**Joint Standing Committee on Environment and Natural Resources**

# MEETING AGENDA

**Monday, November 13th, 2023**
Cross State Office Building, Room 216 (ENR Committee Room)

The meeting will be livestreamed at the following link: https://legislature.maine.gov/Audio/#216

---

**9:00 a.m.** **Welcome, introductions and overview of meeting**
- *Committee Chairs*

**9:05 a.m.** **Overview of federal chemicals regulation**
- *Kyla Bennett, PhD, Public Employees for Environmental Responsibility/PEER*

**9:50 a.m.** **Health effects of PFAS exposure**
- *Linda Birnbaum, PhD*

**10:35 a.m.** **Break (15 minutes)**

**10:50 a.m.** **Overview of EPA's PFAS data reporting rule**
- *Stephanie Griffin, United States Environmental Protection Agency*

**11:35 a.m.** **Industry perspective on PFAS reporting/compliance**
- *Diana Rondeau, Director of Produce Compliance, IDEXX Laboratories*

**12:20 p.m.** **Break (15 minutes)**

**12:35 p.m.** **Committee member discussion and next steps**

**2:00 p.m.** **Adjourn**

***Please note that times are approximate and subject to change***

# Overview of Federal Chemical Regulation

# Federal laws regulating chemicals

- Toxic Substances Control Act (TSCA)
- Federal Insecticide, Fungicide, Rodenticide Act (FIFRA)
- Resource Conservation and Recovery Act (RCRA)
- Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA, a.k.a. Superfund)
- Clean Water Act
- Clean Air Act
- Safe Drinking Water Act
- Federal Hazardous Substances Act (FHSA), etc.

# Focus on TSCA and FIFRA

- Both TSCA and FIFRA regulate *products*, as opposed to the regulation of *pollutants, sources of pollutants,* or *the media they pollute* (soil, air, water);

- TSCA regulates all chemicals imported or manufactured in the U.S. ***except***: 1) Pesticides (FIFRA); 2) Tobacco and tobacco products (ATF); 3) Radioactive materials (NRC); and 4) Foods, food additives, drugs, PCPs and cosmetics, or medical devices (FDA)

# There *is* some overlap between TSCA and FIFRA

- While FIFRA regulates pesticides, individual components of a pesticide can be regulated by TSCA if they have a non-pesticidal use. For example:

  - PFAS
  - Formaldehyde
  - Quaternary ammonium compounds
  - Etc.

# TSCA and Lautenberg

- TSCA enacted in 1976:
  - All chemicals in commerce at the time were grandfathered in, and assumed to be safe.
  - 62,000 chemicals have never gone through a risk assessment.
  - Currently, 86,000 chemicals on “the Inventory” (e.g., “Existing” chemicals)

- Lautenberg Chemical Safety for the 21st Century Act (Lautenberg) enacted in 2016
  - Made major changes/strengthened TSCA

# What did the original TSCA do?

- Gathered information on the health and environmental impacts of *new* chemicals;
- Gave EPA authority to regulate any chemical found to present an “unreasonable risk” to health or the environment (but only gave them 90 days to find this);
- Required EPA to exercise their authority in a way so as not to “impede unduly or create unnecessary economic barriers to technological innovation”;
- Gave EPA authority over full life cycle of chemicals (manufacturing, processing, distribution, and use)

# What did the original TSCA do, cont.?

- Mandated that EPA establish an “inventory” of chemicals in commerce (62,000) – these were called “Existing” chemicals; and

- Required companies to notify EPA at least 90 days prior to commencing manufacture of “New” chemicals.

# Flaws in original TSCA

- Required EPA to demonstrate that the benefits of a regulating a chemical outweighed the costs;
- Shrouded in secrecy (EPA could not share information with the public - CBI);
- EPA had to show any regulatory requirements were the “least burdensome”; and
- **Forced EPA to prove *actual* harm in order to regulate or ban a dangerous chemical.**

# In other words…

- …***the burden is on EPA to prove harm!***

- Under FIFRA and the Food, Drug, and Cosmetic Act, applicants must prove their product is safe. *Under TSCA, chemicals are presumed innocent* until EPA proves they are guilty.

# To make matters worse…

- …EPA needed to prove *potential risk* of a chemical in order to require a company to test it to determine whether there was an *actual risk*.
- And, to require testing, EPA had to go through notice-and-comment rulemaking, which an take years.

# What did Lautenberg change?

- Prohibited EPA from considering costs when making its “unreasonable risk” determination (no cost/benefit analysis);
- Required EPA to identify, consider, and regulate the potential and actual risks that chemicals pose to vulnerable subpopulations (e.g., children, pregnant people, workers, or the elderly.);
- Struck the “least burdensome” provision;
- Mandated review of “existing” chemicals;

# What did Lautenberg change, cont.?

- Safety standard is applied to chemicals under their "conditions of use."
- "Conditions of use" means the circumstances, as determined by the EPA Administrator, under which a chemical substance is intended, known, ***or reasonably foreseen*** to be manufactured, processed, distributed in commerce, used, or disposed of.
- In other words, must examine unintended consequences ("What if…?)
- Limits CBI – cannot withhold health and safety data.

# Packaging LC/MS/MS Test Data Summary

[redacted]

| Column1 | LOD (ppt) | >LOQ (ppt) |
|---|---|---|
| PFOA | [redacted] | [redacted] |
| PFNA | | |
| PFDA | | |
| PFunDA | | |
| PFdoDA | | |
| PFtrDA | | |
| PFteDA | | |
| PFHxDA | | |
| PFODA | | |

# In effect, then, Lautenberg…

…split the decision into two parts:

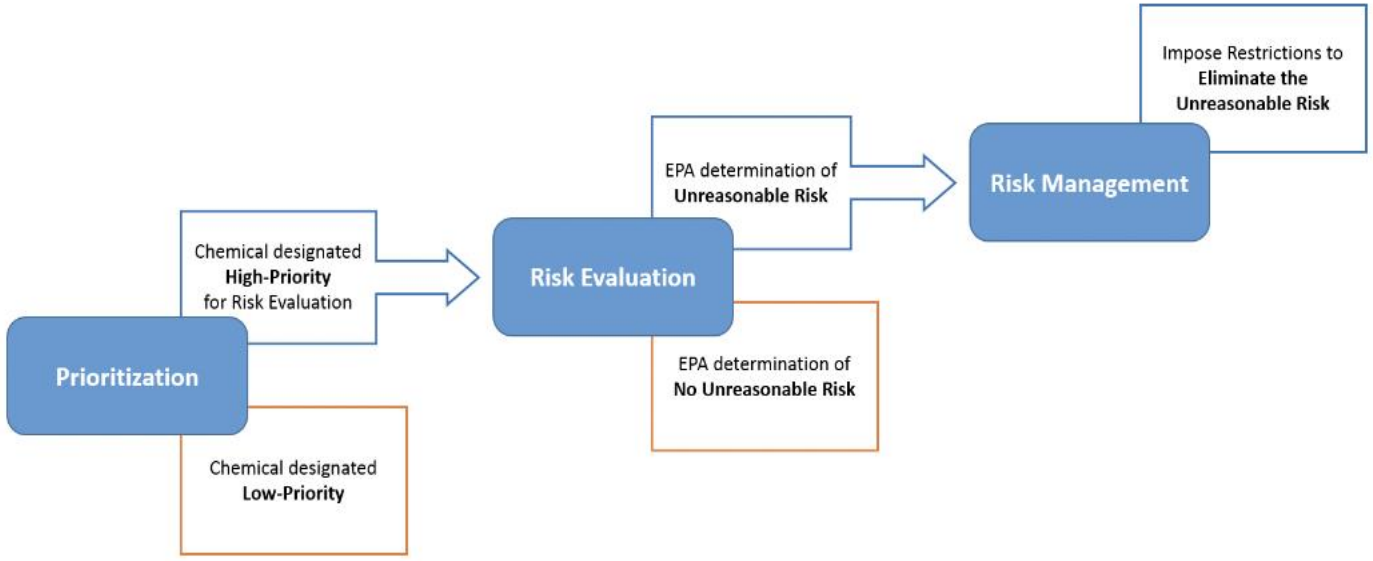
- Is there an unreasonable risk? (**Risk Assessment**)
- If so, can this risk be managed to the point where there is no longer an unreasonable risk? (**Risk Management**)

# “New” chemicals versus “Existing” chemical reviews

What is the difference?

# Existing chemical review

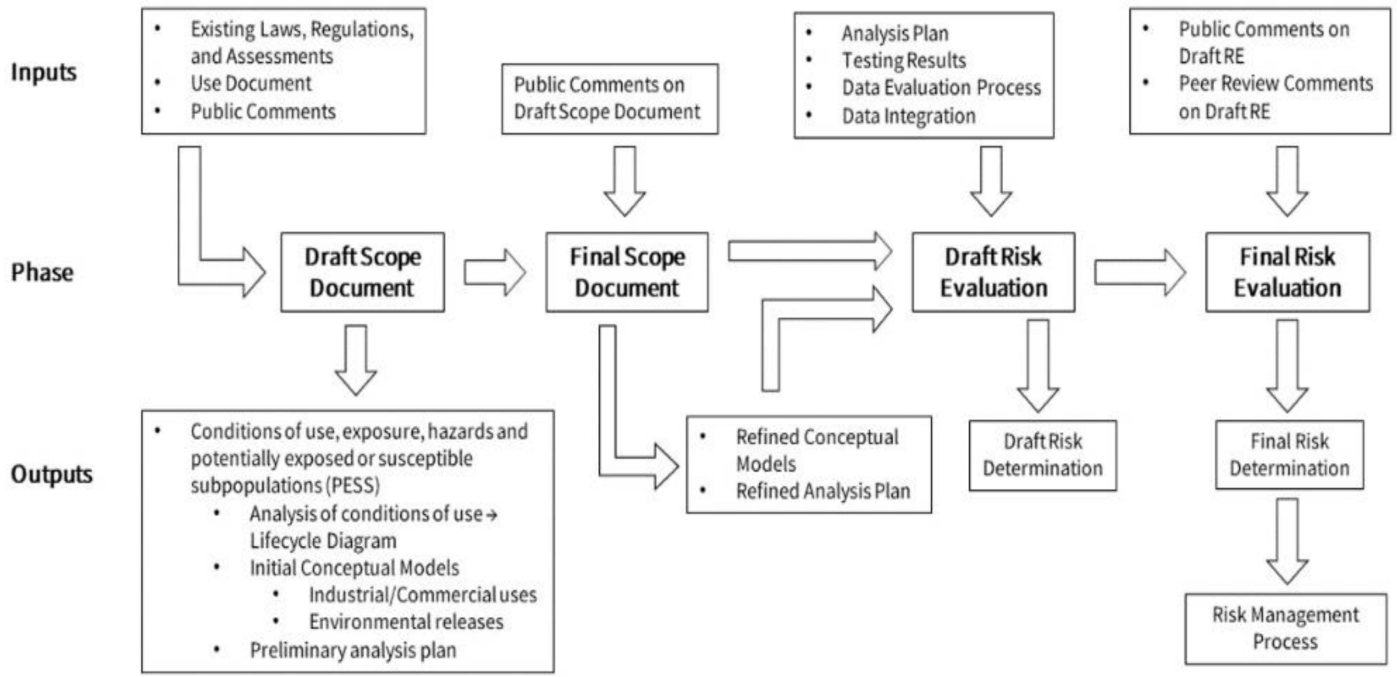
- Requires prioritization of all existing chemicals; and
- Requires a risk determination on all deemed high priority.



