–94 (2000) (STEVENS, J., dissenting); *Allied-Bruce Terminix Cos. v. Dobson*, 513 U. S. 265, 292–293 (1995) (THOMAS, J., dissenting); *Gregory v. Ashcroft*, 501 U. S. 452, 460–464 (1991). In addition, the presumption serves as a limiting principle that prevents federal judges from running amok with our potentially boundless (and perhaps inadequately considered) doctrine of implied conflict pre-emption based on frustration of purposes—*i. e.*, that state law is pre-empted if it "stands as an obstacle to the accomplishment and execu-

STEVENS, J., dissenting

tion of the full purposes and objectives of Congress.” *Hines v. Davidowitz*, 312 U. S. 52, 67 (1941).²²

While the presumption is important in assessing the pre-emptive reach of federal statutes, it becomes crucial when the pre-emptive effect of an administrative regulation is at issue. Unlike Congress, administrative agencies are clearly not designed to represent the interests of States, yet with relative ease they can promulgate comprehensive and detailed regulations that have broad pre-emption ramifications for state law. We have addressed the heightened federalism and nondelegation concerns that agency pre-emption raises by using the presumption to build a procedural bridge across the political accountability gap between States and administrative agencies. Thus, even in cases where implied regulatory pre-emption is at issue, we generally “expect an administrative regulation to declare any intention to pre-empt state law with some specificity.”²³ *California Coastal*

²² Recently, one commentator has argued that our doctrine of frustration-of-purposes (or “obstacle”) pre-emption is not supported by the text or history of the Supremacy Clause, and has suggested that we attempt to bring a measure of rationality to our pre-emption jurisprudence by eliminating it. Nelson, Preemption, 86 Va. L. Rev. 225, 231–232 (2000) (“Under the Supremacy Clause, preemption occurs if and only if state law contradicts a valid rule established by federal law, and the mere fact that the federal law serves certain purposes does not automatically mean that it contradicts everything that might get in the way of those purposes”). Obviously, if we were to do so, there would be much less need for the presumption against pre-emption (which the commentator also criticizes). As matters now stand, however, the presumption reduces the risk that federal judges will draw too deeply on malleable and politically unaccountable sources such as regulatory history in finding pre-emption based on frustration of purposes.

²³ The Court brushes aside our specificity requirement on the ground that the cases in which we relied upon it were not cases of implied conflict pre-emption. *Ante*, at 884. The Court is quite correct that *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U. S. 707 (1985), and *California Coastal Comm’n v. Granite Rock Co.*, 480 U. S. 572 (1987), are cases in which field pre-emption, rather than conflict pre-emption, was at issue. This distinction, however, does not take the Court as far as it

STEVENS, J., dissenting

Comm'n v. Granite Rock Co., 480 U. S. 572, 583 (1987); see *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U. S., at 717–718 (noting that too easily implying pre-emption “would be inconsistent with the federal-state balance embodied in our Supremacy Clause jurisprudence,” and stating that “because agencies normally address problems in a detailed manner and can speak through a variety of means, including regulations, preambles, interpretive statements, and responses to comments, we can expect that they will make their intentions clear if they intend for their regulations to be exclusive”); *Fidelity Fed. Sav. & Loan Assn. v. De la Cuesta*, 458 U. S., at 154 (noting that pre-emption inquiry is initiated “[w]hen the administrator promulgates regulations intended to pre-empt state law”). This expectation, which is shared by the Executive Branch,²⁴ serves to ensure that States will be able to have a dialog

would like. Our cases firmly establish that conflict and field pre-emption are alike in that both are instances of implied pre-emption that by definition do “not [turn] on an express statement of pre-emptive intent.” *Ante*, at 884; see, e. g., *Freightliner Corp. v. Myrick*, 514 U. S. 280, 287 (1995) (quoted *supra*, at 899); *English v. General Elec. Co.*, 496 U. S. 72, 79–80, and n. 5 (1990) (noting that field pre-emption rests on an inference of congressional intent to exclude state regulation and that it “may be understood as a species of conflict pre-emption”); *Fidelity Fed. Sav. & Loan Assn. v. De la Cuesta*, 458 U. S. 141, 153 (1982). Given that our specificity requirement was adopted in cases involving implied pre-emption, the Court cannot persuasively claim that the requirement is incompatible with our implied pre-emption jurisprudence in the federal regulatory context.

²⁴ See Exec. Order No. 12612, § 4(e), 3 CFR 252, 255 (1988) (“When an Executive department or agency proposes to act through adjudication or rule-making to preempt State law, the department or agency shall provide all affected States notice and an opportunity for appropriate participation in the proceedings”); Exec. Order No. 13132, § 4(e), 64 Fed. Reg. 43255, 43257 (1999) (same); cf. *Medtronic, Inc. v. Lohr*, 518 U. S. 470, 496 (1996) (discussing 21 CFR § 808.5 (1995), an FDA regulation allowing a State to request an advisory opinion regarding whether a particular state-law requirement is pre-empted, or exempt from pre-emption, under the Medical Device Amendments of 1976).

STEVENS, J., dissenting

with agencies regarding pre-emption decisions *ex ante* through the normal notice-and-comment procedures of the Administrative Procedure Act (APA), 5 U. S. C. § 553.

When the presumption and its underpinnings are properly understood, it is plain that Honda has not overcome the presumption in this case. Neither Standard 208 nor its accompanying commentary includes the slightest specific indication of an intent to pre-empt common-law no-airbag suits. Indeed, the only mention of such suits in the commentary tends to suggest that they would not be pre-empted. See n. 5, *supra*. In the Court's view, however, "[t]he failure of the Federal Register to address pre-emption explicitly is . . . not determinative," *ante*, at 884, because the Secretary's consistent litigating position since 1989, the history of airbag regulation, and the commentary accompanying the final version of Standard 208 reveal purposes and objectives of the Secretary that would be frustrated by no-airbag suits. Pre-empting on these three bases blatantly contradicts the presumption against pre-emption. When the 1984 version of Standard 208 was under consideration, the States obviously were not afforded any notice that purposes might someday be discerned in the history of airbag regulation that would support pre-emption. Nor does the Court claim that the notice of proposed rulemaking that led to Standard 208 provided the States with notice either that the final version of the standard might contain an express pre-emption provision or that the commentary accompanying it might contain a statement of purposes with arguable pre-emptive effect. Finally, the States plainly had no opportunity to comment upon either the commentary accompanying the final version of the standard or the Secretary's *ex post* litigating position that the standard had implicit pre-emptive effect.

Furthermore, the Court identifies no case in which we have upheld a regulatory claim of frustration-of-purposes implied conflict pre-emption based on nothing more than an *ex post* administrative litigating position and inferences from

STEVENS, J., dissenting

regulatory history and final commentary. The latter two sources are even more malleable than legislative history. Thus, when snippets from them are combined with the Court's broad conception of a doctrine of frustration-of-purposes pre-emption untempered by the presumption, a vast, undefined area of state law becomes vulnerable to pre-emption by any related federal law or regulation. In my view, however, "preemption analysis is, or at least should be, a matter of precise statutory [or regulatory] construction rather than an exercise in free-form judicial policymaking." 1 L. Tribe, *American Constitutional Law* §6-28, p. 1177 (3d ed. 2000).

As to the Secretary's litigating position, it is clear that "an interpretation contained in a [legal brief], not one arrived at after, for example, a formal adjudication or notice-and-comment rulemaking[,] . . . do[es] not warrant *Chevron*-style deference." *Christensen v. Harris County*, *ante*, at 587. Moreover, our pre-emption precedents and the APA establish that even if the Secretary's litigating position were coherent, the lesser deference paid to it by the Court today would be inappropriate. Given the Secretary's contention that he has the authority to promulgate safety standards that pre-empt state law and the fact that he could promulgate a standard such as the one quoted *supra*, at 887, with relative ease, we should be quite reluctant to find pre-emption based only on the Secretary's informal effort to recast the 1984 version of Standard 208 into a pre-emptive mold.²⁵ See *Hillsborough County v. Automated Medical*

²⁵ The cases cited by the Court, *ante*, at 883, are not to the contrary. In *City of New York v. FCC*, 486 U. S. 57 (1988), for example, we were faced with Federal Communications Commission regulations that explicitly "re-affirmed the Commission's established policy of pre-empting local regulation of technical signal quality standards for cable television." *Id.*, at 62, 65. It was only in determining whether the issuance of such regulations was a proper exercise of the authority delegated to the agency by Congress that we afforded a measure of deference to the agency's interpretation of that authority, as *formally* expressed through its explicitly pre-

STEVENS, J., dissenting

Laboratories, Inc., 471 U. S., at 721; cf. *Medtronic, Inc. v. Lohr*, 518 U. S., at 512 (O'CONNOR, J., concurring in part and dissenting in part) ("It is not certain that an agency regulation determining the pre-emptive effect of *any* federal statute is entitled to deference"); *Smiley v. Citibank (South Dakota), N. A.*, 517 U. S. 735, 743–744 (1996). Requiring the Secretary to put his pre-emptive position through formal notice-and-comment rulemaking—whether contemporaneously with the promulgation of the allegedly pre-emptive regulation or at any later time that the need for pre-emption becomes apparent²⁶—respects both the federalism and non-delegation principles that underlie the presumption against pre-emption in the regulatory context and the APA's requirement of new rulemaking when an agency substantially modifies its interpretation of a regulation. 5 U. S. C. §551(5); *Paralyzed Veterans of America v. D. C. Arena L. P.*, 117 F. 3d 579, 586 (CA DC 1997); *National Family Planning & Reproductive Health Assn. v. Sullivan*, 979 F. 2d 227, 240 (CA DC 1992).

* * *

Because neither the text of the statute nor the text of the regulation contains any indication of an intent to pre-empt

emptive regulations. *Id.*, at 64; see also *Capital Cities Cable, Inc. v. Crisp*, 467 U. S. 691, 700–705 (1984) (regulation); *Fidelity Fed. Sav. & Loan Assn. v. De la Cuesta*, 458 U. S., at 158–159 (regulation); *Blum v. Bacon*, 457 U. S. 132, 141–142 (1982) (Action Transmittal by Social Security Administration); *Chicago & North Western Transp. Co. v. Kalo Brick & Tile Co.*, 450 U. S., at 327 (order of Interstate Commerce Commission); *United States v. Shimer*, 367 U. S. 374, 377 (1961) (regulation). I express no opinion on whether any deference would be appropriate in any of these situations, but merely observe that such situations are not presented here.

²⁶ *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U. S., at 721 (noting that agency "can be expected to monitor, on a continuing basis, the effects on the federal program of local requirements" and to promulgate regulations pre-empting local law that imperils the goals of that program).

STEVENS, J., dissenting

petitioners' cause of action, and because I cannot agree with the Court's unprecedented use of inferences from regulatory history and commentary as a basis for implied pre-emption, I am convinced that Honda has not overcome the presumption against pre-emption in this case. I therefore respectfully dissent.

1 College.

2 THE WITNESS: And Geneva

3 College.

4 MR. UGARTE: Thank you.

5 HEARING OFFICER ORTH: All

6 right. Any reason not to excuse

7 Dr. Henry?

8 Will you offer exhibits?

9 MR. TRUJILLO: Madam Chair, I
10 move for the admission of the exhibits
11 associated with Dr. Henry.

12 HEARING OFFICER ORTH: I'll
13 pause for a moment in the event there
14 are objections. No.

15 They are admitted. Thank you.

16 (ACC Exhibit 4 was received in
17 evidence.)

18 (ACC Exhibit 5 was received in
19 evidence.)

