

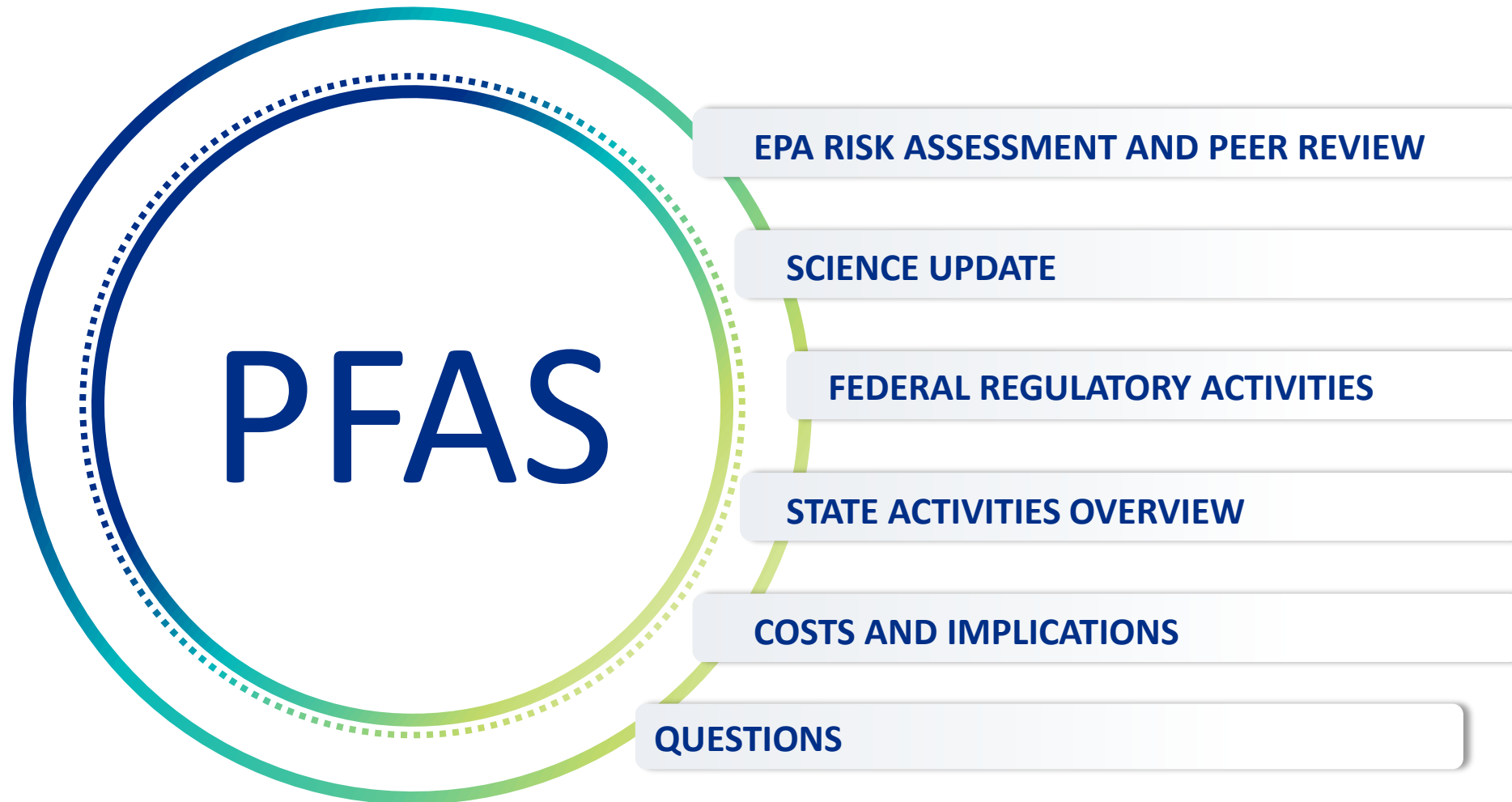
The State of Risk Assessment, Regulation, and Peer Review at EPA: A Case Study of EPA's Priority Actions on PFAS

Alliance for Risk Assessment: Beyond Science and Decision Workshop XI
Washington DC

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Director of Regulatory Science, Hunton Andrews Kurth LLP

October 17, 2023



All views presented today do not necessarily reflect the views of Hunton Andrews Kurth or the views of any firm client

EPA Risk Assessment

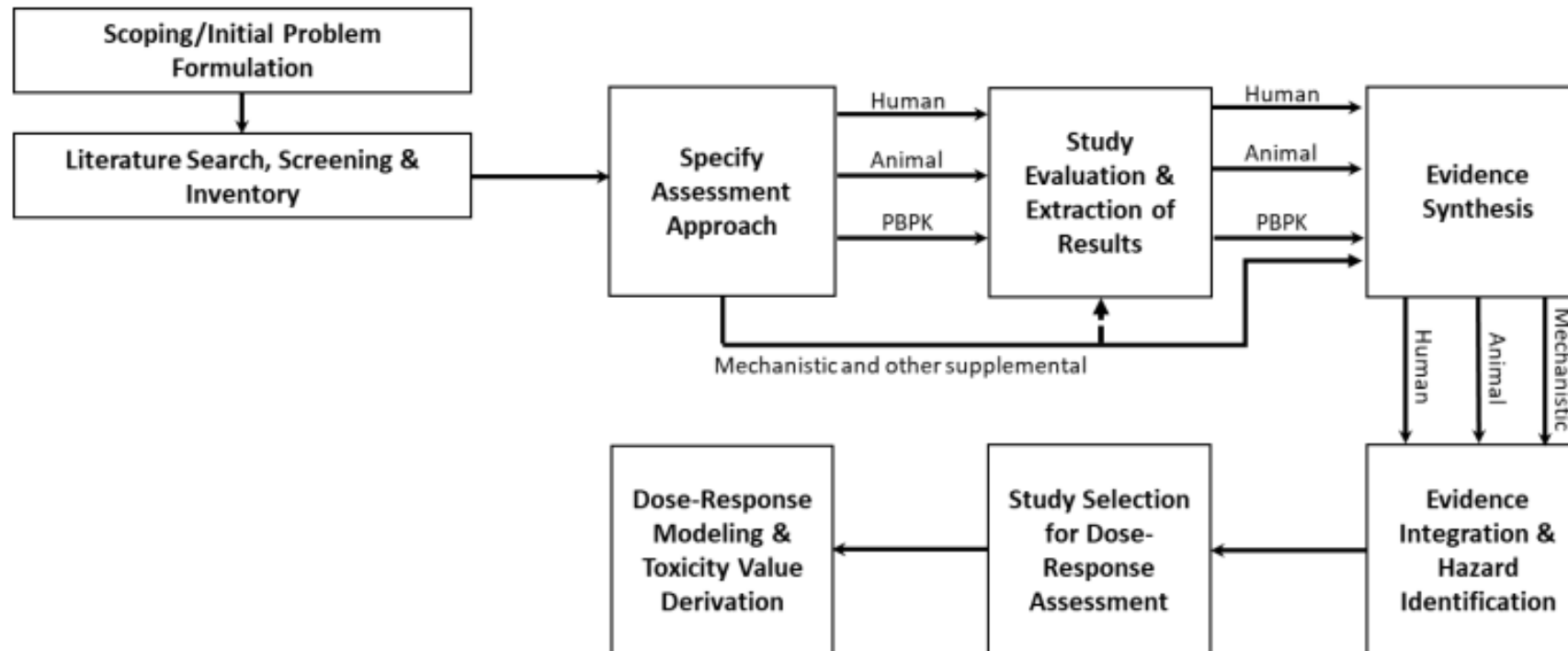
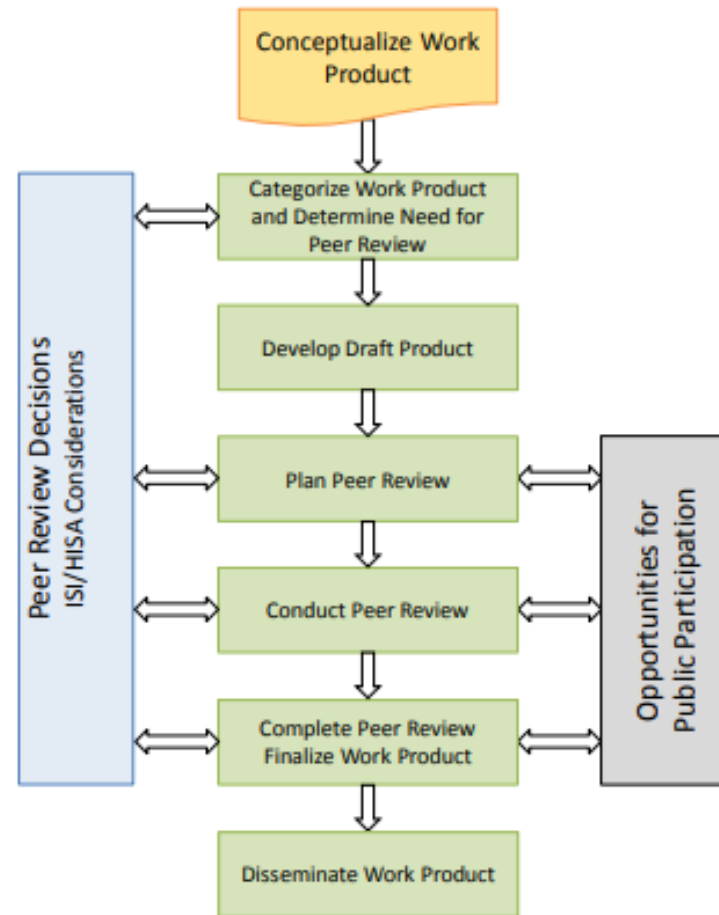
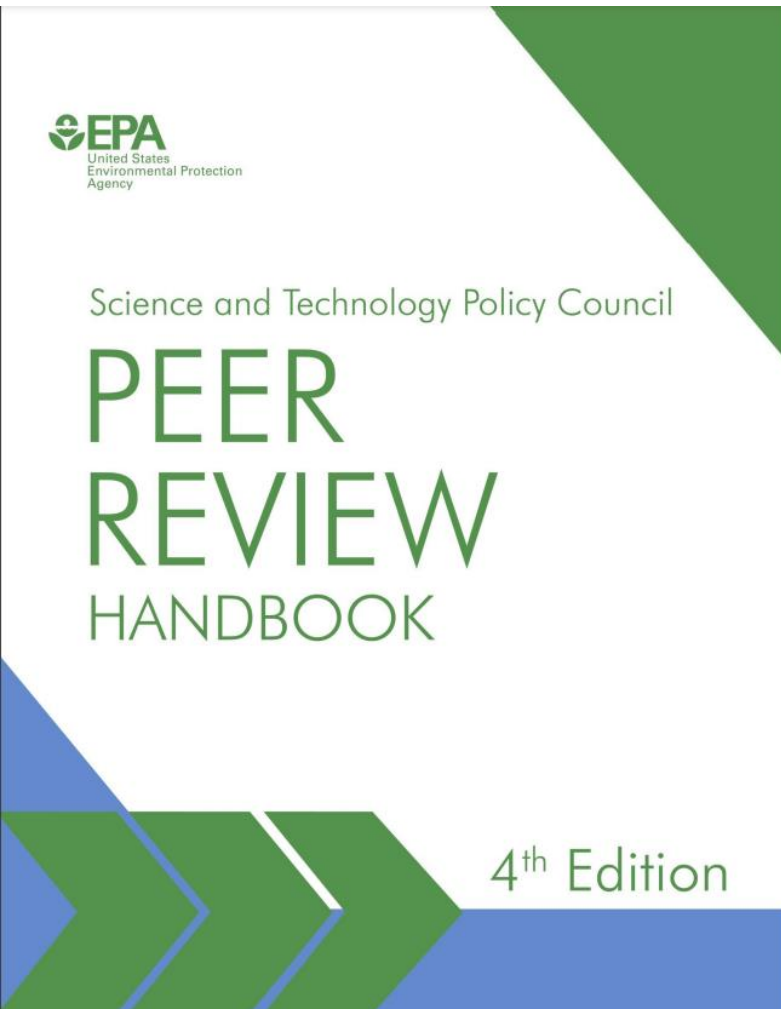