# How many Existing chemicals must be reviewed?

- In 2016, EPA was told to review 10 Existing chemicals. These 10 were completed by January of 2021 (but asbestos must be re-done per court order);

- In 2019, EPA was told it must have at least 20 chemical risk evaluations ongoing at any given time


Inputs
Phase
Outputs
Existing Laws, Regulations, and Assessments
Use Document
Public Comments
Public Comments on Draft Scope Document
Analysis Plan
Testing Results
Data Evaluation Process
Data Integration
Public Comments on Draft RE
Peer Review Comments on Draft RE
Draft Scope Document
Final Scope Document
Draft Risk Evaluation
Final Risk Evaluation
Conditions of use, exposure, hazards and potentially exposed or susceptible subpopulations (PESS)
Analysis of conditions of use → Lifecycle Diagram
Initial Conceptual Models
Industrial/Commercial uses
Environmental releases
Preliminary analysis plan
Refined Conceptual Models
Refined Analysis Plan
Draft Risk Determination
Final Risk Determination
Risk Management Process

# How is EPA doing on reviewing Existing chemicals?

- Of the original 10, nine were completed (court ruled EPA unlawfully limited the scope of the asbestos risk evaluation to chrysotile asbestos. EPA now has to review approximately 12 additional forms of asbestos, and this review is still in progress);
- 33 Existing chemicals have been/are being reviewed.* Of these, the majority have only been scoped.

*https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/ongoing-and-completed-chemical-risk-evaluations-under

**At this rate, EPA will be done in…**

…*48,222 years*

# Why???

- management interference;
- lack of training;
- burdensome systematic review requirements; and
- understaffing

# How many PFAS are currently in commerce?

- Approximately 300 (another 300+ are inactive – have not been manufactured, imported) or processed in the U.S. since June 21, 2006)

- Why don’t we know exactly how many?
  - CBI
  - state and local governments and first responders are be given access to CBI – has yet to happen

# New Chemical Review

- EPA reviews between 500 – 1,000 new chemicals every year.
- Vast majority of new chemical notices are pre-manufacture notices, or PMNs.
- EPA has 90 days to complete its review and make an affirmative finding as to whether the chemical presents or may present an unreasonable risk or not.

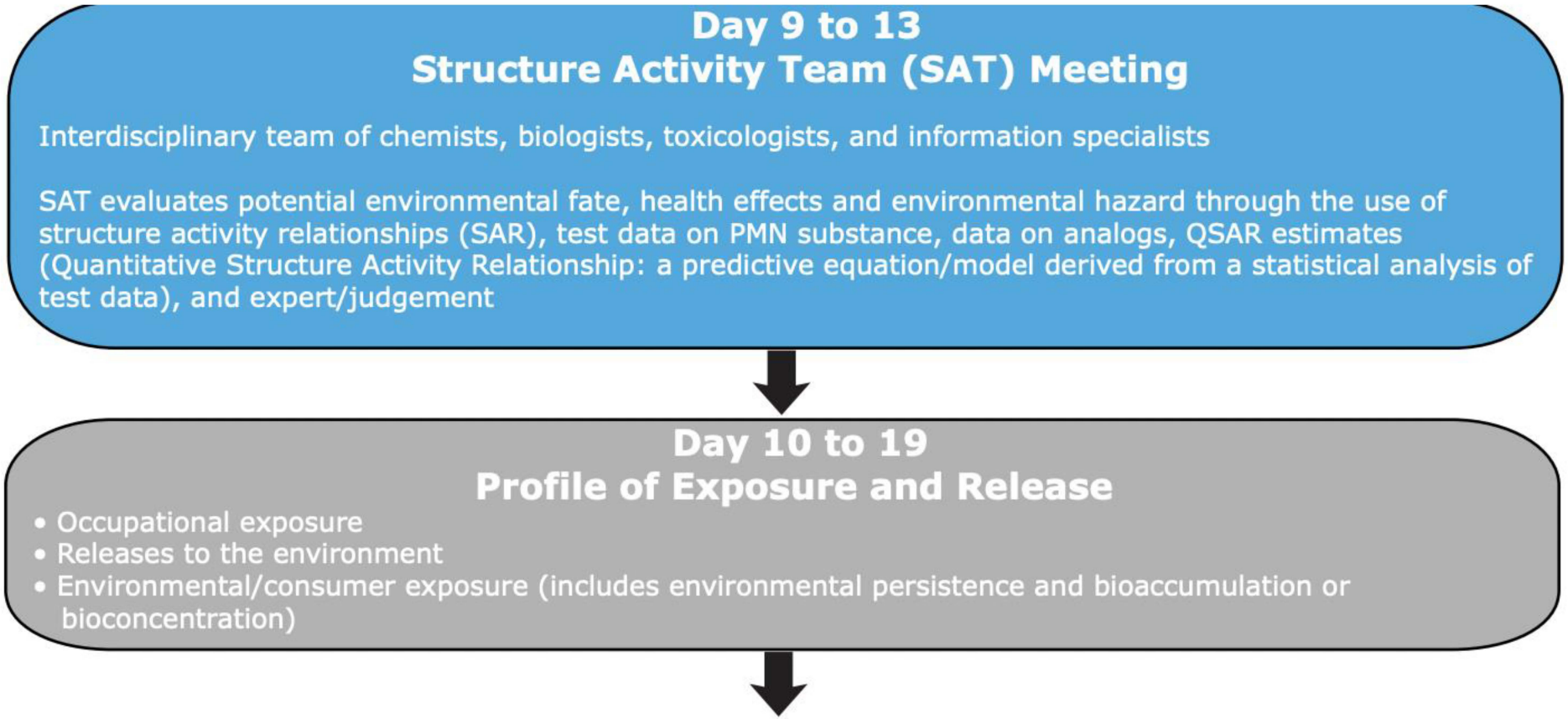
This flowchart describes the technical and decision meetings EPA has as part of its 90-day review process following receipt of a premanufacture notice (PMN) on Day 1. Day 1 to 7 involves initial evaluation of the PMN for completeness.

# Review Process

## Day 8 to 12
## Chemical Review and Search Strategy (CRSS)

- Chemical identity
- Structure /Nomenclature
- Analogs/TSCA inventory status
- Synthesis - includes byproducts and impurities
- Use/TSCA jurisdiction as provided by Submitter, literature, analog use
- Physical/chemical properties - physical state, molecular weight, melting point, boiling point, vapor pressure, solubility, octanol water partition co-efficent, and pH
- Pollution prevention aspects: pollttion prevention information provided by Submitter, EPA Makes suggestions for Alternate Synthetic Pathways

CRSS desicions: Notice completeness, validity, reportability, eligibility for exemption or exclusion, candidacy for exposure-based review, whether notice meets certain CRSS drop criteria


Day 9 to 13
Structure Activity Team (SAT) Meeting
Interdisciplinary team of chemists, biologists, toxicologists, and information specialists
SAT evaluates potential environmental fate, health effects and environmental hazard through the use of structure activity relationships (SAR), test data on PMN substance, data on analogs, QSAR estimates (Quantitative Structure Activity Relationship: a predictive equation/model derived from a statistical analysis of test data), and expert/judgement
Day 10 to 19
Profile of Exposure and Release
• Occupational exposure
• Releases to the environment
• Environmental/consumer exposure (includes environmental persistence and bioaccumulation or bioconcentration)

## Day 15 to 20
## Focus Meeting

- Representatives from each discipline involved in assessment
- Delegated decisions for chemical categories, exposure-based reviews, Exemptions

**Focus meeting decisions:**
**For PMNs:** Ban pending upfront testing, "drop" from further Agency review, short question, TSCA §5(e) Consent Order and/or Significant New Use Rule (SNUR), standard review.
**For Exemptions:** Grant, denial, conditional denial or grant options
If regulated, Submitter will be notified by EPA.

## Day 21 to 85
## Standard Review

Further, in-depth review for non-category/special issue PMN chemicals. The regulatory decision (see Focus meeting decisions, above) is made at the Division Director management level.

# How is this going?

PART 1

**Whistleblowers Expose Corruption in EPA Chemical Safety Office**


PART 2

**Leaked Audio Shows Pressure to Overrule Scientists in “Hair-on-Fire” Cases**

# 10-part series exposing how broken NCP is

https://theintercept.com/series/epa-exposed/

# Preemption of State Authority

- If a state has restrictions on chemical production or use, this may be subject to preemption ***if*** EPA is acting/has acted on the *same* chemical to address the *same uses and risks;*

- States can always impose reporting, monitoring, assessment, or disclosure requirements;

- ***Section 6 of TSCA says that EPA must have taken risk management steps on a chemical in order for preemption to apply!***

# Preemption of State Authority, cont.

Certain existing laws are grandfathered from preemption:

- State laws in place before Aug. 31, 2003

- State/local chemical restrictions in place before Apr. 22, 2016

# Preemption, continued

- “Pause preemption”: limited period of temporary preemption that arises during the risk evaluation itself.

- This so-called “pause preemption” forbids new state chemical regulations applicable to a substance on or after the date that EPA publishes the scope of risk evaluation.

- If a state has acted before scope is out, it can remain in effect until EPA makes a final determination.

# Preemption, continued

- States are *not* preempted if a regulation is adopted pursuant to a state water, air, or waste treatment law.

- BUT…this exception is limited to situations where the regulation does not impose restrictions on manufacturing, processing, distribution in commerce, or use of a chemical substance.

- Not very helpful…

# EPA can waive preemption if…

- There are compelling conditions (e.g., protection of health and environment);
- Waiver would not “unduly burden interstate commerce” in the manufacturing, distribution in commerce, or use of a chemical substance; and
- Consistent with and based on sound science.

# Is preemption a problem for PFAS regulation?

- Remember, EPA's PFAS MCLs are under the SDWA, not TSCA
- Until the EPA makes an unreasonable risk determination under TSCA, or promulgates a rule addressing the identified risks, states are ***not*** preempted from enacting laws to regulate PFAS.*
- *https://digitalcommons.pace.edu/cgi/viewcontent.cgi?article=1835&context=pelr

# When could preemption occur?

- EPA needs to take sufficient measures to trigger the preemption provisions, which means:

  When EPA designates an Existing PFAS as “high-priority” (they are not); or

  When EPA makes an “unreasonable risk” determination on a PFAS; or

  When a State takes an action contrary to a SNUR.

# Preemption and SNURs

- What is a SNUR? Significant New Use Rule (must notify EPA 90 days before commencing manufacture or import of a listed chemical as a significant new use)

- States that have initiated, or are in the process of enacting complete bans on PFAS, could be in direct conflict with this SNUR if the EPA permits certain types of PFAS to be reintroduced to the manufacturing process…

# What can states do?

- Some argue that states should focus less on regulating the manufacturing of PFAS, and instead limit the levels of these chemicals in water supplies.
    - Problem: who pays?
- Given EPA's speed at regulating PFAS, states *should* ban PFAS in products.

# Review process of pesticides under FIFRA

- EPA reviews each registered pesticide at least every 15 years;
- FIFRA requires that a pesticide generally will not cause unreasonable adverse effects on the environment (including human dietary risks from pesticide residues); and
- Submitters are not required to show efficacy!!!

# Preemption under FIFRA

- FIFRA preempts states from imposing any requirements for labeling “in addition to or different from” those imposed under FIFRA;

- FIFRA does not preempt local law (unless states prohibit);

- Maine is one of the seven states that do not provide for preemption.

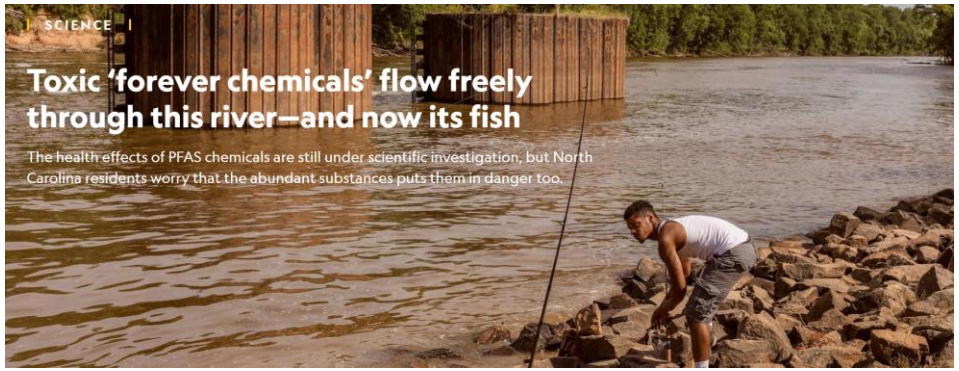
# Can Maine regulate PFAS in pesticides?

