APPENDIX: Characterizing PFAS Chemistries, Sources, Uses, and Regulatory Trends in U.S. and International Markets

Appendices to Final White Paper



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Overview

This document supplements the white paper *Characterizing PFAS Chemistries, Sources, Uses, and Regulatory Trends in U.S. and International Markets.* The information in this document includes additional details on the methods (Appendix A), as well as supplemental information on identified patents (Appendix B), market trends (Appendix C), literature review (Appendix D), and chemical health profile for perfluorooctanoic acids (PFOA) and perfluorooctanesulfonic acids (PFOS; Appendix E).

Appendix A. Methods

A.1 Abbreviations

ADME	Absorption, Distribution, Metabolism, and Excretion
ATSDR	Agency for Toxic Substances and Disease Registry
BEA	Bureau of Economic Analysis
CASRN	Chemical Abstracts Registry
	Number
CBI	Confidential Business Information
CDC	Centers for Disease Control and Prevention
CDR	Chemical Data Reporting Database
CPC	Cooperative Patent Classification
CPSC	Consumer Product Safety Commission
DTXSID	DSSTox Substance Identifier
EPA	Environmental Protection Agency
FEP	Fluorinated Ethylene Propylene
FRS	Facility Registry Service
FTOH	Fluorotelomer Alcohol
GenX	Hexafluoropropylene Oxide Dimer Acid and Its Ammonium Salt
HFPO-DA	Hexafluoropropylene Oxide Dimer Acid
HS	Harmonized System
IARC	International Agency for Research on Cancer
IC2	Interstate Chemicals Clearinghouse
IRIS	Integrated Risk Information System
ITRC	Interstate Technology Regulatory Council
IUCLID	International Uniform Chemical Information Database

NAICS	North American Industry
	Classification System
OECD	Organisation for Economic Co-
	operation and Development
OMB	Office of Management and Budget
PACT	Public activities coordination tool
PFAS	Per- and Polyfluoroalkyl
	Substances
PFBA	Perfluorobutanoic Acid
PFBS	Perfluorobutanesulfonic Acid
PFC	Per- and Polyfluoroalkyl
	Chemicals
PFCA	Perfluoroalkyl Carboxylic Acids
PFDA	Perfluorodecanoic Acid
PFHpA	Perfluoroheptanoic Acid
PFHxA	Perfluorohexanoic Acid
PFHxS	Perfluorohexanesulfonic Acid
PFNA	Perfluorononanoic Acid
PFOA	Perfluorooctanoic Acid
PFOS	Perfluorooctanesulfonic Acid
PFSA	Perfluorosulfonic Acid
POPRC	Persistent Organic Pollutants
	Review Committee
PTFE	Polytetrafluoroethylene
QA	Quality Assurance
SCIP	Substances of Concern In Articles
	as Such or in Complex Objects
	(Products)
SWIFT	Sciome Workbench for Interactive
	Computer-Facilitated Text-Mining
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
UN	United Nations
USPTO	U.S. Patent and Trademark Office

A.2 Introduction

All work for this white paper was conducted in accordance with the Consumer Product Safety Commission's (CPSC's) Information Quality Guidelines (CPSC, n.d.), which stress three aspects of quality—utility, objectivity, and integrity—defined by CPSC as follows:

- **"Utility** involves the usefulness and availability of the information for its intended use. Utility is achieved by continuously monitoring information and developing new information sources or by revising existing information-collection methods, models, and information products, where appropriate."
- "Objectivity involves a focus on ensuring that information is accurate, reliable, and unbiased, and that information products are presented in an accurate, clear, complete, and unbiased manner. Objectivity is achieved by using reliable data sources and sound analytical techniques, by having information products prepared by qualified people using proven methods, and by carefully reviewing the content of all information products."
- "Integrity, as used in the OMB [Office of Management and Budget] Information Quality Guidelines, refers to the security of information from unauthorized access or revision, to ensure that the information is not compromised through corruption or falsification. CPSC policies and practices protect the confidentiality of information the agency holds."

To comply with the utility guidelines and ensure that information and data from this project have usefulness, we:

- Reviewed information for usability and applicability to this project for inclusion in the white paper and supporting database;
- Discussed information and data gathered for each overarching method with CPSC staff to confirm its utility for inclusion in the white paper;
- · Identified and incorporated publicly available data within the project scope; and
- Prepared the white paper in "plain English" (i.e., understandable by the general public) to the degree possible, with technical terms defined.

We complied with objectivity guidelines and ensured that information and data are accurate, reliable, and unbiased by using reliable data sources for secondary data, performing sound analytical techniques, and preparing informational products that are of high quality, as follows.

Use of Reliable Data Sources for Secondary Data: The quality of secondary data bears directly on the quality of the resulting work under this contract. Data and information were collected in support of the white paper from many different sources (e.g., existing electronic databases, domestic and international government reports, scientific literature, and expert elicitation from select interviews) and varied greatly in quality. Our approach to quality assurance (QA) for secondary data included upfront systematic planning to define the goals and objectives of the study, and, in consultation with CPSC staff, to determine what indicators and levels of quality would be required to satisfy the needs of the project. Often, a critical issue with secondary data is the amount and quality of information about the dataset itself (i.e., the "meta data"). Usually, we needed to know how and why the data were originally collected and where and when each observation was made. QA and quality check data and reports were crucial in evaluating whether a secondary dataset would serve our study's needs. The effort required to obtain original source materials to answer these questions is usually prohibitively expensive. Hence the crucial requirement became accessibility of quality information in the electronic or published dataset. We established what magnitude and rigor of QA effort were appropriate

before data collection began. Additional information on data sources is discussed throughout the methods.

Use of Sound Analytical Techniques: The quality of the results of analyses largely depends on the experience, qualifications, and talents of the key and supporting staff conducting the work. We have extensive knowledge and research experience related to per- and polyfluoroalkyl substances (PFAS) chemistries, sources, uses, current and in-progress regulatory actions, and domestic and international market trends. Senior key personnel led and monitored all activities. As work was conducted, assumptions and inferences were documented clearly, and scientific and logical reasoning were linked to references in the literature. Senior key personnel and a toxicology consultant, Dr. Jamie DeWitt, conducted internal peer reviews to ensure the soundness of the approach. QA and quality checks on calculations were performed and documented to verify accurate reporting.

Preparation of Information Products: All deliverables were critically reviewed, and all technical and editorial reviews were clearly documented. We used reliable data sources to satisfy CPSC's Information Quality Guidelines. We followed a plain English style for documents prepared for the public, ensuring that they are written clearly and transparently with a minimum of jargon. The information was designed to improve CPSC staff and public understanding of PFAS in consumer products, trends, and overall risks. The QA personnel from each area of the organization had final review of the data to ensure quality and approve the data for reporting.

In producing this report, the authors maintained independence and authority with respect to decisions on data quality. Furthermore, the authors prioritized the use of newer data and information using, as a rule of thumb, January 2000 to April 2023 as a general cutoff for data and information included in the white paper.

Collectively, the multidisciplinary team members 1) conducted literature and data searches and reviews; 2) reviewed the information sources and databases that form the basis of the white paper; and 3) summarized and presented scientific information and data in a clear, accessible, complete, and well-documented way.

A.3 PFAS in U.S. Consumer Products

A.3.1 Publicly Available Datasets

PFAS List

To identify a comprehensive list of per-and polyflouroalkyl substances (PFAS), initial gueries were conducted for PFAS that have a Chemical Abstracts Registry Number (CASRN) in the U.S. Environmental Protection Agency's (EPA's) CompTox Chemicals Dashboard, retrieved via the ChemView search tool (U.S. EPA, n.d.). The CompTox Chemicals Dashboard is a publicly available online tool that integrates available chemical information including physicochemical properties, environmental fate and transport, exposure, usage, in vivo toxicity, and in vitro bioassay. Data are compiled from sources including the EPA's computational toxicology research databases, and public domain databases such as the National Center for Biotechnology Information's PubChem database and EPA's ECOTox Knowledgebase. A database of PFAS was compiled using U.S. EPA's predetermined list of PFAS with explicit chemical structures (referred to as PFASSTRUCTV5) (U.S. EPA, 2022) and PFAS without explicit chemical structures (referred to as PFASDEV1) (U.S. EPA, 2021), last updated in August 2022. These lists were supplemented with the Toxic Substances Control Act (TSCA) list of PFAS chemicals with CASRN or Accession Numbers introduced in 2021, as well as with the Toxics Release Inventory (TRI) list of PFAS which was updated in January 2023. Combined, these four lists identified 16,229 PFAS.

A subset of PFAS were grouped into the chemical structure categories described in the white paper. The subset was determined based on which chemicals were identified in consumer products, industry, regulations, and exposure, hazard (toxicity), and risk assessments. The chemical structure categories were determined by assessing available chemical structures and leveraging the categorizations provided by the Organisation for Economic Co-operation and Development (OECD, 2018). Substances that did not fit into one of the structural group categories defined in the main white paper, were either binned at the class or subclass level (e.g., perfluoroalkyl substances, polyfluoroalkyl substances, or polymers) or considered "undetermined." For example, fluorinated hydrocarbons (refrigerants) and fluorinated alkanes and alkenes containing other halogens (chlorine, bromine, or iodine) were classified simply as per- or polyfluorinated substances.

PFAS in Consumer Products Databases

Identified Datasets. The datasets were initially identified using the PFAS Data Hub developed by the Green Science Policy Institute (Green Science Policy Institute, n.d.). Among datasets for PFAS in products, the PFAS Data Hub lists eight: 1) peer-reviewed paper (Glüge et al., 2020), 2) U.S. EPA's Chemical and Products Database (CPDat), 3) U.S. EPA's Chemical Data Reporting Database (CDR), 4) European Chemicals Agency's Substances of Concern in Articles as Such or in Complex Objects (Products) (SCIP), 5) Association of State Drinking Water Administrators' PFAS Source Water Protection Guidance Project, 6) U.S. Food and Drug Administration's Inventory of Effective Food Contact Substance (FCS) Notifications, 7) European Union Cosmetics Ingredients Database, 8) Food Packaging Forum Food Contact Chemicals Database (FCCdb). Among the datasets from the PFAS Data Hub, the electronic supplementary information from Glüge et al. (2020), U.S. EPA's CPDat, U.S. EPA's CDR, and Food Packaging Forum's Food Contact Chemicals Database (FCCdb) were incorporated into the database for consumer products that use or may contain PFAS. The remaining datasets from the PFAS Data Hub were excluded because data could not be exported in a usable format without extensive extraction and cleaning, specific consumer products were not reported, or specific PFAS could not be identified.

Data from CPDat were from the 2020 release, while data from CDR included data from 2006 (previously called the Inventory Update Reporting [IUR]), 2012, 2016, and 2020. Data from FCCdb were published in 2020.

Additional datasets were identified from targeted searches among state, federal, and international-level agencies/organizations, including the ChemSec PFAS Guide and Interstate Chemicals Clearinghouse (IC2) High Priority Chemicals Data System, and one overview on PFAS uses (Interstate Chemicals Clearinghouse, 2020; ChemSec, 2023; Gaines, 2023). The overview on PFAS uses identified in the targeted searches was also included because, like Glüge et al. (2020), the electronic supplementary information was comprehensive and readily available as Microsoft Excel spreadsheets.

Data Cleaning. Some datasets included information that was not considered for the purposes of this white paper and database. Products with explicit industrial use were excluded. **Table A-1** documents which categories or sectors were included based upon consideration of the consumer product categories described in the white paper.

Incl	uded	Excluded		
ChemSec, 2023				
 Cables and Wiring Cleaning Products Coatings, Paints and Varnishes Electronic Devices Flooring Food Contact Material Food Sector Lubricants and Greases 	 Music Instruments Packaging Personal Care Products and Cosmetics Plastics and Rubber Printing Inks Sealants and Adhesives Sports Articles Textile, Apparel, and Upholstery 	 Aerospace Agriculture Automotive Industry Biotechnology Building and Construction Ceramic Industry Chemical Manufacturing Defense Industry Electronic Industry Electronic Industry Energy Sector F-Gases Glass Industry Healthcare Industrial Use - General Applications Laboratory Equipment Leather Industry 	 Marine Industry Medical Devices Metal Industry Mining Industry Optical Equipment Petroleum Industry Photographic Industry Propellant Refrigerant Systems Semiconductor Industry Solvent Stone, Concrete, and Tile Transportation Watchmaking Wood Processing 	
	Gaine	s, 2023		
 Adhesives Cleaning Products Coatings, Wax, Paint, Varnish, and Inks Cosmetics and Personal Care Dry Cleaning Etching Fire-Fighting Foam 	 Medical Uses Metal Plating and Finishing Packaging, Paper, and Cardboard Pesticides and Fertilizers Plastics, Resins, and Rubber Refrigerant Textiles 	 Building And Construction Electronics Industry Explosives and Ammunition Mining Industry Oil and Gas Industry 	 Photographic and Lithography Industries Recycling and Material Recovery Scientific, General Use Semiconductor Industry Transportation 	
	Glüge	e, 2020		
 Aerosol Propellants Air Conditioning Antifoaming Agent Apparel Automotive* Cleaning Compositions Conservation of Books and Manuscripts Cook- and Pokingwore 	 Metallic and Ceramic Surfaces Music Instruments Optical Devices Paper and Packaging Personal Care Products and Cosmetics Pesticides Pharmaceuticals Pipes, Pumps Fittings, and Line 	 Aerospace Biotechnology Building and Construction Chemical Industry Dispersions Electroless Plating Electroplating Electroplating Energy Sector Fingerprint Development 	 Mining Oil and Gas Industry Particle Physics Pharmaceutical Industry Photographic Industry Production of Plastic & Rubber Semiconductor Industry Soil Remediation Soldering 	

Development

Industry

•

Food Production

and Line

Resins

Plastic, Rubber, &

•

Bakingware

Varnishes

٠

Coverings, Paints, &

Table A-1. Categories Included or Excluded from the Consumer Products Database

Soldering

Textile Production

• Tracing and Tagging

Inc	cluded	Exc	luded
 Electronic Devices Fire-fighting Foam Flame Retardants Floor Covering Glass Household Applications Leather* Lubricants and Greases Medicinal Utensils* 	 Printing (Inks) Refrigerant Systems Sealants & Adhesives Sport Article Stone, Concrete, and Tile Textile and Upholstery Wire and Cable Insulations 	 Laboratory Supplies Machinery and Equipment Manufacture of Metal Products 	 Watchmaking Industry Water and Effluent Treatment Wood Processing

* Some data was selected in these categories. For example, under "Medicinal Utensils," surgical drapes and gowns were excluded while contact lenses and dental floss were included. Specific considerations were given to each category to ensure the proper information was included.

PFAS were identified in each of the datasets by using the master list of PFAS described previously and filtering based on the Chemical ID, CASRN, or DTXSID. Additionally, the product categories were determined based on brand and/or product title using the consumer product classification described in the white paper.

Patent Review

Initially, we conducted a search of patent literature using keywords derived from the overarching consumer product categories described in the white paper. We also used PFAS terms used in the literature search for exposure and human health risks (**Appendix B**) to target patents where PFAS were a part of the invention. Keywords included "PFAS" or "PFASs" or "fluoro* or "PFHxS" (perfluorohexanesulfonic acid) or "PFNA" (perfluorononanoic acid) or "PFOA" or "PFC" (per- and polyfluoroalkyl chemicals) or "PFCs" or "PFSA*" (perfluorosulfonic acid) or "FTOH*" (fluorotelomer alcohol) or "GenX" or "PFOS*" (perfluorobutanesulfonic acid) or "PFBS" (perfluorobutanesulfonic acid) or "PFBA" (perfluorobutanesulfonic acid) or "PFDA" (perfluorobutanesulfonic acid) or "PFBA" (perfluo

To further reduce the number of resulting patent documents, we refined the search strategy by leveraging the Cooperative Patent Classification (CPC) system² to target patents specifically related to consumer products and to reduce the noise of irrelevant patents. Relevant CPC codes, at the class, subclass, or group level were selected based on their relevancy to consumer product categories of interest. We searched the code descriptions on the U.S. Patent and Trademark Office (USPTO) database (U.S. Patent and Trademark Office, 2023) using keywords and phrases that matched with the prioritized consumer product categories and identified 24 relevant CPC codes.

¹ A simple patent family is a set of patent documents that relates to a single invention.

² The CPC system is the patent classification system adopted by the European Patent Office and USPTO in 2013. Patents published prior to 2013 have been updated to be classified by this system.