Figure O-1. Integrated Risk Information System (IRIS) assessment draft development process.

Source: 2022, EPA IRIS Staff Handbook

EPA Peer Review



- Peer review must be fit-for-purpose.
- Influential and highly influential scientific information undergo more rigorous peer review.
- Federal Advisory Committees (SAB, CASAC) are used for the most important and complex scientific and technical issues
- National Academy of Sciences (NAS) is used for significantly controversial or high-visibility products

EPA Peer Review Committee Elements

- Balance of Expertise
- Balance of points of view/perspectives
- Geographic location, diversity in work sector
- Avoid conflicts of interest
- Public participation and stakeholder involvement
- Independence
- Transparency

Importance of the Peer Review Charge

NAS Formaldehyde Charge

(EPA IRIS)

“The committee will assess whether EPA’s draft document *adequately and transparently* evaluated the scientific literature, used appropriate methods to synthesize the current state-of-the science, and *presented conclusions* regarding the hazard identification analysis and dose-response analysis of formaldehyde that are *supported by the scientific evidence*. The committee *will not conduct its own hazard assessment of formaldehyde*.”

NAS Formaldehyde Final Report

“[t]he committee did not conduct an independent hazard evaluation or dose-response assessment, and therefore does not recommend alternative hazard identification conclusions or toxicity values.

The committee also was not charged with commenting on other interpretations of scientific information relevant to the hazards and risks of formaldehyde, nor did its statement of task call for a review of alternative opinions on EPA’s formaldehyde assessment.”

Importance of the Peer Review Charge (2)

HSRB Formaldehyde Charge

(EPA OCSPP)

“evaluate four specific studies and determine whether they were each “scientifically sound, providing reliable data for use in a weight-of-evidence to determine a point of departure for acute inhalation exposures to formaldehyde.”

HSRB Formaldehyde Consensus Report

“For their evaluation and discussion, the Board considered materials presented at both meetings, both from the EPA and from the public comments, research articles, and related materials, the Agency’s review, the Agency’s statistical analysis of the research data, and oral comments from Agency staff during the HSRB meeting discussions.”

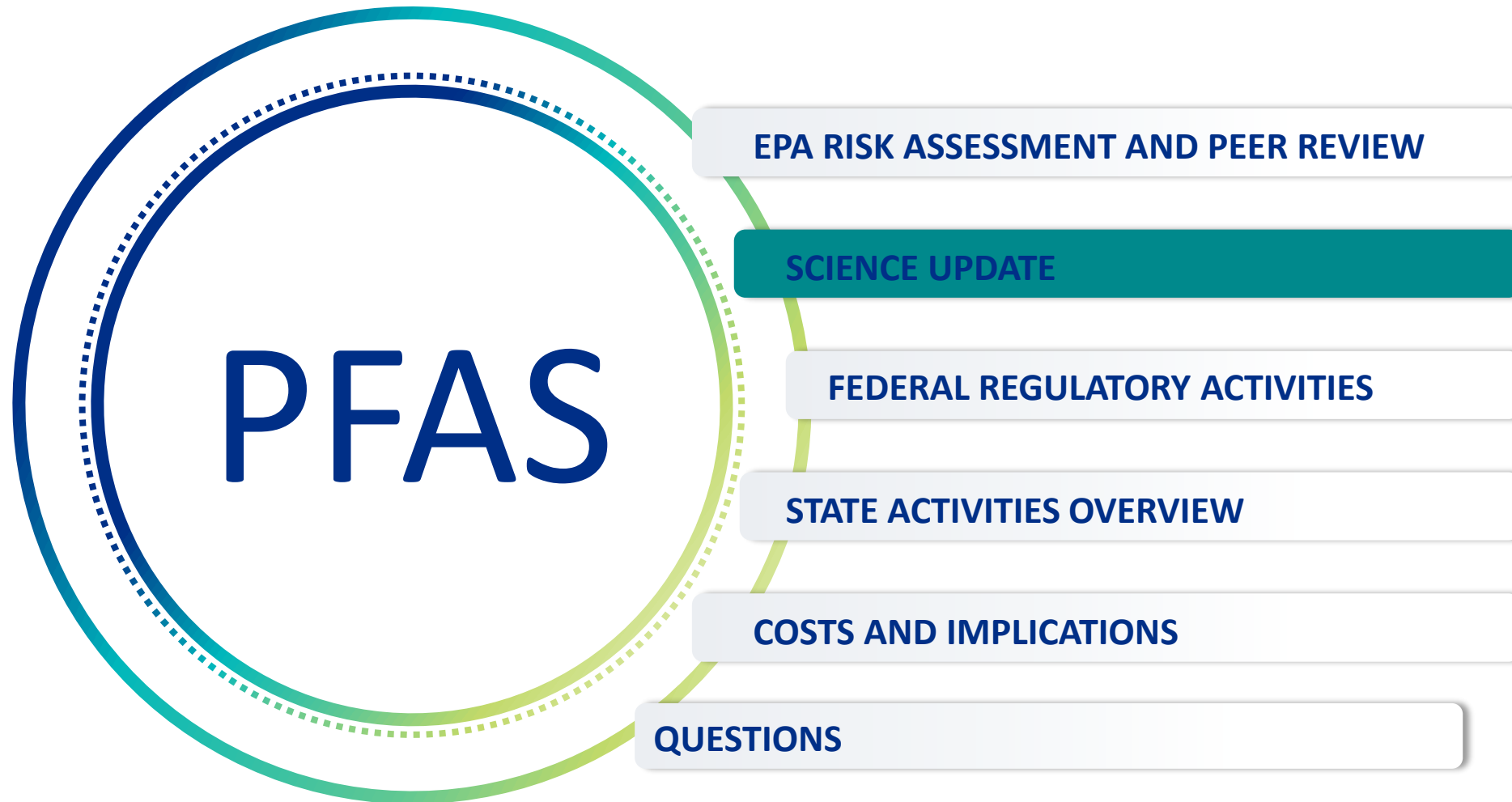
Importance of the Peer Review Charge (3)