20 HEARING OFFICER ORTH: Thank
21 you very much, Dr. Henry.

22 THE WITNESS: Thank you very
23 much.

24 MR. TRUJILLO: Madam Chair,
25 next we'd call -- I call him Dr. K.

1 I've got to get used to saying his
2 name; Dr. Korzeniowski.

3 Thank you, Dr. K.

4 HEARING OFFICER ORTH: All
5 right.

6 Dr. Korzeniowski, would you --
7 good morning -- spell your first and
8 last name, please.

9 THE WITNESS: Stephen,
10 S-T-E-P-H-E-N; last name is
11 K-O-R-Z-E-N-I-O-W-S-K-I.

12 HEARING OFFICER ORTH: Thank
13 you.

14 Do you swear or affirm to tell
15 the truth.

16 THE WITNESS: I do.

17 HEARING OFFICER ORTH: Thank
18 you very much.

19 Go ahead, Mr. Trujillo.

20

21 STEPHEN H. KORZENIOWSKI, PH.D.,
22 after having been first duly sworn,
23 was examined and testified as follows:

24 ///

25 ///



1 DIRECT EXAMINATION

2 BY MR. TRUJILLO:

3 Q. Good morning, Dr. K.

4 Who is your current employer?

5 A. My current employer is my own
6 company, BeachEdge Consulting. I
7 started my company ON August 1st, 2015,
8 when I retired from my corporate job.

9 Q. And on whose behalf are you
10 Testifying today?

11 A. ACC, or the American Chemistry
12 Council.

13 Q. Did you provide a Resumé filed
14 as ACC Exhibit 1?

15 A. I did.

16 Q. And that states your employment
17 history, qualifications, and
18 experience.

19 A. Through today, yes.

20 Q. Can you briefly summarize your
21 relevant experience for the Board.

22 A. Yeah, I guess I can.

23 I started in this chemistry,
24 and they didn't call it "PFAS" at the
25 time, but I started in 1977. I worked

1 for about 7 years, 6, 7 years in the
2 lab and doing a few other things in
3 this kind of chemistry.

4 Like many large companies I got
5 the opportunity to do many other jobs
6 between 1984 and 1996.

7 Then I came back in 1996, and
8 for the last 30 years, I've been in
9 this business, so about 36 years
10 direct experience in fluorochemical
11 technology.

12 Q. Thank you.

13 Can you briefly describe any
14 peer-reviewed papers you have authored
15 that are important to this proceeding?

16 A. What I've done is as an
17 industry person you often don't get a
18 lot of chance to publish, but I was
19 fortunate. I got a chance to publish
20 as well as do a number of posters and
21 major talks, and so I have about 60,
22 about 20 of which are peer-reviewed
23 publications.

24 Those publications are on:
25 Analytical chemistry;

1 Toxicology;
2 Pharmacokinetics;
3 Degradation or biodegradation;
4 Sources;
5 Fate; and,
6 Transport.

7 We, me and 3 other authors,
8 did the first major publication to
9 figure out where PFOA came from, from
10 the companies and in the environment
11 in 2006.

12 Then we published one of the
13 "Polymers of Low Concern" papers in
14 2022/2023.

15 In that span I did a whole host
16 of different chemistries, but I think
17 my publication days are done.

18 Q. Thank you, Dr. K.

19 Did you provide Written
20 District Testimony that was filed in
21 this matter as ACC Exhibit 2?

22 A. I did.

23 Q. Do you have any corrections to
24 your Written Direct Testimony?

25 A. I do not.

1 Q. Do you adopt your Written
2 Direct Testimony as your own Testimony
3 for this matter?

4 A. I do.

5 Q. What is the purpose of your
6 Direct Testimony?

7 A. What I wanted to do was to
8 take a few moments -- and I'm only
9 going to take about 15 or 16 in my
10 Direct, and I have about 11 or 12 in
11 the Rebuttal, just to frame for the
12 Board and those in the room some of
13 the things that I saw in the Testimony
14 that was given by others that didn't
15 quite make sense to me.

16 I wanted to take the
17 opportunity to give my point of view,
18 as did Dr. Henry, on what we see and
19 what the Board needs to hear from an
20 alternative point of view from
21 chemistry and science.

22 Q. Go ahead and please present
23 your summary of your Direct Testimony
24 today.

25 A. Okay. Madam Hearing Chair and

1 the Members of the Board, good day to
2 you all. Thank you for allowing me to
3 be here today.

4 I'm an Organic Chemist, as you
5 heard, who started in fluorochemistry
6 in 1977. I have a Bachelor's of Arts
7 degree in Science and Chemistry from
8 Rutgers. I went and got a Ph.D. in
9 Organic Chemistry from Penn state
10 University. Then after 3 or 4 years
11 of working, I went back and got an MBA
12 in finance.

13 I transitioned to many roles,
14 as I described, and all of those roles
15 where science and business allowed me
16 to take the science as well as put in
17 perspective what it means in:

18 Business;
19 Environmental; and,
20 Other worlds.

21 I've been a member of ITRC, as
22 Dr. Olson had testified the other day,
23 the same thing since 2017.

24 I've been a member of the Fire
25 Fighting Foam Coalition since 2021;

1 that's the uses AFFF or firefighting
2 foam with fluorinated surfactants.

3 I've been a member of a number
4 of industry groups since 2000, of which
5 ACC has been a partner for many of
6 those years.

7 I'm here today on behalf of
8 ACC in support of the ACC position
9 that the Warning Label provisions in
10 the Proposed Rule treat all PFAS the
11 same, when PFAS, as we know, are quite
12 different. I'll spend a fair amount
13 of time describing that today:

14 There are very, very diverse
15 group of substances with vastly
16 different physical and chemical
17 properties. The central concern is
18 that this Proposed Rule treats all PFAS
19 the same despite the huge differences,
20 and I'll explain some of those
21 differences.

22 It requires a Warning Label on
23 all products with intentionally added
24 PFAS, but it includes products
25 otherwise exempt under Reporting and

1 Unavoidable Use provisions.

2 As you've heard over the past
3 3 days of hearings, and in the
4 documents you have received, there are
5 several...

6 Well there is a few schools of
7 thought on how to treat the PFAS
8 chemicals. Since they all have carbon
9 and fluorine, they have a fully
10 fluorinated carbon in their structure,
11 and more on this in a minute.

12 One group says, and you've
13 heard this many times this week, that
14 if it meets the PFAS definition, and
15 given that persistence is sufficient,
16 PFAS should be grouped together and
17 treated as 1, group them as 1.

18 Others, like me myself, say
19 that PFAS are not the same. Even if
20 they have a fully fluorinated carbon,
21 they should not be treated -- they
22 should be treated separately and not
23 grouped as 1.

24 If the question is whether
25 there is a consensus, absolutely not.

1 There is no consensus. I'm not sure
2 there is ever going to be consensus.
3 You all have seen and agreed
4 on the definition of PFAS; that, over
5 the past few days in the Rule, 1 fully
6 fluorinated carbon, and Barb Henry
7 talked about that a few minutes ago.
8 This definition was proposed by OECD
9 in 2021.

10 As the definition has changed,
11 so have the number of potential number
12 of PFAS compounds in the list. You've
13 heard nonstop either today and the
14 past 3 days, as well as in all the
15 Testimony how many PFAS really are
16 there.

17 I put this chart together, and
18 it's evolved, obviously. The last
19 time I put this together was 2021, but
20 what's the definition and what does it
21 mean? Really, are there 14- or 15,000
22 PFAS compounds hanging around? The
23 answer is no.

24 There is lists and databases
25 where you can say there is 14,000, but

1 the fact of the matter is, as the
2 definition has evolved, the number of
3 PFAS have evolved that are captured in
4 that list.

5 I mean I charted this back to
6 1994. There were no real numbers at
7 that point, and Hekster in the
8 Netherlands starting using "PFAS," but
9 only mentioned "perfluorinated
10 substance," not "PFAS" as we know it
11 today.

12 The OECD in 2007 created sort
13 of the first list. That was 982 when
14 the OECD in 2007. 982 compounds is a
15 far cry from where we are today.

16 Buck in 2011, they are credited
17 with the first creation of the
18 definition of PFAS in 2011, the
19 Buck/Franklin paper.

20 HEARING OFFICER ORTH: Please
21 keep it slow.

22 THE WITNESS: Okay. Then in
23 the OECD paper in 2018, which we base
24 one of our studies on, which I'll talk
25 about in a moment, because the

1 definition changed, and there was that
2 4730.

3 When the EU called for
4 evidence in 2020, it was about 8,000.

5 Then you have got the new OECD
6 definition from 2021 and EPA database
7 and lists, and now it's about 14,000.

8 I said this a minute ago, the
9 14,000 are based on lists and databases,
10 not a commercial context, and we heard
11 that this morning.

12 The EPA list was 7- or 800;
13 when we did our study it was 600, so
14 same ballpark.

15 The work we did and we
16 published in a peer-reviewed article
17 in 2021 took the OECD list from 2018,
18 and of the 4730, and we found 6%. The
19 survey we did, it was 256, but it was
20 only 3 companies, so we extrapolated
21 that to be maybe it was 6- or 700
22 directly on top of what you just heard
23 this morning.

24 If you're looking at what
25 compounds are relevant and important

1 in commerce and potentially consumer
2 products, it's hundreds, not thousands.

3 Next chart.

4 PFAS are not 1 uniform
5 substance; Dr. Henry gave you a little
6 flavor of that this morning.

7 Also Drs. Chapman and Olson
8 gave a broad overview of what PFAS is
9 with their Testimony, and I don't need
10 to repeat that. I don't think you
11 want a chemistry lesson this morning;
12 enough is enough. You will see some
13 chemistry in a few minutes.

14 You have heard that PFAS are a
15 diverse group of chemicals that vary
16 very significantly in their physical
17 and chemical properties:

18 Their environmental behavior;
19 Environmental fate and
20 effects;

21 Their toxicological profiles.

22 Assuming equal risk across all
23 PFAS is simply not scientifically
24 justified.

25 On the other hand, many believe,

1 and you heard this a few minutes ago
2 too, despite what I just said here,
3 many believe that if you have a PFAS
4 with a fully fluorinated carbon -- go
5 back one -- and given that they are
6 viewed as persistent, persistence is
7 sufficient. My view is it's not. I
8 am not in that camp; we are opposed to
9 the grouping as 1.

10 Now you can change the chart.

11 All right. Perspective:

12 I want to give you some
13 examples, and, you know, you hear me
14 say that they are not the same, but
15 give me a moment here to provide a
16 little education and then see if I can
17 help you as to why we believe they are
18 not the same: This is on Labeling and
19 grouping at a high level. After
20 this -- don't change yet -- I'm going
21 to go to a granular level:

22 An important question that
23 we've been asking for several days now
24 is are they all the same? Let me start
25 with carbon and hydrogen compounds:

1 You see the solid, which is
2 "polyethylene," which is a tubing that
3 you use in your home and water
4 systems.

5 You see "ethyl alcohol," and
6 we'll talk a little bit about that in
7 a minute. You know what ethyl alcohol
8 is and where it's used, and where it
9 comes from.

10 Then if you're like me at
11 home, I have no services in my house.
12 I have to have propane for heat so I
13 have gas.

14 These are carbon and hydrogen
15 compounds. Are they the same? Would
16 you group them the same just because
17 they have carbon and hydrogen in their
18 backbone? The answer is no.

19 That is the same question you
20 should ask for fluorocarbons. They
21 are also really a large universe of
22 very different, very diverse substances.

23 For the carbon and fluorine
24 compounds, you can say they're CF₃s;
25 solid is PTFE,

1 polytetrafluoroethylene.

2 The liquid could be what we
3 call the 6:2 fluorotelomer alcohol.
4 This alcohol is what you've heard over
5 the past few days as the newer
6 chemistry, or the short chains, but
7 that's a liquid.

8 Then for gas would be
9 refrigerants or blowing agents.

10 And so, you know, you look at
11 these and you say, "Okay. Are these
12 compounds the same?" The answer is I
13 don't think so.

14 Let's go to a more granular
15 example, actually 2 of them on the
16 next chart. These substances will be
17 very familiar to you:

18 These are hydrocarbon
19 examples, and I'll follow with
20 fluorocarbon in just a second.

21 On the left-hand side you have
22 2 common chemical examples. You have
23 ethanol, and you know what ethanol is.
24 It's in your beer, your wine, your
25 spirits. It's used as a solvent.

1 Then if you just change the
2 structure and you get rid of that CH₂
3 in the middle, you have ethanol. They
4 look the same. They are carbon,
5 hydrogen, and oxygen, they are alcohols,
6 but they have vastly different hazards.
7 Ethanol you can drink; methanol, if
8 you drink it, you go blind.