Consumer Product Categories	CPC Code	Description
Childcare Products	A47	Furniture; Domestic Articles or Appliances
	A61J	Containers Specifically Adapted for Medical or Pharmaceutical Purposes
	B60N	Seats Specifically Adapted for Vehicles; Vehicle Passenger Accommodation
	B62B	Hand-Propelled Vehicles; Sledges
Clothing, Apparel,	A41	Wearing Apparel
Jewelry, and Accessories	A41G	Artificial Flowers; Wigs; Masks; Feathers
Accessories	A42B	Hats; Head Coverings
	A43	Footwear
	A44	Haberdashery; Jewelry
	A45C	Purses; Luggage; Hand Carried Bags
Containers and Packaging	B65D	Containers for Storage or Transport of Articles or Materials
Electronics	H04M	Telephonic Communication
	H04N	Pictorial Communication; Television
	H04R	Loudspeakers, Microphones
	H04W	Wireless Communication Networks
Food Products	A23L	Food, Foodstuffs, or Non-Alcoholic Beverages
Furniture, Furnishings,	A47	Furniture; Domestic Articles or Appliances
and Décor	B68G	Methods, Equipment, or Machines for Use in Upholstering; Upholstery
	C04B	Cement/Mortar (incl. for flooring)
Household Products	A47	Furniture; Domestic Articles or Appliances
	C09D	Coating Compositions (e.g., Paints, Varnishes, etc.)
	D06L	Dry-Cleaning, Washing, or Bleaching
	D06M	Treatment of Fibers, Threads, Yarns, Fabrics, etc.
Infant Formula	A23C	Dairy Products
	A23L 33/40	Food Formulations (e.g., Infant Formula)
Outdoors, Outdoor	A45F	Travelling or Camping Equipment
Recreation, Sports, Fitness	C08L 2555/34	Recycled Waste Materials (e.g., Asphalt, Crumb Rubber)
1 111033	C09G	Polishing Compositions; Ski Waxes
	E01 C13/00	Pavings or Foundations Adapted for Playgrounds or Sports Grounds
Small and Large Appliances	A47	Furniture; Domestic Articles or Appliances
Toys, Hobbies, Crafts	A63	Sports; Games; Amusements
	A46B	Brushes

 Table A-2.
 CPC Codes Relevant to High Priority Consumer Product Categories

Consumer Product Categories	CPC Code	Description
Cosmetics and	A45D	Hairdressing or Shaving Equipment
Personal Care Products	A61K 8/00	Cosmetics or Similar Toilet Preparations
FIDUUCIS	A61Q	Specific Use of Cosmetics or Similar Toilet Preparations
	A45B	Walking Sticks; Umbrellas
	C11D	Detergent Compositions; Soap or Soap-Making

As a quality control check, we compared the CPC codes identified from the USPTO database search to all CPC codes identified in the original patent set from the keyword search. Any CPC codes that were missing from the set resulting from the USPTO database search were evaluated. An additional seven relevant CPC codes were identified and included in the final patent set. The final search strategy used the CPC codes specified in **Table A-2** above.

The resulting set of 31 CPC codes were used to filter the patent documents based on consumer product category. The CPC codes of interest included sections A (Human Necessities), B (Performing Operations; Transporting), C (Chemistry; Metallurgy), D (Textiles; Paper), and H (Electricity). Sections E (Fixed Construction), F (Mechanical Engineering; Lighting; Heating; Weapons Blasting), G (Physics), and Y (General Tagging of New Technological Developments) were excluded as these categories were deemed not relevant to consumer products.

Targeted Literature Searches

Targeted literature searches were not limited to certain types of literature sources (gray literature, government reports, peer-reviewed articles, etc.) or search platform; however, systematic reviews and other high-quality summary documents were prioritized for retrieval and review. Initial search terms included general chemical terms, specific legacy chemical terms (i.e., "perfluorooctanoic acid" [PFOA] and "perfluorooctanesulfonic acid"), and topical terms. The searches were an iterative process wherein search terms were refined based on results.

PFAS in Consumer Products

Given that patents span beyond consumer products (patents can pertain to component parts, designs, methodologies, processes, etc.), a targeted literature search was conducted to supplement the results of the patent review. As noted previously, the patent review resulted in several thousands of patent documents. Therefore, it was not feasible to go through individual patent documents and determine high frequency use consumer products. Based on the overall results of the patent review, the targeted literature search focused on the categories with the greatest number of patent documents to provide examples of products in everyday use. Additionally, to ensure that any data gaps in the patent review were addressed, the targeted literature search also broadly searched for consumer products.

Lifecycle Information

Lifecycle information, including the potential breakdown of materials over time and use of recycled materials that may contain PFAS, was considered of interest to understand human exposure to PFAS. Specifically, the following lifecycle information was prioritized: 1) potential for breakdown of materials over time and 2) consumer products made from recycled materials that are known to contain PFAS. Knowing that much of this information may not be available through

datasets, targeted literature searches were conducted to better understand the current state of the science and identify data gaps.

In addition, information on PFAS as a potential byproduct, contaminant, or impurity throughout the lifecycle process was of interest. We sought to further understand what PFAS may be present as a byproduct or precursor during production or as an impurity from another production process. Topical terms for the searches included "byproducts," "degradation products," "contaminants," "impurities," and similar terms.

Select Interviews for Expert Elicitation

Use of the following interview guide helped to ensure standardization across interviews. The interview guide was reviewed by CPSC staff prior to use.

Interview Guide

1. PFAS as a byproduct, contaminant, or impurity during production

General Questions

- Are industries aware of byproducts and/or residues of PFAS in products that aren't intended to have PFAS?
- Are there processes in place to minimize the unintended contamination of PFAS during production?
- Is industry seeking replacements for those processing aids?
- How has industry evolved in the past 5–10 years regarding reducing exposure to PFAS, and what role has your company played in that evolution?

2. Indirect Exposure to PFAS and Dermal Exposure to PFAS from Leaching or Migration of PFAS from Products

Regarding Use and Data

- Are you familiar with the process in which PFAS may migrate out of consumer products?
- How much of a concern is dermal exposure versus ingestion, inhalation, or other routes of exposure?
- How do potential hazards differ from other types of exposure (such as ingestion or inhalation)?
- Are you aware of any relevant research, published recently or otherwise, of indirect exposure, especially as it relates to dermal exposure?
- How do PFAS migrate from consumer products to the skin, and what factors can influence this process?
- Are there certain use cases or applications where PFAS migration is more likely to occur? Less likely to occur?

Regarding Stakeholders

- What steps can consumers take to minimize their exposure to these products?
- What steps do you think should be taken to better understand and address the issue of PFAS migration from consumer products, and how can stakeholders from different sectors collaborate to achieve these goals?
- What steps do you think should be taken to raise awareness of the potential dermal hazards associated with PFAS exposure, and how can consumers be empowered to make informed choices about the products they use?

- How has industry evolved in the past 5–10 years regarding reducing exposure to PFAS, and what role has your company played in that evolution?
- 3. Challenges and Trends in Identifying Alternatives to Replace PFAS in Consumer Products

General Questions

- Can you describe some of the challenges associated with eliminating PFAS in consumer products within the industry? How has the industry eliminated PFAS in consumer products? What were the challenges faced?
- What are the current trends in the industry when it comes to finding alternative materials to replace PFAS?
- Are there any particular industries or product categories that are finding it more difficult to eliminate PFAS? If so, why?
- What role do regulations and policies play in driving the search for PFAS alternatives within the industry, and how is your company working with regulatory bodies to identify PFAS alternatives?
- What role did your company play in eliminating PFAS from consumer products?
- How do you see the industry changing regarding the elimination of PFAS in consumer products?

4. Industry Perspective on Lowering Health Benchmarks and Whether PFAS Are Perceived as a Human Health Concern

General Questions

- Has the industry's perception of PFAS as a threat changed considering the lower health benchmarks such as the maximum contaminant levels proposed by the U.S. EPA for drinking water? If so, in what ways?
- Are there any particular consumer products or industries that are at a higher risk for exposure to PFAS? If so, what steps has the industry taken to address this?
- How are regulatory bodies and policymakers responding to the changing health benchmarks for PFAS, and what impact is this having on the industry?
- What role do you see industry collaboration playing in addressing the threat of PFAS exposure? Provide an example of something your company has done in work with stakeholders to address the threat of PFAS exposure.
- How are consumers influencing the industry's approach to PFAS exposure, and what steps is your company taking to meet consumer demands for safer products?
- How has industry evolved in the past 5–10 years regarding reducing exposure to PFAS, and what role has your company played in that evolution?

A.4 PFAS Commodity Market Trends

Our methodology identified patterns and trends using economic data and policy research. While detailed publicly available data exist that identify facilities handling PFAS including location and production volumes, these data have significant reporting gaps including required reporting for only a limited subset of chemistries and reporting censorship to protect confidential business information (CBI). Moreover, publicly available data on economic commodity production and use do not distinguish production of PFAS from a wide variety of non-PFAS chemicals. We aggregate PFAS chemistries into three categories throughout our methods: perfluoroalkyl substances, polyfluoroalkyl substances, and polymers. Data limitations identified in our research precluded accurate characterizations of specific PFAS chemistries or a comprehensive

assessment of PFAS content in consumer products. Given these limitations, our methods are designed to characterize the scale and trends of the overall PFAS commodity market in terms of observable domestic production, international trade, and potential direct uses.

A.4.1 Supply and Demand Characterization

Prior to establishing overall spatial distribution and temporal trends for PFAS, we surveyed the best available public information on domestic and foreign sources of PFAS. To characterize the overall scale of the PFAS market and spatial distribution, we identified domestic PFAS-producing facilities, PFAS import and export volumes by port, and direct PFAS-using sectors. PFAS products can travel through a long supply chain in the economy that introduces many potential points of exposure risk before being sold to final consumers as part of other products. Beyond the supply chain, disposal of PFAS via air, liquid, and solid waste streams further expand the network of potential PFAS exposure. Our methods best capture potential PFAS exposures in the initial production, import, and sale of PFAS in their chemical form. The total supply of PFAS products to the U.S. market is a valuable reference point for the broader potential exposure associated with indirect and final uses and disposal. To characterize these broader risks throughout PFAS-containing product supply chains, we supplement our producer and direct-user identification with reported TRI releases of PFAS, which may come from producers, consumers, waste management sites, or other facilities.

PFAS-Producing Facilities

We compiled, cleaned, and narrowed the 1998–2020 CDR datasets to include only PFAS chemicals using the CASRN or Accession Number from the comprehensive PFAS list. Using the Facility Registry Service (FRS) ID, a unique identifier by facility, we deduplicated the facilities across all reporting years to identify a distinct list of 150 PFAS-producing facilities, including both manufacturers and importers. The facility's associated industry, designated by a North American Industry Classification System (NAICS) code, was only available for the 40 facilities that reported in the most recent 2020 CDR dataset, as this was a recent requirement. To identify the industry associated with facilities without NAICS codes in the 2020 CDR data, we used the EPA's FRS Facilities and Linkages dataset to match to NAICS code by FRS ID and the EPA's NAICS and Industrial Sector Codes Crosswalk table to match NAICS codes to an additional 88 facilities, for a total of 128 facilities with industry information. When multiple NAICS codes matched to a facility, all NAICS codes were included. The EPA does not have publicly available information on the associated industry for the remaining 22 facilities.

The 2020 CDR data also include limited information on foreign parent companies associated with the PFAS-producing facilities; however, none of the previous reporting cycles provide this information. Given these limitations, we conducted targeted literature searches to identify foreign PFAS-producing facilities that may be importing PFAS chemicals to the U.S. market. We did not limit these searches to any type of literature source (gray literature, government reports, peer-reviewed articles, etc.) or searching platform. Initial search terms included general chemical terms, specific legacy chemical terms (i.e., "perfluorooctanoic acid" [PFOA] and "perfluorooctanesulfonic acid"), and general facility terms (i.e., "industry" and "manufacturer"). The searches were an iterative process wherein we refined our search terms based on search results and searched further. The resulting data granularity and type of information that could be extracted was highly variable depending on the source, but, at a minimum, included the facility name and country. We were not able to identify any numerical quantity data (e.g., PFAS production volume) for foreign facilities but we were able to characterize the quantity of PFAS exports by country, described in the section below.

Trade Quantities

Ad described in the white paper, 28 Harmonized System (HS) codes were identified to characterize trade. The resulting HS codes by PFAS category are listed in **Table A-3**.

Table A-3. HS Codes Identified for PFA
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HS Code	Description		
	Categorized as Perfluoroalkyl Substances		
290341	Trichlorofluoromethane		
290342	Dichlorodifluoromethane		
290343	Trichlorotrifluoroethanes		
290344	Dichlorotetrafluoroethanes and chloropentafluoroethane		
290346	Bromochlorodifluoromethane, bromotrifluoromethane and dibromotetrafluoroethanes		
290376	Bromochlorodifluoromethane, bromotrifluoromethane, and dibromotetrafluoroethanes		
290431	Derivatives of hydrocarbons; perfluorooctane sulphonic acid, whether or not halogenated		
290432	Derivatives of hydrocarbons; ammonium perfluorooctane sulphonate, whether or not halogenated		
290433	Derivatives of hydrocarbons; lithium perfluorooctane sulphonate, whether or not halogenated		
290434	Derivatives of hydrocarbons; potassium perfluorooctane sulphonate, whether or not halogenated		
290435	Derivatives of hydrocarbons; salts of perfluorooctane sulphonic acid not elsewhere classified in heading no. 2904, whether or not halogenated		
290436	Derivatives of hydrocarbons; perfluorooctane sulphonyl fluoride, whether or not halogenated		
292216	Amino-alcohols, other than those containing more than one kind of oxygen function; their ethers and esters; salts thereof, diethanolammonium perfluorooctane sulphonate		
292330	Quaternary ammonium salts and hydroxides; tetraethylammonium perfluorooctane sulphonate, whether or not chemically defined		
292340	Quaternary ammonium salts and hydroxides; didecyldimethylammonium perfluorooctane sulphonate, whether or not chemically defined		
293510	Sulphonamides; N-methylperfluorooctane sulphonamide		
293520	Sulphonamides; N-ethylperfluorooctane sulphonamide		
293530	Sulphonamides; N-ethyl-N-(2-hydroxyethyl) perfluorooctane sulphonamide		
293540	Sulphonamides; N-(2-hydroxyethyl)-N-methylperfluorooctane sulphonamide		
293550	Sulphonamides; other perfluorooctane sulphonamides		
	Categorized as Polyfluoroalkyl Substances		
290371	Chlorodifluoromethane		
290372	Dichlorotrifluoroethane		
290373	Dichlorofluoroethanes		
290374 Chlorodifluoroethanes			

HS Code	Description
290375	Dichloropentafluoropropanes
292412	Acyclic amides (including acyclic carbamates) and their derivatives: salts thereof: fluoroacetamide (ISO), monocrotophos (ISO) and phosphamidon (ISO)

Categorized as Polymers

390461	Polytetrafluoroethylene (PTFE)
390469	Other fluoropolymers

For U.S. trade, we queried United Nations (UN) Comtrade for import and export volumes reported by the United States for all trade partners. For global trade, we queried UN Comtrade for import and export volumes for all reporting countries with the "World" trading partner (i.e., all their reported trade).

PFAS Domestic Supply

The reporting cycles align to the manufacturing and importing volumes for one year prior (i.e., 2011, 2015, and 2019), but will be referred to as their reporting year for the remainder of the paper.

Reported PFAS Releases

Like the CDR data, EPA's TRI program requires the reporting of chemical information from industry facilities. Many of the chemicals and facilities in the CDR data are also reported to TRI. The key difference between the reporting programs is that the goal of the CDR data is to provide EPA with information on the production and use of chemicals in industry whereas the goal of the TRI data is to inform the public about releases of toxic chemicals to the environment. Over 99% of the TRI data are publicly available in contrast to the high degree of CBI claims made on the CDR data. A facility is required to report to TRI if it is associated with a TRI-covered NAICS code, if it has ten or more full-time employees, and if it manufactures, imports, processes, or uses any of the designated chemicals greater than established thresholds. The reporting thresholds are typically 25,000 or 10,000 pounds but can be lowered to 10 pounds, depending on how the chemical is processed by the facility. The current TRI toxic chemical list contains 787 unique chemicals.

We identified facilities reporting PFAS releases using the TRI On-Site Releases dataset. The data were filtered to include only CASRN or Accession Numbers that matched our list of 16,229 PFAS chemicals. These chemicals were classified by PFAS category, and the reporting facility was deduplicated using the distinct FRS IDs. The resulting dataset included the amount of each PFAS category released in pounds by 89 distinct facilities for 2012–2021. These facilities were compared to the PFAS-producing facilities from the CDR dataset to identify which producing facilities also reported PFAS releases.

We also tabulated the reported PFAS releases by PFAS category, reporting year, and industry using the TRI assigned Industry Sector, derived from the NAICS code associated with each facility. The release rate was calculated by dividing the total reported TRI releases for each PFAS category by the total supply of PFAS calculated from the CDR nationally aggregated production volumes. Additional information on the equation used to calculate the PFAS release rate can be found in the **Appendix D**.

A.4.2 Spatial Distribution of PFAS Production and Releases

PFAS Supply

We mapped the 150 distinct PFAS-producing facilities according to the latitude and longitude reported in the CDR data. Using the compiled facility-level production volume data described in the "Supply and Demand Characterization" section, we determined the amount of PFAS each facility manufactured and imported for the years 2012, 2016, and 2020 by PFAS category. The manufacturing and importing volumes for all categories were averaged across years to get a total average annual production volume (pounds) for each facility. We produced maps using the size of the point for each facility to indicate the average annual production volume (i.e., facilities with more PFAS have larger markers). The maps also provided information on the facility's activity as a manufacturer of PFAS, importer of PFAS, or both and sector of each facility (using the NAICS code). If a facility was only associated with one NAICS code, we used the first three digits to assign the sector. For facilities that reported multiple NAICS in the CDR dataset, we used the first three digits of the primary CDR-reported code. For the facilities that were matched to multiple NAICS from the FRS Facilities and Linkages dataset, we prioritized the "325 chemical manufacturing" sector first and then sectors that overlapped with CDR-reported sectors. Facilities without any NAICS codes were assigned a sector of "999" for unknown.