**Yes!**

EPA considers any amount of PFAS in pesticides as toxicologically significant.

# Conclusion

- Maine is a national leader in PFAS regulation;
- EPA is not moving quickly;
- Maine should attempt to get CBI clearance;
- Maine can, and should, continue to regulate PFAS in the absence of EPA’s action.




# Everything, Everywhere, All At Once: PFAS

PFAS-contaminated foam is seen on the beach near Ocean Crest Fishing Pier in Oak Island, N.C., on May 13, 2021. Photo: Emily Donovan/Clean Cape Fear

***Linda S. Birnbaum, PhD, DABT, ATS***

***Scientist Emeritus and Former Director***

***NIEHS and NTP***

***Scholar in Residence, Duke University***

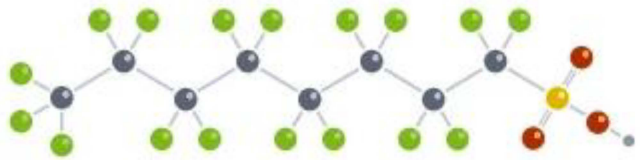
**Maine Legislature – November 13, 2023**

*The Haw River, drinking water supply for the Town of Pittsboro, as seen from the Bynum Bridge (File photo: Lisa Sorg)*

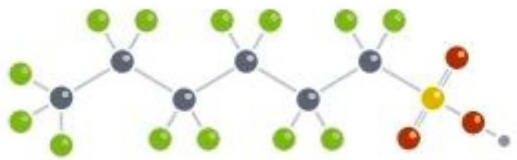
# FLUORINATED WORLD

## Fluorosurfactants

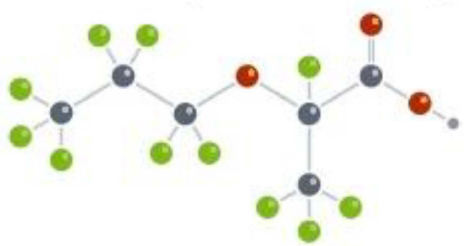
**PFOS**



**PFHxS**



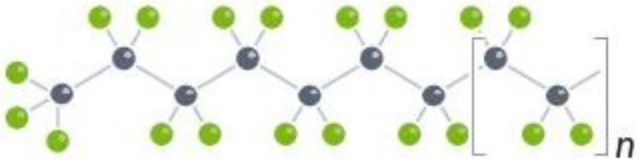
**HFPO-DA (sold as GenX*)**



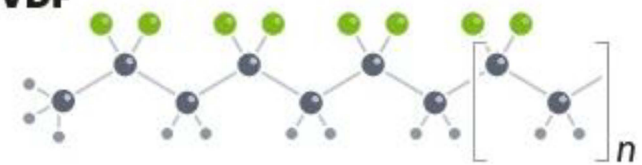
● Carbon ● Fluorine ● Sulfur
● Oxygen ● Hydrogen

## Fluoropolymers

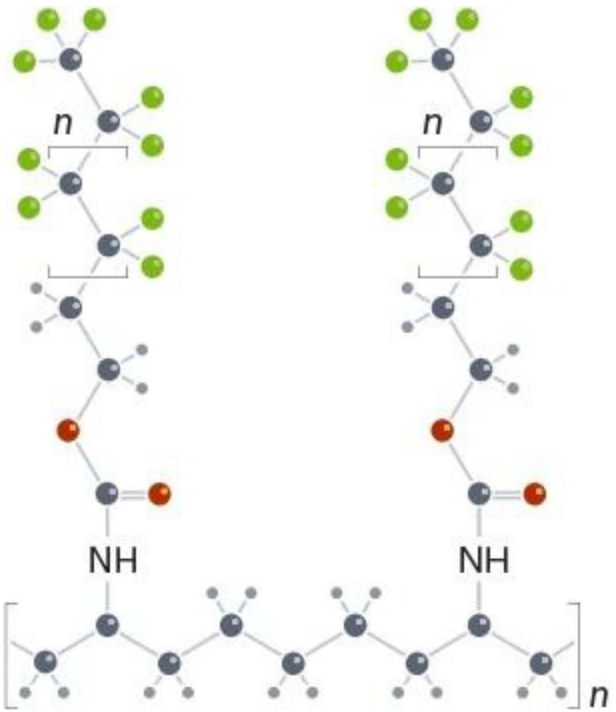
**PTFE ('Teflon')**




**PVDF**




**Side-chain fluorinated polymers**



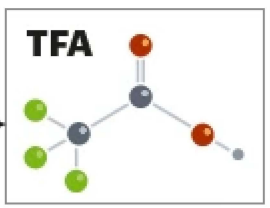

***OECD Definition: At least one fully fluorinated CF3 or CF2***

## Fluorocarbons

**R134a**

**HFO1234yf**

**TFA**



*Nature* **620**, 24-27 (2023)

*doi: https://doi.org/10.1038/d41586-023-02444-5*

# What are Per- and Polyfluoroalkyl Substances (PFAS)?

**Total number of PFAS**

**>14,000 chemicals**

Includes products, impurities and degradants

Teflon

Scotchguard

Aqueous Film Forming Foams (AFFFs)

Many unknown formulation

Resistant to grease, water & oil

Surfactants, stain repellants

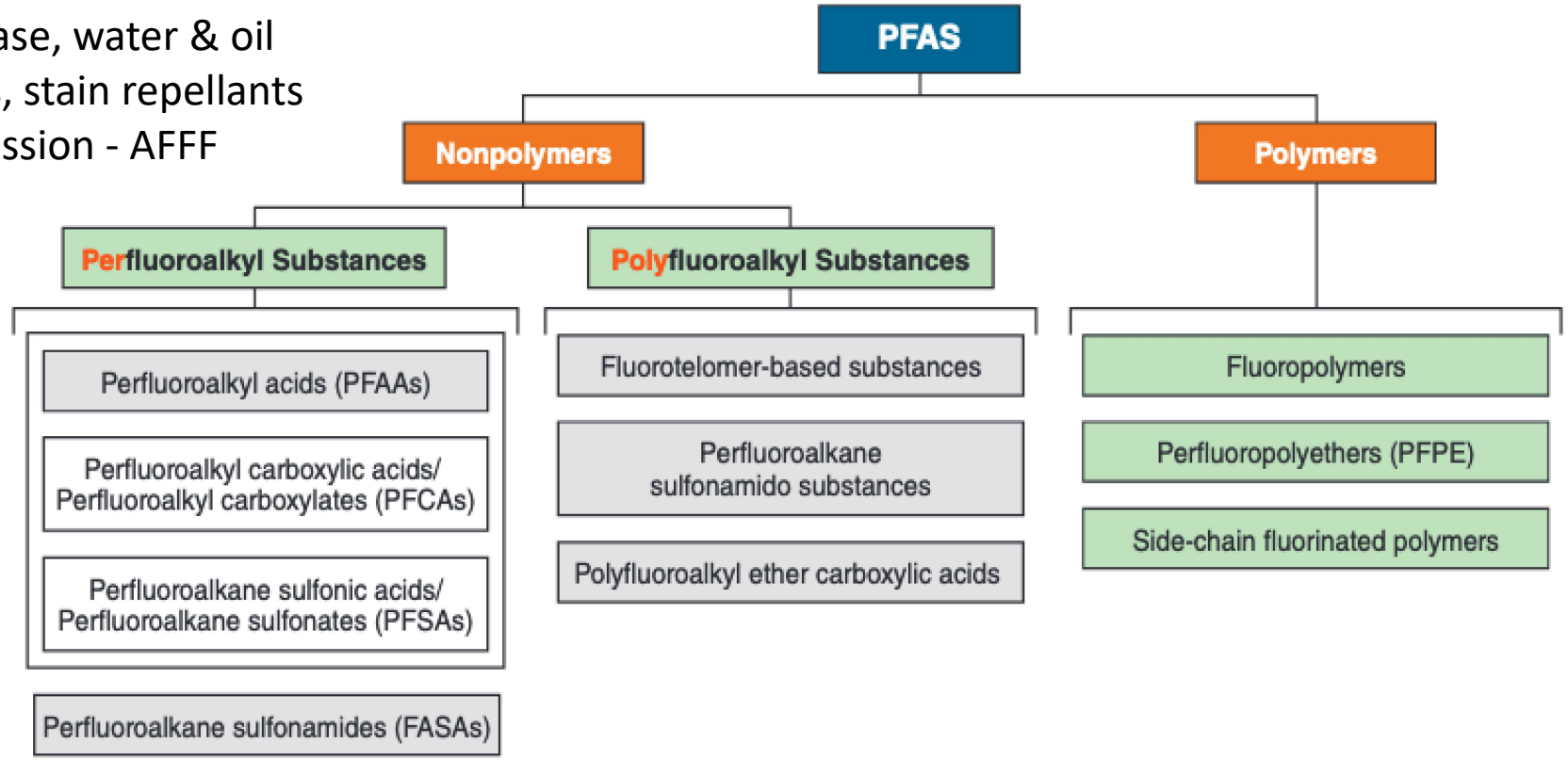
Fire suppression - AFFF

Persistent, mobile, and bioaccumulative

Emergence of short-chain alternatives - less well studied

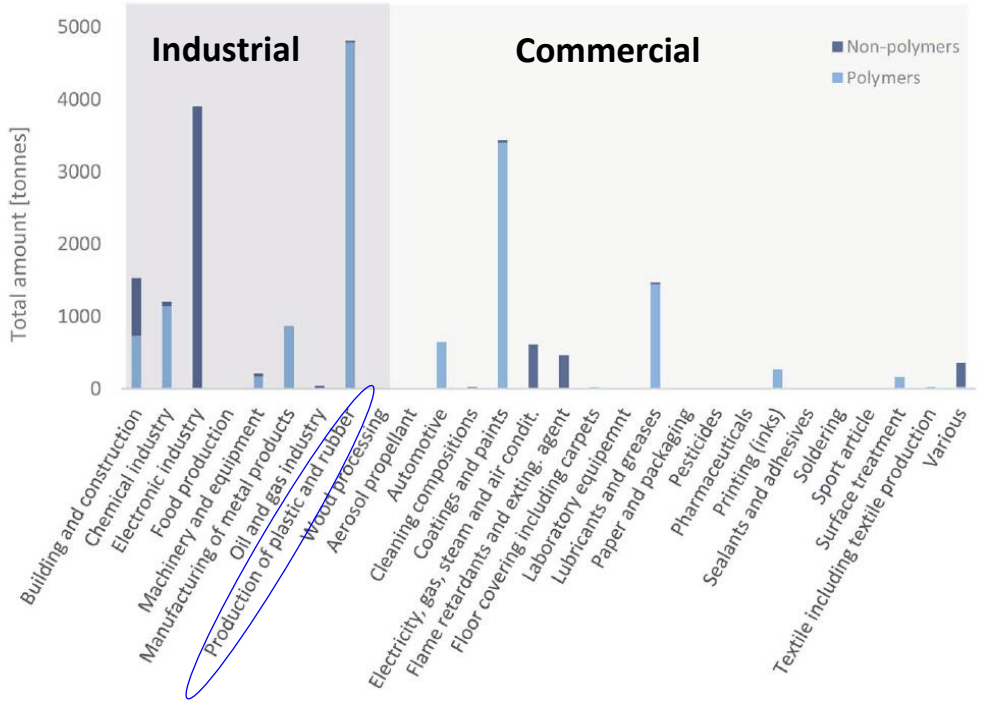
Few studied – same effects as long chains

Ultra short chains (e,g, CF3, CF3COOH)