9 Saying something is in the
10 same family implying the same hazards
11 makes no sense with 2 simple
12 hydrocarbon examples.

13 Let me give you one more on
14 the right-hand side:

15 For those of you who have ever
16 worked on a car, you know you need
17 antifreeze. Ethylene glycol was the
18 common antifreeze that's been used for
19 years and years and years. It's great
20 if you don't have a pet, because if
21 that antifreeze is leaking and your
22 dog or cat licks that antifreeze, they
23 can have kidney failure or die. My
24 Wife's a veterinarian, so I get this
25 story all the time.

1 However many years ago you may
2 remember there was an alternative
3 glycol called propylene glycol that
4 just had one more carbon, but had
5 vastly different properties such that
6 it's generally regarded as safe by the
7 FDA.

8 The fact that you have a
9 structure, 2 simple examples, doesn't
10 mean they have the same hazards and
11 they don't require the same labels.

12 Next chart please.

13 All right. You heard a fair
14 amount of this from Mark:

15 "PFAS include many
16 different substances with
17 very different properties."

18 They are similar, yes. They
19 have CF₃, but from that point on it
20 changes because you do have gases,
21 liquids, and solids. I said that a
22 few minutes ago.

23 Barb started to highlight some
24 of the key features you have to really
25 think about when you think about PFAS

1 as a class. In this case you've got
2 stability from seconds to thousands of
3 years. Do they degrade?

4 Do they photolyze?

5 Do they degrade in soil?

6 Mobility? Barb talked about
7 this also.

8 Are they insoluble or are they
9 highly mobile and soluble in the
10 environment, either in the air or in
11 water?

12 Toxicity.

13 There is different grades.
14 You heard Dr. DeWitt talk about the
15 gradation. This is low to high.
16 There is gradients in between, and
17 size.

18 How big are these? From really
19 large back to really small; Barb
20 highlighted that in several of her
21 charts.

22 One of the things that I have
23 been saying and my colleagues have
24 been saying over the years, and that's
25 one of my major criticisms and one of

1 the reasons I'm talking today, is that
2 PFAS is so big. Unless you tell people
3 what you're talking about, they don't
4 know. They assume it's all the same.

5 PFAS includes hundreds, if not
6 thousands of compounds, so my motto is
7 pretty simple, and I said that I think
8 in my Testimony and elsewhere. To be
9 clear, be specific and be descriptive
10 when you're talking about PFAS.

11 Next chart.

12 You've heard this from us and
13 you've heard this from Barb:

14 Fluoropolymers are
15 fundamentally different. They meet
16 the criteria of what we call "polymer
17 of low concern," and as Barb said, and
18 you might have missed it, but it's
19 defined as:

20 "Polymer properties
21 predictive of low health and
22 environmental hazard."

23 I'll elaborate more when I do
24 my Rebuttal, but you don't see the
25 word "no" there. These are not

1 "polymers of no concern," they are
2 "polymers of low concern," and that's
3 an important distinction.

4 What you need to do is you need
5 to assess -- which is what we've done,
6 and Barb did with her group in 2018.

7 I did that with my colleagues in
8 2022 -- the world of fluoropolymers
9 against 12, 13 different criteria.

10 What we look at is molecular
11 weight or size.

12 We look at solubility in
13 water.

14 We look at whether the
15 structures are large and stable. Barb
16 was talking about that in terms of
17 degradation either in soil or in air.

18 Are they bioavailable?

19 Are they bioaccumulative?

20 Do they degrade into smaller
21 pieces?

22 Are they precursors, which is
23 a really, really important concept.

24 Environmental mobility concern
25 generally does not apply to

1 fluoropolymers because they are solids
2 and they don't have solubility and
3 they don't have vapor pressure.

4 Now is that an absolute? I
5 can't say it's an absolute, but it's
6 pretty good. It holds pretty good.

7 All right. One of things I
8 want to talk about here, and I'm going
9 to say it again in the Rebuttal in a
10 little bit more detail, but there are
11 2 papers, one by Dr. Henry and her
12 global colleagues in 2018, and another
13 paper in 2022 by myself and 7 other
14 global companies where we talk about
15 "polymers of low concern."

16 These studies combined cover
17 about 96% of the major global
18 fluoropolymers, and include all the
19 properties; residuals, monomers,
20 extractables, and all the fundamental
21 properties.

22 I am going to come back to
23 that because it's really important,
24 because there was a lot of questions
25 yesterday and even today about life

1 cycle.

2 Next chart.

3 There we go; two more charts,
4 this one and the next one.

5 Before I finish with my final
6 2 slides, I want to reiterate that in
7 both of the "polymer concern" papers
8 both 2018 and 2022, that was online,
9 and in 2023 in print. We not only
10 discuss the end of life, which we
11 heard today, the end of life
12 properties of the fluoropolymer life
13 cycle, but we also discuss beginning
14 of life, which is how they are made,
15 and end of life. I'll talk about the
16 life cycle in a few minutes.

17 What do we see as the problems
18 with the proposed Labeling? We've all
19 talked about that for the past four
20 days.

21 "All PFAS have the same
22 properties and the same
23 risk."

24 No, they don't, And a label
25 that covers all of them, which is

1 what's proposed, even though there are
2 exceptions, doesn't make scientific
3 sense in my view, and I am a
4 scientist.

5 The scientific reality is that
6 PFAS vary very significantly.
7 Fluoropolymers differ fundamentally
8 from the very small water soluble PFAS
9 or the PFAAs that Barb talked about
10 this morning.

11 There is growing scientific
12 consensus that PFAS are diverse. As I
13 said earlier, there are different
14 groups that think about these, and I'm
15 not sure we're ever going to get
16 together. We, in good spirit, have
17 spirited discussions and we end up
18 agreeing to disagree.

19 Fluoropolymers -- and you
20 heard this also -- are materially
21 different from other PFAS because of
22 the properties I talked about.

23 NMED's Warning Label approach
24 fails to differentiate amongst the
25 chemicals. It is inconsistent with

1 current scientific understanding, some
2 of which I talked about today. It's
3 not scientific and robust.

4 You know, my question is, and
5 we all have many questions, but I'm
6 still trying to figure out what an
7 Erlenmeyer flask with a "PFAS" symbol
8 in it is really going to do here. I
9 am not a label expert, but I've used
10 many Erlenmeyer flasks in my day with
11 "PFAS" in them. We're going to need
12 to figure out what it really means in
13 the end; not an expert there.

14 Last chart.

15 I'll finish up with the concept
16 we've talked about 3 times already in
17 this. It's important Because there's
18 2 major schools of thought:

19 The premise for treating PFAS
20 the same as one, well, if you take it
21 historically, historic or legacy long-
22 chain, and you substitute it with
23 another PFAS, that's called a
24 "regrettable substitution."

25 "There is a large number

1 of PFAS on the commercial
2 market."

3 Well that's not really true
4 and not conducive to classic risk
5 assessment, and that's one of the
6 reasons why we did our 2021 paper. We
7 wanted to put perspective on how many
8 of these chemicals really there were.

9 The big barrier, my view --
10 and I'm not an Epidemiologist, I'm an
11 Organic Chemist. The big barrier to
12 doing risk assessment is there's too
13 many of them. The answer is no,
14 there's not; that's what we concluded
15 in 2021, but There's still a lot. Can
16 you subgroup them and then do them as
17 a risk assessment? That was our
18 message coming out of that 2021 paper.

19 "The intrinsic property of
20 persistence alone is
21 sufficient justification."

22 That's what the one group
23 thinks.

24 What you also heard Monday or
25 Tuesday is that there's increased

1 probability of adverse effects in
2 human health and the environment if
3 these are put in the environment Even
4 if they are not bioavailable, not
5 soluble, not bioaccumulative, and too
6 big to do anything, but then there is
7 the other side.

8 The other side is persistence
9 is an intrinsic property, but not an
10 intrinsic hazard, and it does not, by
11 itself, imply an adverse effect just
12 because it's persistent. It is not
13 scientifically justified to classify
14 inert solids, salts, liquids, and
15 gases in a single class as 1, where
16 properties like vapor pressure,
17 environmental partitioning, aqueous
18 solubility and hazard itself, as well
19 as surface and material properties
20 vary greatly. Thank you.

21 Q. Thank you, Dr. Korzeniowski.

22 Let me next turn to Rebuttal
23 and ask you a few questions, and then
24 we'll get into your summary.

25 A. All right.

1 Q. Did you review the Direct
2 Written Testimony of NMED's witnesses
3 filed in this matter, particularly
4 Dr. Chapman's, Dr. Olson's, and
5 Dr. Ling's Testimonies?

6 A. I did.

7 Q. Did you also provide written
8 Rebuttal Testimony of these NMED
9 witnesses that was filed in this matter
10 as ACC Exhibit 3?

11 A. I did.

12 Q. Do you have any corrections to
13 your written Rebuttal Testimony?

14 A. They are not corrections, but
15 what I did, and I discussed this with
16 Dal, is I didn't change the headings,
17 I didn't change the references, I just
18 added some more text, so I'm happy to
19 provide a copy of that to the Board
20 and to the group.

21 Q. Okay. Thank you.

22 A. No corrections, it's just,
23 again, the same references; no change
24 in references, no change in context.

25 Q. Do you adopt your written

1 Rebuttal Testimony, then, with those
2 additions, as your own Testimony here
3 today?

4 A. I do.

5 Q. Let's proceed with your
6 summary.

7 For this round, before we
8 begin, I'm going to ask you questions,
9 and when you're done with your answer
10 I'll ask you the next question?

11 A. Please do. Thank you.

12 Q. Thank you.

13 In your opinion, did the
14 Testimony presented by NMED in this
15 proceeding use scientifically precise
16 terminology when referring to PFAS?

17 A. No.

18 The term "PFAS" is an umbrella
19 term encompassing more than 14,000
20 substances, which we just talked about
21 a few minutes ago, as included in
22 databases and lists, but not in
23 commerce, with very diverse chemical,
24 physical, and toxicological properties.

25 To the best of my knowledge

1 only a small subset of substances
2 classified as PFAS are actually in
3 commerce or of commercial relevance.

4 This set of commercially
5 relevant PFAS, as I said a few minutes
6 ago, likely numbers in the hundreds
7 and not tens of thousands, and that's
8 the Buck, et al., as a co-author with
9 Bob and 2 others in 2021.

10 The Department's Testimony
11 appeared to largely rely on data
12 specific to PFAAs, or the per-
13 fluoroalkyl acids, yet framed
14 conclusions as applying to PFAS
15 broadly. That approach does not
16 reflect the scientific distinctions
17 among PFAS subclasses and may create
18 confusion in risk communication.

19 It would be helpful, and in
20 most cases necessary, to be clear,
21 specific, and descriptive when talking
22 about PFAS and which ones are being
23 referred to in each case.

24 As an example is the statement
25 that:

1 "PFAS are persistent and
2 mobile."

3 This is an overgeneralization,
4 as many PFAS are not considered mobile
5 due to their very limited solubility
6 and lack of vapor pressure.

7 Q. Does the scientific evidence
8 presented by NMED support regulating
9 or Labeling all products containing
10 any substance with 1 fully fluorinated
11 carbon atom in the same manner?

12 A. No.

13 A structure-based definition,
14 which is what we're talking about, of
15 PFAS that captures all substances with
16 at least 1 fully fluorinated carbon
17 does not align with hazards, exposure,
18 and risk conclusions presented.

19 Much of the Department's Expert
20 Testimony focused on PFAAs and certain
21 related compounds. Extending those
22 conclusions to all PFAS-containing
23 products is not supported by the
24 scientific data discussed in this
25 proceeding.

1 Q. What types of PFAS substances
2 have been phased out voluntarily or
3 restricted via regulation in the
4 United States?

5 A. I'm going to go off script for
6 just a second:

7 We've heard that PFOA and PFOS
8 are still sort of used and back in the
9 U.S., and we can comment on that at
10 some point.

11 PFOA and PFOS, and closely
12 related substances, have been
13 voluntarily phased out by industry.
14 PFAS and related long-chain PFASs,
15 perfluorosulfonic acids, were phased
16 out by the sole U.S. manufacturer in
17 the early 2000s.

