



Understanding the EPA's new TSCA Section 8(a)(7) Rule on PFAS Reporting

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This session will be recorded.

Speaker Introduction

Monika E. Kotkowska

CDX Consultant / Regulatory Product Compliance Expert

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- Specializes in Regulatory Product Compliance, ESG, and Chemical Management Solutions.
- Certified Agile and PRINCE Project Manager.
- Currently pursuing a Master of Business Administration (MBA) with a focus on ESG topics
- Holds a Master's degree in Chemistry and Engineering from the University of Technology in Wroclaw, Poland.
- Over a decade of experience in diverse regulatory RA.
- Actively involved in IAEG, AIAG, and more recently, AEM.
- Outside of work, a true travel backpacker at heart.



Speaker Introduction

Will Martin

Managing Director of EPR Consulting Ltd

Will.Martin@epr-consulting.co.uk

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- Provider of Chemical Service to DXC Technology, managing substance & regulatory updates in IMDS & CDX
- DXC Training partner for UK
- Consultant to ACEA supporting Substance Impact Assessment Process (SIAP), and GADSL processes
- Member of Institute of Environmental Assessment and Management (IEMA)
- Developed software and data to support M&P compliance and risk assessments, integrated with product development for aerospace companies



Speaker Introduction

Chuck Lepard

Executive Consultant, IMDS & CDX Americas Representative

Chuck.Lepard@dxc.com

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- Degrees in Electrical & Computer Engineering and Computer Science
- Honorable Discharge, United States Navy
- 39+ Years EDS/General Motors/Hewlett Packard/HPE / EntServ / DXC
- Decades of plant floor and engineering experience in related areas
- Advisor to multiple manufacturing industry groups
 - Automotive Industry Action Group, International Aerospace Environmental Group,
 - Association of Equipment Manufacturers, Responsible Materials Initiative
- Leader in Standards Development organizations
 - American National Standards Institute (ANSI), International Standards Organization (ISO) Technical Committee TC-111 on Environmental Sustainability Data Exchange
 - IPC E-31 175x family for Product Declaration and Compliance reporting



Webinar Agenda

What are Per- and polyfluoroalkyl Substances (PFAS)?

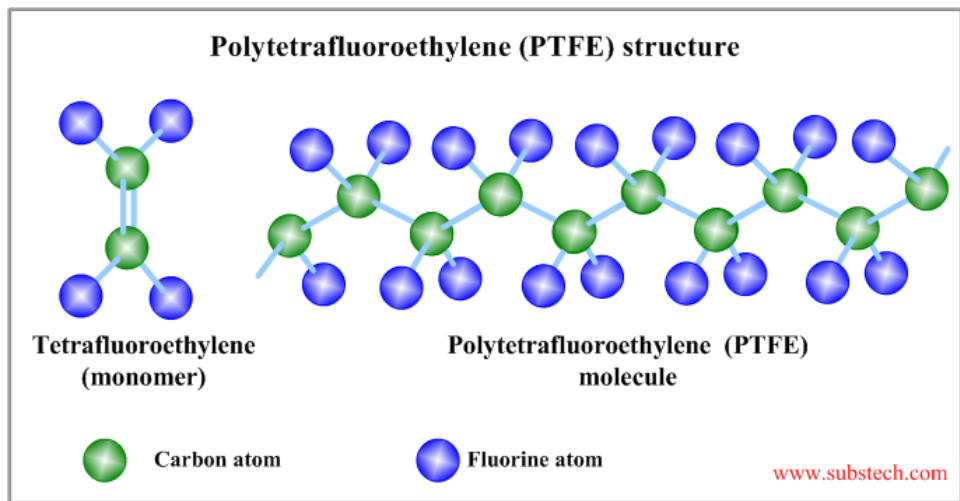
TSCA Section 8(a)(7) PFAS

1. Reporting and Recordkeeping
2. Implementation Process
3. Strategic Steps

Life Audience Questions

What are Per- and polyfluoroalkyl Substances (PFAS) ?

„Forever chemicals” – From Discovery to Uncovering in Blood



1938

PTFE INVENTED

Roy Plunkett accidentally invented polytetrafluorethylene (PTFE).

1940s

PTFE FOR INDUSTRIAL PRODUCTION

DuPont commercialized PTFE as Teflon "extremely heat-tolerant and stick-resistant".

1950s

PTFE, PFOS AND PFOA IN CONSUMER PRODUCTS

1947/49

PFOA AND PFOS INVENTED

3M invents PFOA. Starting in 1951, DuPont purchased PFOA from 3M for use in the manufacturing of specific fluoropolymers

1970s

**IN HUMAN BLOOD
EPA FORMED**

3M "knew as early as the 1970s that PFAS was accumulating in human blood."

1960s

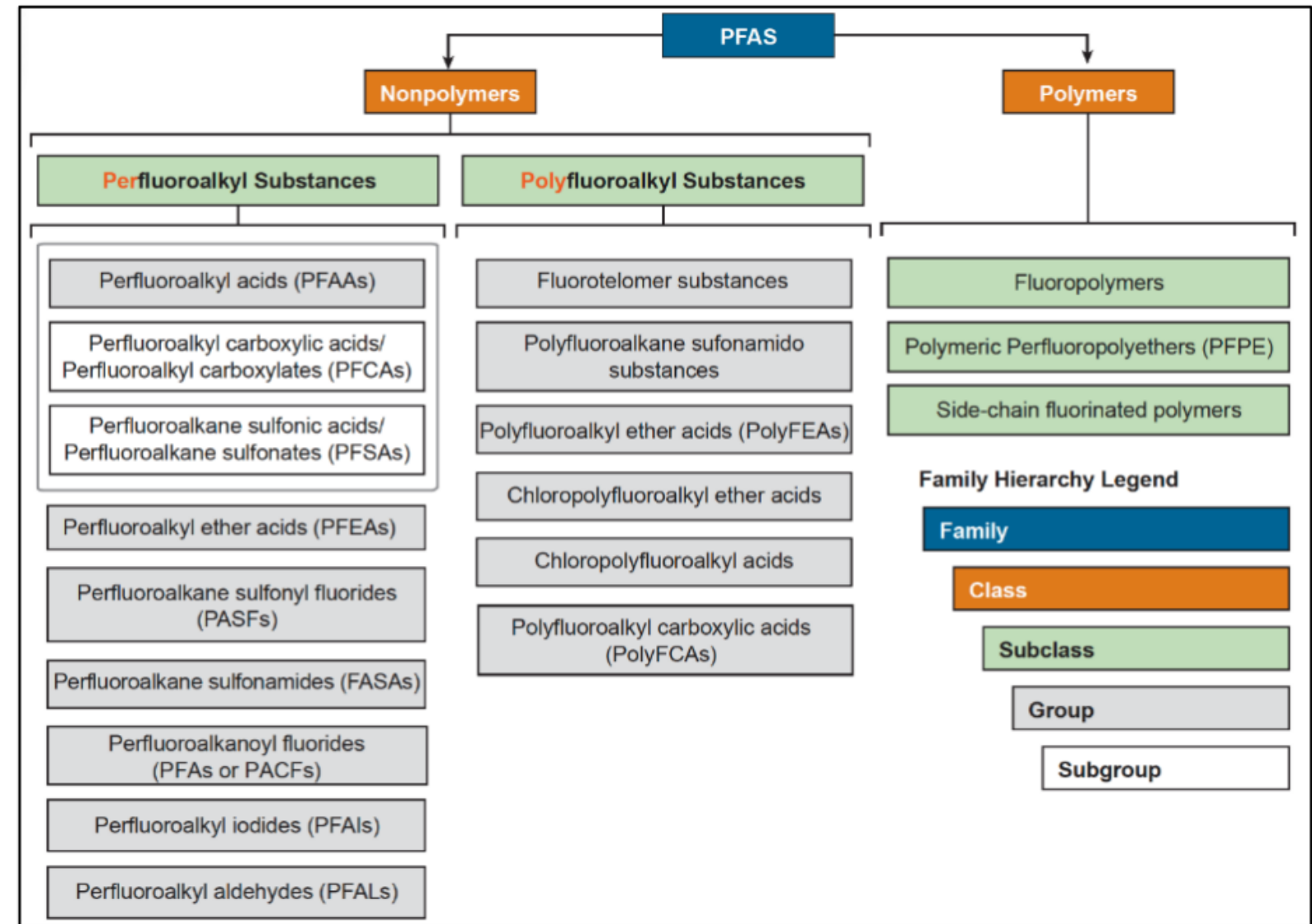
AFFF

aqueous film-forming foams (AFFF) developed by 3M and began to be used by US military

What are Per- and polyfluoroalkyl Substances (PFAS) ?