E. Panieri et al., Toxics (2022) 10:44

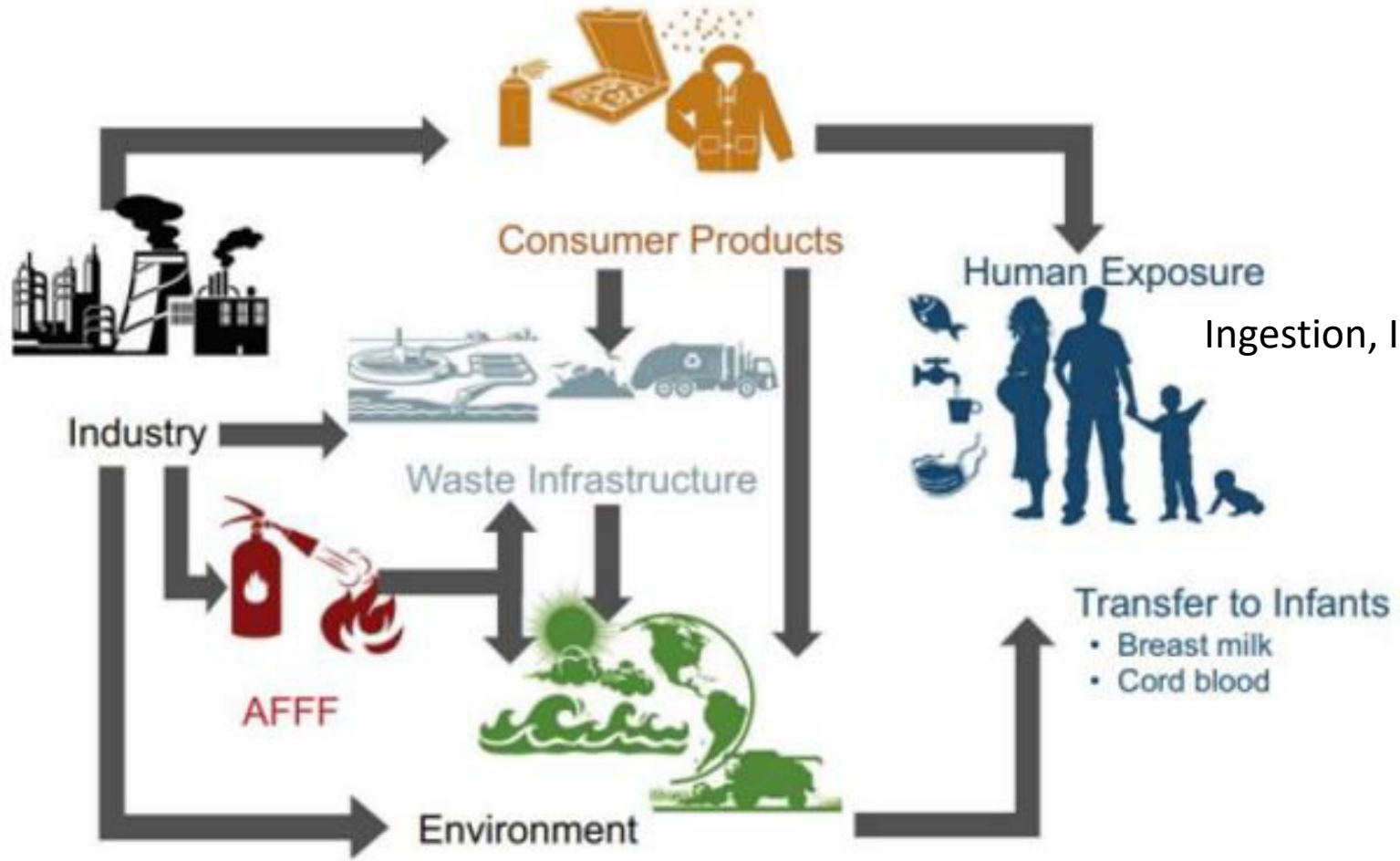
# Occurrence of PFAS in various goods:


A 2020 European report found that the largest use of PFAS was in the production of plastics & rubber

*Understanding PFAS*; Riverside Public Utilities: https://riversideca.gov/press/understanding-pfas, 2020.
Gluge, J.; et. al, Environmental Science Processes & Impacts 2020, 1462-1468.

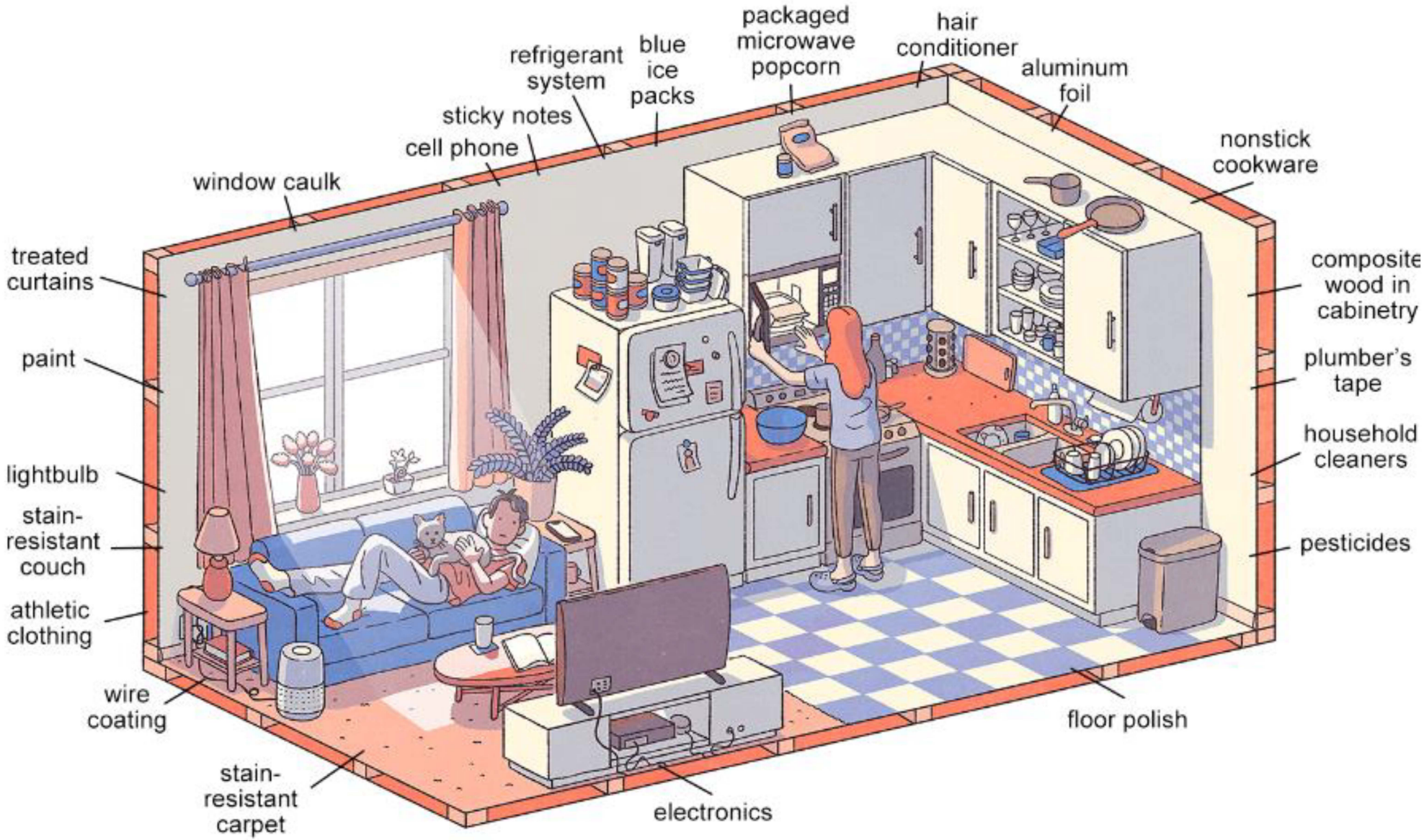
# PFAS Exposure




Ingestion, Inhalation, Dermal

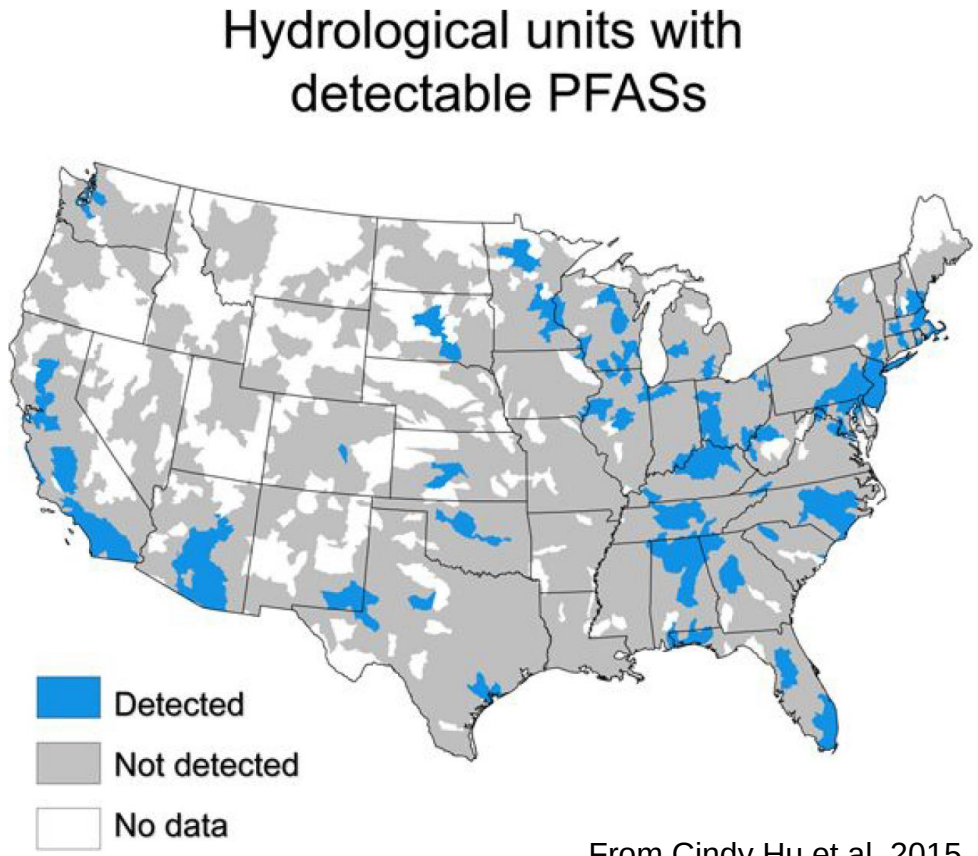
Sunderland et al. 2019

*PFAS do not degrade and pass through Water Treatment Plants*

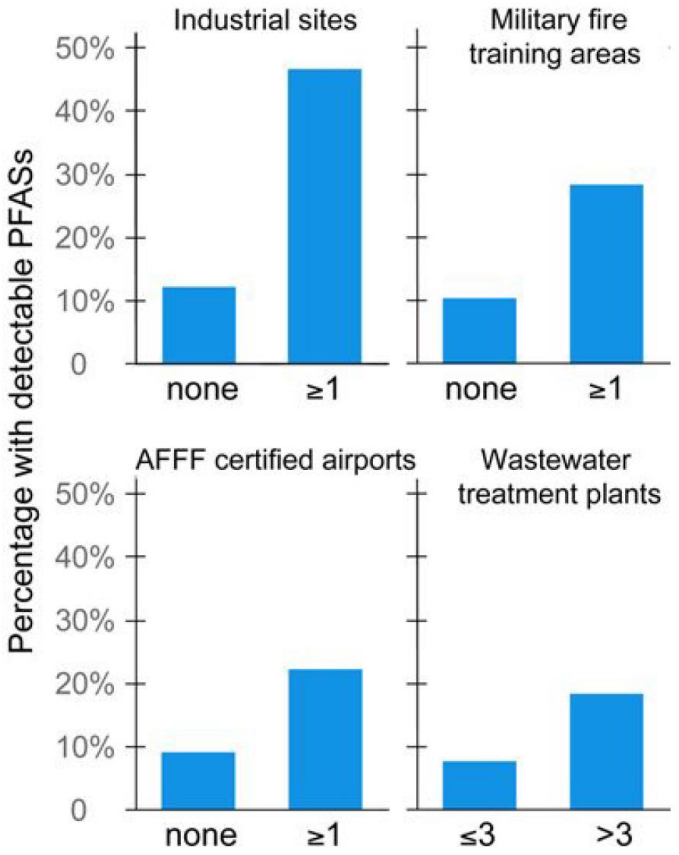



*PFAS permeate modern life, with water, food, dust, work settings and countless household materials all potential sources of exposure. Settings and jobs with high PFAS exposure raise concerns about long-term medical impacts. Illustration by Tim Peacock. Source: Environ. Sci.: Processes Impacts, 2020,22, 2345-2373.*