18 And PFOA and its related higher
19 homologues and precursors were phased
20 out through the U.S. EPA 2010/2015
21 PFOA voluntary Stewardship Program.
22 This Program was global in nature and
23 included the 8 major global
24 manufacturers. The Program included
25 both products and plant emissions.

1 The U.S. EPA, however, did
2 grant a few SNUR Exemptions for
3 PFOS-type products to be used until
4 replacements were found. This could
5 be the thinking that PFOS products are
6 still coming back into the United
7 States.

8 It has not been discussed here,
9 but many of these products were used
10 in very specific formulations. Like
11 in the photographic industry,
12 photolithography, the hydraulic fluid
13 in your jets and your aircraft. There
14 were no replacements even in the
15 2000s.

16 EPA provided at least 4 PFOS
17 compound Exemptions, and then the
18 right to manufacture outside the U.S.,
19 so that's like 5 SNURs. That might be
20 the source of...

21 Listen, I don't know whether
22 there's replacements yet; some of
23 these were very difficult to requalify.

24 Some states are regulating
25 products containing intentionally added

1 PFAS by restricting the distribution
2 and selling of such products, and we've
3 talked about this; Maine and Minnesota
4 are 2 examples.

5 Q. How does this apply to
6 international agreements such as the
7 Stockholm Convention on Persistent
8 Organic Pollutants?

9 A. The Stockholm Convention
10 addresses specific non-polymeric PFAS,
11 such as PFOA and PFOS, and other per-
12 fluoroalkyl acids, normally hyperchain
13 links like C9 to C20, or C9 to C21.

14 The Stockholm Convention does
15 not address PFAS as a single
16 undifferentiated class. Its listings
17 reflect evaluations based on the
18 combination of persistence,
19 bioaccumulation, and toxicity rather
20 than a blanket approach to all PFAS.

21 Q. Why is this distinction
22 important for accurately characterizing
23 the current Proposed Rule by the
24 Department?

25 A. Suggesting that PFAS broadly

1 have been phased out or restricted
2 implies a scientific and regulatory
3 consensus that all PFAS present
4 comparable risk.

5 In reality most regulatory
6 actions have been narrowly focused on
7 specific non-polymeric PFAS based on
8 substance-specific evidence.

9 It should be noted that the New
10 Mexico Legislature itself determined
11 that certain classes of PFAS, such as
12 fluoropolymers that are solids at
13 standard temperature and pressure, do
14 not present risk warning regulation,
15 and NMED appropriately recognized that
16 implementing Legislative judgment in
17 the Proposed Rule.

18 It is important that the record
19 and supporting Testimony accurately
20 characterize those substances and not
21 conflate them with PFAS classes that
22 the Legislature expressly chose to
23 treat differently.

24 Q. I'm going to move on to
25 Labeling requirements now.

1 A. Sure.

2 Q. Would Labeling all PFAS-
3 containing products in the same manner
4 accurately reflect differences in
5 hazard, exposure, and potential risk?

6 A. No.

7 PFAS encompasses substances
8 with significantly different chemical,
9 physical, and toxicological properties
10 that inform their uses and potential
11 exposure and risk profiles. Applying
12 a single uniform warning, like an
13 Erlenmeyer flask with "PFAS" embedded
14 in the middle implies comparable risk
15 across all PFAS, which is not supported
16 by the scientific distinctions
17 discussed in this proceeding.

18 Q. How does that concern, then,
19 apply to fluoropolymers?

20 A. Recognizing the diversity of
21 physical and chemical properties within
22 the PFAS family of chemistries is
23 critical for understanding whether a
24 particular PFAS, or subgroup of PFAS,
25 might be of potential concern to human

1 health or the environment.

2 Fluoropolymers do have a
3 markedly different physical and
4 toxicological characteristics compared
5 to non-polymeric PFAS, such as PFOA or
6 PFOS, even versus what you heard talked
7 about this morning; these side-chain
8 fluorinated polymers.

9 A general statement or
10 pronouncement that, as a whole, PFAS
11 are bioaccumulative, persistent, and
12 mobile is simply incorrect and
13 misleading.

14 In addition, 2 recently peer-
15 reviewed publications that we talked
16 about a few minutes ago -- 1 in 2018
17 by Dr. Barb Henry and her colleagues
18 at Gore, and the other in 2022 online,
19 and 2023 in print by myself and
20 members of 7 global fluorocarbon
21 manufacturers -- made a compelling
22 case that fluoropolymers have a unique
23 set of properties that set them apart
24 from the other PFAS.

25 From one of the witness

1 statements and Testimony on Monday, to
2 label these important publication as
3 tainted or conflicted because industry
4 did them is a clear mischaracterization
5 of the compelling analytical testing
6 and toxicological data presented in
7 these publications.

8 Another generalization noting
9 that fluoropolymers in use or in life
10 are not safe is directly contrary to
11 what is published in the 2 journal
12 articles cited above.

13 Directly contrary to what you
14 have read in Exhibit 71 and heard on
15 Monday in Testimony, fluoropolymer
16 manufacturers have recognized that
17 there are potential emissions of
18 fluorinated species across the complete
19 life cycle, manufacturing, which is
20 beginning of life; end use or end
21 life; and end of life disposal. That
22 can be recycled; that can be
23 incineration.

24 There are no disingenuous
25 claims about no emissions and no

1 claims about polymers of no versus low
2 concern.

3 For example, the fluoropolymer
4 manufacturing group in Europe called
5 FPG have created and are executing a
6 Manufacturing Emissions Reduction
7 Program with defined goals.

8 You have also heard a fair
9 amount of talk about the use of
10 fluorinated polymerization aids. You
11 heard that this morning, FPAs. They
12 are no longer in use. These particular
13 ones are generally no longer in use,
14 not by at least the Stewardship
15 companies. Some companies have
16 replaced them with short-chain, and
17 you heard that this morning also.

18 What is more important,
19 though, about that is that the
20 fluoropolymer industry has been
21 working for years to eliminate the use
22 of these fluorinated polymerization
23 aids, and as of 2022 -- I don't have
24 new data -- when we published our
25 paper, about 55% of those FPAs have

1 already been eliminated from use in
2 manufacture; I don't know whether it's
3 70 today or 75. I don't know what the
4 percentage is, but it's clear the
5 industry understands there is potential
6 emissions and is doing what it needs
7 to do to eliminate them.

8 As far as end of life -- you
9 heard about it this morning also --
10 there have been several incineration
11 studies since 2019 with several more
12 in the works. Many of these studies
13 show, as Barb said, several '9s
14 destruction -- I think she said
15 99.9999%, something like that -- of
16 the fluoropolymer and what they call
17 PICs, or "Products of Incomplete
18 Combustion."

19 The studies that have been
20 done recently are done in commercial-
21 waste-to-energy plants, and they are
22 getting several '9s destruction.

23 Now can you get incomplete
24 destruction in PICs, if you do
25 backyard burning, which is illegal,

1 sure you can. If you do the
2 destruction and incineration in a
3 regulated facility, and that facility
4 is operating properly, the potential
5 for emissions is extremely low. I
6 can't say it's zero, but extremely
7 low, and many other studies are going
8 on at the moment.

9 In 2018 and 2022 papers that we
10 have talked about as conflicted covered
11 96% of the global fluoropolymer market
12 in terms of polymer types, 18 major
13 types of fluoropolymers. If one
14 actually reads these 2 papers, the
15 actual assessment data and criteria as
16 described in excruciating detail either
17 in the paper or the supplementary
18 information, it is clear that there is
19 complete life cycle discussion
20 particularly in the 2022 paper.

21 The "Conflict" designation,
22 which we've heard a few times in the
23 Testimony, appears to arise because,
24 like myself no longer, but I was an
25 industry guy. That "Conflict" means

1 that the work we were doing wasn't good
2 and wasn't genuine, but the fact of
3 the matter is that these authors,
4 including myself, we have to sign a
5 Conflict of Interest or a Disclaimer
6 Statement from the journal or we can't
7 publish the paper; it's a requirement.

8 Does the fact that we signed
9 Disclaimers and Conflict statements,
10 does that mean that there is something
11 wrong? No, it raises no flags; it's
12 required. You see that in all major
13 journals, and I've always had to sign
14 a Disclaimer.

15 A uniform one-size-fits-all
16 warning could mislead consumers into
17 believing that all of these materials
18 pose similar risks, which is not
19 consistent with the available
20 scientific evidence as described above
21 and elsewhere.

22 Q. Dr. K, my final question is
23 how does that concern apply to other
24 Exemptions in the Statute?

25 A. The same concern about

1 misleading consumers applies to blanket
2 Labeling of the other exceptions listed
3 in the Statute.

4 PFAS are not monolithic in
5 their properties and uses. Many of
6 the exempted applications involving
7 highly technical market materials are
8 critical in the industry to serve as
9 the underpinning for modern life in
10 numerous contexts such as:

11 Healthcare;
12 Energy systems;
13 Transportation;
14 Electronics; and,
15 Other infrastructure. These
16 substances are essential to:
17 Safety;
18 Durability; and,
19 Performance.

20 Viable alternatives are not
21 reasonably available without
22 compromising function or introducing
23 other risks.

24 Applying a uniform label to
25 these categories would:

1 Obscure these distinctions;
2 Potentially confuse consumers;
3 and,
4 Fail to reflect the careful
5 policy judgments already embedded in
6 the statutory Exemptions.

7 Due to these concerns the
8 American Chemistry Council is proposing
9 to exclude the proposed Exemptions in
10 Section 20.13.2.10 from the Labeling
11 requirements.

12 Q. I believe that concludes your
13 Testimony.

14 A. It does.

15 MR. TRUJILLO: Madam Hearing
16 Officer, we offer Dr. K up for
17 questioning.

18 HEARING OFFICER ORTH: All
19 right. Thank you very much,
20 Mr. Trujillo.

21 Ms. Fiebig, do you have
22 questions of Dr. K?

23 MS. FIEBIG: Just a couple.
24 Thank you.

25 ///

1 CROSS-EXAMINATION

2 BY MS. FIEBIG:

3 Q. Dr. K, you've been present in
4 the hearing room for the duration of
5 these proceedings.

6 A. Monday I was actually online.
7 But yes, I've been here every day, yes.

8 Q. You've been observing how
9 things have gone.

10 A. I have, yes.

11 Q. I wanted to ask you a couple
12 of questions about some of the
13 information that we've learned over
14 the course of the week:

15 In your report, or in your
16 Written Testimony, and as you've
17 described today, you've highlighted
18 the relatively safe nature of
19 fluoropolymers as a subclass of PFAS
20 chemicals; right?

21 A. I have, and Barb has also. We
22 both have, yes.

23 Q. Right, due in large part to
24 they don't really bioaccumulate, they
25 are not soluble in water, those sorts

1 of characteristics.

2 A. Understood, yes.

3 Q. We've also seen some concern
4 raised over the course of the week by
5 different witnesses about, you know,
6 learning information later on about
7 risks. You know, science is such that
8 it evolves. Sometimes we learn later
9 there are risks associated with
10 products that we didn't appreciate
11 earlier.

12 With that context I wanted to
13 ask you if there are any fluoropolymers
14 that have a lengthy history of safe use.

15 A. Well I think I'm going to agree
16 with Barb; I'm not going to use the
17 same, when I was 18, I thought I knew
18 everything. I'm not going to use the
19 same language she did.

20 Barb should have done herself
21 justice. Her and her Gore colleagues
22 published a paper in 2018. This was
23 the first of the 2 "Polymers of Low
24 Concern" studies, but what Barb didn't
25 mention, but is a good example, is

1 these fluoropolymers, particularly
2 PTFE and things like PTFE, have been
3 used in body for 40-, 50 years as
4 implants and so on.

5 The significant amount of data
6 that Barb put in that paper, as well
7 as all the requirements that
8 fluoropolymers need to be used in the
9 body is a pretty good example of a 40-
10 or 50-year history of safe
11 fluoropolymer use.

12 PTFE is the largest, by the
13 way, about 50% or 65% of the global
14 fluoropolymer use. If we're looking
15 at the majority of the fluoropolymers,
16 and there is various PTFE grades, as
17 Barb talked about, but that's a really
18 good example of in your body and being
19 safe.