A.5 **PFAS Regulatory Trends and Alternatives**

A.5.1 Regulatory Trends

Federal, State, and Local U.S. Regulations

Current regulatory activities, including bans and restrictions, were reviewed at the federal and state levels of government. The PFAS Team at the Interstate Technology Regulatory Council (ITRC) developed an online document for technical resources on PFAS starting in 2017 (ITRC PFAS Team, 2022). They created a Microsoft Excel spreadsheet with summary information for the regulation of PFAS at several levels: state and territory programs, federal programs, and international programs. The federal programs represented four agencies: the Centers for Disease Control and Prevention (CDC), U.S. Department of Defense, U.S. Food and Drug Administration (U.S. FDA), and the U.S. EPA. The state and territory programs include each state with the addition of the District of Columbia and Puerto Rico. The spreadsheet was last updated in October 2022, and therefore, we used it to initially identify regulations and guidelines (or policies) related to PFAS.

In addition to the technical resource by ITRC, Safer States, an alliance of diverse environmental health organizations and coalitions, has a bill tracker specific to PFAS. The bill tracker identifies adopted and current policies by states. The listing of adopted and current policies was extracted from the Safer States website to contribute to the listing of current regulatory activities at the state level. Individual searches on state-level policies, particularly among states that were not listed in Safer States, were conducted to further determine which states had current regulatory activities at the federal level.

Regulatory activities at the local (i.e., county or city) level were searched to determine current regulatory activities, if any, that extend beyond those at the federal level. An exhaustive search was not conducted for local regulations.

All U.S. regulations were catalogued in a searchable database that can be used to gauge trends over time and by PFAS-containing product category and/or topics. Extracted information included the year of adoption or most recent update, regulatory level (local, state or territory, federal, or international), geographic area, whether the regulation was adopted or proposed (as

of May 2023), title, description, general or specific PFAS addressed, primary focus or topic area, consumer product category (if applicable), whether it pertained to a ban or notification/reporting requirement, source, and URL (*'PFAS Regulation Index.xlsx'*).

Select International Regulations

Regulatory activities at the international level of government were searched to determine current regulatory activities that extend beyond those at the federal U.S. level of government. Among the technical resources developed by the PFAS Team at the ITRC, the international programs represented 10 different locations: Australia and New Zealand, Canada, Denmark, the European Union, Germany, Italy, the Netherlands, Norway, Sweden, and the United Kingdom.

Additionally, the European Chemicals Agency's (ECHA) website and OECD's *Portal on Per and Poly Fluorinated Chemicals* were searched (OECD, n.d.). In OECD's portal, country information includes a summary on recent initiatives and policy approaches for 15 locations: Australia, Canada, China, Denmark, the European Union, Finland, Germany, Japan, Korea, the Netherlands, Norway, Poland, Russia, Sweden, and the United States.

A.5.2 PFAS Substitutes

Data Collection

Expert elicitation and targeted literature searches were used to identify existing and/or potential PFAS substitutes. The targeted literature searches helped to understand the current state of the science. The searches were not limited to any type of literature source (e.g., gray literature, government reports, peer-reviewed articles) or searching platform. Initial search terms included general chemical terms, specific legacy chemical terms (i.e., "perfluorooctanoic acid" [PFOA] and "perfluorooctanesulfonic acid"), and general terms to encompass the use of alternatives or substitutes. The searches were an iterative process wherein search terms were refined based on results.

PFAS Price Considerations

As part of this effort, we characterized the role price has played on how industry selects PFAS and the degree to which international trade supports or complicates the demand for PFAS in domestically available consumer products. Based on our experience, we know that price is not the only factor motivating industry to select PFAS molecules. The strength of the carbon-fluorine bond is unique and provides performance characteristics that consumers desire in many product categories. From a formulary lens, PFAS provide high performance at a very low concentration, which has driven industry adoption.

Price considerations can help inform how producers are likely to substitute toward alternative chemistries. Based on the targeted literature search results on substitutes, we characterized the role that price has played in the selection of PFAS and substitutes, as well as the impact of regulatory and other non-price factors on industrial and consumer use. We also summarized trends in the use of non-PFAS substances and identified examples of common PFAS substitutes.

A.6 **PFAS Exposure and Human Health Risk**

A.6.1 Literature Review: PFAS Exposure, Toxicity, and Human Health Risk

Overview

We identified existing literature to characterize the current state of knowledge on exposure, toxicity, and human health risk to PFAS. Literature sources were compiled using a combination

of targeted, online searches and formal literature searches to develop an evidence base of diverse resources related to exposure, toxicity, and human health risk.

We developed a tiered approach for classifying evidence related to exposure, toxicity, and human health risk: Tier 1 evidence (highest priority evidence, produced or endorsed by international and domestic government agencies or similarly authoritative sources); Tier 2 evidence (peer-reviewed literature); and Tier 3 evidence (expert opinion and other sources). Tier 1 evidence was compiled until May 2023, while Tier 2 evidence was searched between January 2000 and January 2023.

Sources of Evidence

Sources of Tier 1 Evidence (Highest Priority—Government Agencies or Authoritative Sources)

Governments around the world are investigating the human health impacts of PFAS exposure and routes of PFAS exposure within their populations. Subsequently, they are developing regulations and policies to address these issues. As such, numerous authoritative bodies have developed resources to synthesize existing, high-quality evidence that can inform and support decision-making.

Tier 1 evidence represents high-quality evidence from authoritative sources related to the current state of knowledge on PFAS exposure, toxicity, and human health risk. Tier 1 evidence includes reviews, evidence syntheses, assessments, regulatory technical support documents, or other information produced by or endorsed by domestic and international governmental agencies and similarly authoritative sources.

Tier 1 evidence was identified using targeted online searches of authoritative bodies' publicly available webpages including U.S. EPA, the European Union, the UN, the U.S. CDC, and the National Toxicology Program, among others. Webpages were manually searched for common PFAS terms. Resources related to exposure, toxicity, or human health risk were retrieved for further review and summarization.

Sources of Tier 2 Evidence (Peer-Reviewed Literature Sources)

We completed a review of peer-reviewed literature to complement the review of Tier 1 sources of evidence. Although we heavily rely on Tier 1 sources of evidence herein, additional research has been conducted in the interim and the overall body of evidence continues to advance each year. This literature review was intended to ensure we characterized the present-day state of the science and addressed data gaps or further areas of interest identified in Tier 1 references. We conducted two separate literature searches to broadly identify peer-reviewed resources related to 1) PFAS exposure and completed exposure assessments; and 2) toxicity, human health hazards, and human health risk associated with PFAS. Within the search strategies, we included search terms to specifically identify references relevant to consumer products and susceptible populations (e.g., fetuses, infants, children, pregnant persons, elderly persons).

We conducted the searches in PubMed, Web of Science, and Scopus.

Sources of Tier 3 Evidence (Other Sources and Expert Opinion)

Additional targeted searches for peer-reviewed publications and gray literature were conducted as needed. PubMed, Google Scholar, and the reference lists of other Tier 1 and 2 references were the primary sources for these searches and additional references.

Screening Reviews of Evidence

Review of Tier 1 Evidence (Highest Priority—Government Agencies or Authoritative Sources)

Tier 1 evidence was reviewed using the web-based software application SWIFT-Active Screener (SWIFT stands for Sciome Workbench for Interactive computer-Facilitated Textmining; Sciome, LLC, Research Triangle Park, NC). The application is used for collaborative work on systematic reviews with behind-the-scenes "active learning" and statistical models to prioritize references considered relevant. Due to the smaller number of Tier 1 references and their selection via manual methods, SWIFT-Active Screener's "active learning" models were not used to prioritize Tier 1 references and the platform was used only for screening and tagging activities. All references were first screened at the title-abstract level for general relevancy to this section's aims and to tag basic information about the resource. The resources were then screened and tagged at the full-text level to characterize more detailed attributes about the resource. Tagging fields included available information such as resource type, PFAS species noted in the resource, population characteristics, study design, exposure matrices, health endpoints, any identified links to consumer products (using product categories defined in **Table A-2**), and available quantitative health-related information. Not all tagging fields apply to all resources.

Review of Tier 2 Evidence (Peer-Reviewed Literature Sources)

We used SWIFT-Review (Sciome, LLC) to aid in the prioritization and conceptualization of the Tier 2 evidence base developed from the literature searches. SWIFT-Review uses statistical text mining and machine learning to support prioritization and visualization of large evidence bases. The platform has well-documented search strings from which it derives its automatic tagging categories and subcategories of interest to environmental health researchers (Sciome, 2023). We manually annotated a set of approximately 200 references in each bin of Tier 2 literature searches to denote them as either "Include" or "Exclude." These training sets were imported to SWIFT-Review to use in the platform's prioritization algorithm. This algorithm ranks articles by a predicted relevancy score. Articles that ranked above the lowest ranked, manually annotated article were included in the smaller subset of highly relevant references from the Tier 2 literature sources.

The final, smaller subset of highly relevant Tier 2 resources were then reviewed and tagged using SWIFT-Active Screener using the "active learning" model (Howard et al., 2020) with screening limited to a 95% inclusion threshold. Tier 2 evidence was screened and tagged using the same data entry forms as Tier 1 evidence to ensure consistency and facilitate direct comparisons among resource types within the database. Note that Tier 2 evidence was only screened at the title-abstract level. Full-text screening was not completed for the purposes of this white paper.

Review of Tier 3 Evidence (Other Sources and Expert Opinion)

Additional peer-reviewed publications were retrieved to supplement data gaps or further areas of interest not already covered by Tier 1 or Tier 2 references. Tier 3 evidence was not screened or tagged.

Tier 1 Evidence Methods

The following entities' webpages were manually searched for references related to PFAS exposure, toxicity, and human health risk. Relevant references were retrieved and uploaded to EndNote for further review. A summary of searches for Tier 1 evidence is presented in **Table A-4.**

Authoritative Body	Agency, Department, or Sub-Entity	Primary Landing Page(s)	Summary of Manual Search Strategy
Australian Department of Health and Aged Care	Australian Industrial Chemicals Introduction Scheme	https://www.industrialchemicals. gov.au/consumers-and- community/and-poly-fluorinated- substances-pfas	The Industrial Chemicals Introduction Scheme website was searched for common PFAS terms. The National Industrial Chemicals Notification and Assessment Scheme has completed numerous assessments of PFAS. These assessments include exposure and hazard information and risk management recommendations for industry. Human health assessments were retrieved for a subset of the available key PFAS and their direct precursors (PFBS, PFOA, PFOS, PFSA [5-7 carbon chain (C5-C7); >C8], perfluoroheptanoic acid [PFHpA], PFHxS). Resources were not retrieved or reviewed for the subset of indirect precursors or derivatives.
Danish EPA	Ministry of Environment and Food	https://eng.mst.dk/	The site search function was used to search for common PFAS terms; this yielded a list of several Danish surveys on PFAS chemicals in consumer products.
European Union	European Union Chemicals Agency	https://echa.europa.eu/candidat e-list-table https://iuclid6.echa.europa.eu/ https://echa.europa.eu/scip	The "Candidate List of substances of very high concern for Authorisation" page was searched for known PFAS species and PFAS prefixes, where PFBS, PFHxS, perfluorodecanoic acid (PFDA). and PFOA were listed. We accessed the links to their Substance Infocards, then each substance's public activities coordination tool (PACT) to find potential references supporting their consideration for listing on the Substances of Very High Concern list. Multiple technical support documents were added for PFBS, PFHxS, PFDA, and PFOA. A general Annex XV Report was also identified by manually searching common PFAS terms in the European Chemicals Agency's home page search function. The IUCLID (International Uniform Chemical Information Database software) database for PFBS was cursorily reviewed but not used as a primary reference due to access issues. The SCIP database was reviewed and found to be not relevant for health- related topics but would be helpful for other topics in the white paper.
European Union	European Food Safety Authority	https://www.efsa.europa.eu/en	The website was searched using "fluor"; Google was also searched for the entity name and common PFAS terms. Several references were identified related to exposure and risk associated with PFAS in food; additional scientific opinions of safety assessments of PFAS in food contact materials were identified.
Health Canada	Water and Air Quality Bureau	https://www.canada.ca/en/health -canada/services/chemical- substances/other-chemical- substances-interest/per- polyfluoroalkyl-substances.html	Health Canada's webpage was searched for "PFAS" and "Per- and Polyfluoroalkyl Substances"; Google was also searched for the entity name and common PFAS terms. Technical support documents were identified for the development of Canadian drinking water quality guidelines for PFOA and PFOS. Documents included summaries on exposure and toxicity evidence, and cancer and noncancer risk assessments were developed. A summary report of PFAS biomonitoring data in Canadians was also identified but not retrieved, as the emphasis of this search topic was not internal exposure levels.

Table A-4. Summary of Manual Searches for References from Key Authoritative Bodies

	Agency, Department, or		
Authoritative Body	Sub-Entity	Primary Landing Page(s)	Summary of Manual Search Strategy
Interstate Chemicals Clearinghouse (IC2)	High Priority Chemicals Data System	<u>https://theic2.org/hpcds#gsc.tab</u> <u>=0</u>	The High Priority Chemicals Data System was identified as relevant for both health topics and sources of PFAS in products (see Section 4.1 of the white paper).
National Academies of Sciences, Engineering, and Medicine	-	https://www.nationalacademies. org/our-work/guidance-on-pfas- testing-and-health-outcomes	The National Academies webpage was searched for "PFAS" and "Per- and Polyfluoroalkyl Substances." The recent publication related to PFAS Exposure, Testing, and Clinical Follow-Up was retrieved to review the evidence summaries on health effects and exposure.
The Netherlands: National Institute for Public Health and the Environment	Ministry of Health, Welfare and Sport	https://www.rivm.nl/en/pfas/relev ant-publications	The English-translated homepage was searched for "PFAS" and "Per- and Polyfluoroalkyl Substances"; Google was also searched for the entity name and common PFAS terms. A publication list was identified on the Ministry's website; most full-text publications were available in Dutch-language only and were not retrieved, with the exception of three relevant reports with full-text English translations (PFAS in food contact material; literature review of PFOA exposure and health; and PFAS mixture exposure assessment methods).
Norwegian Environment Agency	_	https://www.miljodirektoratet.no/	The English-translated homepage was searched for "PFAS" and "Per- and Polyfluoroalkyl Substances"; Google was also searched for the entity name and PFAS terms. Several relevant, English-language documents were located, primarily related to sources of specific PFAS (PFBS, PFHxS) in the environment; one report detailed several PFAS analytes' concentrations in a selection of household products.
North American Agreement on Environmental Cooperation	Commission for Environmental Cooperation	http://www.cec.org/	A previously known report from the Commission for Environmental Cooperation was uploaded to the database. Additional, manual searches on the homepage using keywords "PFAS" and "Per- and Polyfluoroalkyl Substances" did not yield additional, relevant resources.
Organisation for Economic Co- operation and Development	_	https://www.oecd.org/chemicals afety/portal-perfluorinated- chemicals/	The "Portal on Per and Poly Fluorinated Chemicals" webpage was accessed to pull additional references. On the "Country Information" page, there were links to additional countries' resources on PFAS. We went to each country's link to pull additional references. A PFOS hazard assessment document was also identified and retrieved.
Swedish EPA	-	https://www.naturvardsverket.se/ en	English-translated tabs were searched for "PFAS" and "fluor"; Google was also searched for the entity name and PFAS terms. An environmental and human health risk assessment was identified and retrieved.
U.S. Centers for Disease Control and Prevention	Agency for Toxic Substances and Disease Registry (ATSDR)	https://www.atsdr.cdc.gov/	The ATSDR website was searched for "PFAS" and "Per- and Polyfluoroalkyl Substances"; a toxicological profile, minimum risk levels, environmental media evaluation guides, and information about several ongoing exposure assessment studies were identified and retrieved.