NAS Ethylene Oxide Charge (TCEQ)

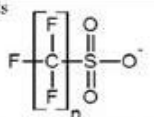
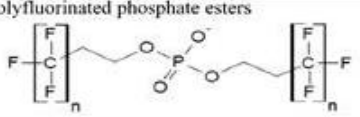
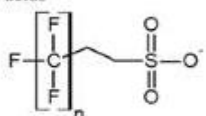
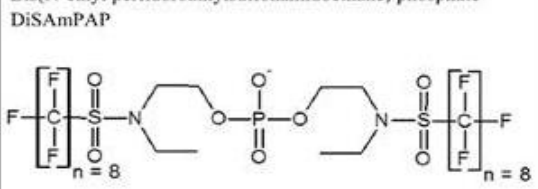
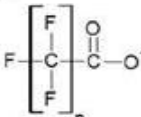
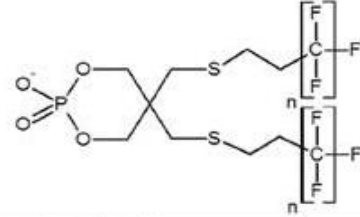
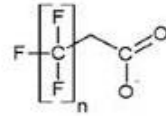
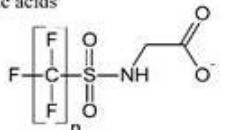
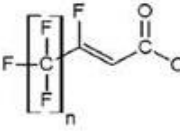
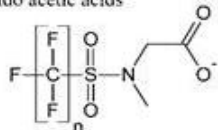
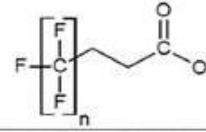
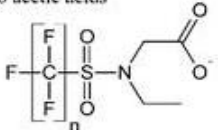
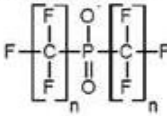
“The committee will review the methods, results, and conclusions of TCEQ’s assessment document and consider whether the conclusions are clearly presented, scientifically supported, and based on the *best available scientific information*.”

NAS Final Report

Expected 2024



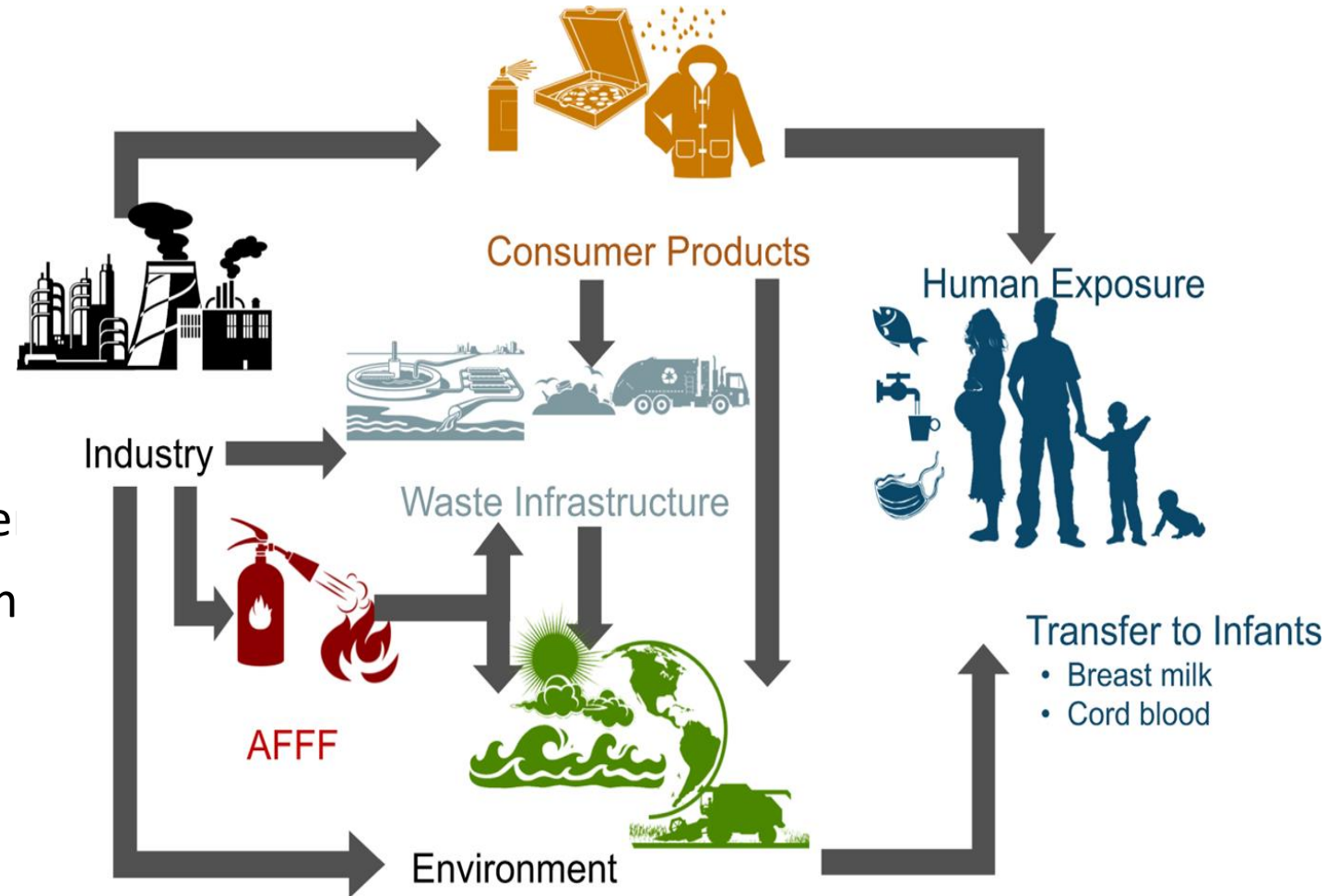
PFAS Overview

Perfluoroalkyl sulfonic acids PFSAAs n = 4-10 	Di-substituted polyfluorinated phosphate esters DiPAPs n = 4, 6, 8, 10 
Fluorotelomer sulfonic acids n:2 FTSAAs n = 4, 6, 8 	Bis(N-ethyl perfluoroalkylsulfonamidoethane) phosphate DiSAMPA 
Perfluoroalkyl carboxylic acid PFCAs Short Chain n = 4-7 Long Chain n = 8-18 	Fluorotelomer mercaptoalkyl phosphate esters FTMAPs n = 4, 6, 8, 10 
Fluorotelomer carboxylic acids FTCAs n:2 FTCA n = 4, 6, 8, 10 	Fluoroalkyl sulfonamido acetic acids FASAAs n = 4-8 
n:2 FTUCAs n = 4, 6, 8, 10 	N-methyl fluoroalkyl sulfonamido acetic acids MeFASAAs n = 4-8 
n:3 FTCA n = 3, 5, 7, 9 	N-ethyl fluoroalkyl sulfonamido acetic acids EtFASAAs n = 4-8 
Disubstituted perfluoroalkyl phosphinic acids PFPIAs n = 4, 6, 8 	

- Thousands of shapes/sizes/structures
 - 669 on EPA's active inventory
 - Over 1300 identified by EPA, >3000 internationally
- Not naturally occurring; now ubiquitous in the environment
- Carbon-Fluorine bond is the hallmark; some definitions require one fully fluorinated carbon, others require two or three
- C-F bond is very stable, leads to environmental persistence and persistence in the body; provides the beneficial properties as a surfactant and repellent

Where May PFAS Be Found?