“Forever chemicals” – from Production Giants to Recognizable Brands

- nearly 15,000 PFAS substances
- PFAS production: AGC, Arkema, Chemours, Daikin, 3M, Solvay, Dongyue, Archroma, Merck, Bayer, BASF and Honeywell.
- 3M will stop making PFAS and work to discontinue the use of PFAS across its product portfolio by the end of 2025.
- In 2022, the global market size for PFAS was just over \$28 billion, with estimated profits of around \$4 billion
- PFAS well-known brands
 - ❖ PTFE - Teflon™, Tarflen®, Boraflon, Tecaflon, Fluon®, Halon, Polyflon, Reproflon
 - ❖ ePTFE - Gore-Tex®
 - ❖ MFA (Perfluoroalkoxy) - Hyflon®
 - ❖ ETFE (Ethylene tetra-fluoro ethylene) - Tefzel®, Neoflon®
 - ❖ PVDF (Poly vinylidene fluoride) - Solef®, Hylar®, Kynar®
 - ❖ PCTFE (Poly chloro tri-fluoro ethylene) - Solef®, Hylar®, Kynar®



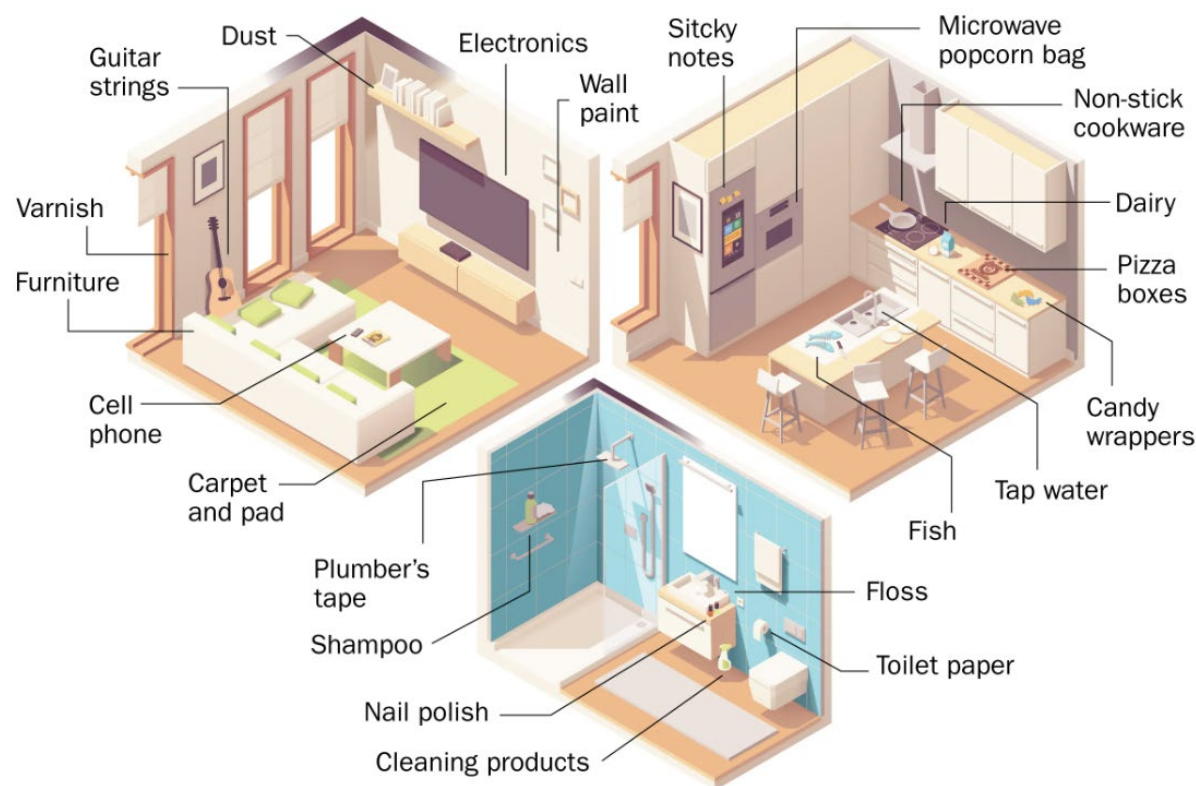
[Source: Naming Conventions for Per- and Polyfluoroalkyl Substances \(PFAS\);](#)
The Interstate Technology & Regulatory Council (ITRC); Sep 2023.

What are Per- and polyfluoroalkyl Substances (PFAS) ?

Is Your Product Free from „Forever Chemicals”?

There aren't many places in your home that are PFAS-free.

All The Stuff in Your Home That Might Contain
PFAS 'Forever Chemicals'



Source: <https://time.com/6281242/pfas-forever-chemicals-home-beauty-body-products/>

ChemSec's PFAS Guide serves as a starting point for **identifying common applications** within various industries/sectors and **provides potential alternatives** for some of these applications.

Source: <https://pfas.chemsec.org/>

What are Per- and polyfluoroalkyl Substances (PFAS) ?

“Forever chemicals” - Unveiling the Strength Within Single Bonds

Persistent in the Environment: Chemicals resistant to breakdown, persisting in the environment long after being banned.

- Exposure continues from various sources even years after a chemical is phased out.
- Polymer Half-life in the Environment surpasses 1000 years
- PFASs exceed criteria for very persistent substances in REACH Annex XIII.

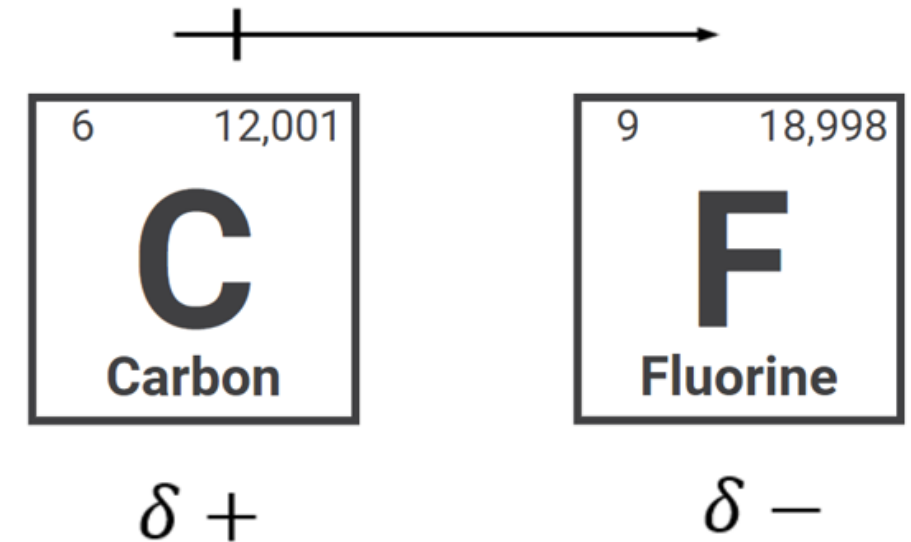
Bioaccumulative: Accumulates in human and animal bodies.

- Certain PFAS persist for years, concentrating in marine mammals, birds of prey, and humans.
- Resistant to conventional treatment in wastewater and drinking water.
- According to the EPA, over 98% of U.S. Participants of studies has revealed detectable levels of PFAS in their bodies

Mobile: Travels extensively, found globally in deep oceans, mountain lakes, and polar regions.

- Presence far from original production and usage locations.

Toxic: Linked to liver damage, high cholesterol, obesity, diabetes, cancer, thyroid disease, asthma, immune system dysfunction, reduced fertility, low birth weight, and impacts on children’s cognitive and neurobehavioral development.



What are Per- and polyfluoroalkyl Substances (PFAS) ?