	Agency, Department, or		
Authoritative Body	Sub-Entity	Primary Landing Page(s)	Summary of Manual Search Strategy
U.S. EPA	Office of Research and Development	https://www.epa.gov/chemical- research/research-and- polyfluoroalkyl-substances-pfas	The Integrated Risk Information System (IRIS) Assessments database was searched by CASRN for key PFAS species. Records were created in the database for all species with available toxicological reviews (PFBA, PFHxA); records of the IRIS Chemical Landing Page were also created for species with in- progress or draft IRIS Assessments that are not yet publicly available or finalized (PFDA, PFNA, PFHxS). Human health toxicity assessments were identified and retrieved for PFBS and GenX.
U.S. EPA	Office of Water	https://www.epa.gov/sdwa/and- polyfluoroalkyl-substances-pfas	Health effects support documents were retrieved for PFOA and PFOS. The Proposed Derivation for Maximum Contaminant Level Goals documents, which build on the 2016 health effects summary documents, were retrieved for PFOA and PFOS. Drinking Water Health Advisories were retrieved for GenX and PFBS; the more recently updated Interim Drinking Water Health Advisories were also retrieved for PFOA, PFOS. In March 2023, EPA proposed new National Primary Drinking Water Regulations and released several new documents that build on previous work conducted by EPA. The new Public Review Draft "Toxicity Assessment and Proposed Maximum Contaminant Level Goal" reports were retrieved for PFOA and PFOS, and the Public Comment Draft "Maximum Contaminant Level Goal Summary Document for a Mixture of Four PFAS" was retrieved (covers hexafluoropropylene oxide dimer acid [HFPO-DA], PFBS, PFNA, and PFHxS). The Economic Analysis document supporting the proposed drinking water regulations was also retrieved.
U.S. National Institutes of Health	National Toxicology Program	https://ntp.niehs.nih.gov/whatwe study/topics/pfas/index.html	Records were created for available toxicity studies (PFBS, PFHxS, PFOS; PFHxA, PFOA, PFNA, PFDA), technical report (PFOA), and the completed Immunotoxicity Monograph (PFOA and PFOS); National Toxicology Program– affiliated peer-reviewed articles were not recorded as Tier 1.
U.S. – Domestic States	_	Numerous	Individual webpages for relevant state agencies (e.g., state Health or Environmental Departments) were searched for common PFAS terms; Google was also searched for the entity names and common PFAS terms. A variety of potentially relevant resources (for this white paper topic and others) were identified and retrieved, including Notification Levels for Drinking Water, other environmental media goals, regulations/executive orders, State PFAS Action Plans, and department-affiliated exposure studies.
United Nations	Stockholm Convention on Persistent Organic Pollutants	http://chm.pops.int/TheConventi on/POPsReviewCommittee/Rec ommendations/	The Persistent Organic Pollutants Review Committee's (POPRC's) webpage "POPRC Recommendations" was searched for PFAS chemicals under review or previously reviewed. Risk profiles and accompanying risk management evaluations were retrieved for PFOS, PFOA, PFHxS. A standalone risk profile was also retrieved for long-chain perfluorocarboxylic acids.

Authoritative Body	Agency, Department, or Sub-Entity	Primary Landing Page(s)	Summary of Manual Search Strategy
United Nations	International Agency for Research on Cancer (World Health Organization)	https://www.iarc.who.int/	IARC's webpage was searched for "PFAS" and "Per- and Polyfluoroalkyl Substances"; Google was also searched for the entity name and common PFAS terms. The IARC Priorities for 2020-2024 was searched for common PFAS terms. A single, completed IARC monograph was retrieved for PFOA. Additional work on PFOA and PFOS is expected in 2023–2024.

A summary of the literature tagging fields is available in **Tables A-5** and **A-6**. A summary of the literature tagging fields is available in **Tables A-5** and **A-6**.

Table A-5.Inclusion Criteria and Literature Attribute Tags for Evidence Related to PFAS
Exposure, Toxicity, and Human Health Risk – Used in SWIFT-Active Screener for
Level 1

Category	Option Selection	Notes
Reference Type	 INCLUDE Original research Review with systematic protocol (e.g., systematic review, systematic evidence mapping, or scoping review) Other review or evidence synthesis Supporting or supplementary document (used for an overarching document [e.g., original research or systematic review] that has documents to support it [e.g., data tables, review protocols]) Database Decision-making support document (supports the process of making a determination, new regulation, etc.) Regulatory document (issuance or documentation of the regulation; official document) Conference proceedings Website page or factsheet (include for Tier 1 sources only) EXCLUDE News 	Based on selections in EndNote.
Evidence Qualifier	 N/A Draft or deliberative document, AVAILABLE FOR REVIEW BUT NOT FINAL; DO NOT FORMALLY CITE Identified as forthcoming or in progress, NOT AVAILABLE FOR REVIEW Key document, but newer version is now available, SUPERSEDED 	Not all references will have a qualifier.
Evidence Topic	 INCLUDE Toxicity Exposure Human Health Risk EXCLUDE Not related to toxicity, exposure, or human health risk 	_
Language	INCLUDE: English language EXCLUDE: Non-English language	-
Date Range	INCLUDE: Published after 2000 EXCLUDE: Published before 2000, or primary data source relies on data collected before 2000 <i>(latter</i> <i>applies to Tier 2 only).</i>	

Appendix A

Category	Option Selection	Notes
Chemicals	 INCLUDE PFOA PFOS PFHxS PFHxA PFBS PFBA PFDA PFDA HFPO-DA [i.e., GenX] General, or otherwise not specified Identified only as a group or subclass (if given, enter category in "other" option below) Identified only as a brand name (if given, enter brand name in "other" option below) EXCLUDE: Not PFAS 	Key PFAS species for this literature base have specific tags; for other PFAS species, copy name and CASRN into the free- text "Other" field

Table A-6.	Inclusion Criteria and Literature Attribute Tags for Evidence Related to PFAS
	Exposure, Toxicity, & Human Health Risk (Used in SWIFT-Active Screener for
	Level 2)

Category	Option Selection	Notes
Study Design(s)	 INCLUDE Completed Exposure Assessment Completed Risk Assessment Epidemiology (or Other Human) Study 	<i>Multiple study designs can be selected, as appropriate.</i>
	 Field Study (i.e., quantification of PFAS in media) Lab Study (i.e., animal model or cell-based study) Animal Model: Non-Human Primate Animal Model: Other Non-Human Mammal In Vitro – Human In Vitro – Non-Human Mammal Absorption, Metabolism, Distribution, and Excretion (ADME) 	For references that synthesize other studies, "Review or Other Evidence Synthesis" is selected in addition to the key study design(s) it cites.
	 Modeling or <i>In Silico</i> Study Benchmark Dose Modeling Physiological Based Pharmacokinetic Review or Other Evidence Synthesis Epidemiological Studies Field-Based Studies Laboratory-Based Studies Modeling or <i>In Silico</i> Studies 	Not all field studies are relevant. Field studies used for ecotoxicology, environmental media treatment, and/or fate/transport are not relevant for this section of the white paper.

Category	Option	Selection	Notes
	Devices or Theraper – Biomonitoring Only • Field – Environmental Medi – Fate/Transport – Ecotoxicology • Lab – Animal Model: Non- – In Vitro – Non-Mami – Analytical Methods I • Modeling or in silico stud – Quantitative Structu • Miscellaneous	To PFAS-containing Medical utics a Treatment Mammalian malian Development y re-Activity Relationship	
	Mechanism of Action or A	Adverse Outcome Pathway	
Population Characteristics of Interest	 N/A Pregnancy or lactation Fetal, infant, or child Elderly 	 Immunocompromised Genetically susceptible Occupational General population 	-
Exposure Route(s)	N/AOralDermal	InhalationIn uteroOther [free-text]	-
Exposure Matrix	 N/A Environmental Air Dust Soil Water High-Priority Consumer Product, or Product- Adjacent to CPSC Jurisdiction Toys, Hobbies, Crafts Childcare Products Infant Formula Household Products Electronics Kitchen Appliances Outdoors, Outdoor Recreation, Sports, Fitness Furniture, Furnishings, & Décor 	 Clothing, Apparel, Jewelry, Accessories Cosmetics and Personal Care Products Containers/Packaging Food Products Non-Consumer Product or Material Industrial Product or Material Manufacturing Product or Material Recycled Product or Waste Supplemental Product or Material Miscellaneous Household or Industrial Products Controlled Items Medical Products 	

Category	Option	Selection	Notes
Endpoint Category or Organ System(s)	 N/A Carcinogenicity or Mutagenicity Cardiovascular Developmental Endocrine Hematologic Hepatic 	 Immunological Musculoskeletal Neurological Renal Reproductive Respiratory Other [free-text] 	_
Available quantitative, health-related information?	 N/A Benchmark Dose (Level) Cancer Slope Factor Lowest-Observed- Adverse-Effect Level 	 Maximum Contaminant Level No-Observed-Adverse- Effect Level Reference Concentration/Dose Other [free-text] 	_
Location of Quantitative Health-Related Information in document	[Free Text]		-

Tier 2 Evidence Methods

Search Strategy for the Literature Review

We completed a review of peer-reviewed literature to complement the review of Tier 1 sources of evidence. Although we heavily rely on Tier 1 sources of evidence for the white paper, additional research has been conducted in the interim and the overall body of evidence continues to advance each year. This literature review was intended to ensure that we characterize the present-day state of the science and address data gaps or further areas of interest identified in Tier 1 references. We conducted two separate literature searches to broadly identify peer-reviewed resources related to 1) PFAS exposure and completed exposure assessments; and 2) toxicity, human health hazards, and human health risk associated with PFAS. Within the search strategies, we included search terms to specifically identify references relevant to consumer products and susceptible populations (e.g., fetuses, infants, children, pregnant persons, elderly persons).

We conducted the searches in PubMed, Web of Science, and Scopus. Full search strategies and search strings are available below.

Topic: The goal is to characterize the current state of the science related to PFAS: 1) exposure and completed exposure assessments; and 2) toxicity, human health hazards, and human health risk.

Research Questions:

- How are people exposed to PFAS?
- What are the health effects associated with PFAS exposure?
- What risks do PFAS pose to certain populations?
- What types of exposure scenarios pose risks to human health?

Search Part 1: PFAS Exposure and Completed Exposure Assessments

Language: English

Years: 2000-present

Search Date: January 5, 2023

Databases (number of resulting records):

- Web of Science (5,112)
- PubMed (4,242)
- Scopus (5,396)

Search Strategy: Chemical Search Term AND Exposure Search Term

Terms searched in: Title, Abstract, Author Keywords

Chemical Search Terms

("PFAS" OR "PFASs" OR "per- and polyfluoroalkyl substance*" OR "per- and poly-fluoroalkyl substance*" OR "perfluoroalkyl substance*" OR "perfluorohexane sulfonic acid" OR "perfluorohexanesulfonic acid" OR "PFHXS" OR "perfluorononanoic acid" OR "PFNA" OR "perfluorooctanoic acid" OR "PFOA" OR "perfluorooctane sulfonic acid" OR "PFOA" OR "PFC" OR "PFCS" OR "PFSA*" OR "FTOH*" OR "GenX" OR "PFOA*" OR "PFOS*" OR "fluorinated chemical*" OR "fluorinated compound*" OR "fluoropolymer*" OR "fluorinated polymer*" OR "PFBS" OR "PFCA" OR "PFCAS" (perfluorosulfonic acid*" OR "fluorinated compound*" OR "fluorotelomer alcohol*" OR "perfluorinated compound*" OR "PFCA" OR "PFCAS" (perfluorosulfonic acid*" OR "perfluoroalkyl carboxylic acid*" OR "perfluoroalkyl carboxylic acid*" OR "perfluorosulfonic acid*" OR "PFCAS" (perfluorosulfonic acid*" OR "perfluoroalkyl carboxylic acid*" OR "perfluoroalkyl carboxylic acid*" OR "perfluorobutane sulfonic acid*" OR "perfluoroalkyl carboxylic acid*" OR "perfluoroalkyl carboxylic acid*" OR "perfluorobutane sulfonic acid*" OR "perfluoroalkyl carboxylic acid*" OR "perfluoroalkyl carboxylic acid*" OR "perfluorobutane sulfonic acid*" OR "perfluorobut

Exposure Search Terms

("expos*") AND ("inhal*" OR "air" OR "derm*" OR "ingest*" OR "dust" OR "occupation*" OR "mixture" OR "complex" OR "dose" OR "level" OR "levels" OR "duration" OR "frequency" OR "in-utero" OR "fetal" OR "embryo" OR "infant*" OR "child*" OR "pregnant*" OR "maternal*" OR "breast feed*" OR "breast fed" OR "elder*")

Search Part 2: PFAS Toxicity, Human Health Hazards, and Human Health Risk

Language: English

Years: 2000-present

Search Date: January 5, 2023

Databases (number of resulting records)

- Web of Science (3,746)
- PubMed (3,910)
- Scopus (4,583)

Search Strategy: Chemical Search Term **AND** (Toxicity/Hazard Search Term **OR** Risk Search Term)

Terms searched in: Title, Abstract, Author Keywords

Chemical Search Terms

("PFAS" OR "PFASs" OR "per- and polyfluoroalkyl substance*" OR "per- and poly-fluoroalkyl substance*" OR "perfluoroalkyl substance*" OR "perfluoroalkyl substance*" OR "perfluoroalkyl substance*" OR "perfluorohexane sulfonic acid" OR "perfluorohexanesulfonic acid" OR "PFHxS" OR "perfluorononanoic acid" OR "PFNA" OR "perfluorooctanoic acid" OR "PFOA" OR "perfluorooctane sulfonic acid" OR "PFOA" OR "PFOA" OR "PFOA" OR "PFOA*" OR "PFBS*" OR "PFBA*" OR "PFBA*" OR "PFBA*" OR "fluorinated polymer*" OR "PFBA*" OR "PFFA*" OR "PFFA*

OR "perfluorochemical*" OR "perfluoroctane sulfonate" OR "perfluorobutane sulfonic acid" OR "perfluorobutanoic acid" OR "perfluorohexanoic acid")

Toxicological or Health Hazard Search Terms

("toxic*" OR "toxif*" OR "hazard" OR "hazards") AND ("effect" OR "effects" OR "endpoint" OR "endpoints" OR "risk" OR "morbid*" OR "mortal*" OR "dose-response" OR "dose response" OR "point of departure" OR "in vitro" OR "in vivo" OR "in silico" OR "animal model*" OR "alternative method*" OR "epidemiolog*" OR "human health" OR "adverse outcome*" OR "developmental toxic*" OR "reproductive toxic*" OR "birth weight*" OR "congenital*" OR "neonatal disease*" OR "neonatal abnormal*" OR "terato*" OR "terata*" OR "pregnancy complication*" OR "miscar*" OR "fertility" OR "blood pressure" OR "pre-eclampsia" OR "development*" OR "delay" OR "milestone*" OR "pubescen*" OR "carcinogen*" OR "cancer*" OR "neoplasm*" OR "tumor*" OR "tumour*" OR "mutagen*" OR "cardiotox*" OR "cardiovascular disease*" OR "hepatox*" OR "digestive" OR "endocrine" OR "enzymes and coenzymes" OR "eye disease*" OR "hormone antagonist*" OR "immune system disease*" OR "integumentary system" OR "hormone substitute*" OR "hormone antagonist*" OR "obes*" OR "hypertension" OR "integumentary system" OR "lipid" OR "ipids" OR "cholesterol" OR "macromolec*" OR "mental disorder*" OR "psych*" OR "behavior*" OR "hepatovat" OR "nephrotox*" OR "nucleotides" OR "ccupational disease*" OR "neurotox*" OR "nucleic acid*" OR "nucleosides" OR "nucleotides" OR "ccupational disease*" OR "pathol*" OR "stomatognathic*" OR "respir*" OR "skin" OR "connective tissue*" OR "musculoskeletal" OR "pathol*" OR "urogenital disease*" OR "stomatognathic*" OR

Risk Search Terms

("health") AND ("risk" OR "risk assess*" OR "reference dose" OR "reference concentration" OR "oral toxicity value" OR "cancer slope factor" OR "cancer potency factor" OR "inhalation unit risk" OR "peer reviewed toxicity value" OR "minimum risk level" OR "reference exposure level" OR "public health goal*" OR "uncertainty factor*")

Appendix B. Patents

B.1 Abbreviations

CPC	Cooperative Patent Classification	PCTFE PFAS	Polychlorotrifluoroethylene Per- and Polyfluoroalkyl
ECTFE	Ethylene Chlorotrifluoroethylene		Substances
		PTFE	Polytetrafluoroethylene
ePTFE	Expanded Polytetrafluoroethylene	PVDF	Polyvinylidene Difluoride
ETFE	Ethylene Tetrafluoroethylene	PVF	Polyvinylidene Fluoride
FEP	Fluorinated Ethylene Propylene	TFE	Tetrafluoroethylene

The following provides the search strategy and results of the preliminary search conducted using Innography software to capture patents related to per- and polyfluoroalkyl substances (PFAS)–containing consumer products. The final search conducted resulted in 28,229 patents, which are indexed in the database (*PFAS Source Characterization Database.xlsx*). **Table B-1** lists the preliminary patent search terms and results for PFAS-containing consumer products.

Tables B-2 through **B-12** provide illustrative examples of patents identified across consumer product categories.