- Airports & military bases (AFFF)
- Landfills (leachate)
- Wastewater Treatment Plants (effluent, residuals)
- PFAS Manufacturers
- Paper / Packaging Manufacturers
- Fabric, Carpet, Leather Manufacture
- Platers & Metal Finishers (chromium)
- Surface water
- Rain (mostly urban areas)
- Soil (mostly via land application)



State of The Science: Measuring PFAS

We can reliably measure:

- 30 PFAS in food (FDA)
- 16 PFAS in human blood, serum, or urine (CDC)
- 29 PFAS in drinking water; treatment processes for 37 PFAS in the Drinking Water Treatability Database
- 40 PFAS in wastewater, surface water, groundwater, soil, sediment, biosolids, leachate, and fish tissue (draft released September 2021) (EPA, DOD)
- 50 PFAS in air from sources (under development, but can be used) (EPA)
- 0 PFAS in ambient air (coming soon) (EPA)

Plaintiffs' Alleged Medical Injuries

Science is evolving

C-8 Panel Studies Results

Probable links between PFOA exposure and:

High cholesterol
Testicular cancer
Kidney cancer
Ulcerative colitis
Thyroid disease
Pregnancy-induced hypertension

- Birth defects
- Cancers: bladder, breast, prostate, ovarian, non-Hodgkin lymphoma, liver, pancreatic, thyroid, and uterine
- Cerebrovascular disease
- Coronary artery disease
- Developmental disabilities
- Endocrine disruption
- Guttate psoriasis
- High blood pressure
- Immune suppression
- Leukemia
- Liver disease
- Miscarriages
- Obesity
- Osteoarthritis
- Osteoporosis
- Peripheral Artery Disease
- Sarcoidosis
- Tissue damage
- Tumors
- Uterine polyps

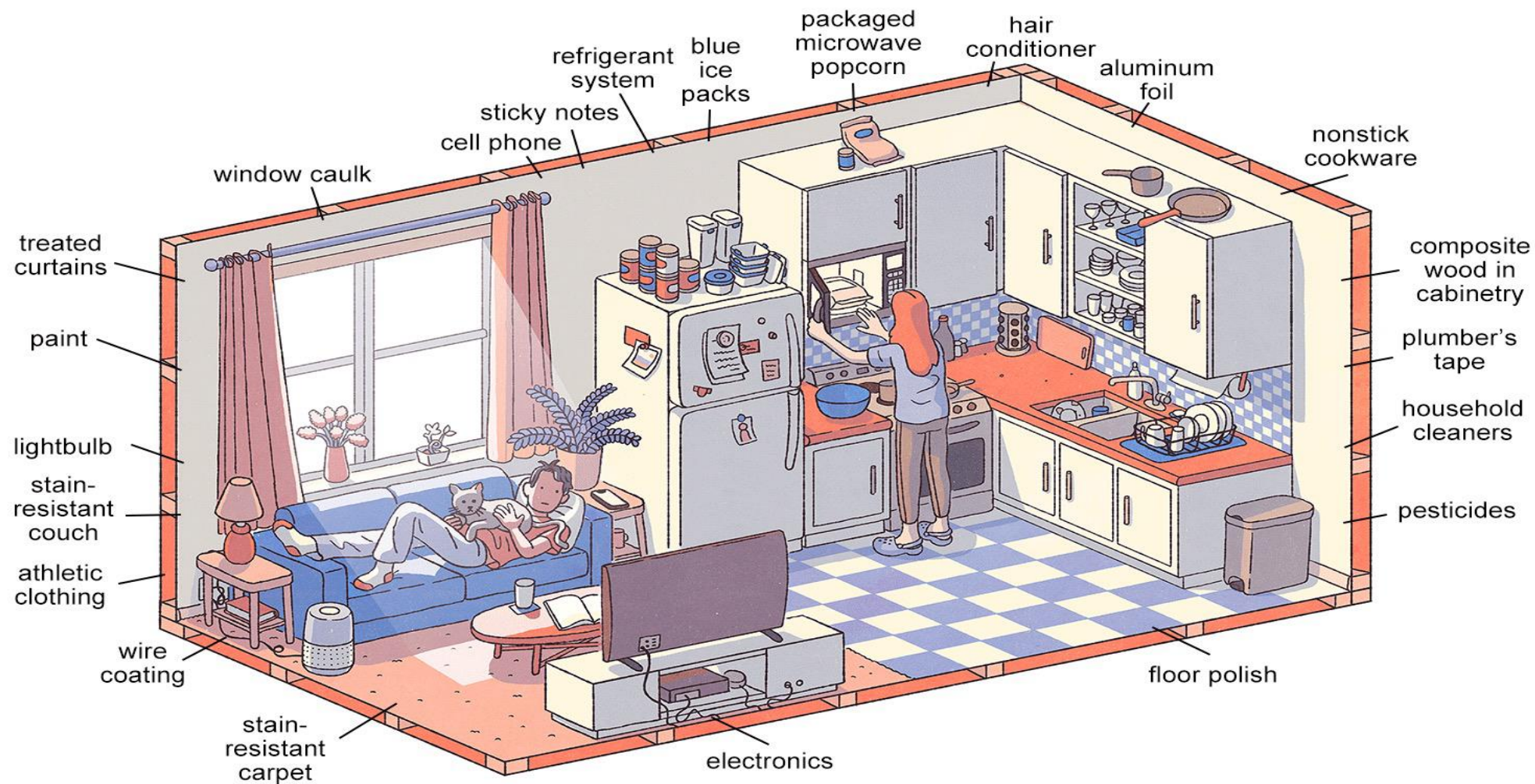
PFAS Used in *Vast Numbers* of Applications



Industries

Healthcare
Chemical/Pharmaceutical Manufacturing
Electronics
First Responders
Automotive
Aerospace/Defense
Building/Construction
Alternative Energy
Semiconductors
Oil & Gas
Military
Outdoor Apparel/Equipment

PFAS in the Home



PFAS Critical Uses

Report on Critical Per- and Polyfluoroalkyl Substance Uses

Pursuant to Section 347 of the James M. Inhofe National Defense Authorization Act for
Fiscal Year 2023 (Public Law 117-263)



August 2023

Office of the Assistant Secretary of Defense for Energy,
Installations, and Environment

Office of the Assistant Secretary of Defense for Industrial
Base Policy

“Mission critical PFAS uses provide significant benefits to the framework of U.S. critical infrastructure, and national and economic security.”

“Losing access to PFAS due to overly broad regulations or severe market contractions would greatly impact national security and DoD’s ability to fulfill its mission, and impact domestic defense industrial base manufacturing and supply.”

“If future PFAS legal and regulatory frameworks ignore the OECD caution on the use of its PFAS definition and seek to broadly restrict the use of PFAS based on chemical structure, there could be extensive economic, industrial competitiveness, and quality-of-life impacts to society.”

Uses include kinetic capabilities; energy storage and batteries; microelectronics and semiconductors; AFFF; lines, hoses, O-rings, seals, gaskets, tapes, cables, connectors; electronic/dielectric fluids; advanced oils, greases, fluids, lubricants; precision cleaning fluids, degreasing fluids; adhesives.....

EPA PFAS Assessments

PFAS Compound	Chronic RfD (mg/kg-day)
PFOA (2016)	0.00002
PFOS (2016)	0.00002
PFBS (2021)	0.0003 (medium confidence)
GenX (2021)	0.000003
PFOA (Proposed 2021)	0.0000000015
PFOS (Proposed 2021)	0.0000000079
PFBA (2022)	0.001 (medium confidence)
PFHxA (2023)	0.0005 (medium confidence)
PFPrA (2023)*	0.0005 (low confidence)
HQ-115 (2023)*	0.0003 (low confidence)
PFHxS (Proposed 2023)	0.0000000004 (medium confidence)
PFDA (Proposed 2023)	0.0000000004 (medium confidence)

HUNTON
ANDREWS KURTH



	EPA (2023)	ATSDR	EPA (2016)	HC	Aus	CAAT
PFOA Advisory (ppt):	0.004	10	70	200	560	30,000

140,000-fold difference

EPA PFOA and PFOS Peer Review (SDWA)

- **November 2021:** EPA begins SAB review of 4 documents to inform the MCLG
 - EPA's Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) in Drinking Water
 - EPA's Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctanesulfonic Acid (PFOS) in Drinking Water
 - EPA's Analysis of Cardiovascular Disease Risk Reduction as a Result of Reduced PFOA and PFOS Exposure in Drinking Water
 - EPA's Draft Framework for Estimating Noncancer Health Risks Associated with Mixtures of PFAS.
- SAB meetings held in December 2021, January and May 2022; draft report released April 2022.
- Over 1750 pages, cited over 1800 publications, public comment period 44 days