Impact of “Forever chemicals” Exposure and Accumulation Over Time

PFAS Exposure Pathways:



Soil



Drinking Water

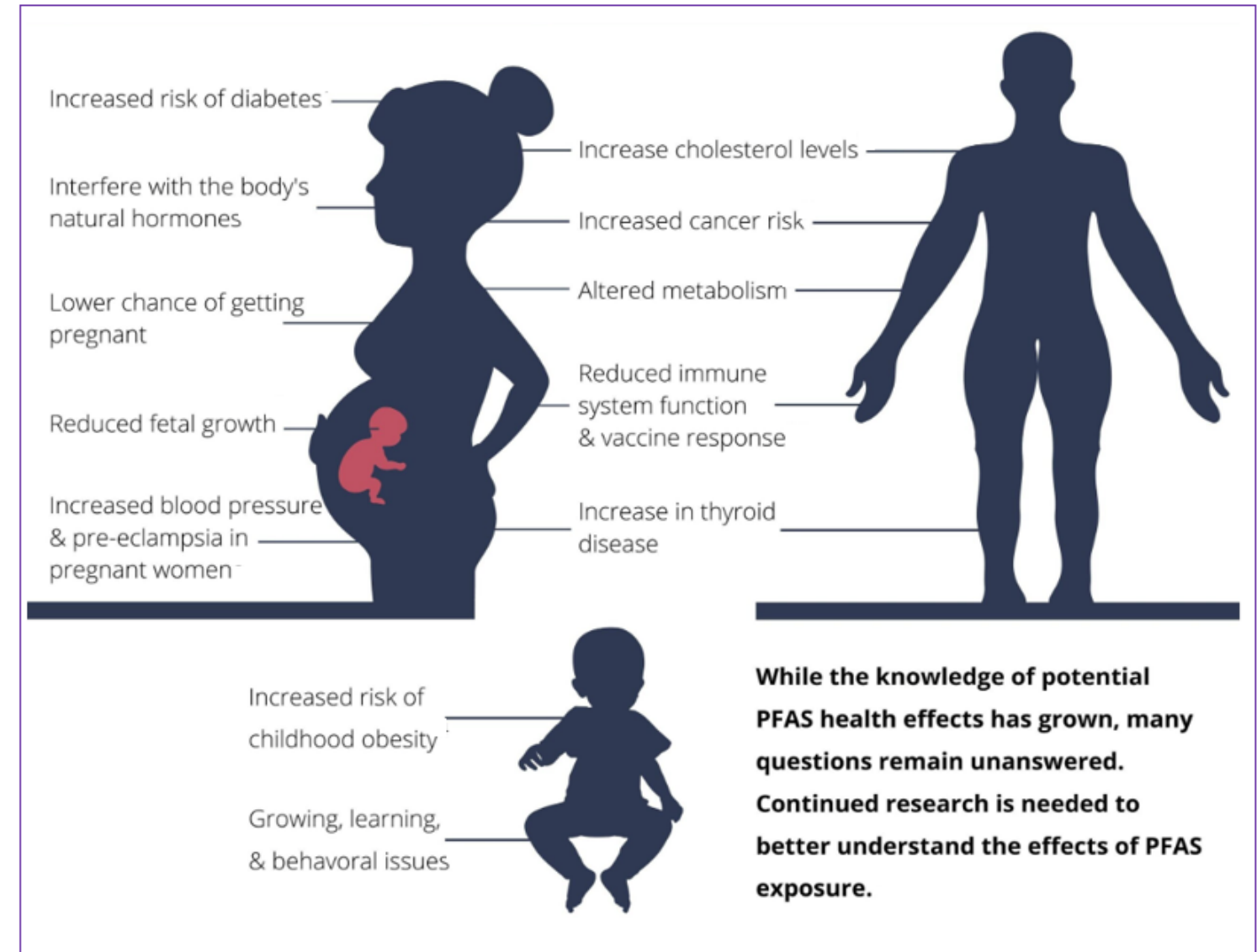


Food



Groundwater

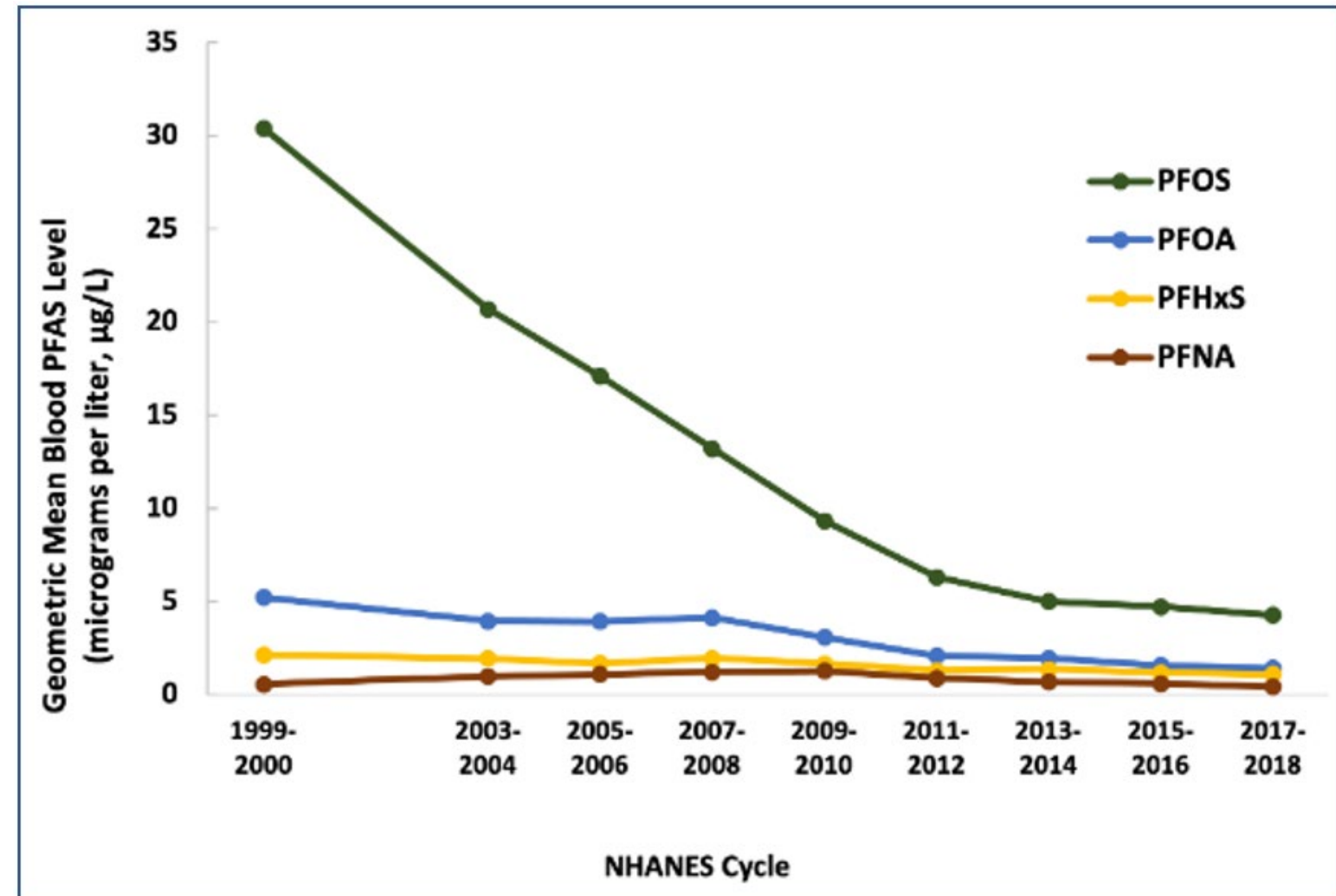
- Exposure to PFAS can negatively impact human health.
- When humans or animals consume products contaminated with PFAS, it is absorbed into the body and can accumulate over time.
- The longer a person is exposed to PFAS from various sources, the higher the levels of PFAS in their body can become, leading to potential health issues.