Consumer Product Categories	Subcategory	Patent Search Terms (Title, Abstract, Claims)	Total Patent Documents*
Childcare Products	General	child* or baby OR infant	4,887
	Strollers and Cribs	"car seat" OR "carseat" OR stroller OR crib OR bassinet OR pram	151
Clothing, Apparel, Jewelry, Accessories	Clothing/Textiles	cloth* OR fabric OR textile OR shirt OR pants OR pajamas	34,952
Containers, Packaging	General	containers OR packaging	292,678
Cosmetics, Personal Care Products	Make-Up	cosmetics OR "personal care" OR "make-up" OR mascara	9,279
Electronics	General	electronics OR screen OR touchscreen OR television OR phone	54,934
Furniture, Furnishings, And Décor	Home Textiles	carpet OR rugs OR upholstery OR furniture	1,976
	Bedding	mattress OR pillow OR bedding	6,551
	Flooring	flooring OR "floor coating" OR "floor adhesive"	5306
Household Products	Cookware	cook* OR "pan" OR "pans" OR "pots" OR "pot" OR "skillet" OR "fryer" OR "saute"	8,285
	Household	house*	8,253
Infant Formula	-	(infant OR baby) AND (formula OR food)	768
Outdoors, Outdoor Recreation, Sports, Fitness	Skiing and Outdoor	ski OR skiing OR "snow sports" OR "outdoor recreation" OR camping OR "tent" OR "sport" OR "sporting"	2,975
	Crumb Rubber	turf OR "crumb rubber"	272
Small and Large Appliances	General	kitchen OR refridg* OR stove OR oven	9,757
Toys, Hobbies, Crafts	General	toy OR hobby OR hobbies OR craft*	1,737

Preliminary Patent Search Terms and Results for PFAS-Containing Consumer Products. Table B-1.

Note: Food products were not included in the preliminary patent search method.

*One document per simple family.

Table B-2. P	Patent Examples	for Childcare	Products
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Patent Title	Cooperative Patent Classification (CPC) Code	CPC Description	Specific PFAS	Description of PFAS Usage			
Baby Bottles							
Container for a pharmaceutical composition ¹	A61J 1	Containers specially adapted for medical or pharmaceutical purposes	TFE, PTFE, ETFE, FEP, PVF, PVDF, PCTFE, perfluoroalkoxy alkanes, ECTFE, perfluoroelastomer	Perfluoroelastomer is inert and provides a barrier between the drug and rubber material			
Glass baby bottle covered with a coating for protection against heat shock, and related manufacture method ²	C03C 17	Surface treatment of glass, not in the form of fibers or filaments, by coating	Fluoropolymer (preferably PTFE)	Hydrophobic nature provides high resistance to blocking and smooth nature			
Multifunctional vacuum feeding bottle ³	A 61 9	Feeding-bottles in general	PTFE, fluorinated ethylene TFE	Fluorinated piston provides self- lubricating properties and is food- grade			
Nursing bottle made of fluororesin ⁴	A61J 9	Feeding-bottles in general	Fluororesin (i.e., tetrafluoroethylene- perfluoroalkoxy ethylene copolymer resin, tetrafluoroethylene- hexafluoropropylene copolymer resin, tetrafluoroethylene- ethylene copolymer resin, vinylidene fluoride resin or vinyl fluoride resin)	Bottle and nipple are molded from a thermoplastic resin due to its higher impact resistance as compared to glass			

Patent Title	Cooperative Patent Classification (CPC) Code	CPC Description	Specific PFAS	Description of PFAS Usage
Self-cooling containers for liquids ⁵	A45F 3	Travelling or camp articles; Sacks or packs carried on the body	PTFE, polyvinylfluoride, PVF, polyethylenetetrafluoroethylene, fluorinated ethylene propylene (FEP) polyperfluoroalkoxyethylene	Hydrophobic surface with a small pore size aids permits sufficient pervaporative flux to allow for adequate cooling
Silicone elastomer material for use with enteric feeding device ⁶	A61J 15	Feeding-tubes for therapeutic purposes	Fluoro-modified polysiloxanes	Resistance to acid and enzymatic degradation when placed in a patient's stomach
		Car Se	eats	
Mat for use in an automobile and a method for manufacturing the same ⁷	B60N 3	Arrangements or adaptations of other passenger fittings, not otherwise provided for	Fluorine resin	Water-repellent agent for textiles used in car seats (not specific to children)

Notes: PTFE = polytetrafluoroethylene; ETFE = ethylene tetrafluoroethylene; FEP = fluorinated ethylene propylene; PVF = polyvinylidene fluoride; PVDF = polyvinylidene difluoride; PCTFE = polychlorotrifluoroethylene; ECTFE = ethylene chlorotrifluoroethylene 1. <u>Patent W02022187332 A1; 2. Patent US20180312427 A1; 3. Patent CN216022170 U; 4. Patent JP2000107259 A; 5. Patent US7107783 B2; 6. Patent US201972720 Patent VII Patent V</u>

US6923786 B2; 7. Patent US20070036936 A1.

Patent Title	CPC Code	CPC Description	Specific PFAS	Description of PFAS Usage
			Apparel	
Absorbent reusable clothing and undergarments ¹	A41B 9	Undergarments	Fluoroalkyl acrylate	Water-proofing treatment
A water-proof, oil-proof and anti-fouling functional cool fiber fabric ²	A41D 31	Materials Adapted for Outerwear	2, 2-bisphenol-hexafluoro propane diglycidyl ether	Fluorinated hydrophobic components are added to the surface of fibers to provide oils and stain repellency
Compressive resistant fabric ³	A41B 11	Hosiery; Panti-hose	Fluoroelastomer, fluoropolymers	Included in the fibers of a compression sock, but specific functionality was not provided
Convertible insulated smart glove ⁴	A41 D15	Convertible Garment	Generic fluorinated compounds	Panels of the insulated gloves, oven mitts, may be coated with a fluoropolymer to provide added functionality such as stain and soil resistance
Fishing garment ⁵	A31 D13	Professional, Industrial or Sporting Protective Garments	Generic fluororesin	Fluororesin spray coating on the fabric provides water and oil repellency, and antifouling properties
Protective sock preventing fungal type infections ⁶	A41B 11	Hosiery; Panti-hose	PTFE; fluoroelastomer, fluorosilicone	Addition to sock fibers provide water resistance
Undergarment with leak control and natural look and feel ⁷	A41B 9	Undergarments	Fluorocarbon-containing groups	Cotton has been chemically modified with acyl or fluorocarbon group to provide hydrophobicity
Wearable motorcycle heat-shield ⁸	A41 D31	Materials Adapted for Outerwear	Generic elastomers	Treatment added to the inner service of a heatshield designed for motorcycle heat protection on the riders' legs
Windproof cotton-padded clothes for children ⁹	A41D 11	Garments for Children	Fluorinated polyurethane film	Water resistance, air permeability and water vapor permeability

Table B-3. Patent Examples for Clothing, Apparel, Jewelry, and Accessories

Patent Title	CPC Code	CPC Description	Specific PFAS	Description of PFAS Usage
			Footwear	
A high wearable thermoplastic elastomer rain boot ¹⁰	A43B 3	Footwear characterized by the shape or the use	Fluorocarbon resin, PTFE	Coating for both wear and water resistance
Children shoes ¹¹	A43B 3	Footwear characterized by the shape or the use	Fluororubber	Pads/insoles of the children's shoes are made from fluororubber for durability
Cushioning element and shoe ¹²	A43B 7	Footwear with health or hygienic arrangements	PTFE, TFE; ETFE	Various fluorinated compounds can be added to the cushioning of a shoe
Hydrophobic polyimide aerogels ¹³	C08J 9	Working-up of macromolecular substances to porous or cellular articles or materials; After-treatment thereof	PTFE and other fluorine-containing monomers	Hydrophobic behavior can be added to aerogels with fluorinated compounds
Liquidproof seam for protective apparel ¹⁴	A43B 23	Uppers; Boot legs; stiffeners; Other single parts of footwear	Fluoropolymers, polyacrylates, co- polyether esters, co-polyether amides, polyurethanes, polyvinylchloride, PTFE, or polyolefins. For waterproof breathable applications, the first layer is preferably formed from ePTFE.	Provides a water-proofing layer for laminates that are providing barriers at seams
Preparation method of waterproof fabric and waterproof vamp ¹⁵	D06M 15	Treating fibers, threads, yarns, fabrics, or fibrous goods made from such materials, with macromolecular compounds; Such treatment combined with mechanical treatment	Highly fluorinated polyurethane	Fluorinated coating provides waterproofing
Tapeless waterproof footwear ¹⁶	A43B 7	Footwear with health or hygienic arrangements	Teflon, microporous PTFE, ePTFE	Used as part of a waterproofing layer in a boot or shoe

Patent Title	CPC Code	CPC Description	Specific PFAS	Description of PFAS Usage
Water repellant meltblown webs and laminates ¹⁷	B32B 5	Layered products characterized by the non- homogeneity or physical structure	Trademarked repellent	Provides water repellency for the nonwoven textile
1. Patent US20150290049 A1 US11330848 B2; 7. Patent US	2. Patent Cl 2012002364	<u>N110522106 B;</u> 3. <u>Patent US20</u> 5 A1; 8. <u>Patent US2020009320</u>		

Patent Title	CPC Code	CPC Description	Specific PFAS	Description of PFAS Usage
		Artificial	Flowers, Feathers, Wigs	
Use of a fluorinated polyurethane for prosthesis ¹	A41G 3	Wigs	Fluorinated polyurethanes	Forms elastic and durable films
Wig and method of manufacturing same ²	A41G 3	Wigs	Fluoropolymer fibers (i.e., PTFE, perfluoroalkoxy, fluoroethylenepropylene, TFE fibers)	Heat tolerance, stain resistance and decreased water absorption
Haberdashery; Jewelry				
Magnetic mascara compositions and related methods ³	A41G 5	Hair pieces, inserts, rolls, pads, or the like; Toupées	Fluorinated acrylate polymer	Water-resistant film-forming properties
Watch bands ⁴	C08G 18	Polymeric products of isocyanates or isothiocyanates	Hydroxy-terminated (per)fluoropolyether polymer	Used for the desired stain, chemical and wear resistance, low temperature flexibility, silky feel, and mechanical properties
		Hats	and Head Coverings	
Hat material ⁵	A42B 1	Hats; Caps; Hoods	Fluororesin	Deodorizing and antibacterial property
Hood including particle barrier ⁶	A62B 17	Protective clothing affording protection against heat or harmful chemical agents or for use at high altitudes	PTFE, ePTFE, another fluoropolymer, polyurethane, polyolefin (e.g., polyethylene, polypropylene), polyimide, polyester, silicone, or a combination	Creates a barrier to reduce or prevent penetration of particles
Protective head guard ⁷	A42B 3	Helmets; Helmet covers; Other protective head coverings	Fluorocarbon polymer	Provides low friction and non-stick properties; polymer is placed between layers of polyurethane foam

Table B-4. Patent Examples for Jewelry, Accessories

Patent Title	CPC Code	CPC Description	Specific PFAS	Description of PFAS Usage
		Purses; Lu	ggage; Hand Carried Bags	
Case for portable levices ⁸	H04B 1	Details of transmission systems; Details of transmission systems not characterized by the medium used for transmission	Fluorinated polyurethan polymer	Provides stain and chemical resistance
unch box structure ⁹	A45C 11/20	Lunch or picnic boxes or the like	Fluorocarbon resin	Coating the fluorocarbon resin on a paper substrate attains the greaseproof paper
			Umbrellas	
Fluoroplastic transparent umbrella ¹⁰	A45B 25	Details of umbrellas	Fluoroplastic (i.e., ETFE, ethylene- vinyl chloride, FEP, fluorinated vinyl chloride and polytetrafluoroethylene- perfluoroalkyl vinyl ether)	Provides stain resistance, hydrophobicity, heat resistance, weather resistance, flame retardance and chemical resistance
iquid repellent cloth, iquid repellent film, umbrella, and product ¹¹	D06M 15	Treating fibers, threads, yarns, fabrics, or fibrous goods made from such materials, with macromolecular compounds; Such treatment combined with mechanical treatment	Fluorine-based liquid repellent membrane, a silane-based compound having a long-chain perfluoroalkyl group	Provides water repellency

1. <u>Patent EP0822209 B1</u>; 2. <u>Patent US20080072918 A1</u>; 3. <u>Patent US20200281828 A1</u>; 4. <u>Patent US20180273675 A1</u>; 5. <u>Patent JP2001248077 A</u>; 6. <u>Patent US11122842 B2</u>; 7. <u>Patent US9392831 B2</u>; 8. <u>Patent US20200112330 A1</u>; 9. <u>Patent TWM608579 U</u>; 10. <u>Patent CN214802887 U</u>; 11. <u>Patent US20210289899 A1</u>.

Patent Title	CPC Code	CPC Description	Specific PFAS	Description of PFAS Usage
Bag-in-container with a coating layer ¹	B05D 1	Processes for applying liquids or other fluent materials	Fluorocarbons	Water-repellent coating
Bulk enhanced paperboard and shaped products made therefrom ²	B65D 81	Containers, packaging elements, or packages, for contents presenting particular transport or storage problems, or adapted to be used for non-packaging purposes after removal of contents	Fluorine containing moiety polymers including fluorochemical copolymers	Grease resistance
Container with recycled plastic ³	B32B 27	Layered products comprising (a layer of) synthetic resin	Fluorinated polyethylene	Provides bacterial barrier and prevents deterioration by moisture
Folding corrugated carton ⁴	B65D 25	Details of other kinds or types of rigid or semi-rigid containers	Fluoroplastic, fluorocarbon	Water and wear-resistant coating on a folding corrugated paper box
Lubricant coated beverage container or conveyor therefor ⁵	C09D 5	Coating compositions (e.g., paints, varnishes, or lacquers), characterized by their physical nature or the effects produced; Filling pastes	Fluoropolymer (e.g., PTFE)	Lubricant
Packaging container and method of making and using the same ⁶	B65D 71	Bundles of articles held together by packaging elements for convenience of storage or transport (e.g., portable segregating carrier for plural receptacles such as beer cans or pop bottles); Bales of material	Fluorinated polymer	Thermoplastic

Table B-5. Patent Examples of Containers, Packaging

Appendix B.

Patent Title	CPC Code	CPC Description	Specific PFAS	Description of PFAS Usage
Pressure-sensitive food grade wrap film and process for manufacturing such a film ⁷	B32B 7	Layered products characterized by the relation between layers; Layered products characterized by the relative orientation of features between layers, or by the relative values of a measurable parameter between layers, i.e., products comprising layers having different physical, chemical, or physicochemical properties; Layered products characterized by the interconnection of layers	Fluorinated copolymer (e.g., perfluoroalkyl phosphate)	Spill-resistance
Retort pouch and retort pouch food ⁸	B65D 81	Containers, packaging elements, or packages, for contents presenting particular transport or storage problems, or adapted to be used for non-packaging purposes after removal of contents	Fluoropolymer containing a fluoroalkyl group	Liquid and oil repellent
Treated paper product ⁹	D21H 27	Special paper not otherwise provided for (e.g., made by multi- step processes)	Fluoropolymer wax	Water and grease repellent

1. Patent US20220401992 A1; 2. Patent US6379497 B1; 3. Patent US6194043 B1; 4. Patent CN216685525 U; 5. Patent US7067182 B2; 6. Patent US20220204232 A1; 7. Patent US20020098348 A1; 8. Patent JP7106905 B2; 9. Patent US7189308 B2.

Patent Title	CPC Code	CPC Description	Specific PFAS	Description of PFAS Usage
			Brushes	
Bristle sub-assemblies and method of making same ¹	A46B 5	Brush bodies; Handles integral with brushware	Fluoropolymers	Creates monofilaments in bristle material
Brush for applying substance to eyelashes and/or eyebrows ²	A45D 40	Casings or accessories specially adapted for storing or handling solid or pasty toiletry or cosmetic substances (e.g., shaving soaps or lipsticks)	PTFE	Low thermal conductivity prevents bristles from sticking to hot surfaces during treatment
Low friction toothbrush ³	A46B 9	Arrangements of the bristles in the brush body	Fluoropolymers; PTFE	Slip agent to ensure low friction between bristle and tooth
Tooth polishing brush ⁴	A46D 1	Bristles; Selection of materials for bristles	Fluoropolymers (e.g., PVDF, fluorinated ethylene-propylene resin)	Creates base material and bristle material
		Cosmetics, I	Personal Care Products	
Cosmetic compositions ⁵	A61K 8	Cosmetics or similar toilet preparations	Non-volatile fluorinated oils	Lipstick–provides the suitable feel and shine
Eyelash compositions containing sugar ⁶	A61Q 1	Make-up preparations; Body powders; Preparations for removing make-up	Fluorinated hard or soft wax	Part of the lipophilic solid "wax" but description does not list function of the wax
Film-forming cosmetic composition ⁷	A61K 8	Cosmetics or similar toilet preparations	Fluoroalkyl copolymer	Film-forming composition to be used as a nail varnish

Table B-6. Patent Examples for Cosmetics, Personal Care Products

Patent Title	CPC Code	CPC Description	Specific PFAS	Description of PFAS Usage
Fluorine surfactants in emulsions ⁸	A61Q 17	Barrier preparations; preparations brought into direct contact with the skin for affording protection against external influences, e.g. sunlight, X-rays or other harmful rays, corrosive materials, bacteria or insect stings	Fluorosurfactants	Lowering ability for superior surface tension; increases light protection effect/UV protection effect
Fluorine-treated powder and external preparation for skin containing the same ⁹	A61K 8	Cosmetics or similar toiletry preparations	Alkyl fluoride group	Increases the hydrophobicity
Powder cosmetic ¹⁰	A61 Q 1	Make-up preparations; Body powders; Preparations for removing make-up	Fluorine-modified silicone resin	Water and oil repellent; durability
Sunscreen compositions containing fluorinated alkyl ethers ¹¹	A61K 8	Cosmetics or similar toilet preparations	Fluorinated alkyl ether	Including a fluorinated alkyl ether in the composition (in place of a portion of the alkanol that would otherwise be present in such compositions) unexpectedly raises SPF value
Water-resistant cosmetic composition ¹²	A61K 8	Cosmetics or similar toilet preparations	Fluorinated oils (e.g., fluorinated perfluoroethers and fluorinated silicones)	Used in part of this formulation as an oil
	Hair	dressing or Shaving Equipment; E	Equipment for Cosmetics or Cosmetic Tre	eatments
Makeup sponge and puff with improving of spreadability, obliterating power and tactility ¹³	C08J 9	Working-up of macromolecular substances to porous or cellular articles or materials; After-treatment	Alkyl fluorosilane	Water repellency/oil repellency is formed on a sponge for make-up and a puff to improve the ruggedness, hiding power and touch feeling

thereof

 Notes:
 PTFE = polytetrafluoroethylene;
 PVDF = polyvinylidene difluoride

 1.
 Patent US20030221271 A1;
 2.
 Patent US20040168698 A1;
 3.
 Patent EP1322199 B1;
 4.
 Patent US6199242 B1;
 5.
 Patent US20010024654 A1;
 6.
 Patent

 FR3120525 A1;
 7.
 Patent US6946123 B2;
 8.
 Patent WO2016142026 A1;
 9.
 Patent JP2004277389 A;
 10.
 Patent US2021155382 A;
 11.
 Patent US8206728 B2;
 12.
 Patent EP3773928 A1; 13. Patent KR101972298 B1.