# Watersheds with point sources have higher detection frequencies for PFAS

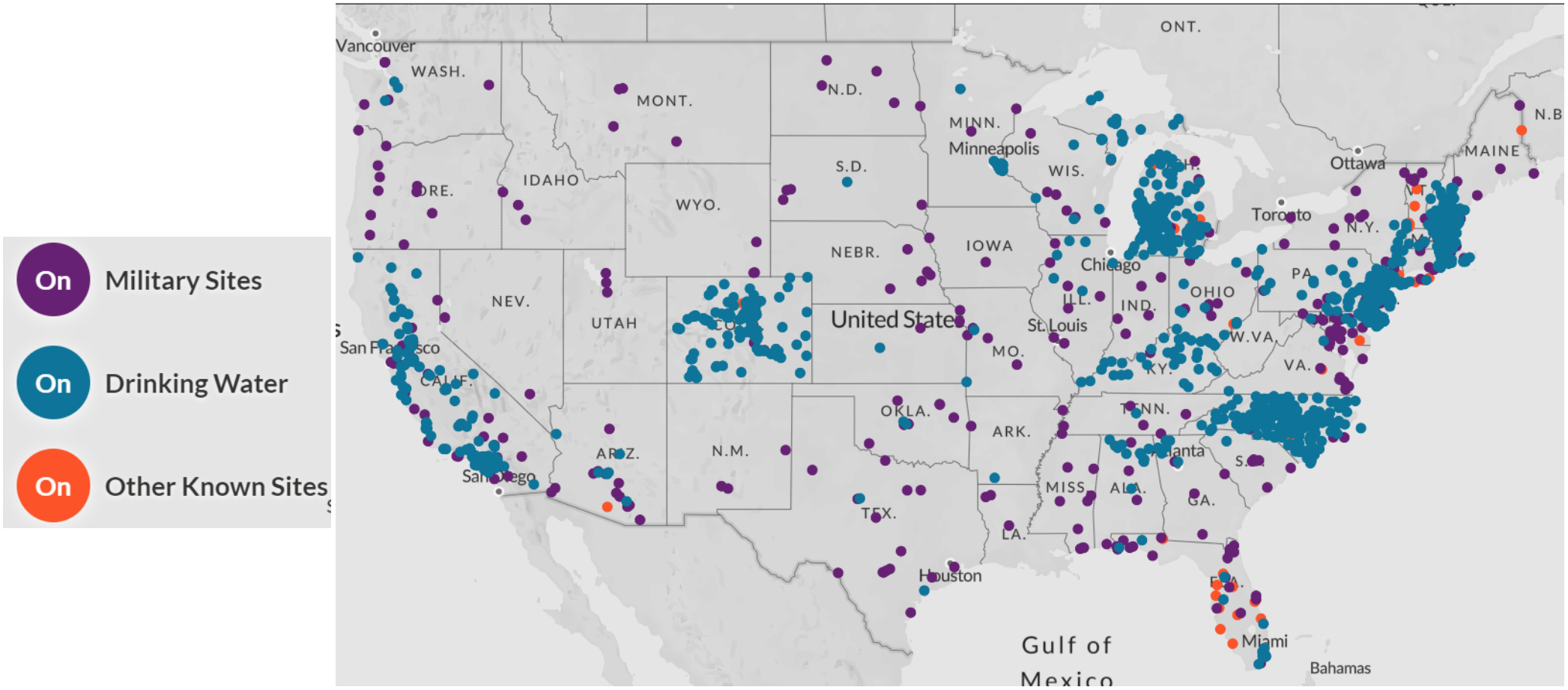



From Cindy Hu et al, 2015



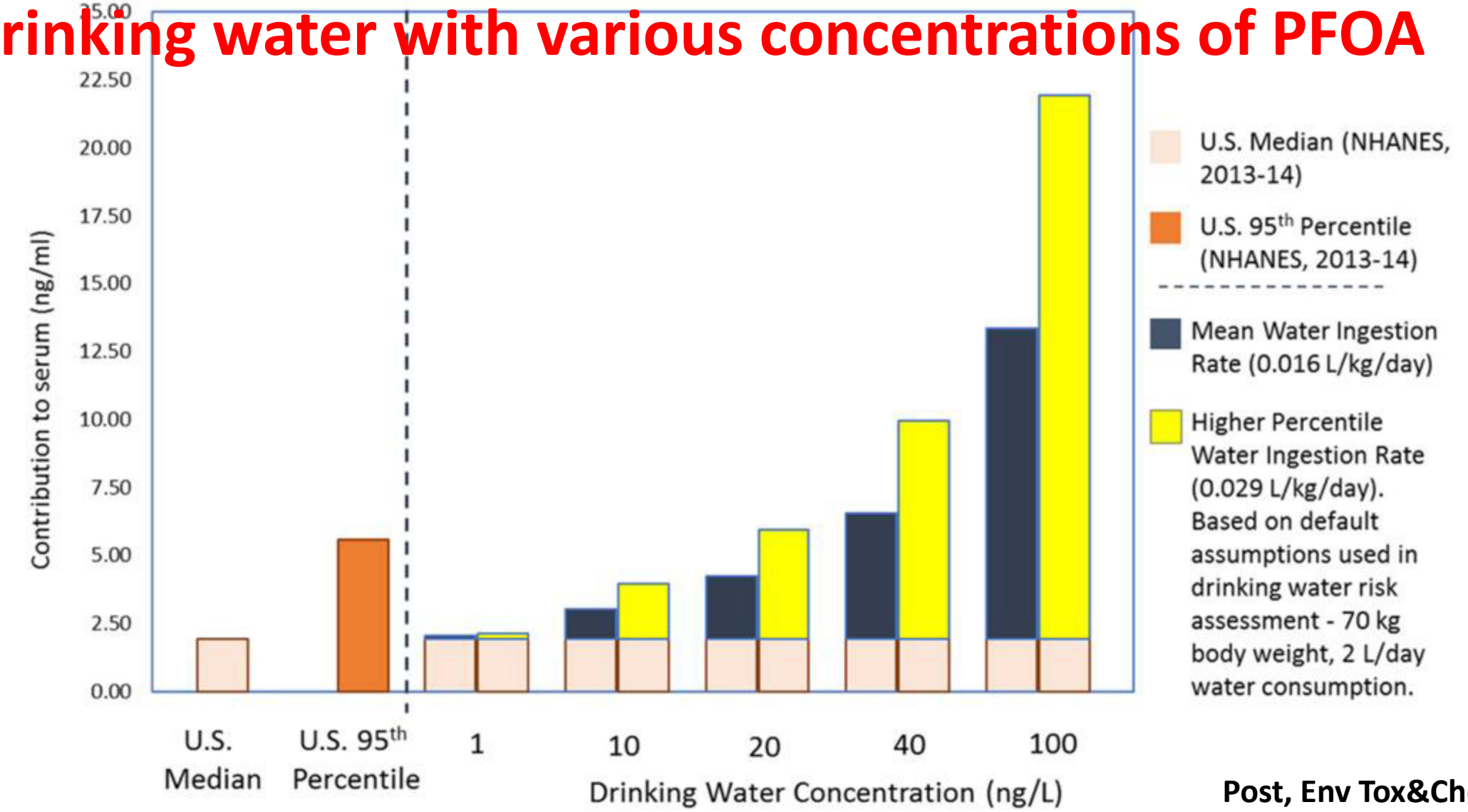

Cindy Hu et al, ES&T Letters, 2016

# PFAS Water Contamination in the United States
# July 20,2020 (EWG)



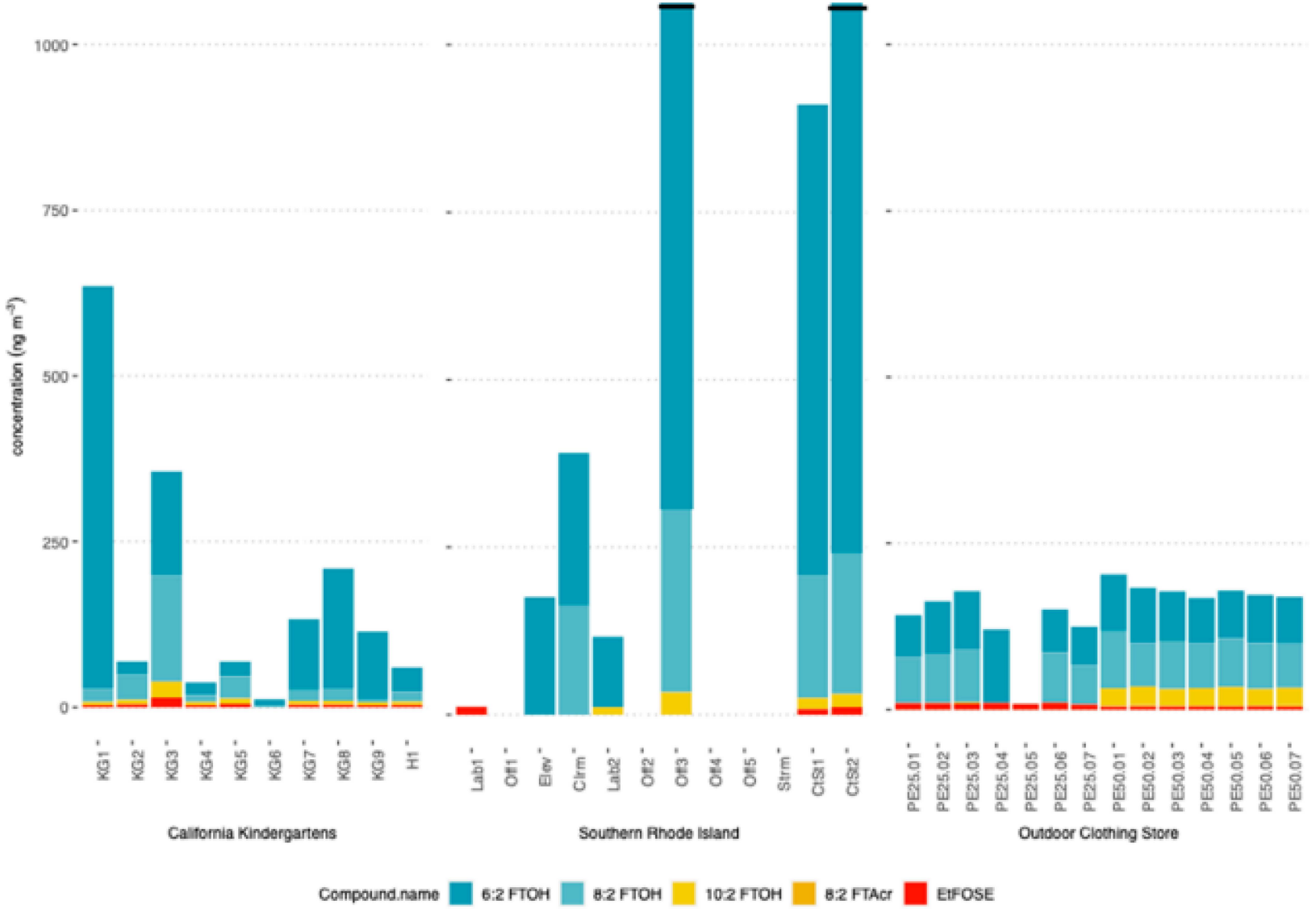

2,230 locations in 49 states are known to have PFAS contamination

# Predicted increases in serum perfluorooctanoic acid (PFOA) concentrations from consumption of drinking water with various concentrations of PFOA