Overall Approach to Hazard Assessment

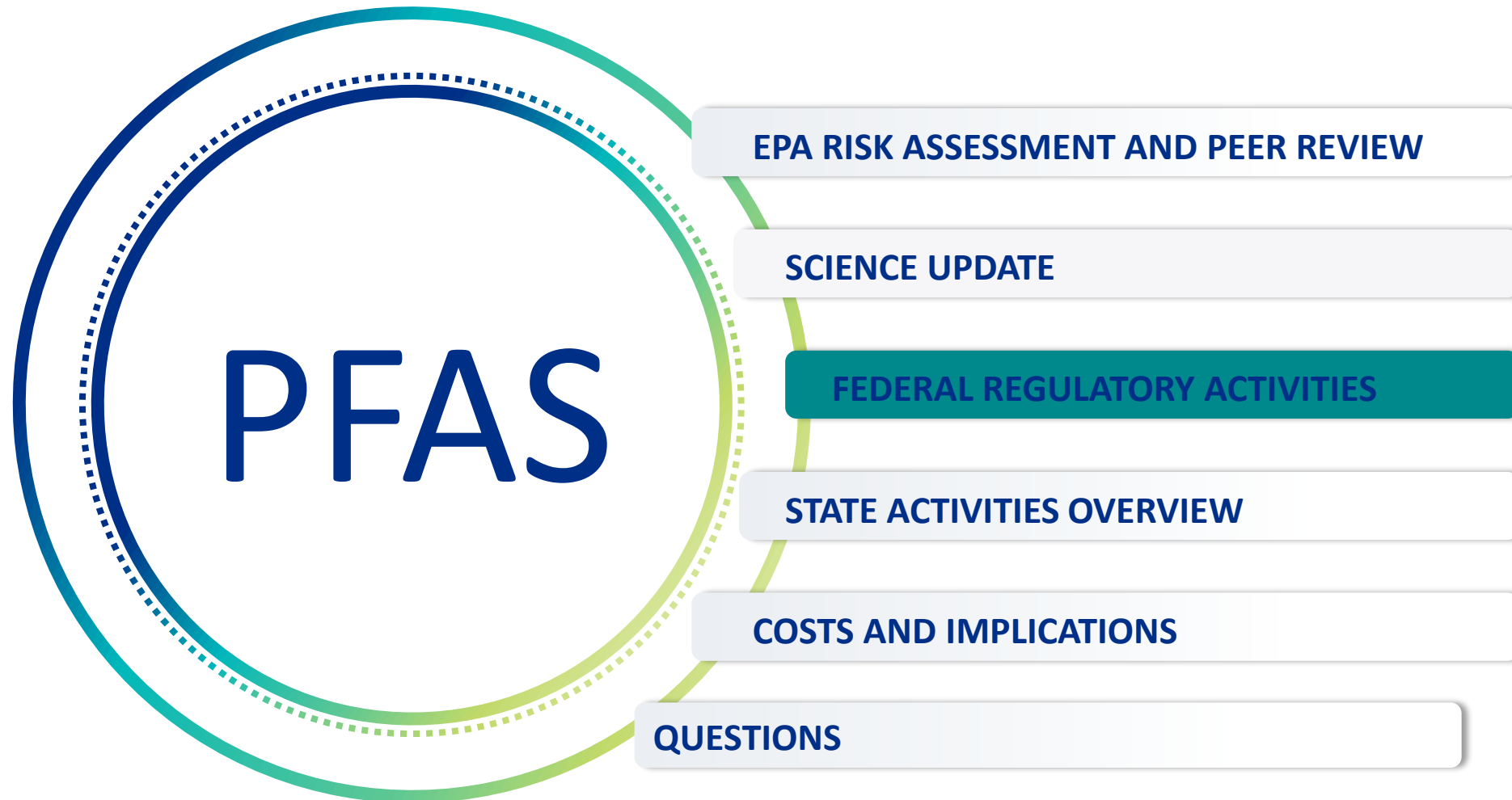
- Incorporated 2016 assessments into 2021 document; not all studies evaluated similarly
- Didn't have a protocol; did not follow ORD IRIS handbook
- Different chapters written by different teams (6 subgroups)

Position/Agency	Leadership/Members	
Chair	Weihsueh Chiu: Texas A&M; former EPA IRIS staff, PhD in Physics	
Members from State Health Departments	Sandeep Burman (MN)	Gloria Post (NJ)
Academia	Aimin Chen	Deborah Cory-Slechta
	Jamie DeWitt	James Hammitt
	Lisa Kamendulis	Daivd Keiser
	Loren Lipworth	Lala Ma
	Sheila Olmstead	David Savitz
	Angela Slitt	
Natural Resources Defense Council	Kristi Pullen-Fedinick	
ScitoVation	Jeffrey Fisher- former FDA, mathematical modeler	

- *EPA used systematic review methods consistent with the current ORD systematic review practice to ensure transparency and completeness of literature identification, sorting, and study quality evaluation. Is the process clearly described?*
- *Do you agree with the strong vs. suggestive evidence designations for the various health outcome categories? Do any other health systems or endpoints need to be considered for POD derivation?*
- *Does the SAB panel agree with EPA's rationale for not considering the ALT endpoint reported in the epidemiological studies for the derivation of a POD for the liver health effects? Please provide your justification and if you suggest that EPA consider this endpoint for POD derivation, please provide your recommendations for a modeling approach.*
- Detailed questions on the toxicokinetic modeling
- Questions on the RfD derivations for the epidemiological data (focusing on the choice of the Grandjean studies on developmental immune health outcomes).
- Questions on relative source contribution
- Questions on the mixtures document
- Questions on the CVD methodology

Non-cancer RfD Recommendations

- EPA should provide additional transparency and completeness in its evidence identification methodology, including development of a protocol with clear inclusion/exclusion criteria and study evaluation approaches.
- Studies, particularly human studies, that were included in the 2016 health effects summary documents (HESDs) should be considered in the same manner as the more recent studies.
- A consistent framework and descriptors should be used for evidence synthesis and integration for each health outcome.
- In the short-term and in consideration of the agency's time constraints, EPA should initially focus on those health outcomes that have been concluded to have the strongest evidence, including the liver disease, immune system dysfunction, serum lipid aberration, impaired fetal growth, and cancer.
- EPA should provide a stronger and more transparent justification for the choice of benchmark responses (BMRs) - not only for decreased antibody response, but also other endpoints for which BMDs were developed.
- In deriving RfDs, EPA should consider using an "internal dose" POD, which is then further adjusted for inter-species and intra-species uncertainty/variability, so that the RfD is expressed in a dose metric equivalent value. This internal dose RfD can then be converted using toxicokinetic (TK) modeling to either an equivalent external dose or an equivalent water concentration, as appropriate.

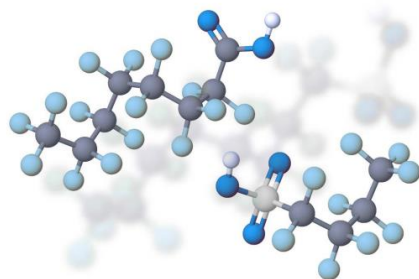


EPA Regulatory and Policy Developments



EPA 823R18004 February 2019 www.epa.gov/pfas

EPA's Per- and Polyfluoroalkyl Substances (PFAS) Action Plan



2019

EPA PFAS Action Plan

"By taking a whole of EPA approach, the [EPA Council on PFAS] will accelerate scientific work, regulatory action, and voluntary approaches to address PFAS contamination."

Radhika Fox,
Principal Deputy Assistant Adm'r,
EPA Off. of Water;
Asked to lead Council

April 2021

EPA Council on PFAS



PFAS Strategic Roadmap: EPA's Commitments to Action 2021–2024



2021

PFAS Strategic Roadmap:
EPA's Commitments to
Action 2021-2024

PROPOSED FY2024–2027 NECIs

- (1) . . . Reducing Excess Emissions of Harmful Pollutants. *Continued.*
- (2) Reducing Risks of Accidental Releases at Industrial & Chemical Facilities. *Continued.*
- (3) Reducing Significant Non-Compliance with NPDES Permits. *Continued.*
- (4) Reducing [Community Water Systems] Non-Compliance with Drinking Water Standards . . . *Continued.*
- (5) Mitigating Climate Change. *New Initiative.*

New Initiative.

- Implement 2021-2024 PFAS Strategic Roadmap.
- Address PFAS contamination and exposure.
- Hold responsible parties accountable for remediation.
- Prevent future releases of PFAS.
- Identify exposure levels threatening to human health and environment.
- If EPA determines PFAS contamination falls under CERCLA, develop enforcement discretion and contribution protection settlement policy to guide cleanup efforts.
- Initial focus on PFAS chemical manufacturers.
- Collaborate with states.

(6) Addressing PFAS Contamination.