Per- and polyfluoroalkyl Substances (PFAS) and Your Health

Monitoring “Forever chemicals” Exposure over the Time

- The Centers for Disease Control and Prevention (CDC) systematically track blood PFAS levels in the U.S. population through The National Health and Nutrition Examination Survey (NHANES)
- Over 98% of U.S. participants, has revealed detectable levels of PFAS in their bodies
- Include both adults and children
- Concerns with the phasing out and substitution of PFOS and PFOA, as it prompts potential exposure to other PFAS within the population



Source: https://www.cdc.gov/exposurereport/data_tables.html

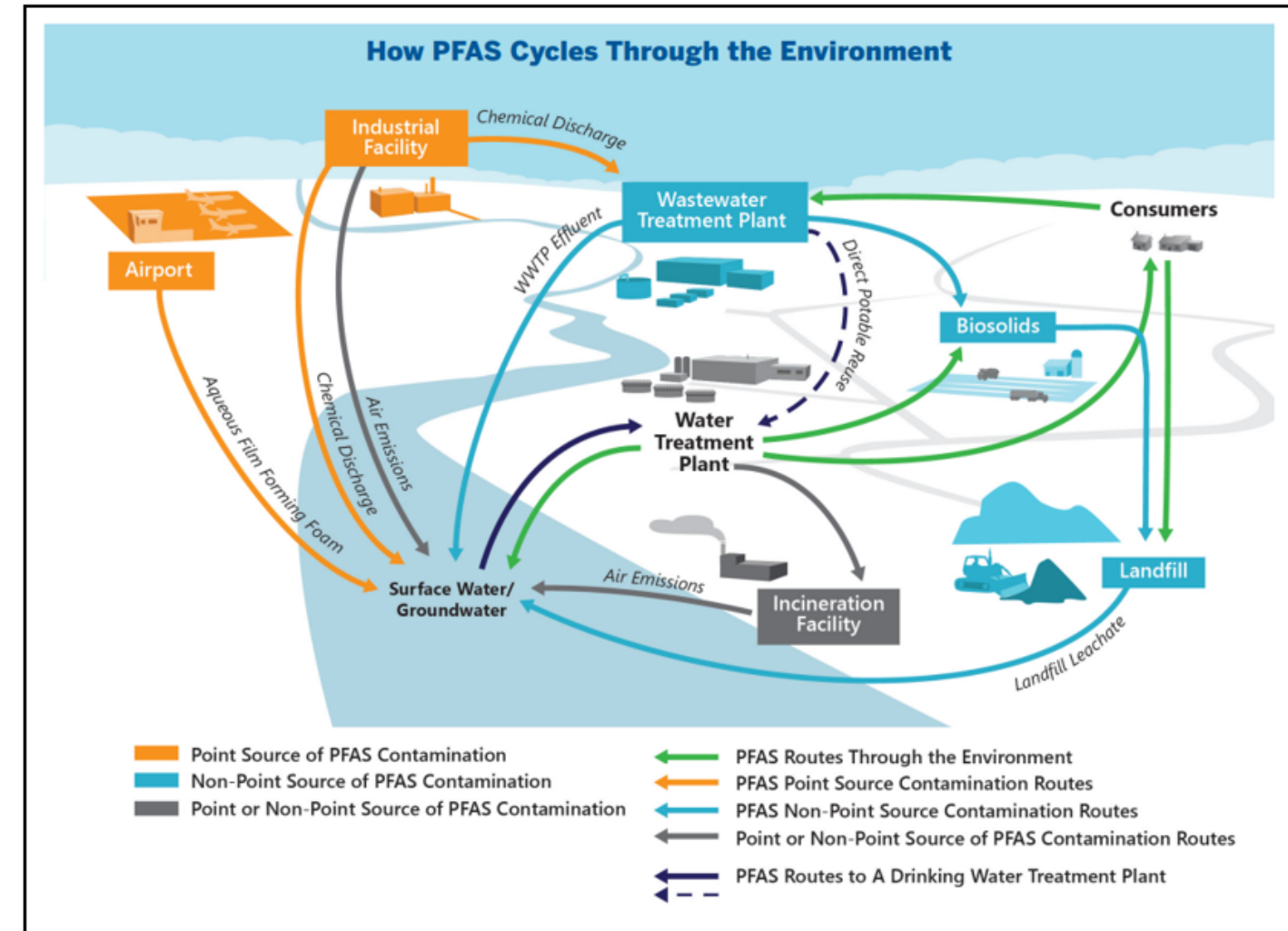
What are Per- and polyfluoroalkyl Substances (PFAS) ?

Understanding Different Levels of “Forever chemicals” Contamination

Major PFAS Contamination

- **Firefighting aqueous film-forming foam (AFFF):** airports, military sites, chemical plants, and facilities with above ground petroleum storage tanks.
- **Industrial Facilities:** contaminated by manufacturing facility i.e. DuPont Teflon

Once emitted to the environment, they are distributed through the water cycle, contaminating drinking water through surface and groundwater and through waste management and water treatment facilities (WTPs).



Source: [https://www.cell.com/one-earth/fulltext/S2590-3322\(22\)00493-6](https://www.cell.com/one-earth/fulltext/S2590-3322(22)00493-6)

Per- and polyfluoroalkyl Substances (PFAS) and Your Health

Mapping the “Forever chemicals” Contamination Crisis Across the United States.

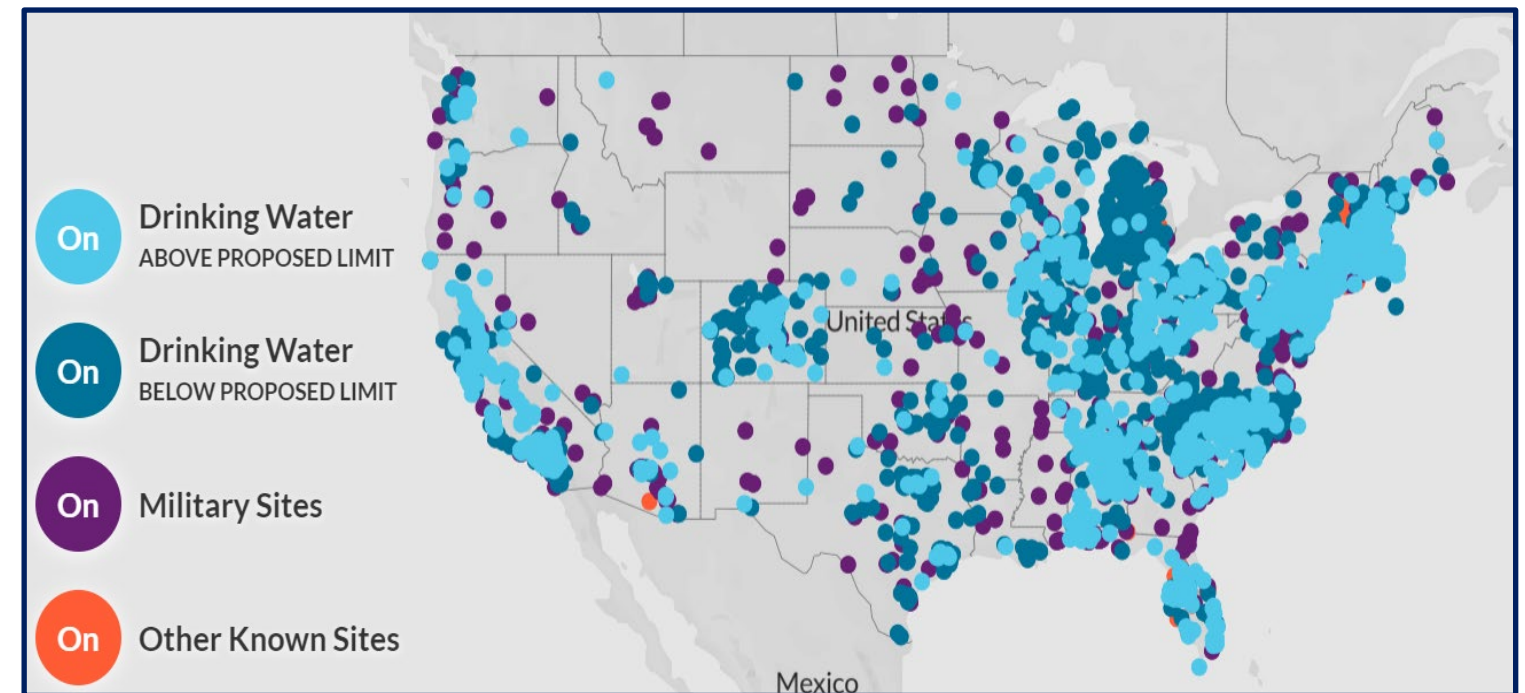
❑ [Environmental Working Group \(EWG\)](#)

- ❖ August 2023
- ❖ Scope: 4,621 sites in 50 states, the District of Columbia and two territories
- ❖ shows PFAS pollution in public and private water systems

❑ EPA Unregulated Contaminant Monitoring Rule (UCMR)

- ❖ Focused on large drinking water systems
- ❖ EPA round of public water system testing data for PFAS
- ❖ [Latest data from November 28, 2023](#)
- ❖ 854 sites in 50 states
- ❖ Check total value of PFAS in sample
- ❖ 29 PFAS: PFPeA, PFHxS, PFOA, PFBA, PFBS, PFHpA, PFHxA, PFOS, PFNA, PFDA, PFPeS ...