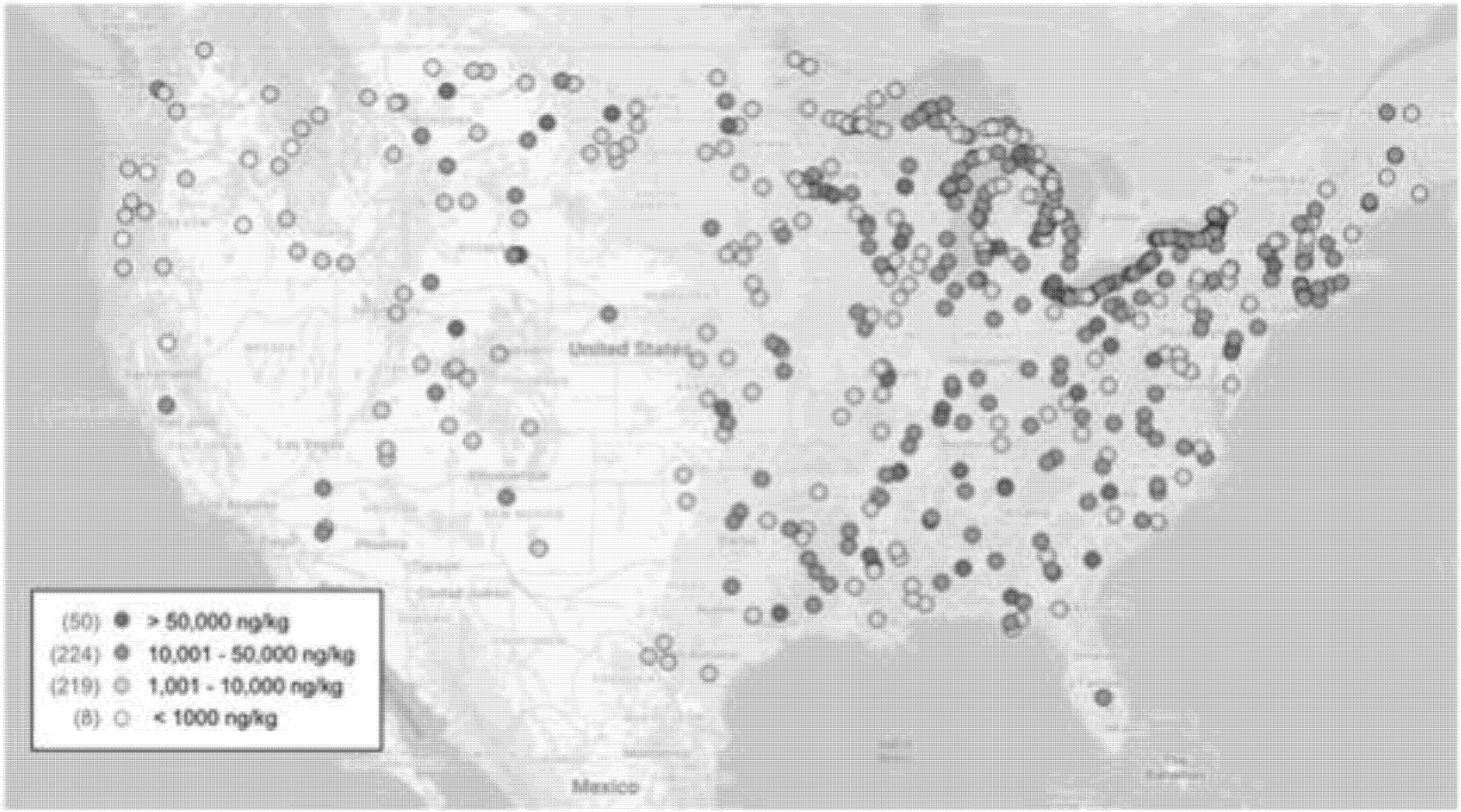

Post, Env Tox&Chem ,2020

# Volatile PFAS in Indoor Air

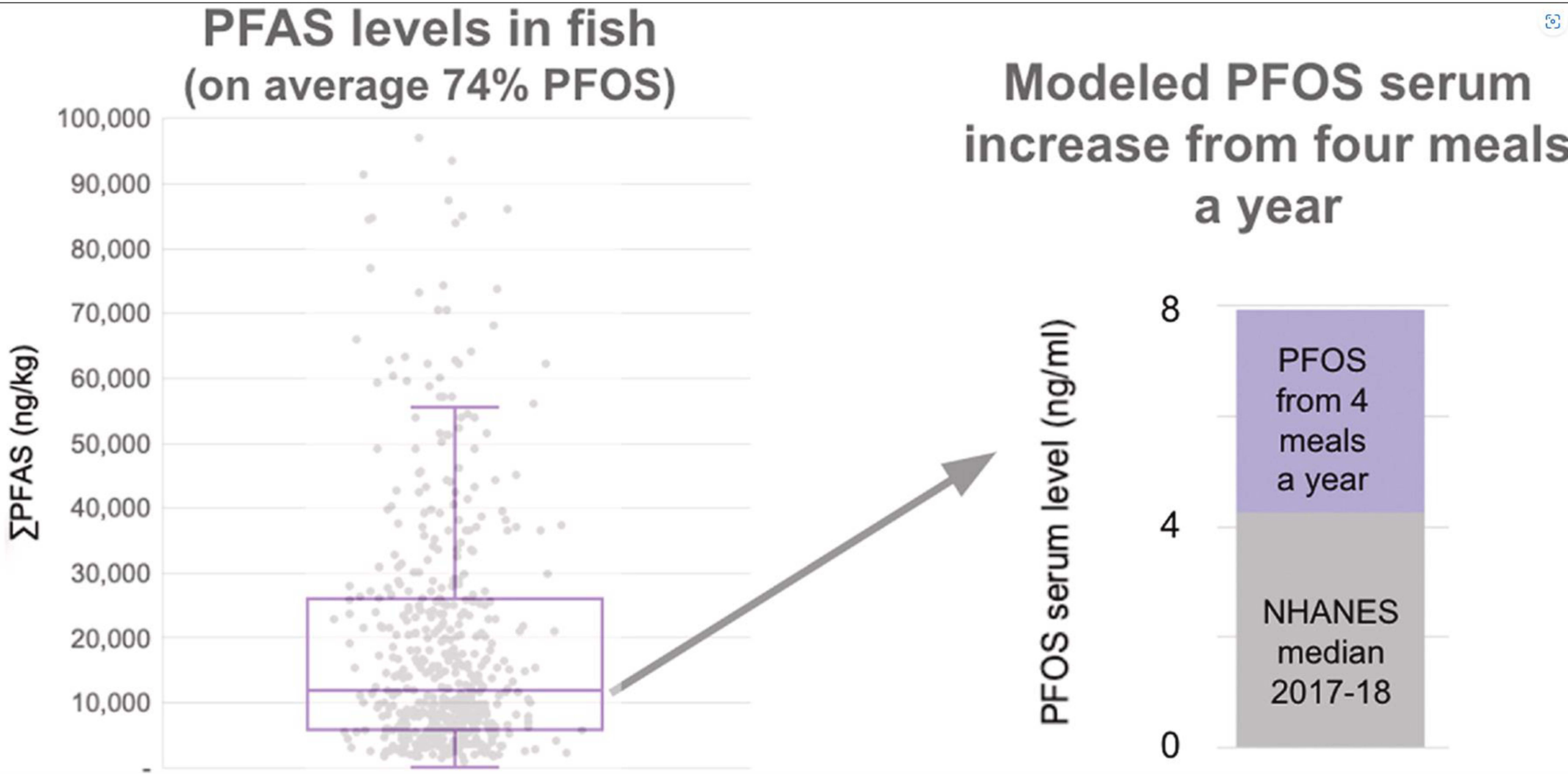



ME Morales-McDevitt et al., ES&T Lett. (2021) 8: 897-902

# PFAS in US Freshwater Fish (2013-15)



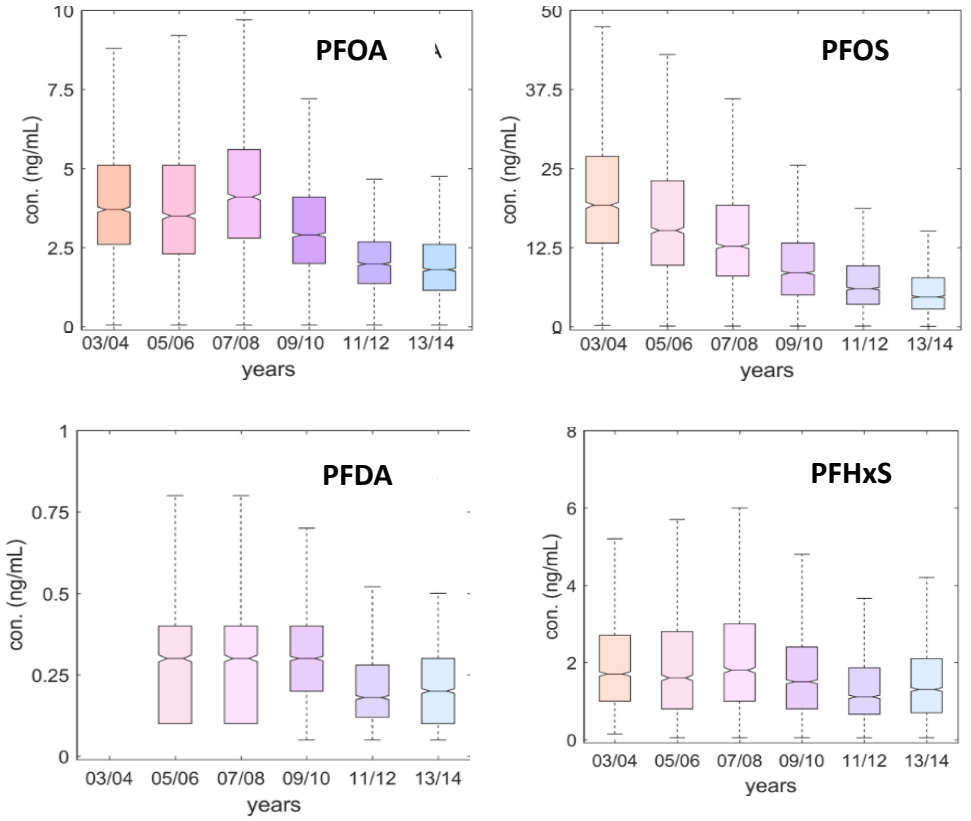

Barbo et al. 2023




Barbo et al., 2023

# We *All* Have PFAS in Our Bodies

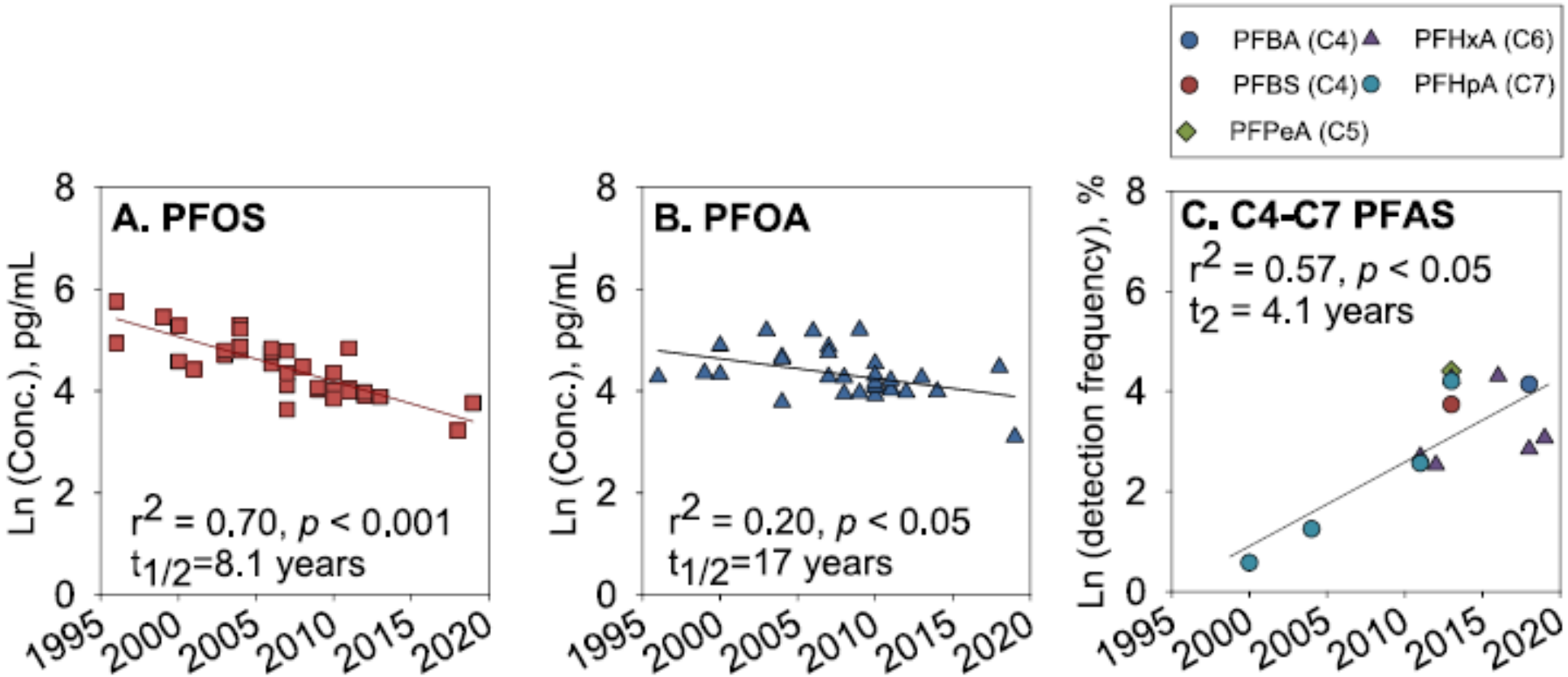
- Detected in humans globally
- >98% of people in the U.S. have measurable amounts of PFAS
- Levels of PFOA and PFOS have declined following phase-outs
- Changes in exposure to other PFAS are less pronounced




PFAS exposure trends in NHANES 2003 – 2014

Sunderland et al., J Expos Sci & Epidemiol, 2019
Dong et al., Ecotox and Environ Safety, 2019

# PFAS in Human Breast Milk

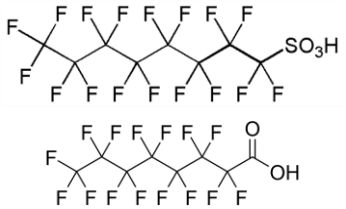



Zheng et al., ES&T 2021

# PFAS-exposure related health concerns began 1960s

1930s
- PTFE (Teflon) invented

1940s
- 1947: PFAS production begins at 3M plant in MN
- PFOS & PFOA begin to be produced PTFE-based non-stick coatings produced



1950s
- PFOS-based stain & water resistant products

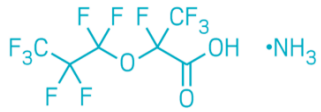
1960s
- PFOS-based fire fighting foam
- PFOA-based protective coatings
- 1962: DuPont raises concerns re: health risks of PFAS in internal document

1970s
- 1978: Unpublished study shows adverse effects of PFOA in monkeys
- 1980: PFAS detected in serum of workers
- 1981: Concerns about birth defects in children born to women workers
- PTFE-based waterproof fabrics
- PFNA & fluorotelomers begin to be produced

1980s
- 1987: PFOA causes cancer in rat study

1990s
- 1993: 3M begins to monitor PFOA in workers

2000s
- 1998: Samples from U.S. blood donors shown to contain PFAS
- 2000: PFOA and PFOS detected in 100% of Americans in study; 3M announces phase-out of PFOA
- 2000-2002: DuPont begins producing PFOA at Chemours facility in Fayetteville, NC



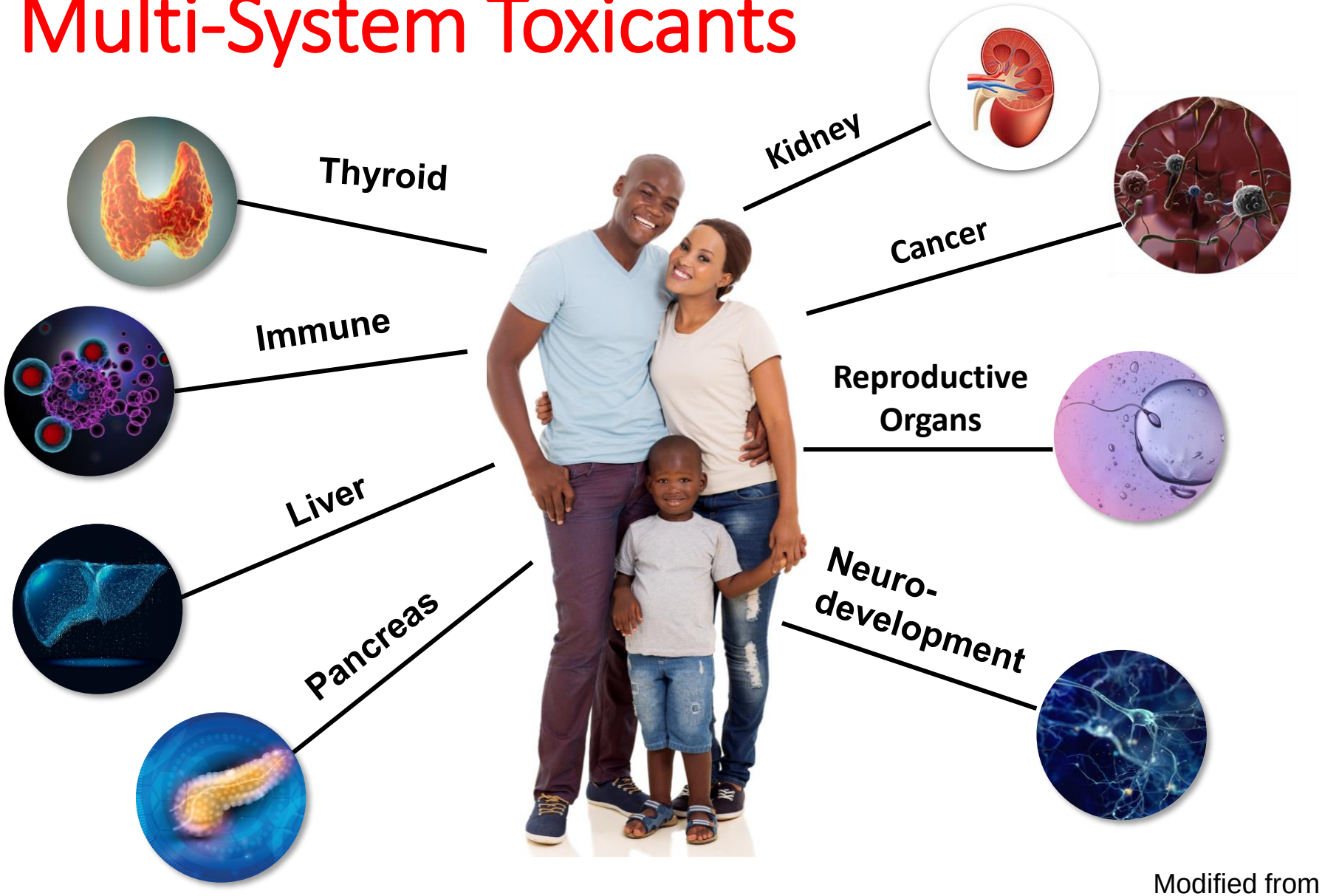