2023

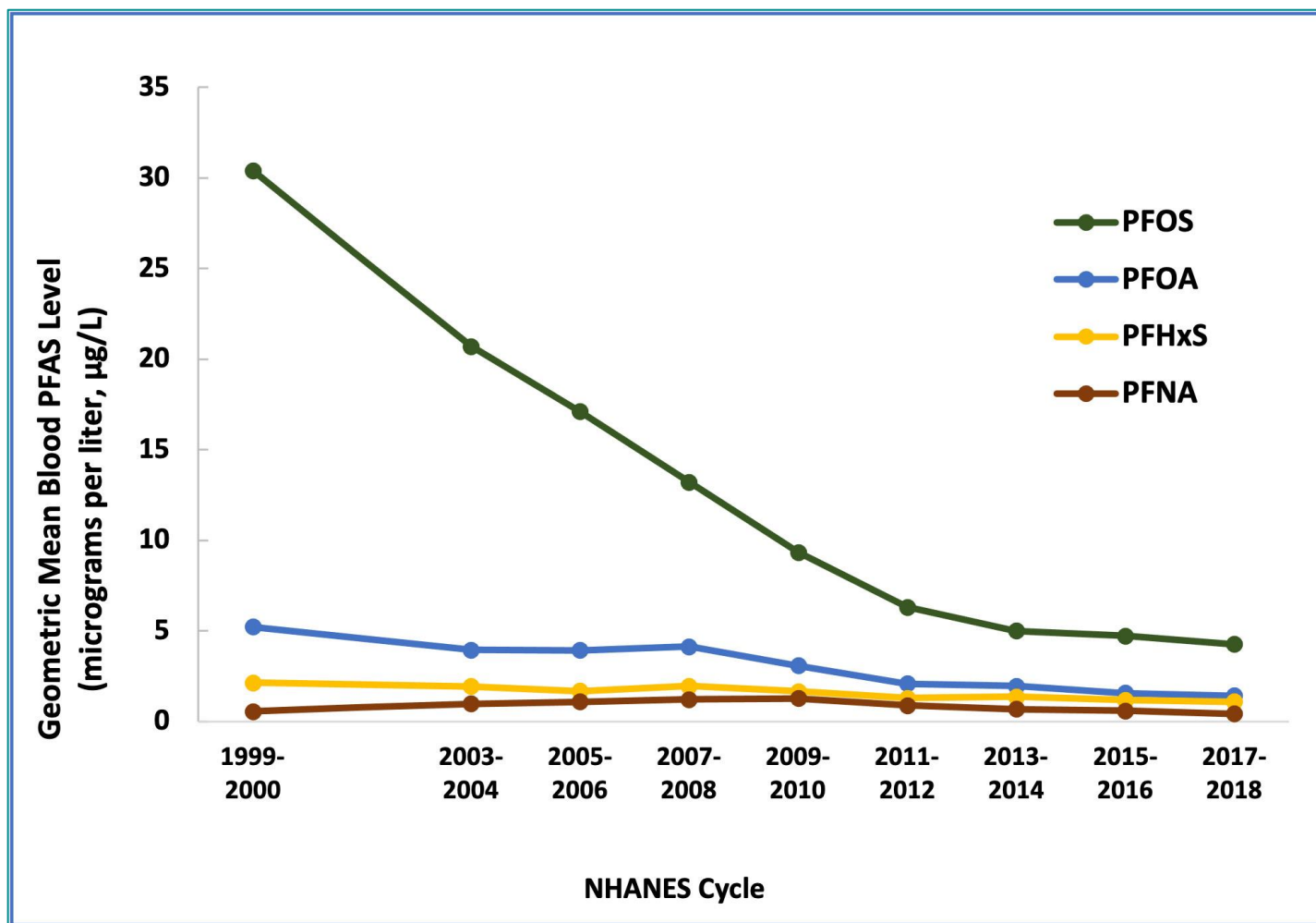
EPA's proposed National
Enforcement & Compliance
Initiatives

Waste: CERCLA, RCRA
Water: SDWA, CWA
Chemicals: EPCRA, TSCA

STATE OF THE SCIENCE: Exposure

Good news: long-chain PFOS levels decreasing since voluntary phase-out (2006)

- PFOS 84% reduction 1999-2016
- PFOA 70% reduction 1999-2016



Timeline for the Science Assessments (PFOA/PFOS)

Dec 16, 2021- May 3,
2022
4 SAB Meetings

July 20, 2022
Chartered
SAB Meeting

Mar 14, 2023
SDWA
Proposal
Released

Nov 16,
2021
Draft
PFOA/PFOS
Values
Released

June 15, 2022
Interim Health
Advisories Released

Aug 22, 2022
SAB Final
Report

Drinking Water: **SDWA**

EPA Health Advisories (unenforceable)

2016: PFOA & PFOS ≤ 70 ppt

2022: PFOA ≤ 0.004 ppt

PFOS ≤ 0.02 ppt (generally undetectable)

2023: EPA proposed ***enforceable*** National Maximum Contaminant Levels (MCLs) for Drinking Water (comment by May 30, 2023)

PFAS to Be Regulated	Proposed MCLs
<u>PFOA</u>	4 ppt
<u>PFOS</u>	4 ppt
PFNA	10 ppt*
PFHxS	9 ppt*
PFBS	2,000 ppt*
GenX	10 ppt*
[PFNA] + [PFHxS] + [PFBS] + [GenX]	Sliding-scale formula*

** Technically treated as one “Hazard Index” MCL—a new approach to determining MCL exceedances in drinking water.*



Site Cleanup: *CERCLA “Hazardous Substance” Listing*

Sept. 6, 2022: Proposed Rule to designate PFOA & PFOS as “hazardous substances” under CERCLA.

- First use of § 102(a) designation authority in 40 years
- Cleanup standards undisclosed
- Costs likely underestimated

Final Rule expected **February 2024** (was August 2023)

April 13, 2023 – EPA considering listing 7 additional PFAS, categories of PFAS, and degradants of PFAS



Site Cleanup: *CERCLA “Hazardous Substance” Listing*

Potential Enforcement & Liability Implications

If finalized, Rule would impact many U.S. industries & property owners, far beyond just PFOA/PFOS manufacturers.

- EPA could respond to releases/threatened releases of PFAS (a “hazardous substance”) without proof of imminent & substantial danger to public health/welfare.
- More sites added to the NPL (Superfund Site List)
- Cleanup plans disrupted at existing sites
- Trigger reopener provisions in settlement agreements
- Enhanced EPA enforcement authority
 - Section 107 cost recovery claims
 - Section 106 unilateral orders
- Potential private party litigation & complications to existing allocation models
- Section 113 contribution claims



Site Cleanup: *EPA Enforcement Discretion*

In **March 2023**, EPA held two listening sessions on a future CERCLA enforcement discretion policy regarding PFAS

EPA's Targets for PFAS Enforcement

- PFAS manufacturers
- Federal facilities
- Parties whose actions contribute to the release of significant amounts of PFAS into the environment

Parties EPA Does Not Intend to Pursue

- Community water utilities and POTWs
- Publicly owned or operated municipal solid waste landfills
- Farmers who apply biosolids to their lands
- State, tribal or municipal airports or fire departments

Not binding on private parties or state, tribal, & local governments

Waste Regulation: *RCRA*

June 23, 2021

New Mexico State Petitioned to EPA

- Requesting to address PFAS under RCRA as “hazardous waste”

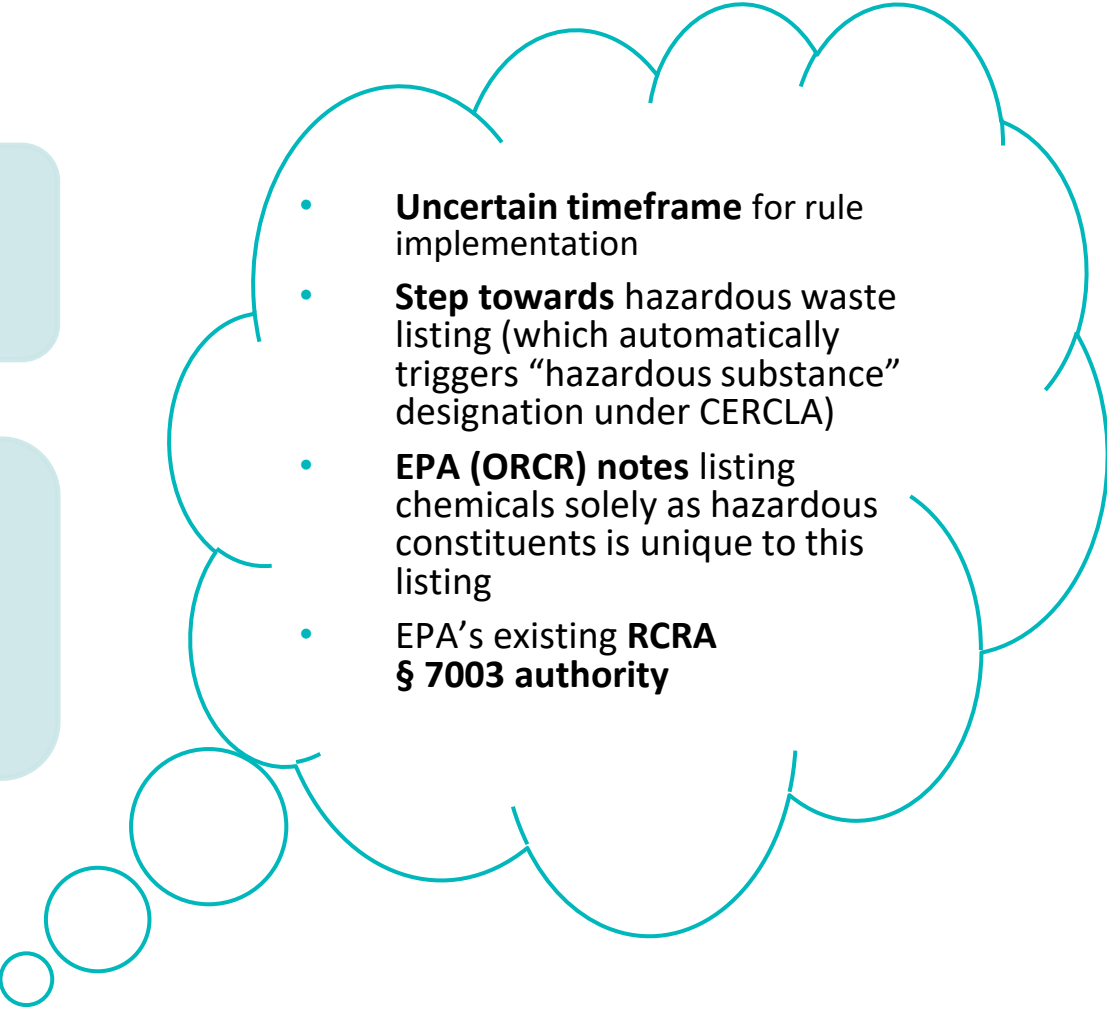
Oct. 26, 2021

EPA initiates rulemaking to list 4 PFAS as RCRA “Hazardous Constituents”