Table B-7. Patent Examples for Electronics

Patent Title	CPC Code	CPC Description	Specific PFAS	Description of PFAS Usage
			Speakers	
Acoustic protective cover including a curable support layer ¹	H04R 19	Electrostatic transducers	ePTFE	Protective acoustic cover
Covers for electronic devices with a hydrophobic coating ²	G06F 3	Input arrangements for transferring data to be processed into a form capable of being handled by the computer; Output arrangements for transferring data from processing unit to output unit (e.g., interface arrangements)	Fluorinated olefin-based polymers	Water-resistant coating
Enclosures for microphone assemblies including a fluoropolymer insulating layer ³	H04R 19	Electrostatic transducers	Fluoropolymer; PTFE	Insulation
			Telephone	
Antireflective treatment for textured enclosure components ⁴	G02B 1	Optical elements characterized by the material of which they are made; optical coatings for optical elements	Fluorinated oligomer or polymer	Water/oil repellent
Coating composition, method of antifouling treatment and antifouling substrate ⁵	C03C 17	Surface treatment of glass, not in the form of fibers or filaments, by coating	Perfluoroalkylene ether; perfluoropolyether	Antifouling
Prevent cell-phone cover plate glass of fingerprint adhesion ⁶	H04 M 1/02	Constructional features of telephone sets	Perfluoropolyether polymer	Prevents fingerprints adhering to the surface; shock-proof

Patent Title	CPC Code	CPC Description	Specific PFAS	Description of PFAS Usage
			Television	
lousings for electronic evices ⁷	C09D 133	Coating compositions based on homopolymers or copolymers of compounds having one or more unsaturated aliphatic radicals, each having only one carbon- to-carbon double bond, and at least one being terminated by only one carboxyl radical, or of salts, anhydrides, esters, amides, imides, or nitriles thereof; Coating compositions based on derivatives of such polymers	Fluoropolymer	Anti-smudge coating
nformation display protectors ⁸	H01J 29	Details of cathode-ray tubes or of electron-beam tubes	Fluorochemical mixtures	Stain and abrasion resistance
Projection television eceiver ⁹	H04N 5	Details of television systems	PTFE	Fluoride resin film used to seal in the receiver which contacts the refrigerar liquid

1. Patent US10945061 B2; 2. Patent WO2021141579 A1; 3. Patent US20220201387 A1; 4. Patent US11199929 B2; 5. Patent WO2010038648 A1; 6. Patent CN214756430 U; 7. Patent WO2022055472 A1; 8. Patent US6660389 B2; 9. Patent US6525784 B1.

Patent Title	CPC Code	CPC Description	Specific PFAS	Description of PFAS Usage
Preparation of frozen buckwheat dough stick ¹	A23L 1	Foods, foodstuffs, or non- alcoholic beverages; Their preparation or treatment; Preservation of foods or foodstuffs, in general	Fluorine	Coating for the pot and stirring rod
Sushi rolls ²	A23L 1	Foods, foodstuffs, or non- alcoholic beverages; Their preparation or treatment; Preservation of foods or foodstuffs, in general	Fluororesin	Coating for the surface of the molded sheet
Notes: 1. Patent JP20010459	<u>97 A; 2. Pater</u>	nt JP4217690 B2.		

Patent Title	CPC Code	CPC Description	Specific PFAS	Description of PFAS Usage	
Fabric Treatment					
Carpet ¹	A47G 27	Floor fabrics; Fastenings therefor	Fluororesin	Antifouling against dry and wet soil	
Fabrics with Improved Barrier Properties ²	D06M 15	Treating fibers, threads, yarns, fabrics, or fibrous goods made from such materials, with macromolecular compounds; Such treatment combined with mechanical treatment	Fluorochemical (i.e., perfluoroalkylethylmethacrylate)	Alcohol repellent	
Liquid repellent cloth, liquid repellent film, umbrella, and product ³	D06M 15	Treating fibers, threads, yarns, fabrics, or fibrous goods made from such materials, with macromolecular compounds; Such treatment combined with mechanical treatment	Fluorine-containing organic compound including a perfluoroalkyl group	Provides water repellency	
Self-lubricating fabric and production method and use thereof ⁴	F16C 33	Parts of bearings; Special methods for making bearings or parts thereof	Fluorinated resin	Oil-free lubrication	
Water/oil repellent article, method for its production and water/oil repellent composition ⁵	B05D 5	Processes for applying liquids or other fluent materials to surfaces to obtain special surface effects, finishes or structures	Fluorinated polymer	Water/oil repellent and friction durability	
Thick floor coating having antistatic properties ⁶	C09D 5	Coating compositions	Fluorinated ionic liquids	Antistatic properties	

Table B-9. Patent Examples for Furniture, Furnishings, Décor

Patent Title	CPC Code	CPC Description	Specific PFAS	Description of PFAS Usage	
Upholstery in General					
A multi-functional thermal A47C 27 Spring, stuffed or fluid mattresses (or cushions) specially adapted for chairs, beds, or sofas					
Highly-waterproof antibacterial breathable sleeping bag and preparation method thereof ⁸	A47G 9	Special paper not otherwise provided for, e.g., made by multi-step processes	PTFE film	Breathable and waterproof coating	
Notes: 1. Patent US20220010486 A1; 2. Patent US20210363690 A1; 3. Patent US20210289899 A1; 4. Patent US10302130 B2; 5. Patent US11504740 B2; 6. Patent US20090068435A1; 7. Patent KR100566043 B1; 8. Patent CN114224143 B.					

Patent Title	CPC Code	CPC Description	Specific PFAS	Description of PFAS Usage	
Dry-Cleaning, Washing, or Bleaching					
Waterproof and oilproof finish technology for jean fabric ¹	D06L 1	Dry-cleaning or washing fibers, filaments, threads, yarns, fabrics, feathers, or made-up fibrous goods	Fluorine	Provides water/oil repellency to be used on jean fabric	
Cleaning Products; Detergents					
Cleaner composition for glass substrate ²	C11D 1	Detergent compositions based essentially on surface-active compounds; Use of these compounds as a detergent	Fluorinated compound	Suppresses stains on glass surface	
Fluorinated tensides ³	C07C 323	Thiols, sulfides, hydropolysulfides or polysulfides substituted by halogen, oxygen, or nitrogen atoms, or by sulfur atoms not being part of thio groups	Fluorosurfactants; perfluoroolefins	Provides efficient reduction of surface tension, low critical micelle concentration, and low foaming behavior	
Method for Removal of Contaminants ⁴	B01D 12	Displacing liquid, e.g., from wet solids or from dispersions of liquids or from solids in liquids, by means of another liquid	Fluorosubstituted organic carbonates	Water, dust, and grease-removing agent; however, this may not be a consumer cleaning product	
Scrubbing-free car washing powder ⁵	C11D 1	Detergent compositions based essentially on surface-active compounds; Use of these compounds as a detergent	Perfluoropolyether and fluorosilicone resin	Reduces surface tension of car washing liquid and repel dust, water, and fog	

Detergent materials or soaps characterized by their shape or physical properties Cooking-vessels Parts, details, or accessories of cooking- vessels Parts, details or accessories of cooking- vessels	Fluorosurfactant (e.g., fluorinated and perfluorinated alkyl carboxylates, fluorinated and perfluorinated alkyl alkoxylates, fluorinated alkyl esters, perfluorinated alkyl sulfonates) Cookware Fluorine-containing polymers (PTFE, perfluoroalkoxy copolymer, hexafluoropropylene) PTFE PTFE, copolymers of TFE with such co-monomers as	Dirt and grease-removing agent Provides anti-adhesion and thermostability Non-stick coating for cookware Coating provides non-stick
Parts, details, or accessories of cooking- vessels Parts, details or accessories of cooking-	Fluorine-containing polymers (PTFE, perfluoroalkoxy copolymer, hexafluoropropylene) PTFE PTFE, copolymers of TFE with such co-monomers as	thermostability Non-stick coating for cookware Coating provides non-stick
Parts, details, or accessories of cooking- vessels Parts, details or accessories of cooking-	perfluoroalkoxy copolymer, hexafluoropropylene) PTFE PTFE, copolymers of TFE with such co-monomers as	thermostability Non-stick coating for cookware Coating provides non-stick
accessories of cooking- vessels Parts, details or accessories of cooking-	PTFE, copolymers of TFE with such co-monomers as	Coating provides non-stick
accessories of cooking-	co-monomers as	
	perfluoromethylvinylether, perfluoropropylvinyl ether, hexafluoropropylene, ethylene, chlorotrifluoroethylene and combinations of the above comonomers with TFE	functionality
Cooking-vessels	Fluoropolymer	Provides a non-stick layer on pots and pans/cookware
Apparatus for making beverages	Fluoropolymer	Corrosion resistance: low friction material to avoid cellulose and coffee particles from easily sticking to the surface
Parts, details, or accessories of cooking- vessels	PTFE, a copolymer of TFE and perfluoroproylvinylether, or a copolymer of TFE and hexafluoropropylene	Anti-adhesive coating to avoid growth of microorganisms
	Apparatus for making beverages Parts, details, or accessories of cooking- vessels E = tetrafluoroethylene 02377875 B1; 3. Patent US115	Cooking-vesselsFluoropolymerApparatus for making beveragesFluoropolymerParts, details, or accessories of cooking- vesselsPTFE, a copolymer of TFE and perfluoroproylvinylether, or a copolymer of TFE and hexafluoroproylene

Patent Title	CPC Code	CPC Description	Specific PFAS	Description of PFAS Usage	
Camping Equipment					
Lacing cord and shoes using the same ¹	A43C 1	Shoe lacing fastenings	Tetrafluoroethylene perfluoroalkyl vinyl ether copolymer, tetrafluoroethylene hexafluoropropylene copolymer, and PTFE	Allows for sliding ability	
Quick absorption and dry function fabric having ultra water-repellent property ²	A45F 3	Travelling or camp articles; Sacks or packs carried on the body	Fluorine-based component	Water-repellent	
Self-cooling containers for liquids ³	A45F 3	Travelling or camp articles; Sacks or packs carried on the body	Fluorinated resins (e.g., FEP, PVF, PVDF, PTFE)	Thermal regulation and allows evaporation	
Paving or Foundations Specifically Adapted for Playgrounds or Sports Grounds					
Artificial turf filaments, and articles made therefrom ⁴	E01C 13	Pavings or foundations specially adapted for playgrounds or sports grounds;	Fluorinated surface	Improves hydrophilicity so that the water sheets off the surface	
A waterproof plastic track ⁵	E01C 13	Pavings or foundations specially adapted for playgrounds or sports grounds;	Fluorine rubber	Corrosion resistance layer	
Personal Computers, Training/Exercise Equipment; Toys; Skis/Skates; Games					
Friction-reducing elements for sports racquet strings ⁶	A63B 51	Stringing tennis, badminton or like rackets; Strings therefor; Maintenance of racket strings	Fluoropolymers comprised of at least one fluoroolefin monomer	Placed between the string of a racquet to prevent friction	
Golf ball ⁷	A63B 37	Solid balls; Marbles	Fluorocarbon polymer (i.e., PTFE)	Reduces surface energy	

Table B-11. Patent Examples for Outdoors, Outdoor Recreation, Sports, Fitness

Patent Title	CPC Code	CPC Description	Specific PFAS	Description of PFAS Usage
Skiing sole coating for ski shoes has polytetrafluoroethylenes and a fluoropolymer mixture with polyethylene segments not fluorinated in macromolecules ⁸	A63C 5	Skis or snowboards	Fluoropolymer (i.e., polyfluoroethylene propylene, ethylene- tetrafluoroethylene copolymer and tetrafluoroethylene- hexafluoropropylene vinylidine fluoride copolymer)	Decreases friction and provide abrasion resistance
			Ski Wax	
Composition for reducing sliding friction of an article on snow, ice and/or water ⁹	C09G 3	Ski waxes	Discusses past usage of PFAS in ski wax but current invention is PFAS-free	Friction reduction/lubrication
Fluorocarbon, lubricant for use on ice and snow, and coating method ¹⁰	C10M 131	Lubricating compositions characterized by the additive being an organic non-macromolecular compound containing halogen	Fluoropolymer and fluroresin	Lubricating coating
Lubricating agent containing fluorinated urethane ¹¹	C09G 3	Ski waxes	Fluorinated urethanes	Lubricating agent
Lubricious coatings for skis and snowboards and related systems and methods of use ¹²	C10M 169	Lubricating compositions characterized by containing as components a mixture of at least two types of ingredients selected from base- materials, thickeners or additives, covered by the preceding groups, each of these compounds being essential	Fluorinated polymer that is at least one of PTFE or FEP	Water-resistant coating and lubrication

Notes: PTFE = polytetrafluoroethylene; FEP = fluorinated ethylenepropylene; PVF = polyvinylfluoride; PVDF = polyvinylidinefluoride 1. <u>Patent US20140196312 A1</u>; 2. <u>Patent KR20050076375 A</u>; 3. <u>Patent US7107783 B2</u>; 4. <u>Patent US20150204027 A1</u>; 5. <u>Patent CN217556608 U</u>; 6. <u>Patent</u>

EP1078655 B1; 7. Patent US11511162 B2; 8. Patent DE202006008755 U1; 9. Patent WO2022117637 A1; 10. Patent US11306222 B2; 11. Patent US20040106821 A1; 12. Patent US20220135841 A1.

Table B-12. Patent Examples of Toys, Hobbies, and Crafts

CPC Code	CPC Description	Specific PFAS	Description of PFAS Usage
A63H 33	Other toys	Fluoroplastics (e.g., PTFE, perfluoro second propylene, ethylene- tetrafluoroethylene copolymer materials such as PTFE and perfluoro second propylene)	Refined into plush materials to reduce dust and bacteria accumulation
A63H 33	Other toys	Fluororubber	Softens material to prevent injuries
	A63H 33	A63H 33 Other toys	A63H 33 Other toys Fluoroplastics (e.g., PTFE, perfluoro second propylene, ethylene- tetrafluoroethylene copolymer materials such as PTFE and perfluoro second propylene)

Notes: PTFE = polytetrafluoroethylene 1. <u>Patent CN202410140 U;</u> 2. <u>Patent JP3194199 U.</u>

Appendix C. Market Trends

C.I ADDIEVIALIUNS	C.1	Abbreviations
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CDR	Chemical Data Reporting Database	PFAS	Per- and Polyfluoroalkyl Substances
HS	Harmonized System	UN	United Nations
NAICS	North American Industry Classification System		

C.2 Technical Supplemental Information

The equations used to determine per- and polyfluoroalkyl substances (PFAS) domestic demand and PFAS release rate are detailed below.

C.2.1 PFAS Domestic Demand Equations

To identify potential direct PFAS-using sectors, we filter the detailed Bureau of Economic Analysis "use tables" to only include commodities with PFAS-producing North American Industry Classification System (NAICS) codes (6-digit; identified above). Potential direct PFAS-using sectors are those with dollar value purchases from PFAS-producing sectors. We apportion the physical quantity of PFAS supply from the national Chemical Data Reporting Database (CDR) data, q_{cs} , by PFAS category, c, from each producing sector, s, to potential PFAS-using sectors, p, according to the dollar value of intermediate purchases among them, v_{sp} . That is, v_{sp} captures the dollar value of purchases by sector p from PFAS-producing sector s. Our estimated quantity of potential PFAS category purchases from sector s by sector p is:

$$q_{csp} = \frac{q_{cs} v_{sp}}{\Sigma_p v_{sp}}$$

Total potential demand for category c by purchasing sector p is then

$$q_{cp} = \Sigma_s q_{csp},$$

and the total demand for PFAS category c in any period t is then

$$q_{ct} = \Sigma_p \, y_{pt} \, \tilde{q}_{cp}.$$

Where y_{pt} is purchasing sector p output in period t and $\tilde{q}_{cp} = \frac{q_{cp}}{y_p}$ is the use intensity of PFAS in

purchasing sector p in our benchmark year (2016). The result of this analysis is a demand index that we can use to estimate the quantity of PFAS that would be supplied to the U.S. economy based on future projections of gross domestic product and historical output to gross domestic product ratios.