- 2001: DuPont sued in class action lawsuit
- 2004: DuPont settles class action suit ( >80,000 plaintiffs) for $343 million; settlement funds C8 Health Study
- 2006: **EPA invites 8 major companies to phase out PFOA by 2015 (95% reduction by 2010)**
- 2009: Chemours commercially manufactures GenX as PFOA substitute

2010s
- 2012: Immune system effects related to PFAS reported in children

Present
- 2015: Researchers publish report of novel PFAS (including GenX) in Cape Fear River

3M DUPONT Chemours SOLVAY

# PFAS: Multi-System Toxicants




Modified from ATSDR, 2018

# PFAS Exposure, Testing, and Clinical Follow-Up (National Academy of Sciences, 2022)

- Sufficient Evidence
  - decreased **antibody response** (in adults and children)
  - **dyslipidemia** (in adults and children),
  - decreased **infant and fetal growth**,
  - increased risk of **kidney cancer** (in adults).
- Limited Evidence
  - increased risk of **breast cancer** (in adults),
  - **liver enzyme** alterations (in adults and children),
  - increased risk of **pregnancy-induced hypertension** (gestational hypertension and preeclampsia),
  - increased risk of **testicular cancer** (in adults),
  - **thyroid disease** and dysfunction (in adults), and
  - increased risk of **ulcerative colitis** (in adults).

# Clinical Follow-up and Care for PFAS Exposure

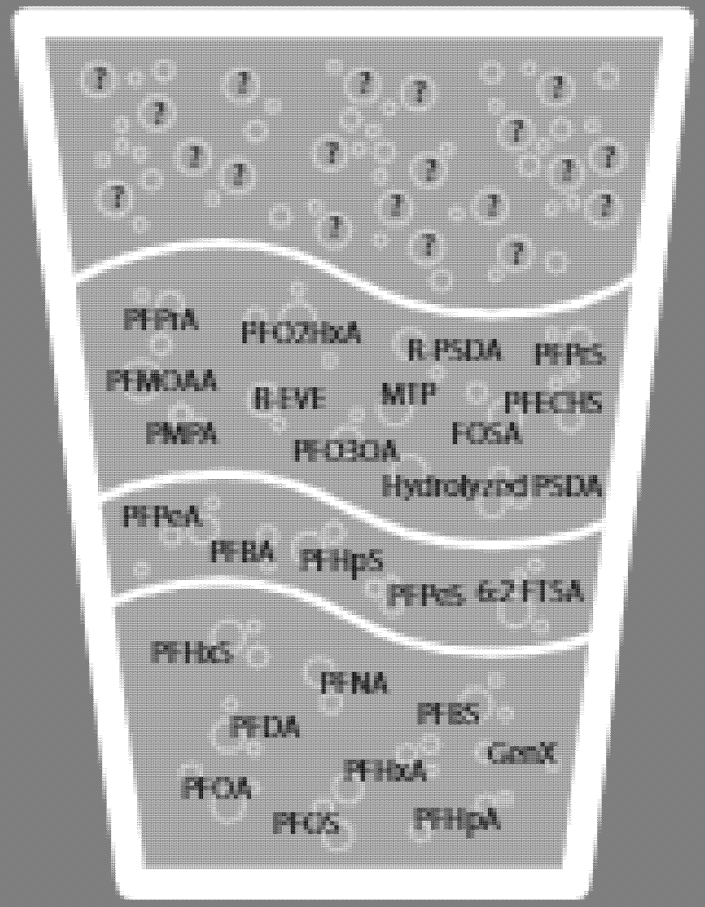
## (NASEM, 2022)

- PFAS blood concentration below  2 ng/mL (ppb) are not expected to have adverse health effects.
- PFAS blood between 2 and 20 ng/mL may face the potential for adverse effects
  - encourage reduction of PFAS exposure
  - prioritize screening for dyslipidemia, hypertensive disorders of pregnancy, and breast cancer
- PFAS  blood above 20 ng/mL may face a higher risk of adverse effects
  - screening for dyslipidemia
  - conduct thyroid function testing
  - assess for signs of kidney and testicular cancer and of ulcerative colitis