- ❑ PFAS affecting the drinking water of approximately 200 million Americans



Source: Environmental Working Group PFAS Contamination in the U.S. (November 28, 2023)

PFAS Update: 2023/24 Federal PFAS Regulatory Recap

PFAS Strategic Roadmap: EPA's Commitments to Action

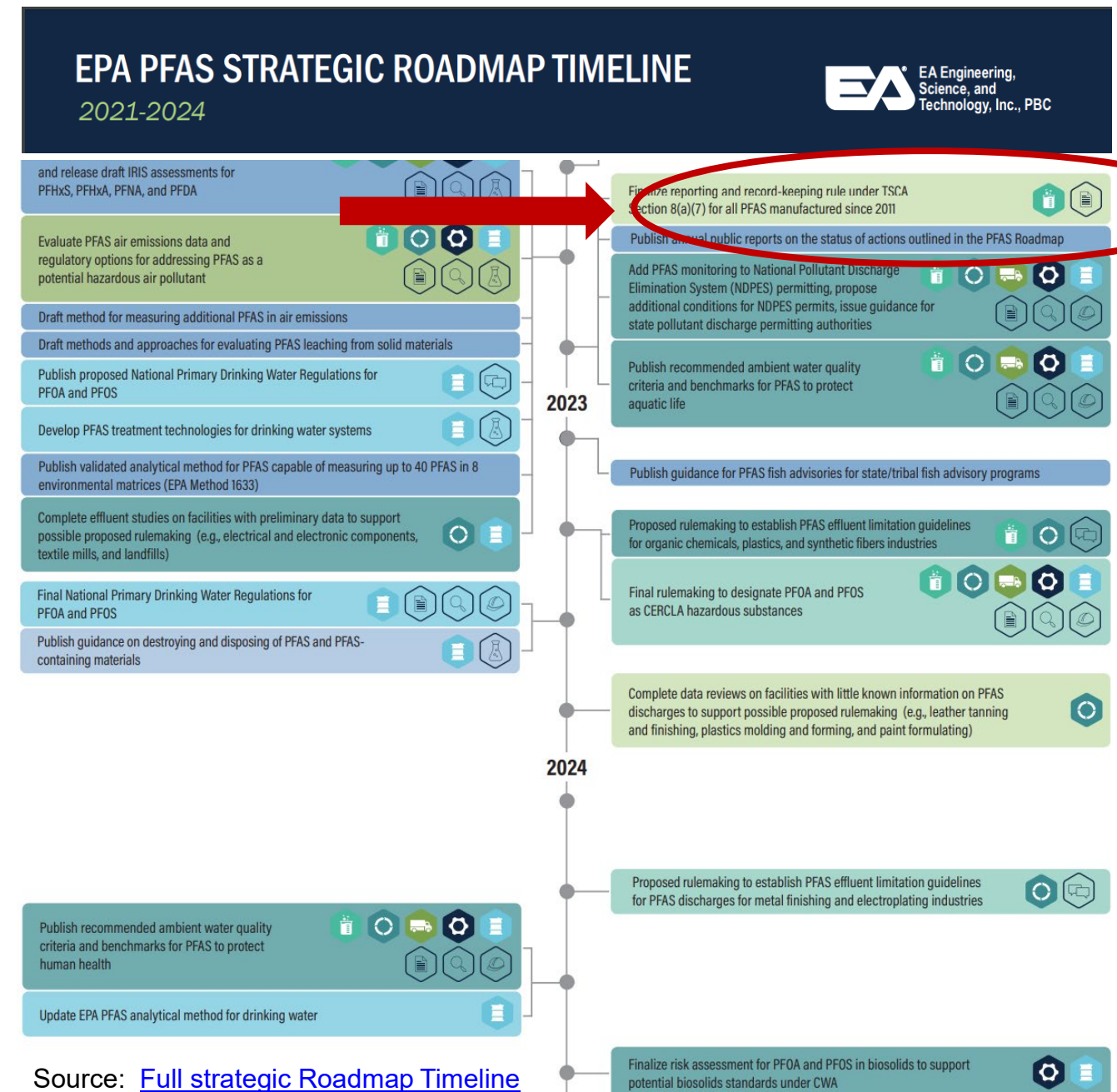
❑ In October 2021, the EPA released a PFAS Strategic Roadmap

- **Three goals: research, restrict, remediate.**
- **Scope:** Manufacturing, Processing, Transportation, Use, Treatment/Disposal
- **Already two Progress Reports** (November 2022, December 2023)
- EA Engineering Science, and Technology Inc., PBC

EPA's full **PFAS Strategic Roadmap**

❑ National Defense Authorization Act for Fiscal Year 2020.

- Establish an all-encompassing database of previously manufactured PFAS.
- “Better characterize the sources and quantities” of manufactured and imported PFAS in the United States
- Support actions to address PFAS exposure and contamination



TSCA Section 8(a)(7) PFAS Reporting and Recordkeeping

Guiding Through TSCA Section 8(a)(7) Reporting: Responsibilities and Requirements

Anyone who has manufactured or imported consumer, industrial, or commercial products, goods, or other **articles for commercial purposes containing PFAS**, which includes mixtures containing PFAS, as well as manufacturing or importing PFAS substances within the U.S. customs between **January 1, 2011 –December 31, 2022.**

- ✓ The rule **also applies** to the coincidental manufacture of PFAS as **byproducts** or **impurities** and **R&D PFAS** that were manufactured including imported, for a commercial purpose
- ✓ Rule requires information **for each year** in which PFAS was manufactured
- ✓ There is **NO** reporting **threshold** or **de minimis** level for PFAS – any amount of PFAS known to be manufactured is reportable.



TSCA Section 8(a)(7) PFAS Reporting and Recordkeeping

Guiding Through TSCA Section 8(a)(7) Reporting: Responsibilities and Requirements

- > This is a **one-time reporting** requirement.
- > **Electronic submission** via EPA's Central Data eXchange (CDX).



- > **5 –year Recordkeeping** period following final date of submission period

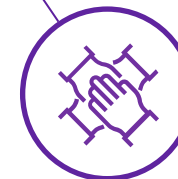
- > **"Reasonable estimates"**
- > **Not Known or Reasonably Ascertainable" (NKRA)**



- > **Streamlined Reporting Form** is available for:

- > Article Importers, and
- > Manufacturers (including importers) of R&D substances manufactured below 10 kg/year

- > Under TSCA, violators can be subject to a civil **penalty of up to \$46,989** per violation for each day