20 Q. Are there any other examples
21 of PFAS substances, fluoropolymer or
22 otherwise, that have a long history of
23 safe use?

24 A. Well I think, you know, one of
25 the things that I did as part of my

1 work with T.J. and his colleagues at
2 ACC is, you know, you've heard about
3 doing your own regulatory Rulemaking
4 process here, but Europe has been very
5 active in this area.

6 One of the things that we
7 needed to do was to provide
8 substantiation of the safety and use
9 and utility of fluoropolymers in
10 commerce. One of the things we
11 heard -- I'm thinking it was Monday or
12 Tuesday -- was from the coatings
13 industry where he was talking about
14 how it would impact coatings.

15 Most people don't appreciate
16 the value of fluoropolymers in coatings
17 and not necessarily in body, but in
18 the external world as an example.

19 There is PBDF, which is a
20 fluoropolymer. There is the Lumiflon
21 fluoropolymer, and these are used in
22 solar panels, building panels, bridges
23 and things like that. Without these
24 materials, as an example, you would
25 see your bridges full of scaffolding.

1 They would have to replace and repair
2 every 5 to 7 years. If you use the
3 fluoropolymers like the Lumiflon or
4 PBDF in solar panels, you're 50- to
5 100-year replacement. They not only
6 work, but they are very effective in
7 what they do.

8 These products are used in
9 sunlight and weather and saltwater,
10 and they function perfectly fine, so
11 it is a good example of how tough they
12 are as an example.

13 Q. My last question:

14 In your Written Testimony, you
15 had referred to the proposal that the
16 Erlenmeyer flask be added. We've been
17 characterizing that as sort of a
18 Warning Label. I think we have heard
19 some evidence this week to suggest
20 that the Department is contending that
21 it's really just intended to be
22 informative and not a warning. I
23 wanted to hear your reaction to that.

24 A. Well I'm going to start off
25 first by saying I've got great respect

1 for what you're doing, and I don't
2 disagree that labels can have
3 significant importance.

4 I also don't disagree with the
5 fact that Labeling and informing
6 consumers is a really good thing to
7 do; I have no issue with that. I
8 think to the extent that you can
9 educate the consumers on a subject
10 like this is really important.

11 I mean I've been in this a long
12 time, so I've been involved in the ups
13 and downs for all these years and seen
14 all that's gone on in the company I
15 worked for. It is important to
16 educate, and we are learning new
17 things.

18 The question for this label is
19 what is it going to do, particularly
20 an Erlenmeyer flask? I made a model
21 for my cell phone, but it was blue, or
22 about what color your water is. My
23 water was blue. But does it have the
24 appropriate impact on a set of
25 chemistries that are, by the

1 literature that we see and literature
2 that we're adding every day with
3 properties, hazards, exposure, which
4 is largely completely different than
5 the other PFAS.

6 That's what I was concerned
7 about. Is that label going to have
8 benefit to consumer products when
9 there is no real exposure in most
10 cases?

11 The risk of that exposure,
12 given what I'll cautiously say is the
13 potential inertness of fluoropolymers,
14 that inertness also has a graduated
15 meaning, but I'm not sure it's
16 appropriate.

17 That's my thoughts. Nothing
18 against the Labeling, and noting that
19 it might not have a benefit for other
20 consumer products who want to know
21 what's in their products, and I think
22 it's a good idea. The question is
23 where is that label applied?

24 Q. Do you think it's likely to be
25 perceived as a warning?

1 A. Well --

2 MR. ROSEBROUGH: Madam Hearing
3 Officer, I object to the question; he
4 stated he is not an expert on Labeling.

5 HEARING OFFICER ORTH: Can you
6 rephrase this question, Ms. Fiebig.

7 MS. FIEBIG: I will. I was
8 just -- he had referred to it as a
9 "warning" in his papers, and so I just
10 wanted to see if he still perceives it
11 as potentially sending that message.

12 HEARING OFFICER ORTH: I
13 happen to remember that actually.

14 THE WITNESS: When I see a
15 label I try to figure out what it
16 means. Normally when I see a label,
17 it's on products, and it's usually a
18 warning. It's implying some risk. It
19 often will prompt you to go look,
20 especially if you don't know what the
21 label means.

22 If there is an explanation with
23 the label, then you don't have to go
24 look any further. But with an
25 Erlenmeyer flask with "PFAS" in the

1 middle, if I weren't doing this for a
2 living I'd be scratching my head.

3 The idea is it might prompt
4 consumers to go look, and if that's
5 what it does, that's probably a good
6 thing, but it is a Warning Label in
7 some form.

8 MS. FIEBIG: Thank you.

9 HEARING OFFICER ORTH: All
10 right. We are 6 minutes before noon,
11 so rather than proceeding to the next
12 examiner, let's take our lunch break.
13 We will return at 1:00 for Public
14 Comment.

15 Sir, as soon as the Public
16 Comment is over we will go back to
17 you. Thank you.

18 (The Evidentiary Hearing
19 recessed from 11:54 a.m. to 1:00 p.m.)

20 HEARING OFFICER ORTH: Good
21 afternoon. Let's come back from the
22 lunch break.

23 We are at Day 4 of the hearing
24 in EIB 25-61, the Per- and Poly-
25 Fluoroalkyl Rulemaking. We've reached

1 our fourth Public Comment session.

2 I have at least 3 names here
3 to call on, and I'll issue a general
4 invitation.

5 Just a few things about Public
6 Comment:

7 The hearing is being recorded
8 and transcribed in its entirety by
9 David Lee of Cumbre Reporters, so he
10 will be trying to capture your words.

11 The hearing is also being
12 interpreted between English and
13 Spanish and Spanish and English, so we
14 also have Interpreters trying to catch
15 your words, so I would just ask you to
16 speak slowly and clearly.

17 Ms. O'Grady, would you please
18 tell people how to find the
19 interpretation.

20 MS. O'GRADY: Madam Hearing
21 Officer, clarification:

22 Do you want me to explain for
23 the afternoon session how to find the
24 channels again, or just for the Public
25 Comment?

1 HEARING OFFICER ORTH: For the
2 Public Comment.

3 MS. O'GRADY: Thank you.

4 (Speaking Spanish.)

5 If there is anybody present in
6 this hearing room that would also like
7 to offer Public Comment, would you
8 please let us know, and that way we
9 can be ready when you're ready. Thank
10 you.

11 HEARING OFFICER ORTH: Thank
12 you, Ms. O'Grady.

13 Just 2 more things:

14 One, I'll ask you to Comment
15 just once. You can submit as much
16 written Public Comment as you'd like,
17 But I'll ask you to keep your oral
18 Comments to 3 minutes;

19 I will ask you to spell your
20 first and last name; and,

21 Pursuant to the Board rules
22 I'll ask if you swear or affirm to
23 tell the truth.

24 We'll start with
25 Mr. Meiklejohn.

1 Mr. Meiklejohn, if you'd come
2 up to this lighted microphone at the
3 front of the room.

4 MR. DOUGLAS MEIKLEJOHN: Thank
5 you, Madam Hearing Officer.

6 HEARING OFFICER ORTH: Would
7 you spell your first and last name,
8 please.

9 MR. DOUGLAS MEIKLEJOHN: Yes,
10 certainly.

11 The first name is Douglas,
12 D-O-U-G-L-A-S; last name is
13 Meiklejohn, M- as in Mary,
14 E-I-K-L-E-J-O-H-N. That's all one
15 word.

16 HEARING OFFICER ORTH: All
17 right. Thank you.

18 Do you swear or affirm to tell
19 the truth.

20 MR. DOUGLAS MEIKLEJOHN: Yes.

21 HEARING OFFICER ORTH: I'll
22 start your time.

23 MR. DOUGLAS MEIKLEJOHN: Thank
24 you, Madam Hearing Officer, Board
25 Members:

1 As I said, my name is Douglas
2 Meiklejohn. I'm an Attorney, and I
3 work on water quality issues for
4 Conservation Voters New Mexico.

5 Conservation Voters applauds
6 the Environment Department and the
7 Environmental Improvement Board for
8 addressing the proliferation of
9 PFAS -- pardon me, I can't pronounce
10 the full name of that -- and the
11 pollution that they cause,
12 particularly pollution of water, and
13 especially pollution of groundwater,
14 which, as you know, is the source of
15 drinking water for many people in New
16 Mexico.

17 Conservation Voters has some
18 concern about some of the Exemptions
19 that are in the proposed regulations.
20 We recognize that some of those
21 Exemptions are not discretionary; that
22 is, they are required by the Statute
23 passed by the Legislature or required
24 by the preemptive effect of federal
25 law.

1 On the other hand, some of the
2 Exemptions are discretionary with the
3 Board and possibly also the Department.
4 They are generally classified as
5 Currently Unavoidable Use.

6 Conservation Voters urges that
7 because of the problems that PFAS have
8 caused in the environment, that those
9 and any other discretionary Exemptions
10 be construed and applied as narrowly
11 as possible.

12 Finally, as an Attorney who
13 spent several decades litigating for
14 protection of communities and the
15 environment, I personally am gratified
16 to see the meaningful enforcement
17 provisions that were enacted by the
18 Legislature included in the proposed
19 regulations. Thank you very much.

20 HEARING OFFICER ORTH: Thank
21 you, Mr. Meiklejohn.

22 Is there anyone else in the
23 room here to offer Public Comment? I
24 know we have a few folks online.

25 No. All right.

1 Let's turn to Lindsey "Hueer"
2 or "Hueer." If I'm mispronouncing
3 your name, please just let me know.

4 MS. LINDSEY HUEER: No
5 worries.

6 Good afternoon; I'll spell my
7 name.

8 HEARING OFFICER ORTH: Thank
9 you.

10 MS. LINDSEY HUEER: It is
11 L-I-N-D-S-E-Y, and my last name is
12 H-U-E-E-R.

13 HEARING OFFICER ORTH: Do you
14 swear or affirm to tell the truth?

15 MS. LINDSEY HUEER: Yes, I do.

16 HEARING OFFICER ORTH: Thank
17 you. I'll start your time.

18 MS. LINDSEY HUEER: Thank you.

19 Good afternoon, Madam Hearing
20 Officer and Members of the Board:

21 Again, my name is Lindsey Hueer
22 and I'm with The Toy Association. The
23 Toy Association represents more than
24 800 businesses, some inventors,
25 designers, manufacturers, and

1 retailers, all committed to bringing
2 safe, fun, educational toys to
3 children.

4 In New Mexico specifically the
5 toy sector generates \$238 million in
6 annual economic impact. We're deeply
7 invested in ensuring that children and
8 families in the state continue to have
9 access to safe and affordable play.

10 We share many of the concerns
11 expressed by other associations, but
12 for my public comments today I want to
13 focus specifically on concerns related
14 to toys.

15 Toy safety and environmental
16 stewardship are core values of our
17 industry. PFAS is found only in a
18 small percentage of toys, primarily in
19 internal electronic components. In
20 those cases the materials serve
21 critical fire prevention and heat
22 resistant functions. We don't want
23 Kids' toys to catch fire due to
24 overheating.

25 The components are fully

1 enclosed, inaccessible to children
2 during play, and present no risk of
3 exposure to the child or the
4 caregiver.

5 Additionally, there is no
6 suitable alternative yet available to
7 ensure safety of these products.

8 The products are expressly
9 exempted from the ban in Senate Bill
10 212, but they would fall under the
11 Labeling and reporting requirements in
12 the Proposed Rule.

13 For toys, a mandate to label
14 these products doesn't empower
15 consumer choice over non-exposure. On
16 the contrary, requiring a Warning
17 Label on a product that presents no
18 exposure risk would mislead consumers
19 into believing that a toy poses a
20 danger when it does not, undermining
21 consumer confidence in safe products.

22 As a Mom myself, I know that a
23 Warning Label should be a meaningful
24 notice of a bona fide toxic risk,
25 which is not the case with toys.

1 Over-Labeling will lead consumers to
2 not knowing the actual risk presence
3 and leading to consumer fatigue for
4 the label itself.