- PFOA, PFOS, PFBS, & Gen X
- Clarify applicability of RCRA Corrective Action Program based on statutory definition of “hazardous waste”

Aug. 2023

EPA expected to release proposed rule

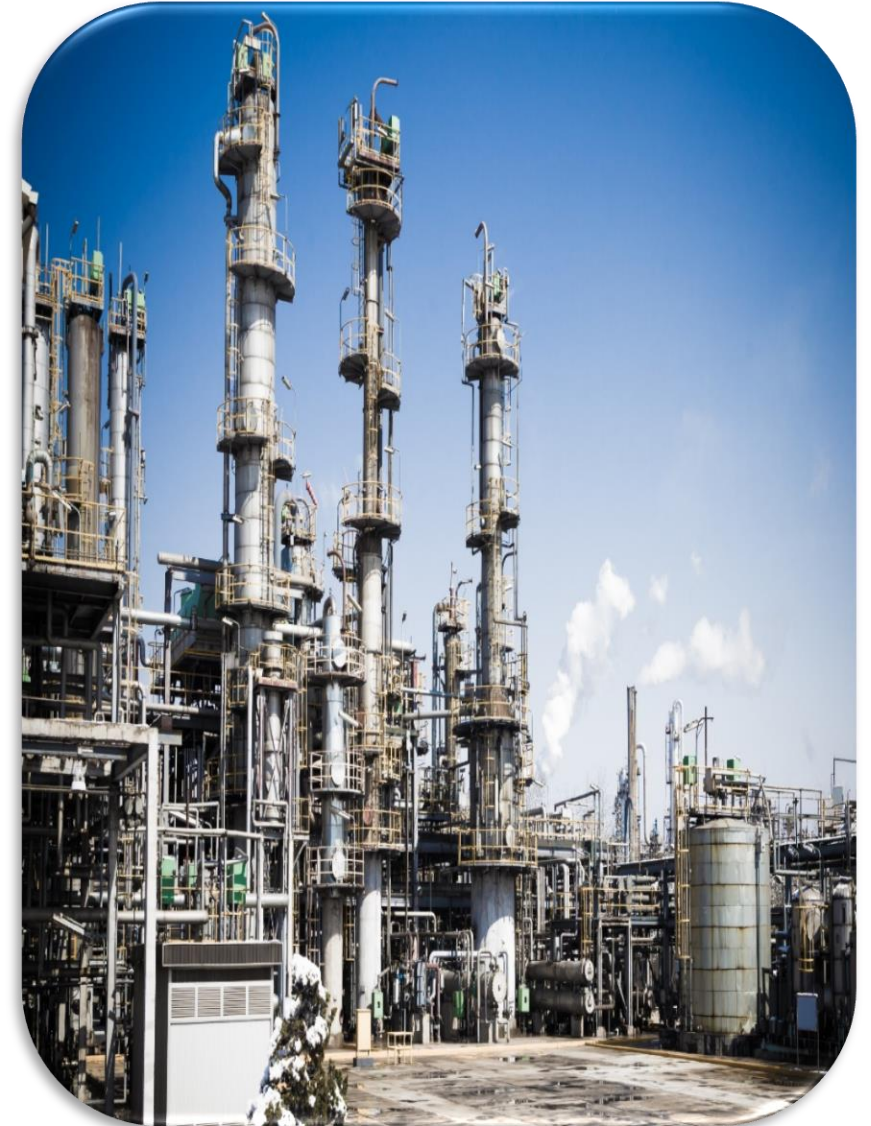
- 
- **Uncertain timeframe** for rule implementation
 - **Step towards** hazardous waste listing (which automatically triggers “hazardous substance” designation under CERCLA)
 - **EPA (ORCR) notes** listing chemicals solely as hazardous constituents is unique to this listing
 - EPA’s existing **RCRA § 7003** authority

CHEMICALS: *FACILITY REPORTING*

EPA added 180 PFAS to the Toxic Release Inventory (TRI). This requirement came from the FY2020 NDAA.

- 100-pound reporting threshold was established for facilities identified by certain SIC codes that manufacture, process, or otherwise use listed PFAS compounds
- Report on-site releases to air, water, land, and transfer to off-site locations
- First reports were due to EPA July 1, 2021 (172 PFAS)
- Information may be used to identify locations with PFAS releases or potential releases to inform CERCLA approaches

Dec 2022 Proposed Rule to remove the 100-lb reporting threshold for all PFAS. Final Rule expected in 2023.

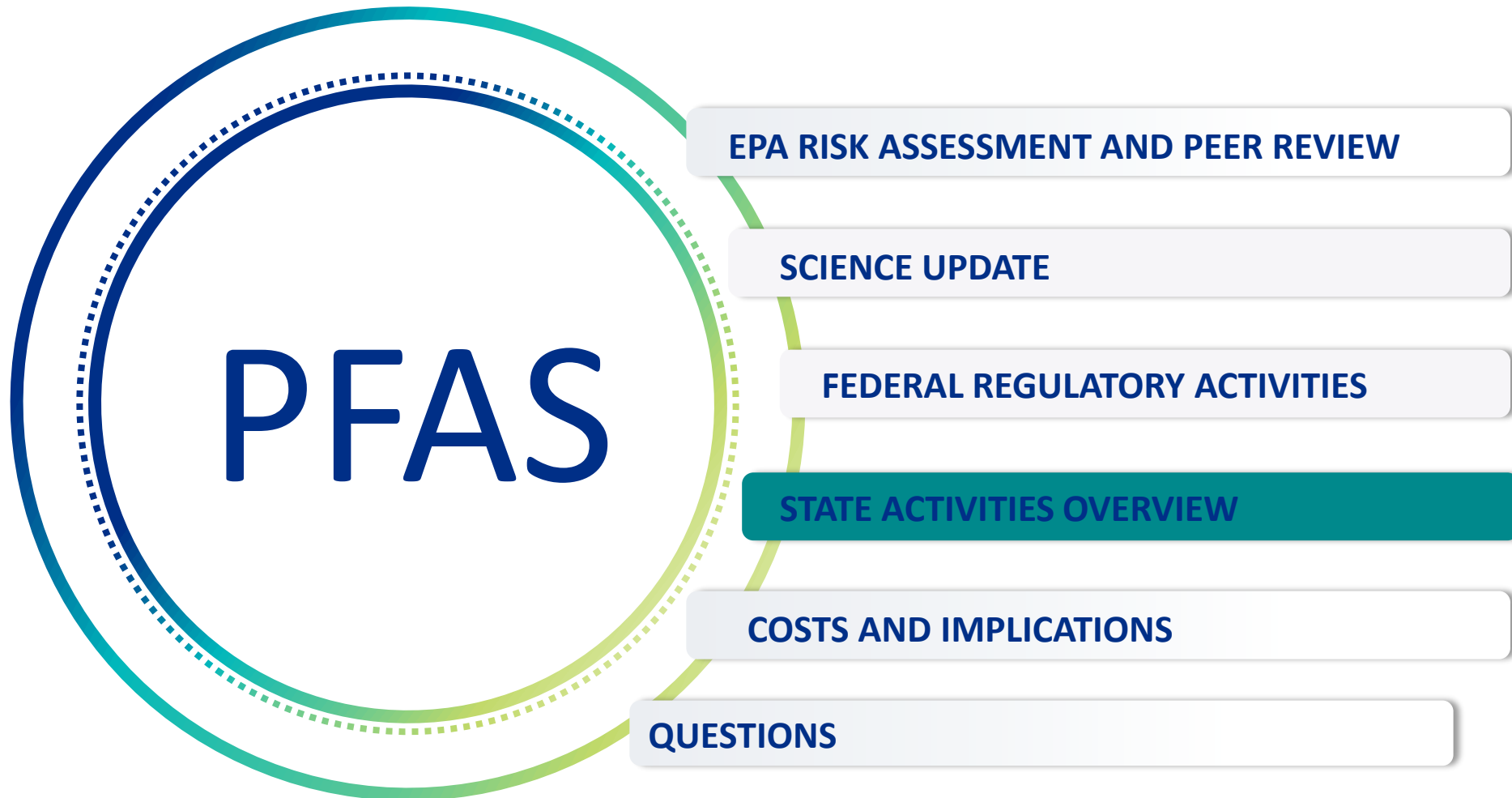


October 11, 2023: Final Rule to address PFAS reporting under TSCA Section 8(a)(7), which was added by the FY2020 NDAA