- > **Join submission** possible
- > **Mitigate duplication** report

TSCA Section 8(a)(7) PFAS Reporting and Recordkeeping

Exemptions and Exclusions from PFAS Reporting Obligations

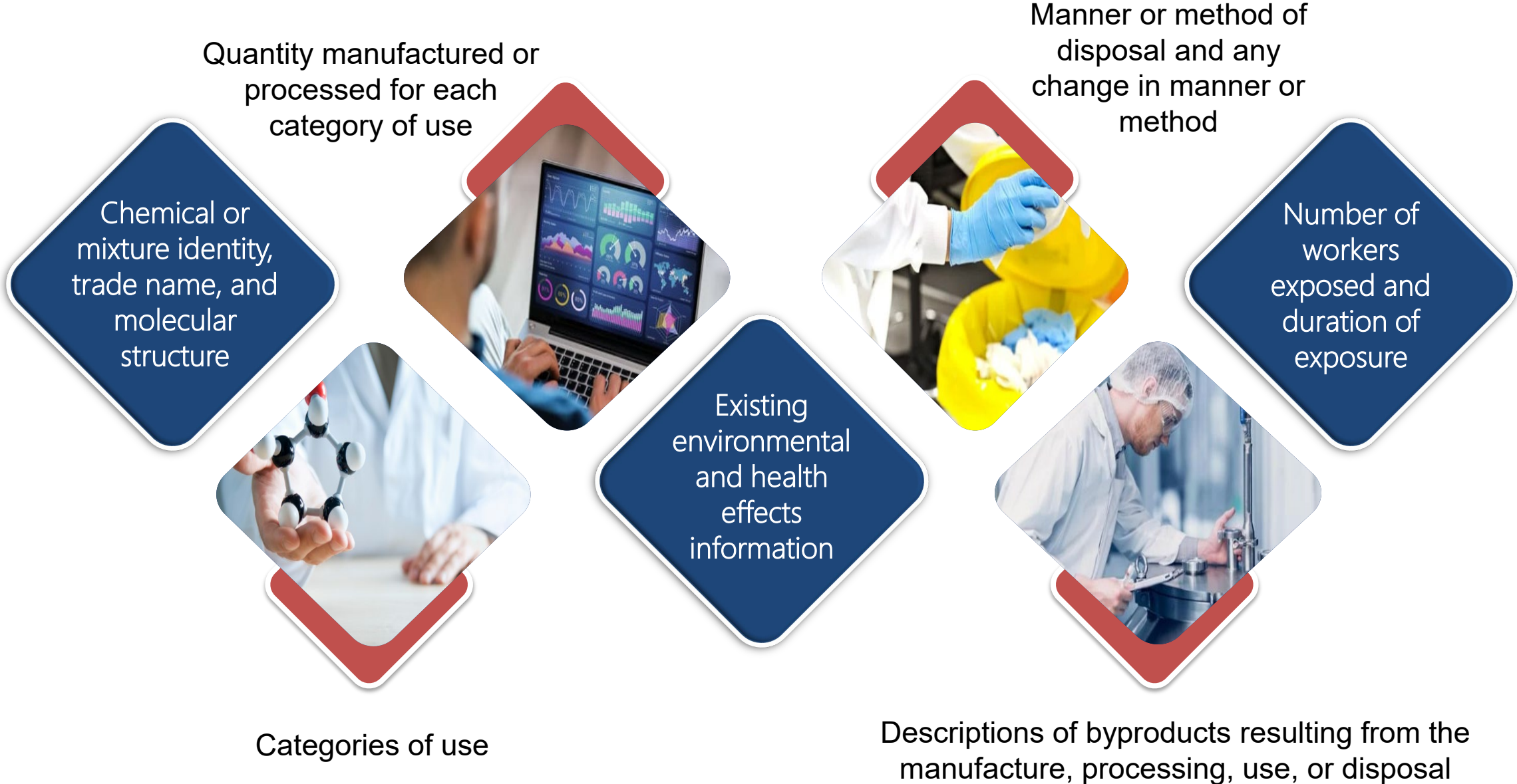
- ✓ PFAS Substances Not Meeting the Definition
- ✓ Entities not engaged in manufacturing (including importing) activities since 2011
- ✓ Activities that are not considered to be “manufacture/import for a commercial purpose” under TSCA, such as non-commercial R&D activities (science experimentation, research, or analysis conducted by academic, government, or independent non-profit research organizations).
- ✓ Waste management activities involving the importation of municipal solid waste (MSW) streams for the purpose of disposal or destruction.
- ✓ Products exempted from TSCA section 3(2): food additives, drugs, medical devices, cosmetics and pesticides.
- ✓ Ammunition



„Entities that simply process PFAS they receive domestically are not covered by the rule, unless they also manufacture PFAS (a different PFAS is formed).”

TSCA Section 8(a)(7) PFAS Reporting and Recordkeeping

Critical Reporting Elements: Navigating Key Criteria



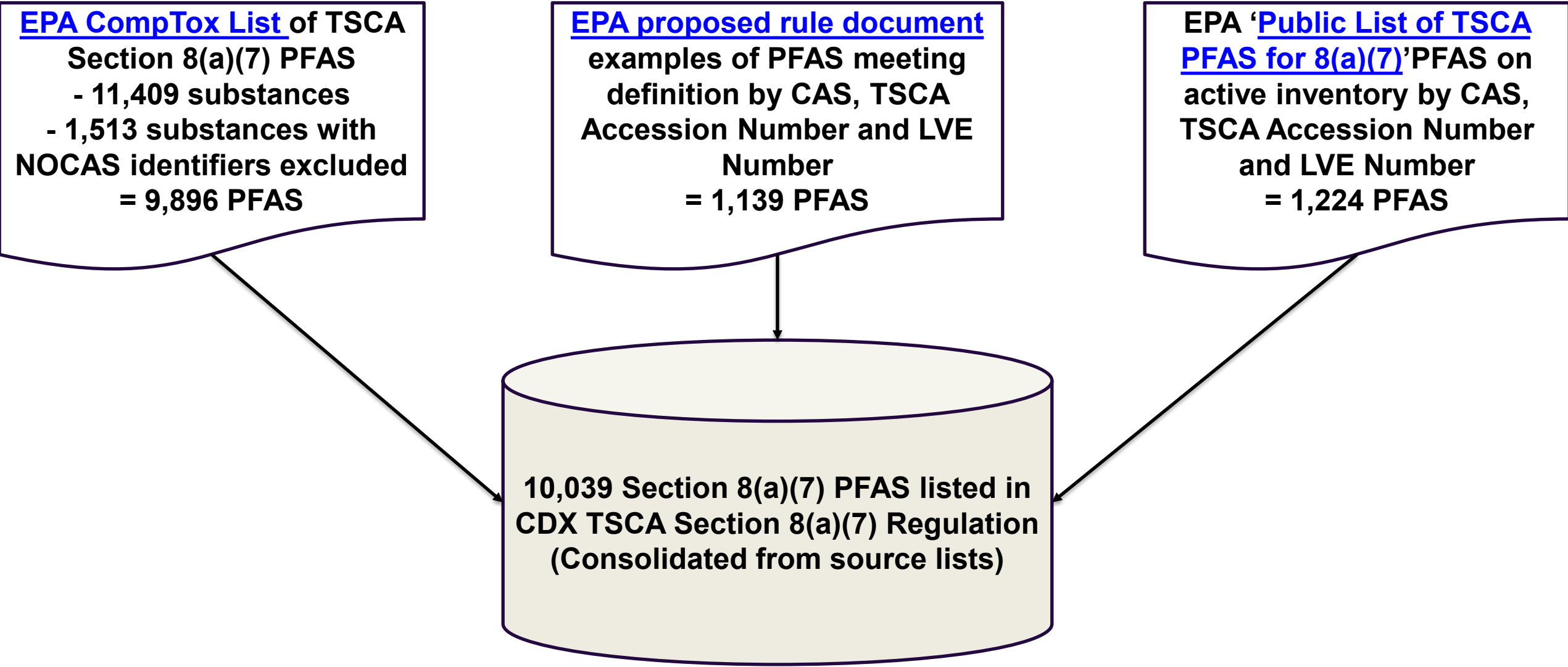
TSCA Section 8(a)(7) PFAS Reporting and Recordkeeping

➡ Is There a 'Right' Definition of PFAS?