5 We think that the goals of
6 Senate Bill 212 can be met with a few
7 changes. We submitted comments, but
8 again, for today's Public Comment, I
9 want to focus on a couple of
10 toy-specific items:

11 First, while we appreciate
12 that there has been a label Exemption
13 process in the proposed rules, we ask
14 to outright exempt Labeling
15 requirements where the PFAS in a toy
16 is fully enclosed and inaccessible in
17 those electronic component. A label
18 is inappropriate for these products
19 and should not be required to go
20 through a recurring waiver process.

21 Second is having practical
22 label standards for small toys and
23 packaging. As we all know toys can be
24 incredibly small, and requiring larger
25 packaging to accommodate a label

1 actually is worse for the environment.

2 Last, toy manufacturers are

3 continually introducing new products.

4 We would like to see streamlined

5 reporting requirements at the product

6 category level rather than SKU by SKU

7 with the fees applying per manufacturer,

8 not per product.

9 I appreciate your

10 consideration of these issues and for

11 the opportunity to provide comment

12 today.

13 HEARING OFFICER ORTH: Thank

14 you, Ms. Hueer.

15 We go now to Mr. Parkhomenko,

16 Konstantin Parkhomenko.

17 MR. KONSTANTIN PARKHOMENKO:

18 Can you hear me? I will spell my

19 name.

20 HEARING OFFICER ORTH: Thank

21 you.

22 MR. KONSTANTIN PARKHOMENKO:

23 K-O-N-S-T-A-N-T-I-N, Konstantin;

24 Parkhomenko is P-A-R-K-H-O-M-E-N-K-O.

25 HEARING OFFICER ORTH: Thank

1 you. Do you swear or affirm to tell
2 the truth?

3 MR. KONSTANTIN PARKHOMENKO: I
4 do.

5 HEARING OFFICER ORTH: Thanks.
6 I'll start your time.

7 MR. KONSTANTIN PARKHOMENKO:
8 Thank you. Madam Hearing Officer,
9 esteemed members of the Board:

10 My name is Konstantin
11 Parkhomenko. I am an Environmental
12 Attorney for the Sandia National
13 Laboratories complex.

14 You may be asking yourselves,
15 you know, if this is about protecting
16 consumers, why is a National
17 Laboratory Attorney giving Public
18 Comment here?

19 Well as we all understand very
20 well, the devil is really in the
21 details in these kind of rules. We
22 have some concerns about potentially
23 an overbroad, potentially an
24 unintentionally overbroad definition
25 of "consumer" that will rope in

1 organizations such as ours, which are
2 really very sophisticated laboratories
3 who really know what they are doing in
4 the industry and understand the
5 chemicals they are working with, and
6 engaged in very important and sometimes
7 classified work for the good of the
8 nation. E are concerned about
9 potentially overbroad rules that might
10 impact the mission.

11 I do have some more specific
12 comments, and they are a little bit
13 technical, so please bear with me:

14 So we all know the Act defines
15 "consumer product"; right?

16 "'Consumer Product' means
17 tangible personal property
18 that's distributed in
19 commerce, normally used for
20 personal, family, or household
21 use, including product
22 categories that are normally
23 used in households," so on
24 and so forth.

25 We are aware of that

1 definition. We are also aware of the
2 definition of "product," which,
3 strictly speaking, is:

4 "An item created, produced,
5 assembled, packaged, or
6 otherwise prepared for sale
7 to a consumer," and it goes
8 on.

9 The Rule proposes to define
10 "consumer" in a very broad way as:

11 "An individual,
12 partnership, corporation,
13 state agency, or subdivision
14 of a state who seeks or
15 acquires to purchase or lease
16 any goods or services."

17 My comment, my supplemental
18 comment, and I did submit written
19 comments, which I do encourage
20 everybody to review. My supplemental
21 comment deals with the fact that I
22 think the definition of the term
23 "consumer" really should be defined in
24 a way that's compatible with the
25 definition of "consumer product" in

1 the Act such that we don't get
2 overbroad with the definition and rope
3 in unintentional parties that really
4 weren't ever meant to be within that
5 scope.

6 As to Labeling, the Board may
7 adopt rules to carry out the provisions
8 of the Per-Fluoroalkyl Substances Act,
9 including the requirement of Labeling
10 products in English and Spanish. This
11 appears to allow the Labeling of
12 products as defined by the Act, but
13 the Act really only concerns products
14 sold to a consumer.

15 Organizations such as the
16 National Laboratories, we are never
17 really meant to be "consumers" within
18 that scope of the Act. Therefore, I
19 would encourage this body to adopt a
20 suitably broad exception that will
21 exclude or clarify the definition of
22 "consumer" in a way that really makes
23 it clear that it doesn't apply to
24 entities such as ours.

25 HEARING OFFICER ORTH: Thank

1 you, Mr. Parkhomenko.

2 MR. KONSTANTIN PARKHOMENKO:

3 Thank you. I will submit written
4 comments as well.

5 HEARING OFFICER ORTH: Sir, a
6 Board Member has a question.

7 Chair Ely.

8 CHAIR ELY: Thank you for your
9 comments this afternoon. I'm just
10 wondering if your comments are
11 comments from the lab, or are they
12 your own personal comments? Thank
13 you.

14 MR. KONSTANTIN PARKHOMENKO:
15 Yes, my comments today do represent
16 the position of the Sandia National
17 Laboratories.

18 HEARING OFFICER ORTH: Thank
19 you very much.

20 Let's see. Next we have Bill
21 Rodgers.

22 There you are.

23 Are you unmuted?

24 Mr. Rodgers.

25 Okay. We'll wait a minute.

1 MR. BILL RODGERS: How's that?

2 HEARING OFFICER ORTH: Much
3 better, sir.

4 If you would spell your first
5 and last name, please.

6 MR. BILL RODGERS: Yes, my
7 name is Bill Rodgers. That's "B" as
8 in boy, I-L-L; R-O-D as in dog,
9 G-E-R-S.

10 HEARING OFFICER ORTH: Do you
11 swear or affirm to tell the truth?

12 MR. BILL RODGERS: I do.

13 HEARING OFFICER ORTH: I'll
14 start your time.

15 MR. BILL RODGERS: Good
16 afternoon, Members of the Environmental
17 Improvement Board and Hearing Officer:

18 My name is Bill Rodgers and I
19 live in La Cieneguilla. My Wife and I
20 bought our home in 2016 and learned in
21 2025 that we live within a massive
22 groundwater plume of PFAS chemicals.
23 Tests of our water told us that we
24 have 4 times the level of PFAS that
25 the EPA deems safe.



1 I reported on this for
2 5050MATIC, and my neighbors talk to me
3 about it almost every time they see me
4 because they, like me, are afraid what
5 this means for themselves and their
6 families.

7 Though we are getting a filter
8 system through the State, we have
9 unknowingly drank, ate, and bathed in
10 dangerous cancer-causing chemicals for
11 almost 10 years. I cannot describe
12 the terror we have lived with since
13 getting these results.

14 I don't want people like
15 ourselves to have to navigate this
16 issue on their own. This issue is so
17 esoteric that even my doctor didn't
18 know what to advise when I told her I
19 was exposed to these chemicals.

20 No one should have to live
21 with this fear. No one should suffer
22 fatal health consequences because of
23 the companies who have exposed us to
24 these chemicals and hid information
25 about how harmful they are.

1 I am grateful to see our state
2 working to address these issues. The
3 prohibition of some PFAS and Labeling
4 are good first steps, but New Mexico
5 is offering polluters loopholes that
6 would limit the benefit people could
7 get from these rules. That would be
8 unacceptable to people like myself who
9 cannot do something as simple as drink
10 a glass of water from their tap.

11 We need to ban all PFAS for
12 all the harms from its production,
13 use, and disposal. I hope that this
14 task force approved in this Legislative
15 session will make sure we are truly
16 and fully safe.

17 Please help us. Approve this
18 Rule, but make it stronger by closing
19 any Labeling loopholes and give New
20 Mexicans greater safety, safety that
21 industry and malfeasance has so far
22 kept from us. Thank you.

23 HEARING OFFICER ORTH: Thank
24 you, Mr. Rodgers.

25 Let me ask if there is anyone

1 else on the platform who would like to
2 offer Public Comment in this Public
3 Comment session, which is very likely
4 our final oral comment session.

5 I see Mr. Holm. John Holm.

6 Can you unmute yourself?

7 Pam or Luis, please...

8 I think you should be able to
9 unmute now.

10 MR. JOHN HOLM: Thank you.

11 Hi, my name is John Holm.

12 HEARING OFFICER ORTH: You're
13 going to have to speak much closer to
14 your microphone.

15 MR. JOHN HOLM: I'm so sorry.

16 Can you hear me now? John Holm.

17 HEARING OFFICER ORTH: Yes,
18 thank you.

19 Spell your first and last
20 name, please.

21 MR. JOHN HOLM: Sure. John,
22 J-O-H-N; last name Holm, H-O-L-M.

23 HEARING OFFICER ORTH: Do you
24 swear or affirm to tell the truth?

25 MR. JOHN HOLM: I do swear to

1 tell the truth.

2 HEARING OFFICER ORTH: Thank
3 you. I'll start your time.

4 MR. JOHN HOLM: Hi. My name
5 is John Holm, and I reside in
6 Washington, D.C. I'm speaking on
7 behalf of my organization, the
8 Circular Supply Chain Coalition, and a
9 lot of the work that we're doing, both
10 in New Mexico and broadly across the
11 United States and the globe.

12 I'm providing this comment
13 today in strong support of the New
14 Mexico Environment Department's
15 Proposed Rule which implements the
16 PFAS protocol. I urge the Board to
17 adopt the Environmental Department's
18 Rule as proposed.

19 Specifically, a lot of the work
20 that we're focusing on is around
21 leveraging urban mining, leveraging
22 material reuse. When we look at PFAS
23 in the space of materials and look at
24 the landscape for materials, PFAS are
25 known to be harmful; harming local

1 communities of which we're operating
2 in, harming the drinking waters of
3 which is ubiquitous across the United
4 States and across the globe.

5 New Mexico's way of looking
6 and dealing with this within this Rule
7 really provides clear context about
8 how to be proactive about dealing with
9 the PFAS solution by leveraging the
10 power to design out PFAS's from
11 inception and bring in materials that
12 consumers can use that will not have
13 this component in it that is harming
14 and causing so much environmental and
15 human harm.

16 Moving forward, I would really
17 like to say that I thank the
18 Environment Department for drafting
19 such a strong and protective Rule.

20 Thank you to the Board and
21 Hearing Officer for your time and
22 commitment to protect New Mexicans and
23 leveraging this as a model that can
24 potentially be lifted across the other
25 48 states that do not have this type

1 of proposal. I strongly urge you to
2 adopt the Environment Department's
3 Rule. Thank you.

4 HEARING OFFICER ORTH: Thank
5 you very much, Mr. Holm.

6 Elena F.

7 MS. ELENA FERNANDEZ: Thank
8 you. My name is Elena Fernandez. I
9 am a Project Specialist for Amigos
10 Bravos.

11 HEARING OFFICER ORTH: Hold on
12 please.

13 If you would spell your first
14 and last name.

15 MS. ELENA FERNANDEZ: My
16 apologies; Elena, E-L-E-N-A, last name
17 Fernandez, F-E-R-N-A-N-D-E-Z.

18 HEARING OFFICER ORTH: Thank
19 you.

20 Do you swear or affirm to tell
21 the truth.

22 MS. ELENA FERNANDEZ: Yes, I
23 do.

24 HEARING OFFICER ORTH: I'll
25 start your time.

1 MS. ELENA FERNANDEZ: Thank
2 you.

3 Again, my name is Elena
4 Fernandez. I am a Project Specialist
5 with Amigos Bravos. Amigos Bravos
6 serves the entire State of New Mexico
7 for water quality, protection, and
8 restoration.

9 One of my projects is concerned
10 with toxic pollutants across the State.
11 I have worked closely with the
12 Environment Department and communities
13 that are impacted by toxic pollutants.

14 PFAS doesn't cause just
15 physical harm, it causes mental harm
16 or psychological fear from the unknown.
17 I'm asking that the Environmental
18 Improvement Board please adopt the
19 PFAS Substances Consumer Protection
20 Act.