- Applies to:
 - Manufacturers & importers of PFAS (since Jan. 1, 2011)
 - Importers of articles containing PFAS must report
 - No exemptions (e.g., for byproducts, impurities, polymers)
- Companies are required to provide information on their uses, production, byproducts, disposal, exposures, & hazards of PFAS for the past 11 years.
- Reports due May 8, 2025 (Nov 10, 2025 for small importers)

For more information, read [our Nickel Report article about the Final Rule](#)

- January 2023 **Proposed Significant New Use Rule (SNUR)**
 - Prevents “inactive” PFAS from being used without EPA review
 - “Inactive” are those PFAS that are on the TSCA Inventory but have not been used since June 2021.
- June 2023 **New Framework for PFAS PMNs**
 - EPA acknowledges some PBT PFAS uses have no exposure and EPA expects to allow these PFAS to enter commerce (PFAS used in a closed system to make semiconductors or other electronic components)
 - For PBT PFAS that have low exposure, EPA generally expects to require test data
 - For PBT PFAS that are expected to have exposures, EPA generally expects to **NOT allow** the substance to enter commerce before “extensive testing is conducted”



State Regulation of PFAS



- Previous targets of regulation
 - *BPA, phthalates, lead, cadmium, flame retardants*
- In 2022, 280 PFAS-related bills were proposed at the state level
- 12 states have enacted laws to ban PFAS in various products; 8 states have reporting requirements
 - *Food packaging, rugs, carpets, textiles, cosmetics, fabric treatments, children's products, furniture, ski wax*
 - 25 states have policies relating to PFAS
- Retailers taking voluntary initiatives to ban PFAS in products from their suppliers in response
 - *Response to public pressure and testing from consumer groups*

Consistencies across states

- Definition of PFAS: “a class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom”
- Bans: “any person” selling or distributing in the state (retailers included)
- Knowledge of presence of PFAS in products not necessarily required



Inconsistencies across states

- Definition of “intentionally added” PFAS;
- Definitions of products regulated (e.g., food packaging)
- Whether laws cover intentionally added PFAS and/or unintentional presence of PFAS
- Whether product packaging is included in scope of law
- Certificates of compliance
- Thresholds for reporting
- Information required for reporting
- Exemptions from bans or reporting; ability to apply for waivers
- Fees
- Safer alternatives

2023 State Legislation and Regulation

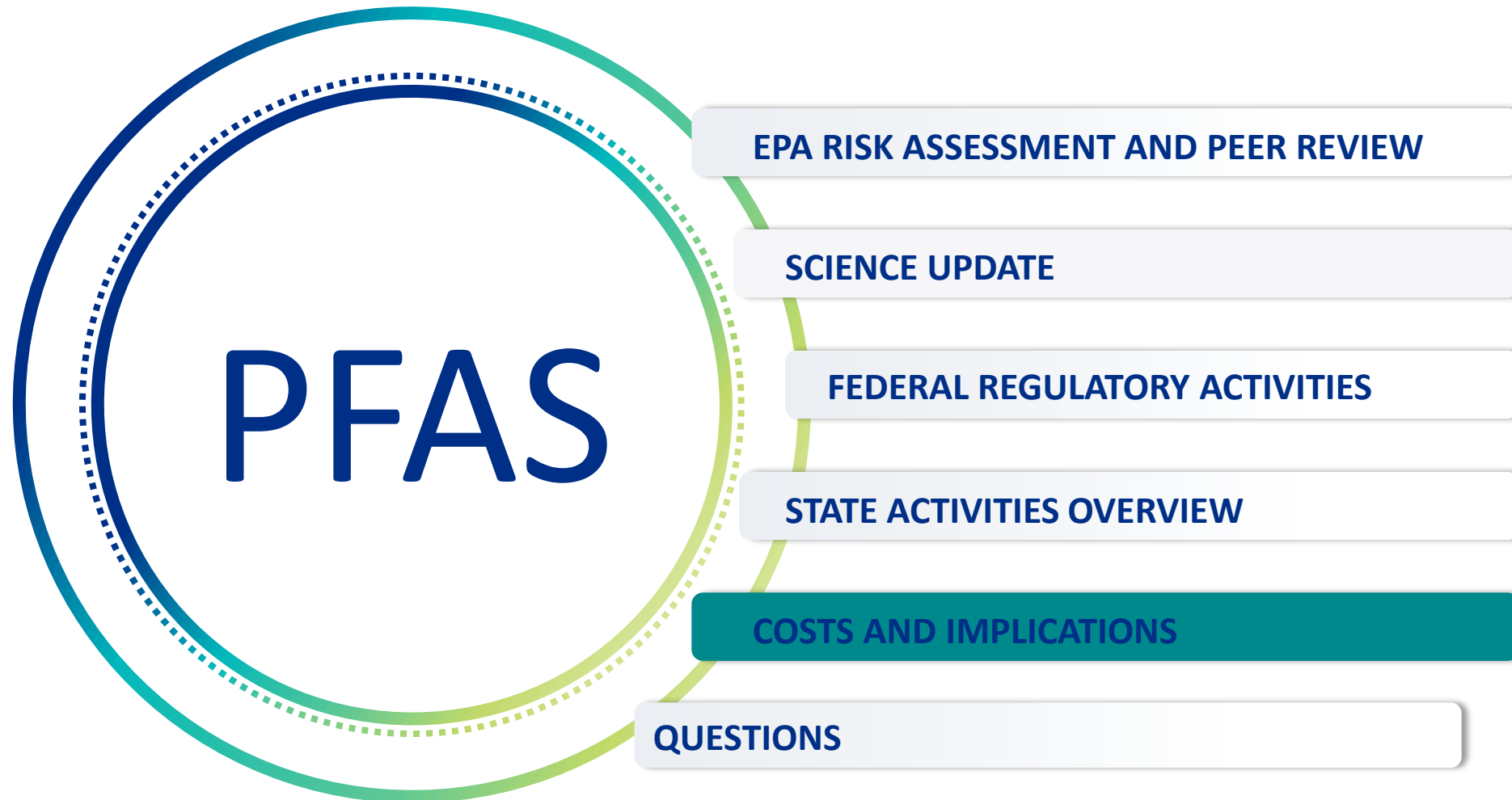
<https://www.huntonak.com/en/pfas-state-tracker.html>

- **Maine- bill passed into law**
 - Extended compliance deadline for reporting of PFAS in products to January 1, 2025
- **Oregon- bill passed into law**
 - Ban on PFAS in foodware containers starting January 1, 2025
 - Ban on PFAS in cosmetics starting January 1, 2027
- **Washington- regulations promulgated**
 - Reporting on PFAS in leather and textile furniture for outdoor use
 - Ban on PFAS in carpets and rugs, cosmetics, leather and textile furnishings for indoor use, aftermarket stain and water-resistant treatments for application to textile and leather consumer products starting January 1, 2025
- **Minnesota- bill passed into law**
 - Ban on PFAS in carpets, rugs, cleaning products, cookware, cosmetics, fabric treatments, children's products, menstruation products, textiles, ski wax, and upholstered furniture starting January 1, 2025
 - Reporting requirements for all products starting January 1, 2026
 - Ban on all products containing PFAS beginning January 1, 2032

State Attorney General PFAS Lawsuits



August 24, 2023, <https://www.saferstates.org/news/>



Costs and implications

Regulation	Total Costs (3%)	Total Net Benefits (3%)
Final PFAS Reporting Rule	\$845,000,000	Not Quantified
Proposed CERCLA Rule*	\$370,000	Not Quantified
Proposed Drinking Water Rule	\$771,770,000	\$461,210,000

*Chamber of Commerce Analysis estimates costs at \$17.4 billion

<https://www.uschamber.com/environment/pfos-and-pfoa-private-cleanup-costs-at-non-federal-superfund-sites>

Costs and implications of the EU PFAS Restrictions

Table 1 – Total economic and fiscal impacts of goods exported from the U.S. to the European Union that contain PFAS in 2022

Metric	Total Impacts	Unit
 Employment	502,000	Jobs (units)
 Output	\$168	2022 USD (billions)
 GDP	\$81	2022 USD (billions)
 Labor Income	\$46	2022 USD (billions)
 Federal Tax Revenues	\$12	2022 USD (billions)
 State and Local Tax Revenues	\$7	2022 USD (billions)

<https://www.uschamber.com/international/impacts-of-the-pfas-restriction-on-trade-between-the-u-s-and-the-european-union>

QUESTIONS



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