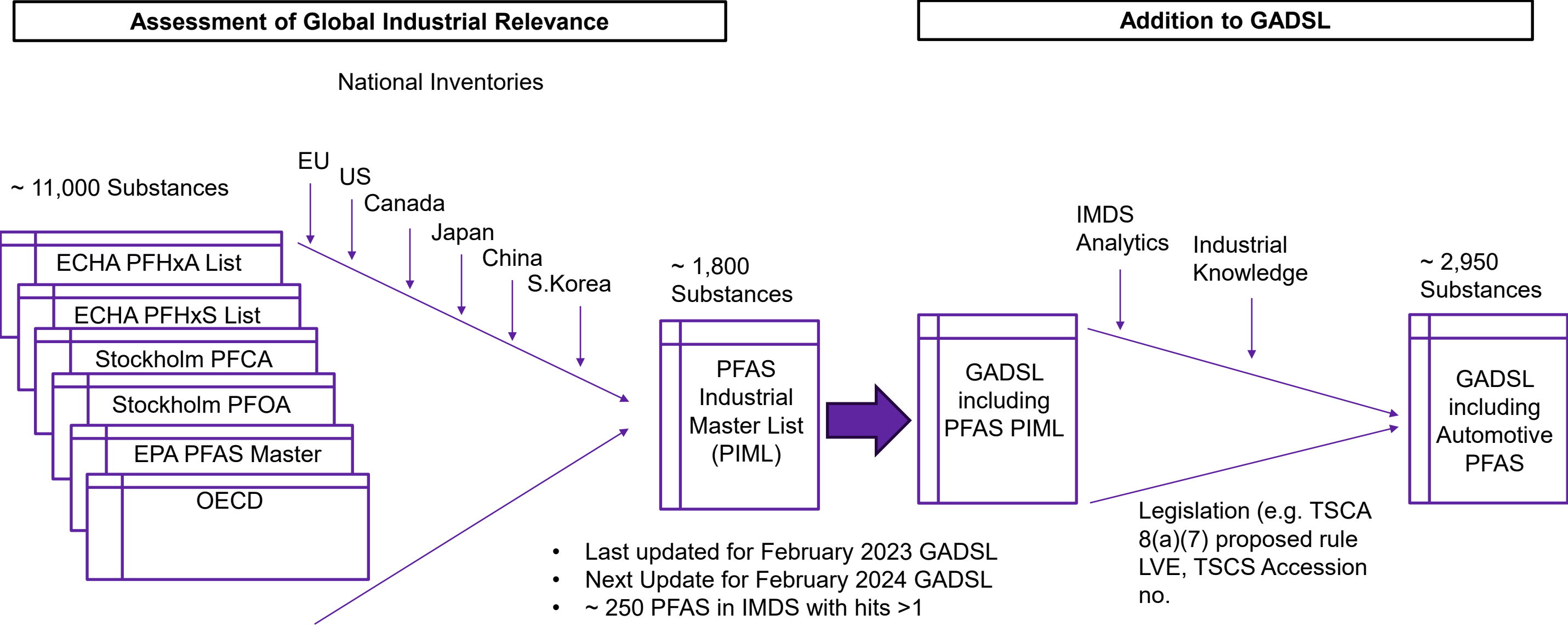
- **Structural definition of PFAS**, at least one of these three structures:
 - $R-(CF_2)-CF(R')R''$, featuring saturated carbons in both the CF_2 and CF moieties;
 - $R-CF_2OCF_2-R'$, where R and R' can be F , O , or saturated carbons;
 - $CF_3C(CF_3)R'R''$, where R' and R'' can be F or saturated carbons.
Fluoropolymers may meet this scope!
- There is **no discrete list of individual** PFAS subject to the reporting rule.
- EPA has identified at least 1,462 PFAS under the structural definition:
 - All PFAS listed as active on the February 203 TSCA Inventory
 - All PFAS with TSCA section 5 (new chemicals) low-volume exemption (LVE) claims
- [CompTox Chemicals Dashboard](#) -14,735 substances
- This is not exhaustive scope of PFAS !



TSCA Section 8(a)(7) Implementation in CDX

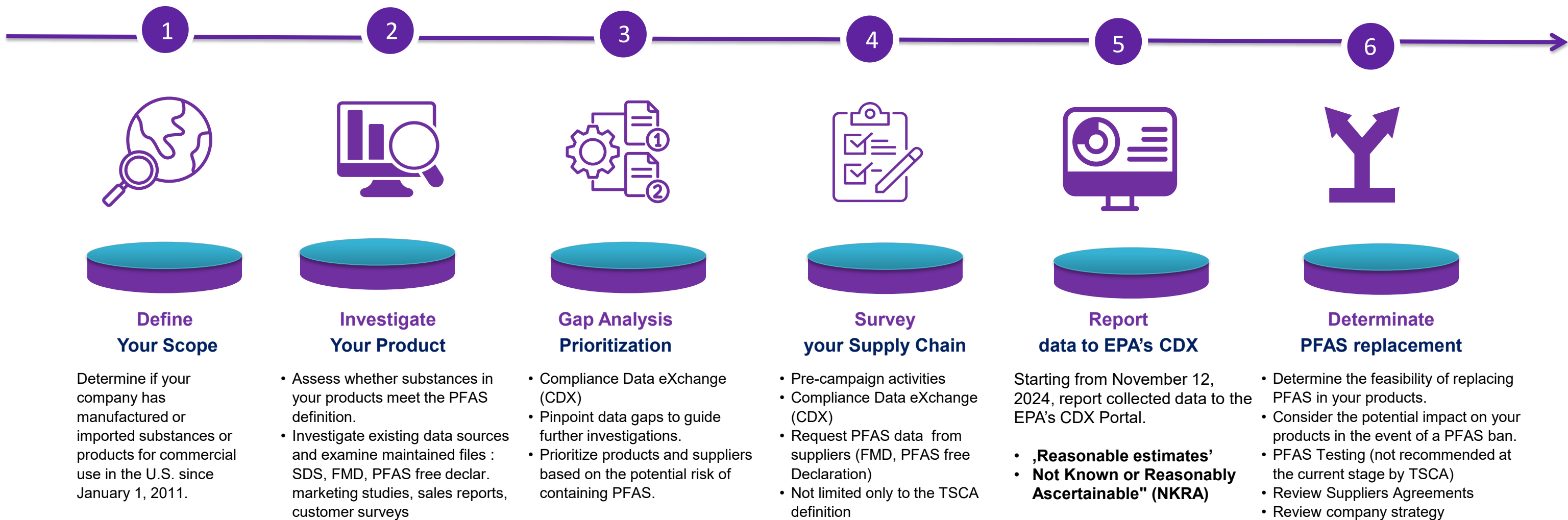


PFAS Declarable Substance List in CDX



TSCA Section 8(a)(7) PFAS Reporting and Recordkeeping

Strategic Steps to TSCA 8(a)(7) Compliance: A Practical Handbook



Steps to PFAS compliance and financial risk avoidance

Best Practices for Global PFAS Compliance



How Regulators Now View Product Content Compliance

End-of-Life Vehicle - The first modern product content legislation

Original Stated Goal:

- Reduce heavy metals in vehicle product waste

Results:

- New, lighter metals and materials
- Lighter vehicles
- Better fuel efficiency
- Optimized manufacturing processes
- Improved operator and passenger safety
- Extended product life
- Improved recycling and less waste



New regulations compel us to delve continually deeper & broader into our products

Automotive Results of subsequent legislations (REACH, etc.)

Product-content-legislation inspired technology in modern vehicles

Making your car do more for you

Vehicle Systems

- Engine control
- Throttle control
- Transmission control
- Adaptive suspension
- Active Steering
- Anti-lock braking
- Battery management
- Passenger airbags
- Tire pressure monitoring
- Immobilizer and alarms
- Telematics
- Communication gateway

Driver cockpit

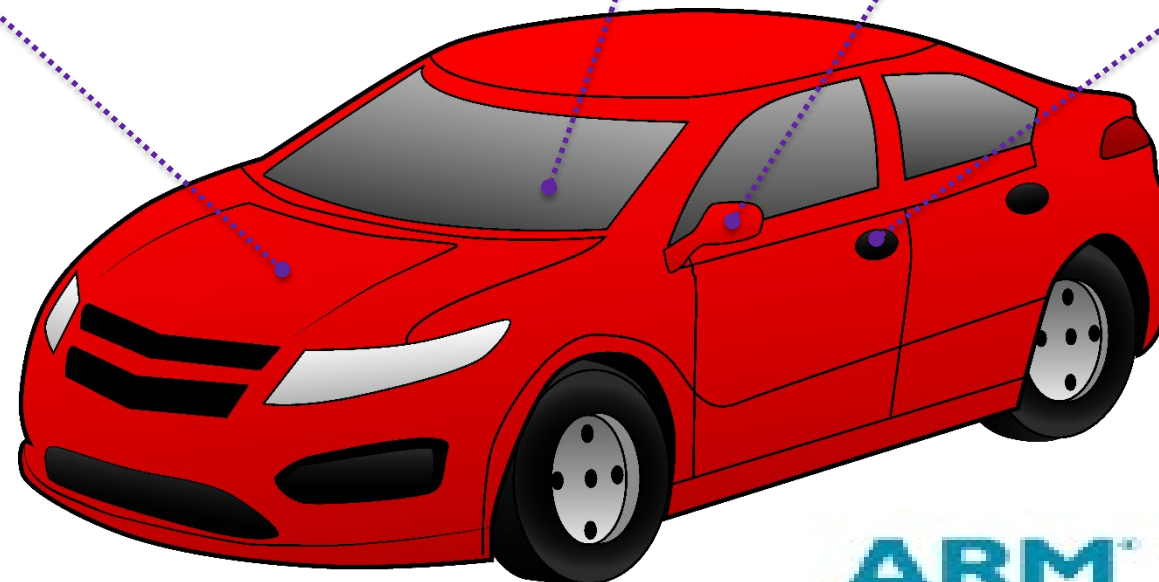
- Instrument cluster
- Heads-up display
- Infotainment
- Drowsy driver detection
- Audio control
- Climate control

Advanced driver assistance

- Back up camera
- Blind spot detection
- 360 surround view
- Automatic parking
- Automatic braking
- Lane keeping
- Pedestrian and sign recognition