C.2.2 Reported PFAS Releases Equation

The release rate for each PFAS category was calculated according to the following equation:

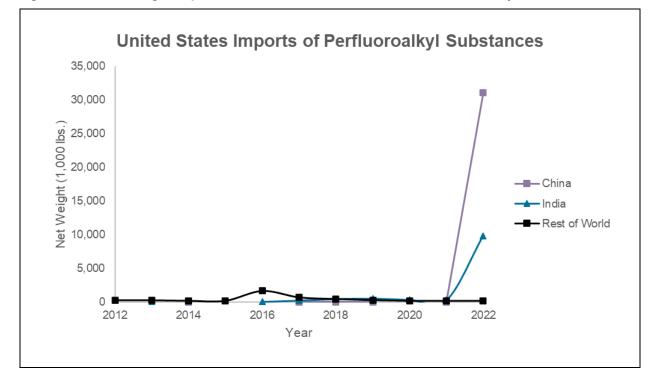
 $\frac{r_c}{q_c}$

where r_c are total reported Toxics Release Inventory releases for PFAS category c and q_c is the total supply of PFAS category *c* from the national CDR data.

C.3 Trade in PFAS

Several factors could contribute to the divergence between import volumes reported in CDR and United Nations (UN) Comtrade data. We are not able to directly measure import coverage from CDR data because national aggregates do not separate import volumes and domestic manufacturing volumes. CDR import data reporting could therefore vary significantly in completeness relative to manufacturing reporting. As with NAICS codes, much of PFAS trade likely occurs under Harmonized System (HS) codes with broader chemical definitions and descriptions that do not mention PFAS and were therefore not identified in our searches. CDRreported polymer import volumes were substantially lower than UN Comtrade import volumes, which averaged approximately 60 million pounds per year over the past decade. The dramatic decline in CDR-reported facility-level polymer import volumes from 2.4 million pounds in 2012 to zero in 2020 against the relatively steady UN Comtrade import volumes suggest potential for increasing reporting and/or confidential business information bias in the CDR data.

Trade volumes by country for the imports and exports of PFAS based on identified HS codes are shown below. **Figures C-1** and **C-2** correspond to the imports and exports of *perf*luoroalkyl substances, respectively. **Figures C-3** and **C-4** correspond to the imports and exports of *poly*fluoroalkyl substances, respectively. Across each of the exhibits, countries that contributed less than 5% of the total U.S. trade volume over the period are grouped as "rest of world." **Table C-1** shows the average annual PFAS exports and imports by the five countries that reported the largest trade volumes from 2012 to 2021.





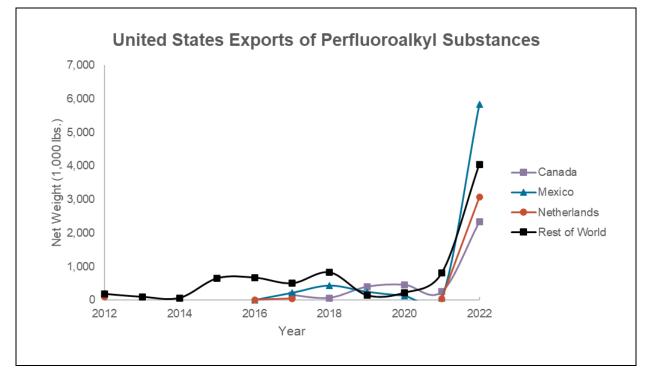
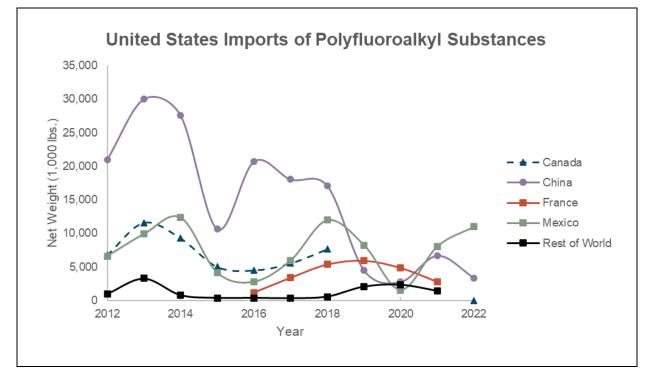


Figure C-2. Net Weight Exported for HS Codes Associated with Perfluoroalkyl Substances

Figure C-3. Net Weight Imported for HS Codes Associated with Polyfluoroalkyl Substances



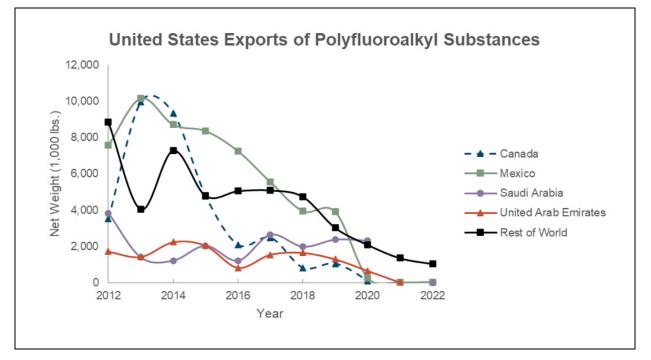


Figure C-4. Net Weight Exported for HS Codes Associated with Polyfluoroalkyl Substances

Table C-1. Average Annual PFAS Exports and Imports (2012–2021)

Country	Exports (lbs.)	Imports (lbs.)
China	333,686,672	40,226,519
United States	90,765,338	97,751,828
Germany	39,820,179	87,314,179
Japan	49,124,355	77,574,930
India	65,330,475	17,178,610

Note: Table comprises the five countries that reported the largest trade volumes with the United States 2012-2021

Appendix D. PFAS Exposure and Human Health Risks: Literature Review Results

D.1 Abbreviations

ATSDR	Agency for Toxic Substances	PFBA	Perfluorobutanoic Acid
	and Disease Registry	PFBS	Perfluorobutanesulfonic Acid
CDC	Centers for Disease Control and Prevention	PFDA	Perfluorodecanoic Acid
CONTAM	Panel on Contaminants in the Food Chain	PFDoDA	Perfluorododecanoic Acid
		PFHpA	Perfluoroheptanoic Acid
CPSC	Consumer Product Safety Commission	PFHxA	Perfluorohexanoic Acid
		PFHxS	Perfluorohexanesulfonic Acid
EPA	Environmental Protection Agency	PFNA	Perfluorononanoic Acid
GenX	Hexafluoropropylene Oxide Dimer Acid (and Its Ammonium Salt)	PFOA	Perfluorooctanoic Acid
		PFOS	Perfluorooctanesulfonic Acid
		PFOSA	Perfluorooctanesulfonamide
HFPO-DA	Hexafluoropropylene Oxide Dimer Acid	PFTeDA	Perfluorotetradecanoic Acid
IRIS	Integrated Risk Information System	PFUnA	Perfluoroundecanoic Acid
		SWIFT	Sciome Workbench for
PFAS	Per- and Polyfluoroalkyl Substances		Interactive Computer- Facilitated Text-Mining
	Cubitanoco	UN	United Nations

D.2 Tier 1 Evidence Results

Critical Tier 1 evidence was identified from various authoritative sources; however, select items of Tier 1 evidence served as the primary basis to summarize topics related to Exposure and Human Health Risks (Table D-1). Several authoritative agencies have conducted reviews to support exposure-specific mandates that are not directly related to Consumer Product Safety Commission (CPSC's) jurisdiction (e.g., drinking water, food); however, these sources still provide high-quality evidence syntheses and summaries on several overarching per- and polyfluoroalkyl substances (PFAS) topics, particularly with respect to toxicity and human health risk.

Oftentimes, different branches or offices of key agencies will conduct distinct reviews of the available evidence. Agency and office priorities naturally differ for which compounds or subclasses are relevant for their decision-making mandates or research areas. This has led to an extensive but patchwork set of available, authoritative evidence reviews across the PFAS family—see, for example, the similar-but-distinct scope of publications from various offices of the U.S. Environmental Protection Agency (EPA), which were heavily cited in this white paper. For example, several PFAS compounds have been identified for assessment under U.S. EPA's Integrated Risk Information System (IRIS) program; IRIS toxicological reviews have already been published for perfluorobutanoic acid (PFBA) and perfluorohexanoic acid (PFHxA), and several others are under development. The U.S. EPA Office of Research and Development also

conducted toxicity assessments to establish human health toxicity reference values for GenX and perfluorobutanesulfonic acid (PFBS); these documents are conceptually similar, but distinct from IRIS toxicological reviews. Meanwhile, the U.S. EPA's Office of Water has conducted numerous reviews of the health hazards evidence over the past decade, culminating in proposed Maximum Contaminant Levels and Maximum Contaminant Level Goals in drinking water for perfluorooctanoic acid (PFOA), perfluorooctanesulfonic acid (PFOS), PFNA (perfluorononanoic acid), perfluorohexanesulfonic acid (PFHxS), PFBS, and GenX; these documents newly derive toxicity reference values for PFOA and PFOS, use existing toxicity reference values from the Human Health Toxicity Assessments for GenX and PFBS, and—in the absence of available toxicity values from within their agency—use modified oral Minimal Risk Levels published by the Agency for Toxic Substances and Disease Registry (ATSDR) for PFNA and PFHxS.

Table D-1 displays the key Tier 1 evidence used as the primary basis for the exposure and human health toxicity and risks section.

Authoritative Body	Agency or Entity	Publication Series or Group(s)	PFAS Referenced
U.S. Centers for Disease Control and Prevention (CDC)	Agency for Toxic Substances and Disease Registry	Toxicological Profile	Perfluoroalkyls (PFBA, PFHxA, perfluoroheptanoic acid [PFHpA], PFOA, PFNA, perfluorodecanoic acid (PFDA), perfluoroundecanoic acid (PFUnA), perfluorododecanoic acid (PFDoDA), PFBS, PFHxS, PFOS, perfluorooctanesulfonamide [PFOSA])
U.S. EPA	Office of Research and Development	IRIS Assessments ^a	PFBA, PFDA, PFNA, PFHxA, PFHxS
U.S. EPA	Office of Research and Development	Human Health Toxicity Assessments ^b	GenX (Hexafluoropropylene Oxide Dimer Acid [HFPO-DA]), PFBS
U.S. EPA	Office of Water	Toxicity Assessment and Proposed Maximum Contaminant Level Goals ^{c:} Maximum Contaminant Level Goal for a Mixture of Four Per- and Polyfluoroalkyl Substances ^d	PFOA, PFOS, PFBS, PFNA, PFHxS, GenX (i.e., HFPO-DA])
European Union	European Union Chemicals Agency	Substances of Very High Concern Candidate List Identification Proposals and Support Documents	PFBS, GenX, PFHxS, PFDA, PFNA, PFOA, others (e.g., PFHpA, PFUnA, perfluorotetradecanoic acid [PFTeDA])
European Union	European Union Chemicals Agency	Proposal for a Restriction ^e	PFAS (as a class)

Table D-1.Key Tier 1 Evidence Used as the Primary Basis for the Exposure and Human Health
Risks Section.

Authoritative Body	Agency or Entity	Publication Series or Group(s)	PFAS Referenced
European Union	European Food Safety Authority	Scientific Opinions on the Safety Evaluation of Food Contact Materials; Scientific Opinion on Contaminants in the Food Chain; Risk to Human Health Related to the Presence of Perfluorooctane Sulfonic Acid and Perfluorooctanoic Acid in Food. (i.e., Panel on Contaminants in the Food Chain [CONTAM] 2018); Risk to Human Health Related to the Presence of Perfluoroalkyl Substances in Food (i.e., CONTAM Panel 2020).	Previous Scientific Opinions on Safety Evaluations include numerous production aids; Opinion on Contaminants in the Food Chain include PFOA and PFOS; CONTAM Panel 2018: PFOA, PFOS; CONTAM Panel 2020: PFOA, PFOS, PFNA, PFHxS
United Nations	Stockholm Convention on Persistent Organic Pollutants	Risk Profiles; Risk Management Evaluations; Listing Proposals	PFOS, PFOA, PFHxS, long-chain perfluorocarboxylic acids
National Academies of Sciences, Engineering, and Medicine	—	Guidance on PFAS Exposure, Testing, and Clinical Follow-up	PFAS (as a class)

^a IRIS Assessment activities are in varying stages of completion for each PFAS selected by the office. As of April 2023, <u>PFBA</u> and <u>PFHxA</u> have finalized toxicological reviews available; <u>PFDA</u> is under public comment and external peer review (Step 4); <u>PFHxS</u> is under Interagency Science Consultation (Step 3); <u>PFNA</u> is in Draft Development (Step 1).

^b Final Human Health Toxicity Assessments are available for GenX and PFBS. Toxicity Assessments are under development for PFOA, PFOS, PFBA, PFHxA, PFHxS, PFNA, and PFDA.

- ^c Individual toxicity assessments were conducted and new toxicity reference values were derived for PFOA and PFOS to support proposed drinking water regulations.
- ^d Existing EPA toxicity assessments and toxicity reference values were used for PFBS and GenX; In the absence of existing information from EPA, toxicity assessments and toxicity reference values were modified from ATSDR's Toxicological Profile and minimal risk levels developed for PFNA and PFHxS.
- ^e The Annex XV Restriction Report is not finalized as of March 2023 and was not formally used for this white paper; final versions are expected in late 2023 to accompany ongoing regulatory action in the European Union. Preliminary (draft) Restriction Report content appears to generally support the information presented in the white paper as of April 2023.

Appendix E. Chemical and Health Profile: PFOA and PFOS

E.1 Abbreviations

ADHD	Attention-Deficit/Hyperactivity Disorder	IARC	International Agency for Research on Cancer
ALT	Alanine Aminotransferase	LDL	Low-Density Lipoproteins
ATSDR	Agency for Toxic Substances and Disease Registry	MCLG	Maximum Contaminant Level Goal
CSF	Cancer Slope Factor	NTP	National Toxicology Program
EFSA	European Food Safety Authority	PFAS	Per- and Polyfluoroalkyl Substances
EPA FGR	Environmental Protection Agency Fetal Growth Restriction	PFOA	Perfluorooctanoic Acid
		PFOS	Perfluorooctanesulfonic Acid
		POD	Point of Departure
		RfD	Reference Dose

E.2 Introduction

Given that perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS) are the primary PFAS chemicals evaluated in the health literature and are among the per- and polyfluoroalkyl substances (PFAS) of focus for decision-makers—due to ubiquity, ecological and biological persistence, severity of health effects, and health effects found in susceptible populations—this appendix provides a more detailed profile on key toxicity information for those chemicals.

The U.S. Environmental Protection Agency (EPA) has conducted significant work on synthesizing evidence related to PFOA and PFOS over the past decade. EPA published health effects summary documents for PFOA and PFOS in 2016, which served as the foundation for several recent milestone updates and actions from EPA. Interim updates to these nonenforceable health advisories were issued in 2022. In March 2023, EPA published for public comment the Toxicity Assessment and Proposed Maximum Contaminant Level Goals (MCLGs) for PFOA and PFOS. To our knowledge, these are the latest evidence syntheses specifically focused on these two key PFAS compounds from an authoritative body, and they take into consideration evaluations from numerous other authoritative sources and reviews of the primary literature. These documents update EPA's previous and extensive literature searches through February 2022, and they incorporate feedback from an expert Scientific Advisory Board. Although the 2022 Interim Health Advisories for PFOA and PFOS will officially remain EPA's non-regulatory health guidance for PFAS in drinking water until the National Primary Drinking Water Regulation is finalized, these public comment drafts are advanced enough to cite; therefore, this white paper uses these documents as the primary basis for a more detailed overview of recent, substantiated evidence for health effects associated with PFOA and PFOS exposure, in addition to citing evidence from other authoritative sources as appropriate.

E.3 **PFOA** and Cancer

PFOA is widely considered to be carcinogenic by most authoritative bodies.

The International Agency for Research on Cancer (IARC) classified PFOA as "possibly carcinogenic to humans" (classification 2B) in 2017, on the basis of *limited* evidence for kidney and testicular cancer (World Health Organization, 2016).