21 New Mexico should adopt this
22 Act to protect the health and well-
23 being of New Mexicans and our State
24 from the harms from intentionally
25 added PFAS in our consumer products,

1 which provide only minor convenience
2 when compared to the very real dangers
3 to ourselves and the State.

4 The choice to reject this Act
5 will have big consequences for New
6 Mexicans' long-term health, negative
7 impacts to medical treatment, and
8 affordability from diseases related to
9 long and constant exposure to PFAS, as
10 well as the constant remediation of
11 waters, lands, and agricultural.

12 Essentially, all New Mexicans
13 and our State's well-being will be
14 negatively affected by continued PFAS
15 pollution and prolonged exposure.
16 Please choose New Mexicans and choose
17 New Mexico to be a leader against PFAS
18 pollution.

19 Lastly, Labeling provides New
20 Mexicans information such that they can
21 make informed personal independent
22 choices and decisions as to which
23 products they deem safe or appropriate
24 for their everyday use and livelihood.

25 Transparency is not punishment

1 or blame, it is the right thing to do.
2 Industry is good at adapting to
3 business needs, and doing the right
4 thing by consumers would be a positive
5 change.

6 I thank you for your time, and
7 I send my thoughts to the people of La
8 Cieneguilla who have been impacted by
9 the groundwater pollution. Thank you.

10 HEARING OFFICER ORTH: Thank
11 you, Ms. Fernandez.

12 Member Curry, do you have your
13 hand raised?

14 BOARD MEMBER CURRY: I do,
15 Madam Hearing Officer. I just wanted
16 to follow up on Chairman Ely's
17 question from the gentleman from
18 Sandia. He said he had a written
19 statement, and I was just curious if
20 he is still on the line or if we've
21 got it.

22 Does the written statement
23 also reflect the position of Sandia
24 Labs?

25 HEARING OFFICER ORTH: Let's

1 see.

2 Mr. Parkhomenko, are you still
3 on the platform?

4 MR. KONSTANTIN PARKHOMENKO:

5 Hello. Can you hear me?

6 HEARING OFFICER ORTH: Yes,
7 hello.

8 MR. KONSTANTIN PARKHOMENKO:

9 Yes, I'm still on the platform.

10 It is on our letterhead, so it
11 should reflect that. There will also
12 be a supplemental set of Public
13 Comments, which will also be on
14 official letterhead and it will also
15 state that it's our official position.

16 BOARD MEMBER CURRY: Thank
17 you.

18 MR. KONSTANTIN PARKHOMENKO:

19 Thank you.

20 HEARING OFFICER ORTH: Thank
21 you, Member Curry, and thank you
22 Mr. Parkhomenko.

23 Is there anyone else on the
24 platform here in what, I believe, will
25 be our final oral Public Comment

1 session?

2 I see no hands. I don't see
3 that anyone has joined us, and no in
4 the room.

5 I think we'll return to the
6 Technical Case. Please know if you
7 are aware of someone who would like to
8 offer Public Comment for this
9 Rulemaking, written Public Comment may
10 still be submitted here for several
11 days more.

12 All right. Let's see. Dr. K,
13 would you rejoin us at the front of
14 the room?

15 Thank you very much. Good
16 afternoon.

17 Let's see, Mr. Smithkier.

18 All right. Mr. Knight.

19 MR. KNIGHT: Thank you.

20

21 CROSS-EXAMINATION

22 BY MR. KNIGHT:

23 Q. Dr. Korzeniowski, I take it
24 from your Testimony, and I think you
25 may have stated this, that you consider

1 yourself to be an expert on PFAS. Is
2 that correct?

3 A. I don't think anybody can be
4 an expert on all PFAS, but certainly
5 I'm a Subject Matter Expert in telomer
6 chemistry with a fair amount of
7 knowledge in fluoropolymers also, no
8 refrigerants.

9 Q. So what specific type of PFAS,
10 if you know what specific types of
11 PFAS are used in food packaging for
12 example.

13 A. They would have been, in
14 general, fluorotelomer-based polymers.
15 There is also some oxygenated materials
16 from companies like Solvay and others,
17 small PFPEs or small molecules, but
18 largely fluorotelomer-based products.

19 They have largely been phased
20 out, but those were generally what was
21 used to provide the oil and water,
22 particularly the oil or grease
23 repellants that was needed on paper
24 products.

25 Q. And what about a product like

1 Scotchgard, what specific types of
2 PFAS, as far as you know, are used in
3 a waterproofing product such as
4 Scotchgard?

5 A. Well I mean, you know,
6 Scotchgard wasn't made by us, it was
7 made by 3M. They had a different set
8 of chemistry and different backbone,
9 but they would start with either the
10 PFOS, which we heard about a lot here,
11 as a raw material, or what we would
12 call the sulfonyl chloride, the PFOS
13 here and the sulfonyl chloride here.
14 They would bolt on different additives
15 and make polymers out of it.

16 They would be applied in the
17 same manner. They are different
18 chemistries, but the end function would
19 be the same for particularly oil, oil
20 and grease repellency.

21 Q. How about a product such as
22 Rain-X; are you familiar with that
23 product?

24 A. Rain-X I thought was silicone
25 based.

1 Q. So not containing PFAS.

2 A. Not that I know of.

3 Q. Okay. Baking paper or
4 something also known as parchment
5 paper.

6 A. Parchment paper.

7 Q. Yes.

8 A. In the old days, many, many --
9 this is 25, 30 years ago, they would
10 use some of the fluorotelomer products
11 or some of the PFAS products,
12 particularly polymers to coat the
13 butter paper, but that's long done.
14 That's long been done.

15 People at FDA that I worked
16 with, I personally spent a lot of time
17 at FDA because some of the products
18 that we had made would have to go
19 through FDA registration, so I spent a
20 lot of time there, but never worked on
21 parchment paper.

22 Q. Do you know whether parchment
23 paper commonly contains PFAS as sold
24 today?

25 A. I don't know that. I think, I

1 mean, we all know, and really know,
2 because of the amount of news on PFAS
3 chemistries, many companies have market
4 deselection. They decided they don't
5 want to deal with PFAS chemistries any
6 longer.

7 Many end-use applications have
8 decided to give up the properties of
9 oil repellency. Textiles is a good
10 example. That industry has largely
11 moved to durable water repellents that
12 have no fluorine.

13 What that means is you will get
14 water repellency, but you couldn't get
15 the durability. You won't get the
16 severe weather protection, and you
17 certainly won't get oil protection, but
18 it works.

19 If you don't need something in
20 hazard areas, then you don't need it,
21 So many markets have moved away for
22 obvious reasons.

23 Q. And what do you know about the
24 use of PFAS in common brands of dental
25 floss? Is; that still something that

1 commonly contains PFAS to your
2 knowledge?

3 A. Dental floss is a polymeric,
4 like a floor polymer, not telomer-
5 based, and that's been studied. I
6 believe that dental floss is still FDA
7 approved.

8 Q. Can you briefly describe the
9 differences between a fluorotelomer
10 and a fluoropolymer?

11 A. Sure. You ready?

12 Q. Go ahead.

13 A. I promised I wasn't going to
14 do chemistry; I lied.

15 For fluorotelomer chemistry,
16 we'll do polymer and polymer. I think
17 that's the easiest way because that's
18 what I think we want to compare:

19 A fluorotelomer-based polymer
20 has a hydrocarbon backbone, not a
21 fluorinated backbone, so just carbon
22 and hydrogen in the backbone. It has
23 appendages, like if you look at a comb
24 or pull out a comb, you've got the
25 backbone and you've got tines in the

1 comb. There is side chains that sit
2 on the side of that backbone of carbon
3 and hydrogen.

4 Now they work relatively well.
5 I mean they do their job. But as
6 we've heard today and during the week
7 and in the literature, they can fall
8 apart. They can hydrolyze.

9 Now it's going to depend on
10 what the media is. We have done
11 studies that show half life of some of
12 these polymers in soil, sediment, and
13 sludge is thousands of years. Others
14 who have done studies say it's hundreds
15 of years, but they will break down.

16 When they break down, they give
17 what we heard about as precursors, And
18 those precursors will break down to
19 PFAAs. That is a fact. It might take
20 a long time, but that'll work.

21 Now fluoropolymers have a
22 backbone of carbon and fluorine. Some
23 of them have oxygen, and that's the
24 perfluoropolyethers. That completely
25 changes the properties. They are not

1 going to break down into the PFAA
2 precursors that we've heard talked
3 about.

4 The fundamental difference is
5 the backbone and how much fluorine is
6 in that molecule. With fluoropolymers
7 it's carbon and fluorine. With
8 fluorotelomer, you've got a hydrocarbon
9 backbone, and the appendages which can
10 be labile depending on what the polymer
11 is and what it's treated with.

12 Q. These side-chain fluorinated
13 polymers represent a high percentage
14 of all PFAS-containing products. Is
15 that correct?

16 A. No, I would not agree with that.

17 Q. What percentage of all PFAS-
18 containing products would you say side-
19 chain fluorinated polymers represent
20 if you could attach a number to it?

21 A. Well I don't think I can
22 answer that now because, as I said a
23 minute ago, there has been very
24 significant market deselection. The
25 textile and carpet industry has

1 basically gone from these chemicals
2 and they have been for years.

3 The textile market has been
4 under tremendous siege, particularly
5 in Europe and the U.S., so people have
6 gone away from those, or away from
7 fluorine, those were side-chain
8 fluorinated polymers.

9 The paper industries may still
10 use some, but they are largely moving
11 away. They are trying to create non-
12 fluorinated alternatives that may not
13 give you the right performance, but
14 they will give you some.

15 We have firefighting foams. We
16 have talked about that, too, where they
17 have gone to fluorine-free foams, but
18 they don't work as well.

19 The military, at least in land-
20 based systems, not ocean or not water-
21 based systems, land-based system have
22 shifted to fluorine free.

23 I mean a lot of it is public
24 pressure and political pressure, so
25 the market has shifted so

1 dramatically. I mean I can't keep up.

2 All I know is it is
3 significantly different than 10 years
4 ago, and another 5 years from now it
5 will be significantly different also.

6 Q. All right. Your typical non-
7 stick skillet, is that using
8 fluoropolymers or something else?

9 A. Well I mean there are some non-
10 stick skillets that are ceramic and
11 they have other technologies.

12 If you're looking at a skillet
13 coated with PTFE, for example, if it
14 was PTFE from DuPont, now Chemours, it
15 was branded "Teflon," but Teflon is a
16 brand that goes with performance.

17 But yes, this is an FDA-
18 regulated use, and my colleagues -- I
19 wasn't in the fluoropolymer business
20 25 years ago, but they spent a lot of
21 time at FDA. In order for you to get
22 FDA approval, you have to do what they
23 call "Extraction Tests." Those
24 Extraction Tests are based on the use
25 that pan is going to get. That's

1 normal use, that's not 500 degrees
2 centigrade. It's normal use of what
3 you would cook at home.

4 They would take the oils,
5 they'd take the pan itself, they heat
6 it up, and then you would measure what
7 transferred from that pan or skillet
8 into the oil, and then they'd measure
9 it. They'd calculate the potential
10 hazard based on the hazard of the
11 coating and what extracted. That's
12 how you get FDA certification. As far
13 as I know, it's still certified.

14 FDA obviously continues to look
15 at this because this is an area that's
16 got a lot of people's focus for sure.

17 Q. But you would acknowledge that
18 a non-stick pan that is left on the
19 stove too long and gets too hot is
20 going to emit fluorinated gases or
21 vapors. Is that right?

22 A. I'm not saying -- I think
23 anything you abuse has the potential
24 to do that. I mean you're not supposed
25 to put your pan on and walk away. If

1 you put the pan on and walk away or
2 you put the pan on and you turn it up
3 to a degree it's not supposed to use,
4 it has the potential to degrade in
5 some manner.

6 Normally what you will see,
7 and you can argue, if you like, that
8 you're not supposed to do that to the
9 pan. Do people make mistakes?
10 Probably. Should they replace the
11 pan? Absolutely.

12 Q. Thank you for that.

13 A. Sure.

14 Q. Your Testimony acknowledges
15 that there are environmental effects
16 from the manufacture of fluoropolymers.
17 Isn't that correct?