Convenience features

- Keyless entry and remote start
- Mirror control
- Power windows
- Seat comfort and adjustment
- Motorized trunks lift gates
- Interior lighting
- Rear seat entertainment
- Wipers



ARM[®]

Product-Content Legislation Inspired industry disruption

Alternate-fuel vehicles

Toyota Prius

Initially unpopular

“Too cramped, not enough power”

Waste of time & money

“Not enough market – no one will buy”

Little or no return on investment

“Costs too much to operate & maintain”

Started a new enthusiast movement

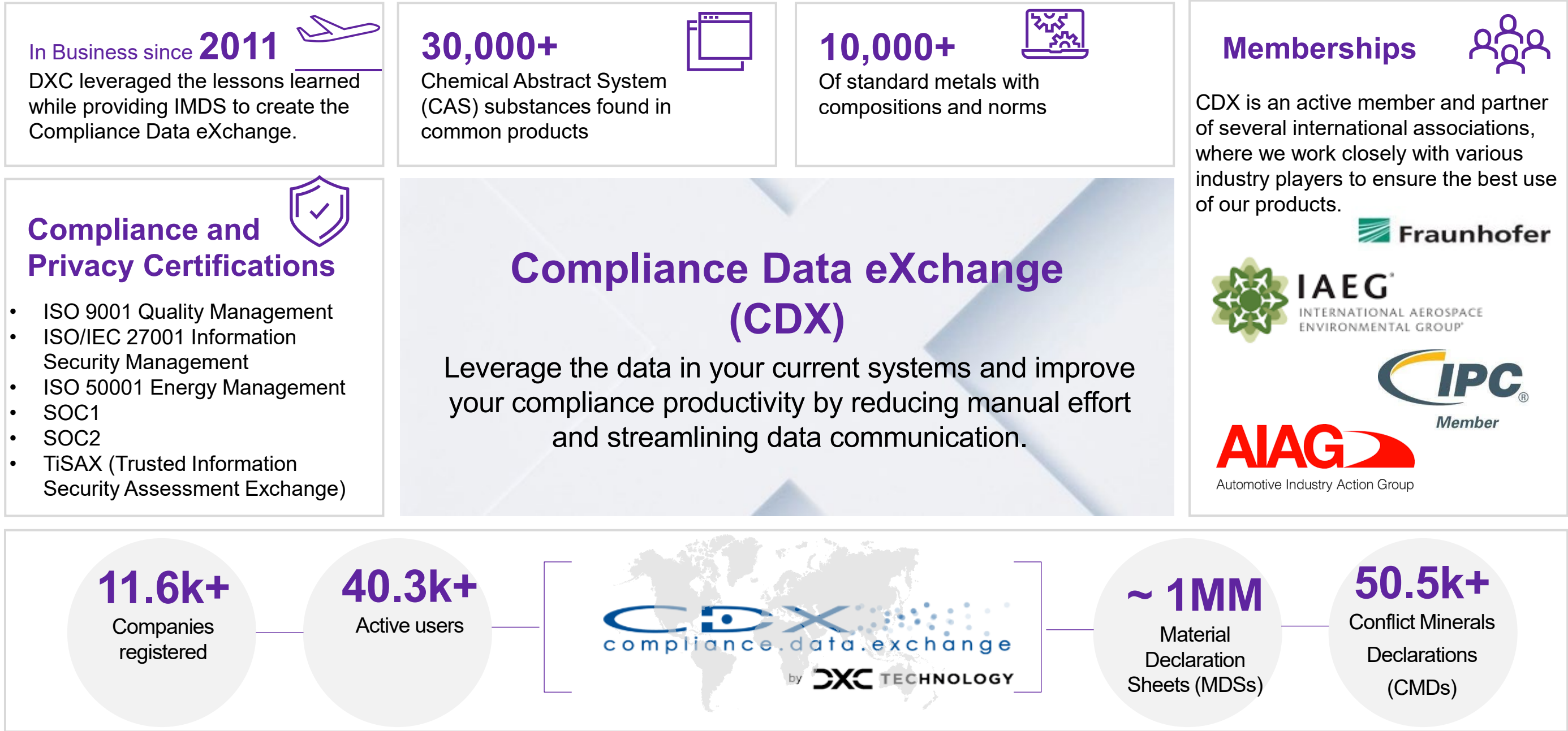
- CA commuter laws changed to endorse
- Embraced by all economic classes
- Bred into a diverse family of vehicles
- Evolved four generations in < 20 years

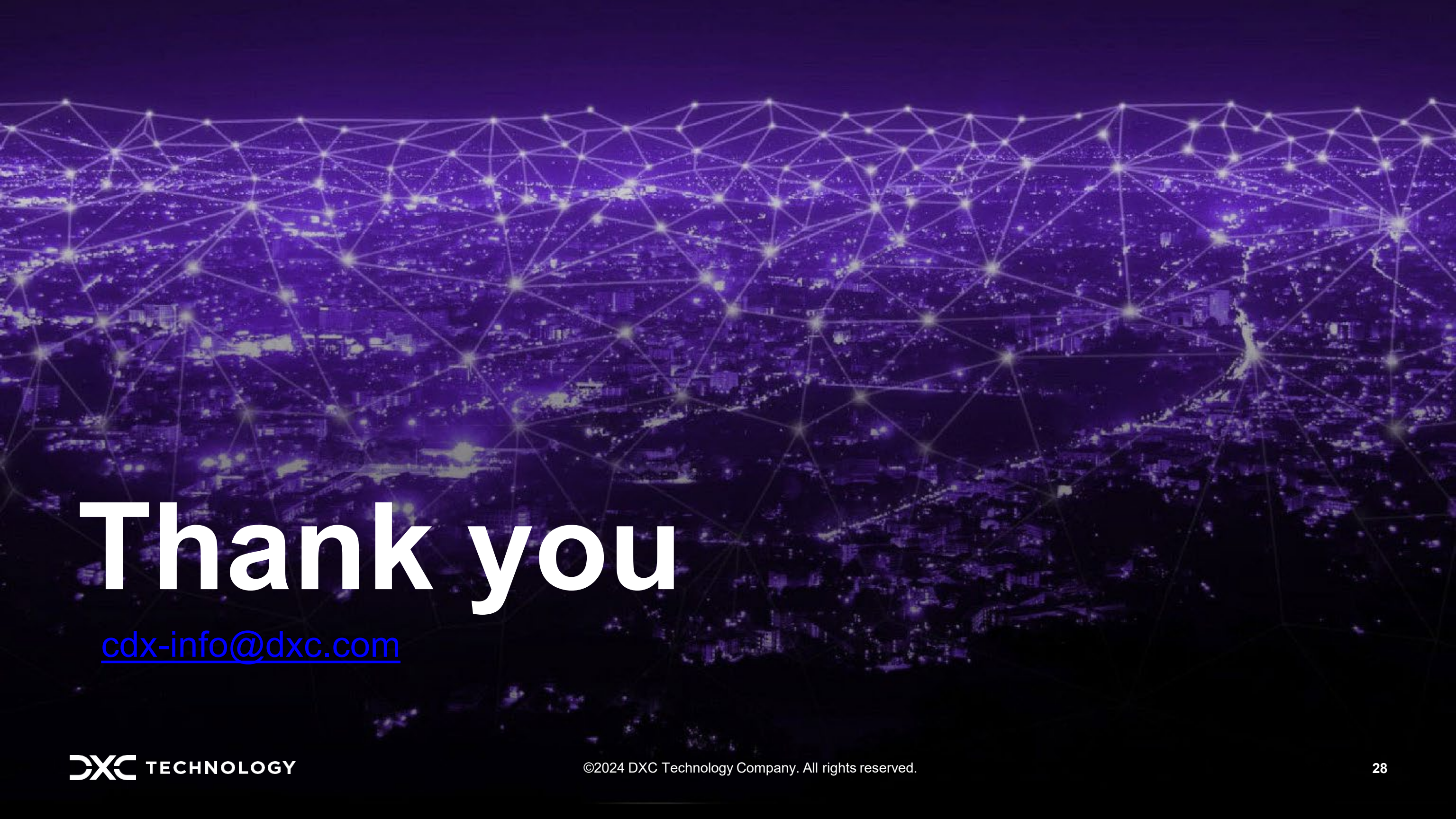
Created new (then) Electric Vehicle industry

- Which in turn is now fostering solar charging and hydrogen-cell vehicles



Compliance Data eXchange (CDX) at-a-glance





Thank you

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