EPA recently integrated available animal, human, and mechanistic data and concluded that "PFOA is likely to be carcinogenic to humans." Per the EPA's Guidelines for Carcinogen Risk Assessment, this rating indicates "the evidence is adequate to demonstrate carcinogenic potential to humans but does not reach the weight-of-evidence for the descriptor Carcinogenic to Humans." EPA noted that "new data...indicate that PFOA is a more potent carcinogen than previously understood and described in the 2016 HESD [health effects summary document]," although "there is not convincing epidemiological evidence supporting a causal association" between human exposure to PFOA and cancer, only a plausible association-thus resulting in a moderated overall rating. The rating of "likely to be carcinogenic to humans" was reached on the basis of kidney and testicular cancer in humans, as well as Leydig cell tumors, pancreatic cell tumors, and hepatocellular adenomas (i.e., a "tumor triad") in rats. Epidemiologic evidence for cancer outcomes in humans were typically only observed in occupationally exposed populations or in highly exposed communities. EPA has concluded there is insufficient information to determine an exposure threshold below which there are no carcinogenic effects for PFOA, and has therefore assumed a linear low-dose exposure model (U.S. EPA, 2023a). See below (PFOA and PFOS Dose-Response Assessments) for select quantitative health and risk information related to PFOA and cancer.

Other prominent authoritative bodies have also identified PFOA as associated with cancer outcomes in humans, including the National Toxicology Program (NTP), the Agency for Toxic Substances and Disease Registry (ATSDR), and the National Academies of Science, Engineering and Medicine (National Toxicology Program, 2020; Agency for Toxic Substances and Disease Registry, 2021; National Academies of Science, Engineering and Medicine, 2022). PFOA is also listed on the State of California's Proposition 65 list in part due to its carcinogenicity (California EPA, 2022).

The European Food Safety Authority (EFSA) differs from the prevailing authoritative opinions, concluding there is insufficient support for the carcinogenicity of PFOA (EFSA Panel on Contaminants in the Food Chain, 2020; EFSA Panel on Contaminants in the Food Chain, 2018).

E.4 PFOS and Cancer

Compared to PFOA, more uncertainty exists regarding the potential carcinogenicity of PFOS.

The International Agency for Research on Cancer has not yet evaluated the carcinogenicity of PFOS but plans to do so in late 2023 (World Health Organization, 2023).

Despite mixed evidence in humans, several authoritative bodies consider PFOS to be carcinogenic, given the overall state of the evidence. EPA integrated available animal, human, and mechanistic data and concluded that "PFOS is *likely to be carcinogenic to humans*." Per the EPA's *Guidelines for Carcinogen Risk Assessment*, this rating indicates "the evidence is adequate to demonstrate carcinogenic potential to humans but does not reach the weight-of-evidence for the descriptor Carcinogenic to Humans." This rating was reached on the basis of hepatocellular tumors and pancreatic islet cell carcinomas in rats, and "mixed but plausible" evidence of bladder, prostate, kidney, and breast cancers in humans. EPA has concluded there is insufficient information to determine an exposure threshold below which there are no

carcinogenic effects for PFOS and has therefore assumed a linear low-dose exposure model (U.S. EPA, 2023b). See below (PFOA and PFOS Dose-Response Assessments) for select quantitative health and risk information related to PFOS and cancer.

PFOS is listed on the State of California's Proposition 65 list in part due to its carcinogenicity although California EPA recognized the epidemiological evidence as mixed for PFOS and cancer, they identify PFOS as carcinogenic overall, meeting seven of the 10 key characteristics of cancer (e.g., induces oxidative stress, is immunosuppressive) (California EPA, 2021).

EFSA has concluded there is insufficient support for the carcinogenicity of PFOS (EFSA Panel on Contaminants in the Food Chain, 2020; EFSA Panel on Contaminants in the Food Chain, 2018).

E.5 **PFOA and Noncancer Endpoints**

PFOA is among the most well-characterized PFAS chemicals with respect to human health risks. The evidence base is further strengthened by animal toxicity studies and a developing mechanistic evidence base. PFOA is widely considered a human toxicant that is associated with an extensive range of health outcomes and impacted target systems. ATSDR has identified associations between PFOA exposure in humans and pregnancy-induced hypertension, increased serum liver enzymes (e.g., alanine aminotransferase [ALT]), decreased serum bilirubin levels, increased serum lipids (e.g., total cholesterol and low-density lipoprotein cholesterol), deceased antibody response to vaccines, and decreased birth weight (Agency for Toxic Substances and Disease Registry, 2021). EFSA has made similar conclusions with respect to PFOA and health outcomes, with the exception of pregnancy-induced hypertension (EFSA Panel on Contaminants in the Food Chain, 2020).

In a monograph on immunotoxicity, NTP concluded that PFOA is "*presumed to be an immune hazard to humans* based on a *high level of evidence* that PFOA suppressed the antibody response from animal studies and a *moderate level of evidence* from studies in humans." NTP further concluded that there is evidence from epidemiological studies that PFOA "reduced infectious disease resistance, increased hypersensitivity-related outcomes, and increased autoimmune disease incidence." Although NTP could not identify modes-of-action for immunotoxicity, they determined that PFOA can affect diverse aspects of the immune system in humans (National Toxicology Program, 2016).

The epidemiological evidence for PFOA advances each year, and the toxicological evidence suggests even more health effects are plausible in humans.

As discussed previously, the recent MCLG proposed by EPA is supported by an associated Toxicity Assessment, which provides substantial and iterative evidence synthesis work on health effects. To our knowledge, this represents the latest review on PFOA conducted by an authoritative source. Although not finalized as of April 2023, this public comment draft document has undergone internal and external peer review and is sufficiently advanced to be cited. For this work, EPA integrated evidence streams related to human epidemiological studies, animal model toxicity studies, and various mechanistic studies to draw conclusions about important health effects and weight-of-evidence. Consistent with other authoritative evidence syntheses and reviews, EPA concluded the evidence is strongest for relationships between PFOA and noncancer outcomes related to hepatoxicity, immunotoxicity, cardiovascular toxicity, and developmental toxicity. A summary of EPA's conclusions and bases from the recent Toxicity Assessment and Proposed MCLGs are provided below.

- Hepatoxicity: EPA concluded, "PFOA exposure is *likely* to cause hepatotoxicity in humans under relevant exposure circumstances." They concluded there is *moderate* evidence of an association between PFOA exposure and hepatoxicity in humans, primarily on the basis of increased ALT levels in the epidemiologic evidence. EPA noted this relationship is found in general population exposure scenarios and occupational exposures, there is a consistency in the overall direction of the relationship (i.e., increased PFOA is associated with increased ALT levels), and there is evidence of an exposure-response gradient. EPA also concluded there is *robust* evidence for PFOA exposure and hepatoxicity in animal studies, with additional hepatoxicity outcomes observed in animal model studies. Points of departure (PODs) were derived for increased ALT in humans and liver necrosis (focal and individual cell) in mice.
- Immunotoxicity: EPA concluded, "PFOA exposure is *likely* to cause adverse immune effects, specifically immunosuppression, in humans under relevant exposure circumstances." There was *moderate* evidence of an association between PFOA exposure and immunotoxicity in humans, primarily on the basis of decreased childhood antibody response to pathogens such as diphtheria and tetanus. There was a consistent direction of effect and relationships were observed for multiple childhood timepoints. There was also supportive but less certain evidence related to the risk of lower respiratory infections in children, and asthma, eczema, and autoimmune diseases. EPA also concluded there is *moderate* evidence for PFOA exposure and immunotoxicity in animal studies. PODs were derived for reduced antibody concentrations for diphtheria and tetanus in human children and reduced immunoglobulin M response in mice.
- Cardiovascular toxicity: EPA concluded, "PFOA exposure is *likely* to cause adverse cardiovascular effects, specifically serum lipid effects, in humans under relevant exposure circumstances." There was *moderate* evidence of an association between PFOA exposure and cardiovascular toxicity in humans, primarily on the basis of altered serum lipids in general population adults. There were consistent perturbations in several serum lipids (e.g., total cholesterol, low-density lipoprotein [LDL], and triglycerides). There was also supportive but less certain evidence related to the risk of hypertension. EPA also concluded there was *moderate* evidence for PFOA exposure and cardiovascular toxicity in animal studies. A POD was derived for increased total cholesterol in humans.
- **Developmental toxicity**: EPA concluded "PFOA exposure is *likely* to cause developmental toxicity in humans under relevant exposure circumstances." There was *moderate* evidence of an association between PFOA exposure and developmental toxicity in humans, primarily on the basis of fetal growth restriction (FGR). There were consistent decreases in birth weight and other FGR metrics, such as birth length and head circumference. EPA also concluded there was *robust* evidence for PFOA exposure and developmental toxicity in animal studies. PODs were derived for decreased birth weight in humans, and decreased offspring survival, decreased fetal body weight, and delayed time to eye opening in mice.

EPA also concluded there is *suggestive*, but not *indicative*, evidence for several other health effects related to PFOA exposure, primarily related to:

• **Reproductive toxicity** (e.g., changes in testosterone levels and sperm parameters in male humans; changes to the testis and epididymis in male animals; preeclampsia and gestational hypertension in female humans; changes in ovary morphology and hormones in female animals).

• Endocrine disruption (e.g., changes in thyroxine levels in children; changes in thyroid/adrenocortical hormone levels, increased thyroid gland weight, and increased thyroid follicular hypertrophy in animals).

E.6 **PFOS and Noncancer Endpoints**

Along with PFOA, PFOS is among the most well-characterized PFAS chemicals with respect to human health risks. PFOS is widely considered a human toxicant that is associated with an extensive range of health outcomes and impacted target systems. ATSDR has identified associations between PFOS exposure in humans and pregnancy-induced hypertension, increased serum liver enzymes (e.g., ALT), decreased serum bilirubin levels, increased serum lipids (e.g., total cholesterol and LDL cholesterol), deceased antibody response to vaccines, and decreased birth weight (Agency for Toxic Substances and Disease Registry, 2021). EFSA has made similar conclusions with respect to PFOS and health outcomes, with the exception of pregnancy-induced hypertension (EFSA Panel on Contaminants in the Food Chain, 2020).

In a monograph on immunotoxicity, NTP concluded that PFOS is "*presumed to be an immune hazard to humans* based on a high level of evidence that PFOS suppressed the antibody response from animal studies and a moderate level of evidence from studies in humans." NTP further concluded that there is evidence from animal studies that PFOS "suppresses disease resistance and natural killer (NK) cell activity" Although NTP could not identify modes-of-action for immunotoxicity, they determined that PFOS can affect diverse aspects of the immune system in humans (National Toxicology Program, 2016).

The epidemiological evidence for PFOS advances each year, and the toxicological evidence suggests even more health effects are plausible in humans.

As discussed previously, the recent MCLG proposed by EPA is supported by an associated Toxicity Assessment, which provides substantial and iterative evidence synthesis work on health effects. To our knowledge, this represents the latest review on PFOS conducted by an authoritative source. Although not finalized as of April 2023, this public comment draft document has undergone internal and external peer review and is sufficiently advanced to be cited. For this work, EPA integrated evidence streams related to human epidemiological studies, animal model toxicity studies, and various mechanistic studies to draw conclusions about important health effects and weight-of-evidence. Consistent with other authoritative evidence syntheses and reviews, EPA concluded the evidence is strongest for relationships between PFOS and noncancer outcomes related to hepatoxicity, immunotoxicity, cardiovascular toxicity, and developmental toxicity.

- Hepatoxicity: EPA concluded, "PFOS exposure is *likely* to cause hepatotoxicity in humans under relevant exposure circumstances." They concluded there is *moderate* evidence of an association between PFOS exposure and hepatoxicity in humans, primarily on the basis of increased ALT levels in the epidemiologic evidence. There was also supportive but less certain evidence related to other biomarkers of liver injury (e.g., aspartate transferase, gamma-glutamyl transferase) in the epidemiological evidence. EPA also concluded there is *robust* evidence for PFOS exposure and hepatoxicity in animal studies, with additional hepatoxicity outcomes observed in animal model studies (e.g., liver weight, nonneoplastic lesions). PODs were derived for increased ALT in humans and liver necrosis (individual cell) in rats.
- Immunotoxicity: EPA concluded, "PFOS exposure is *likely* to cause adverse immune effects, specifically immunosuppression, in humans under relevant exposure circumstances." There was *moderate* evidence of an association between PFOS exposure and immunotoxicity in humans, primarily on the basis of decreased childhood

antibody response to pathogens such as diphtheria and tetanus. There was also supportive but less certain evidence related to the risk of sensitization and other allergic responses. EPA also concluded there is *moderate* evidence for PFOS exposure and immunotoxicity in animal studies. PODs were derived for reduced antibody concentrations for diphtheria and tetanus in human children, decreased plaque forming cell response to sheep red blood cells in mice, and extramedullary hematopoiesis in the spleen of rats.

- Cardiovascular toxicity: EPA concluded "PFOS exposure is likely to cause adverse cardiovascular effects, specifically serum lipids effects, in humans under relevant exposure circumstances." There was *moderate* evidence of an association between PFOS exposure and cardiovascular toxicity in humans, primarily on the basis of altered serum lipids in general population adults. There were consistent perturbations in several serum lipids (e.g., total cholesterol, high-density lipoprotein, LDL, and triglycerides). There was also supportive but less certain evidence related to the risk of hypertension. EPA also concluded there was *moderate* evidence for PFOA exposure and cardiovascular toxicity in animal studies, with similar cardiovascular outcomes observed in animal model studies (i.e., disrupted lipid homeostasis). A POD was derived for increased total cholesterol in humans.
- Developmental toxicity: EPA concluded "PFOS exposure is likely to cause developmental toxicity in humans under relevant exposure circumstances." There was moderate evidence of an association between PFOA exposure and developmental toxicity in humans, primarily on the basis of FGR. There were consistent decreases in birth weight and other FGR metrics, such as birth length, head circumference, and gestational duration. EPA also concluded there was moderate evidence for PFOS exposure and developmental toxicity in animal studies, including increased fetal death, pup mortality, body weight changes, skeletal and soft tissue defects, and delayed eye opening. There was evidence for several dose-dependent developmental outcomes. PODs were derived for decreased birth weight in human infants, decreased fetal body weight and increased number of dead fetuses in mice, and decreased pup body weight in rats.

EPA also concluded there is *suggestive*, but not *indicative*, evidence for several other health effects related to PFOS exposure, primarily related to:

- **Neurotoxicity** (e.g., attention-deficit/hyperactivity disorder [ADHD], autism spectrum disorder or autistic behaviors, and hearing in humans; outcomes related to learning, memory, and neurotransmitter concentrations in animals).
- Endocrine disruption (e.g., thyroid disease in adults; disruption to thyroid stimulating hormone in children; decreased free and total thyroxine and decreased total triiodothyronine in animals).

E.7 PFOA and PFOS Dose-Response Assessments

Human health risk assessments can focus on either the risk of cancer outcomes, or the risk of noncancer health outcomes associated with chemical exposure.

PODs can be used in various risk assessment calculations; they typically represent an animal study dose or human exposure level at which no adverse effects are seen, or the lowest dose or exposure level at which adverse effects start to be seen. To account for variability and uncertainty, uncertainty factors are applied to PODs to ultimately develop a reference dose (RfD), which can be used for noncancer risk assessment. RfDs are estimates of the daily oral

exposure level for humans that does not result in appreciable risk of adverse health effects. When combined with exposure information, RfDs can be used in many types of risk assessment and policymaking activities. EPA used the PODs referenced above to derive several candidate RfDs for PFOA and PFOS.

- An overall RfD of 3×10⁻⁸ mg PFOA per kg body weight per day was established for PFOA; the critical effects supporting this RfD were increased total cholesterol, low birth weight, and decreased anti-tetanus and anti-diphtheria antibody concentrations in children. This RfD is still protective of hepatic effects not selected as critical effects; it is applicable to risks related to both short-term and chronic exposure to PFOA, and it is protective of effects that occur in particularly susceptible populations (e.g., infants and children).
- An overall RfD of 1×10⁻⁷ mg PFOS per kg body weight per day was established for PFOS; the critical effects supporting this RfD were increased total cholesterol and low birth weight. This RfD is still protective of the immune and hepatic effects not selected as critical effects, it is applicable to risks related to both short-term and chronic exposure to PFOS, and it is protective of effects that occur in particularly susceptible populations (e.g., infants).

PODs are also used in cancer risk assessment. After fitting various mathematical models to observed cancer data (e.g., tumors observed at certain dose levels), a final POD is selected and extrapolated to low-dose areas of the dose-response curve. Cancer slope factors (CSFs) are key toxicity values that describe the change in carcinogenic "response" over a change in "dose" at low levels of exposure. This slope can be thought of as the risk of cancer occurring at a specific daily exposure level (i.e., cancer risk per [chemical weight per kg of body weight per day]) over the course of a 70-year lifetime. In 2023, EPA derived updated and new CSFs for PFOA and PFOS, respectively, to support the proposed drinking water regulations (U.S. EPA, 2023a; 2023b). As discussed above, linear low-dose models were assumed due to the absence of a threshold carcinogenic dose. The updated and new CSF values for PFOA and PFOS, respectively, indicate these two PFAS are more potently carcinogenic than previously estimated.

- A CSF for PFOA was derived on the basis of renal cell carcinoma in humans, resulting in a CSF value of 0.0293 (ng/kg/day)⁻¹.
- A CSF for PFOS was derived on the basis of hepatocellular adenomas and carcinomas in rats, resulting in a CSF value of 39.5 (mg/kg/day)⁻¹.

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