18 A. I think that history is long
19 out there. I mean I think the
20 emissions from the fluoropolymer
21 manufacturers has been probably the
22 major issue for this industry for many
23 years.

24 As I mentioned when T.J. was
25 asking me about my background, myself

1 and 3 other colleagues, 2 of which
2 were from the University of Stockholm,
3 we decided in 2004 that we wanted to
4 look at particularly PFOA, but it was
5 PFCAs. We wanted to look at where
6 PFOA was coming from, And it was, I
7 guess, all of a 2-year project.

8 What we did is we looked at
9 every emission source or potential
10 source for PFOA in the environment,
11 and fluoropolymer manufacturing was at
12 the top of the list, yes.

13 Q. And as I think I heard in your
14 Testimony, you stated that the
15 manufacture of fluoropolymers still to
16 this day typically involves the use of
17 non-polymeric PFAS. Is that correct?

18 A. What they do is, as I said --
19 and I don't have a current number, but
20 I think Barb did say this:

21 If the technical end use
22 requires a certain specification of
23 fluoropolymer that the only way you
24 can get that is using a polymerization
25 aid, those companies are still doing

1 that, But they are also doing
2 something else.

3 They are doing everything they
4 can to switch all the other uses over
5 to the non-fluorinated polymerization
6 aids, and they are trying to work on
7 creating new ones. They want to get
8 out of using the small molecules, the
9 fluoropolymerization aids, and I've
10 said that.

11 We've been talking about this
12 for 20 years, And they've made
13 significant progress. I think PVDF,
14 which is the second largest
15 fluoropolymer, is largely out of using
16 the fluorinated polymerization aids.

17 As Barb talked about today,
18 there are some specific uses for PTFE,
19 that's still needed because the
20 customer requirements require it. In
21 other words, the technical purity or
22 the technical properties of the
23 fluoropolymer are required.

24 But the goal is to find a way,
25 and I can tell you this: If the

1 industry could find a way to not use
2 them, they would, and that's their
3 goal.

4 Q. Well that's great to hear, but
5 they are not quite there yet. Is that
6 right?

7 A. You're correct.

8 Q. As you pointed out in your
9 Testimony, "low concern" is not the
10 same as "no concern"; correct?

11 A. That's what I said, yes.

12 Q. Okay.

13 MR. KNIGHT: I think that's
14 all the questions I have.

15 THE WITNESS: Thank you.

16 HEARING OFFICER ORTH: Thank
17 you, Mr. Knight.

18 Mr. Harris, any questions?

19 MR. HARRIS: No questions,
20 Madam Hearing Officer.

21 HEARING OFFICER ORTH: He said
22 "No questions..."

23 Mr. Wetherbee, do you have
24 questions of Dr. K?

25 He may have stepped away.

1 All right. Is there Redirect?

2 MR. TRUJILLO: At this time, I
3 do have some Redirect questions, Madam
4 Hearing Officer.

5 HEARING OFFICER ORTH: Great.
6 Go ahead.

7

8 REDIRECT EXAMINATION

9 BY MR. TRUJILLO:

10 Q. Dr. K, thank you for your
11 Testimony. I do have a couple
12 questions for you:

13 I want to return to your
14 comments on Labeling at the end of
15 your Direct Testimony.

16 A. Okay. Sure.

17 Q. Can you give us some context
18 on your comments?

19 I'm summarizing here, but
20 "Labeling can't be good." Can you
21 give us the context of --

22 A. What I was saying about that
23 is I was giving credit to the State
24 and for having a program to work with
25 their constituents, and clearly based

1 on the comments you heard today and
2 yesterday, it's an important thing to
3 do. My comments were particularly
4 related to -- I'll answer your
5 question in a second:

6 In the Bill you have a list of
7 exempted products. Our position is
8 they should not be labeled because of
9 what I had said this morning and again
10 this afternoon, which is that the risk
11 of exposure from a fluoropolymer...

12 In the days that I've been in
13 this industry there is no such thing
14 as zero, but it's vanishingly small if
15 there is going to be any risk of
16 exposure from a fluoropolymer given
17 all the testing that's been done over
18 the years.

19 What I also did say, though,
20 is that if there is consumer products
21 that have PFAS chemicals that can
22 expose the population, and they can
23 and it does potentially have a risk
24 that can be quantified, then it's
25 possible then that a label would be

1 beneficial.

2 My comments also were --
3 again, I may get counseled on this,
4 but it is that I'm not sure that label
5 would do it, but that's an aside. I'm
6 not a label expert, but to me, as a
7 Chemist, I wouldn't know what to do
8 with that.

9 Q. One last question:

10 Do you have any final thoughts
11 that you would like to leave with the
12 Board relative to your Testimony?

13 A. Listen, the Board needs to
14 understand that I really do appreciate
15 being able to come here today.

16 I would hope, because you've
17 heard lots of Testimony, and you've
18 heard completely different testimonies
19 from different people, especially Barb
20 and I, but I would hope you would take
21 into consideration our backgrounds,
22 our experience, and then take into
23 consideration some of the things that
24 we've given you to think about today.
25 Thank you.

1 MR. TRUJILLO: That's all of
2 my questions. Thank you very much,
3 Madam Hearing Officer.

4 HEARING OFFICER ORTH: Thank
5 you, Mr. Trujillo, and Dr. K.

6 We'll move to the Board:
7 Vice Chair Suina, do you have
8 questions?

9 VICE CHAIR SUINA: No
10 questions. Thank you.

11 HEARING OFFICER ORTH: All
12 right. Chair Ely.

13 CHAIR ELY: Good afternoon,
14 Dr. K. Thank you for being here, too.
15 I appreciate your Testimony.

16 THE WITNESS: Thank you.

17

18 EXAMINATION

19 BY CHAIR ELY:

20 Q. You talked about some studies
21 that looked at incineration of
22 fluoropolymers and --

23 A. I did, yes.

24 Q. -- and the potential for a 99+
25 destruction rate, provided the

1 temperature was high enough. Is that
2 right?

3 A. Yeah, there is no question, no
4 question whatsoever that if you don't
5 have something above 900 C, for
6 example, or 980 C, you have a
7 significant potential of not finishing
8 the job, that's true.

9 Most municipal waste
10 incinerators, if they're running on
11 their permit and following their permit,
12 are going to run at 1,000, 1,000
13 degrees. Hazardous waste may be 11-,
14 1150.

15 We have done a lot of work
16 studying this. When you look at the
17 studies that have been done under
18 controlled conditions, as well as
19 commercial conditions, as Barb said,
20 we're getting several '9s destruction,
21 and you need that.

22 Just for the Board to
23 understand, 99.9% is a wonderful
24 thing, but that's 1,000 parts per
25 million that's still left over, and

1 that is very different from PPTs, which
2 is what we're talking about today.

3 You need several '9s destruction.

4 What you need to do is you need
5 to run the equipment the way it's
6 supposed to. You need to have your
7 proper emission controls in place, and
8 you need to have the right analytical.
9 As long as you do all of that, you
10 have a really good chance of...

11 You know, I mean you're
12 supposed to operate with no emissions,
13 so we're pretty close to that, but we
14 have to get agreement with EPA.

15 Our particular group has been
16 working back and forth with the U.S.
17 EPA; they have extensive experience in
18 incineration.

19 We have been working with a
20 lab out of North Carolina to try to
21 get guidance so that when we do our
22 work, they will say it's okay. They
23 are hard to get to say it's okay, but
24 that's what we're doing.

25 The studies Barb cited and

1 what I cited are really good. The
2 thing that people don't want to see,
3 and you heard this today, is the
4 little things that don't get burned,
5 or the PICs, but the products that get
6 complete combustion. They are the
7 small non-polymeric.

8 Developing the analytical
9 methods to measure those has been a
10 huge challenge, but they are now in
11 place. We can now measure what's
12 coming out to a very, very small
13 amount.

14 Q. So you're talking about
15 needing the 900 C.

16 A. You probably need to be above
17 that.

18 It depends on the polymer also.
19 PTFE is the hardest fluoropolymer to
20 destruct, so if you're using Number 2,
21 which is PPDF, 900 probably would be
22 fine.

23 Q. Okay.

24 A. But we've started with PTFE
25 because that's the hardest, and most

1 people have done the same thing.

2 There is one study that used a
3 mixture and, you know, I didn't design
4 the study and I find it hard to
5 interpret, but the whole idea is if
6 you can get the PTFE to completely
7 burn, you probably got the conditions
8 you need to be safe.

9 Q. I'm just thinking of conditions
10 where, say in New Mexico, I've seen
11 people burning their trash, you know.
12 What kind of --

13 A. Do you want me to cringe now
14 or later?

15 Q. It may not be legal, but it
16 happens.

17 A. Yeah.

18 Backyard burning, you can't
19 control it. That's where a public
20 service campaign would probably be
21 good, though I don't work in New
22 Mexico except for this week.

23 Backyard burning is not a good
24 idea, especially with these products.
25 They are likely not to do you any

1 harm, but the fact of the matter is
2 you're then putting emissions in the
3 air, and that can travel.

4 And it may not be you, but
5 backyard burning, you know, I worked
6 for many years with the U.S. military
7 and the Department of Defense. A lot
8 of work I had done has been in
9 firefighting foams and related products.

10 I spent a lot of time at DOD,
11 and they are just like us today. You
12 really want to discourage burning of
13 these kinds of products.

14 I mean they have armaments.
15 The military coats a number of their
16 products with fluoropolymers and the
17 like to keep them waterproof, and, you
18 know, they need to destroy them.

19 Armament destruction or
20 warfare destruction is a big program.
21 That's where I read about all the
22 backyard burning stories; not a good
23 idea.

24 Q. I think back to the days when
25 my Mother would burn our family trash;

1 I shutter and wish I could go back and
2 tell her.

3 A. If I cringe, I'm sorry.

4 Q. Please stop.

5 All right. You mentioned
6 waste-to-energy plants.

7 A. Yes.

8 Q. Those are regulated.

9 A. They are regulated, yes.

10 Q. In New Mexico I think we only
11 have 1, and I believe they are
12 outlawed in the State's jurisdiction.
13 Do you know of waste-to-energy plants
14 in New Mexico?

15 A. I do not.

16 Just to be on the up-and-up,
17 incineration is tough to do because
18 there is not enough incinerators, so
19 that's the second issue. If you
20 wanted...

21 You know, the...

22 A lot of states, for their own
23 reasons, won't take waste like this,
24 hazardous waste. If you try to find a
25 hazardous waste incinerator, sometimes

1 you have to go to other states. Then
2 if they will take it, great; if they
3 won't, you have to go to Plan B.

4 CHAIR ELY: All right. That's
5 all of my questions. Thank you.

6 THE WITNESS: Thank you.

7 HEARING OFFICER ORTH: Thank
8 you.

9 On the platform, Member
10 Bitzer, do you have questions of
11 Dr. K?

12 Member Carrasco, do you have
13 questions of Dr. K?

14 BOARD MEMBER BITZER: Sorry, I
15 couldn't get to the button properly;
16 it wasn't expanding for me.

17 HEARING OFFICER ORTH: Okay.

18 BOARD MEMBER BITZER: Yeah,
19 no, I don't have any questions. I'm
20 just also old enough to remember
21 burning trash out in the backyard with
22 my Dad once a week. We lived in the
23 Bay Area of California, too; it was
24 pre-EPA days.

25 Anyway, thank you; it's been

1 informative.

2 THE WITNESS: Thank you.

3 HEARING OFFICER ORTH: Thank
4 you.

5 Member Curry, do you have
6 questions of Dr. K?

7 All right. Anything further
8 before we excuse Dr. K?

9 No. Thank you very much, sir.

10 THE WITNESS: Pleasure. Thank
11 you.

12 HEARING OFFICER ORTH: Let me
13 ask the parties if there is anything
14 else they are aware of that we would
15 need to do?

16 We do have a request from the
17 Board for a bit of additional
18 Testimony, but let me ask the parties
19 first. No.

20 MR. MOELLENBERG: Madam
21 Hearing Officer, nothing.

22 Our Technical Testimony has
23 concluded and other than the post-
24 hearing proceedings, I don't think we
25 have anything else.