# Key Research Questions

- **Total organic fluorine analysis** – Are we measuring 90% or 10% of PFAS present in a sample?
- **How can we get rid of PFAS?** – Filtration? Incineration? Landfill?
- **Essentiality** – Where are chemicals really needed and where can we replace with safer alternatives? (*Cousins et al., 2019)*
- **Assessing alternatives** – Are our substitutes safer?
- **Can we get rid of PFAS?** – How?
- **PFAS as a class** – One chemical group or subclasses? *(Kwiatkowski et al., ES&T Lett. 2020; Balan et al., EHP 2021 )*
  - Too many PFAS to do proper toxicity testing (including mixtures)
  - NASEM strongly ***"….an approach that uses subclasses to assess the chemicals is scientifically justifiable…"*** **[NASEM]**

# PFAS in Drinking Water




Currently unmonitored PFAS

Detected in this study but not measured by EPA methods

Measured by EPA Method 533

Measured by EPA Methods 537.1 and

Pelch et al. 2023

# Disposal and Destruction of PFAS

- Currently, NO safe way to dispose of PFAS at scale
- Able to Filter out most PFAS from Drinking water
  - What do you do with the contaminated filters?
- Many efforts underway to find safe and destructive technologies
  - Urgently develop new technologies that actually destroy PFAS
- Turn off the Tap!
- The polluter must shoulder the costs

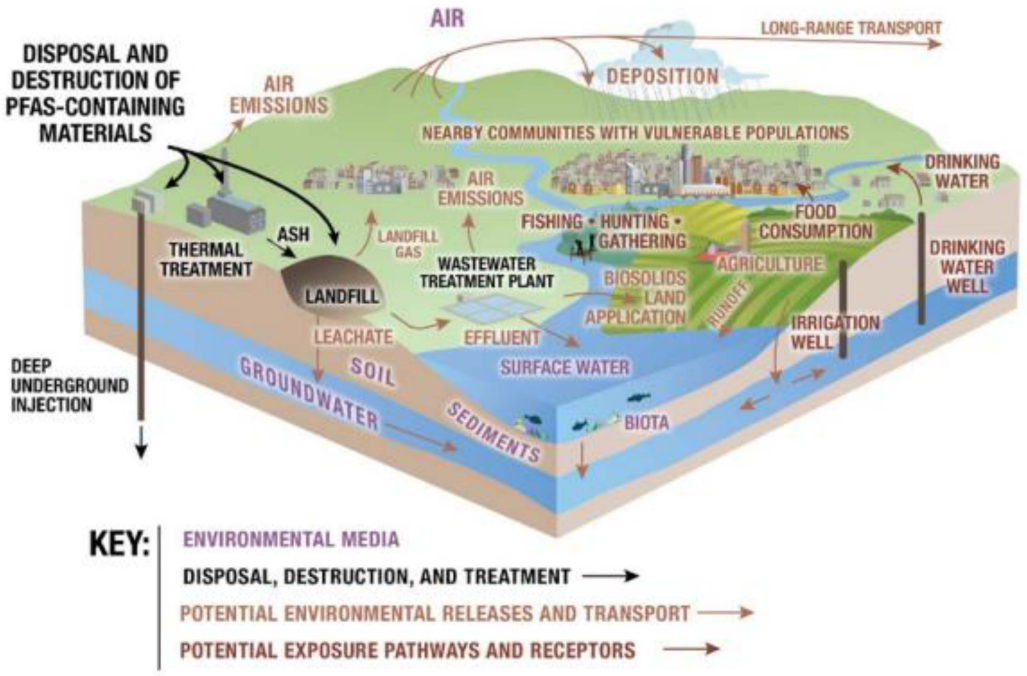



Figure 4-1. Conceptual model providing examples of potential releases from destruction and disposal of PFAS-containing materials, which the technologies covered in this guidance could hel to control.[10]

# Scientific Basis for Managing PFAS as a Chemical Class

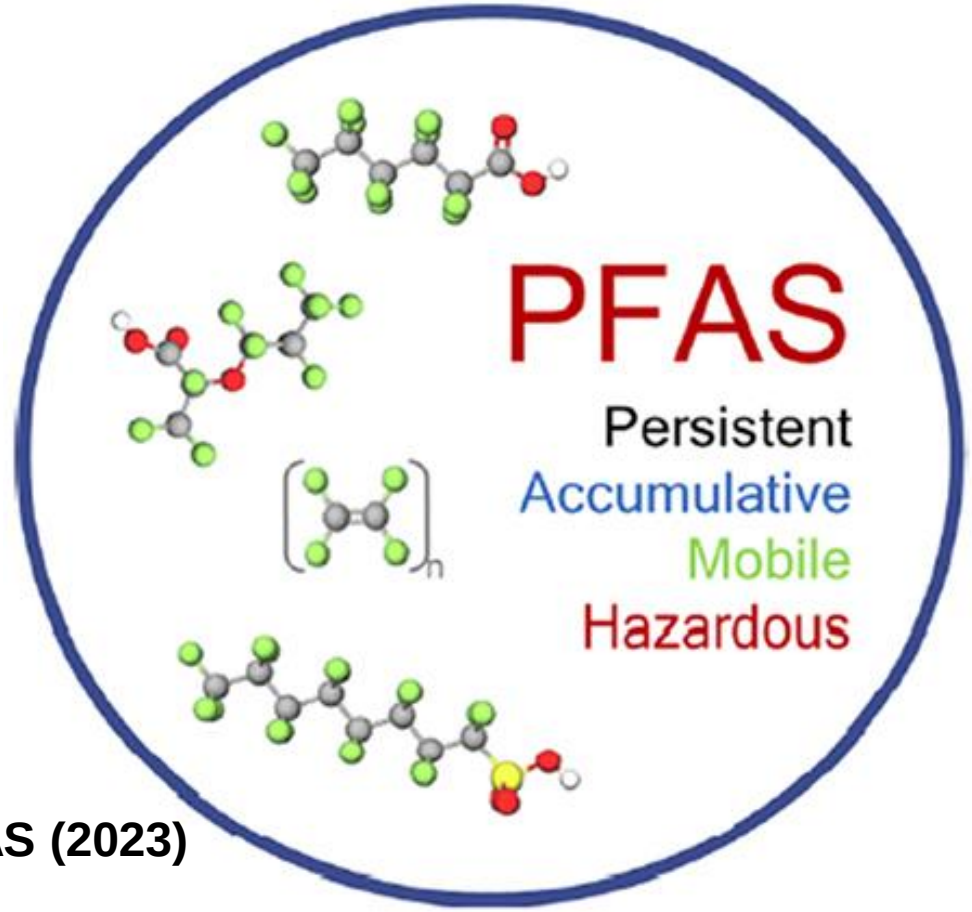
***Chemicals Strategy for Sustainability***
***Towards a Toxic Free Environment***

**European Commission – October 10, 2020**

**PFAS**[62]

The Commission will:

- ban **all PFAS** as a group **in fire-fighting foams** as well as in **other uses**, allowing their use only where they are essential for society;
- address PFAS with a **group approach**, under relevant legislation on water, sustainable products, food, industrial emissions, and waste;
- address PFAS **concerns on a global scale** through the relevant international fora[63] and in bilateral policy dialogues with third countries;
- establish an EU-wide approach and provide financial support under research and innovation programmes to identify and develop **innovative methodologies for remediating PFAS contamination** in the environment and in products;
- provide research and innovation funding for safe **innovations to substitute PFAS** under Horizon Europe.




**EU proposed ban on all nonessential, unintentional uses of PFAS (2023)**

**Kwiatkowski et al, ES&T Lett 2020**

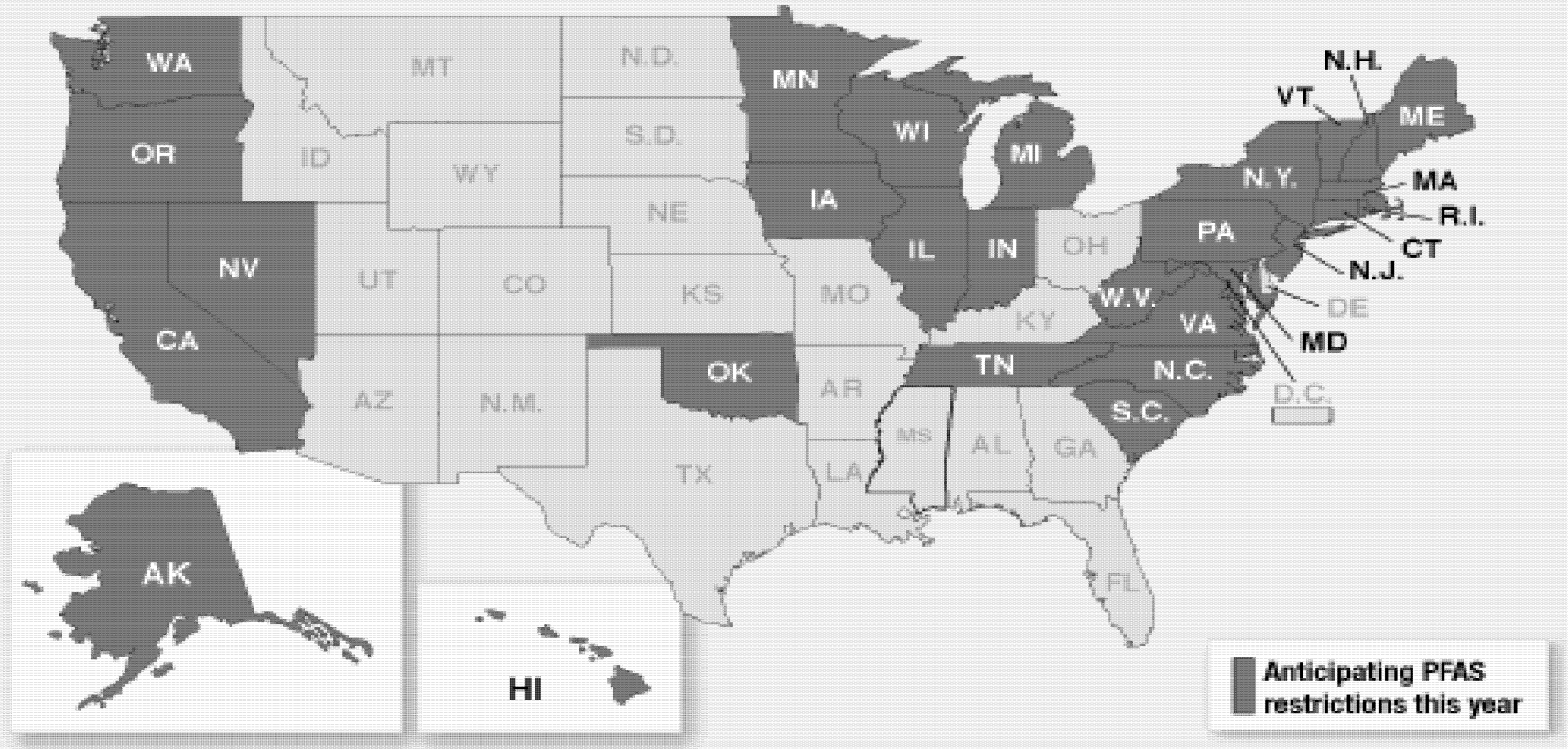
# What are the proposed MCLs?

| Compound | Health Advisory Level (ng/L) | Proposed MCLG (health based not enforceable) | Proposed MCL (enforceable levels) (ng/L or ppt or unitless) |
|---|---|---|---|
| PFOA | 0.004 | Zero | 4.0 |
| PFOS | 0.02 | Zero | 4.0 |
| PFNA | Not yet finalized (using 9 from ATSDR) | 1.0 (unitless) Hazard Index | 1.0 (unitless) Hazard Index |
| PFHxS | Not yet finalized (using 10 from ATSDR) | | |
| PFBS | 2000 | | |
| HFPO-DA (commonly referred to as GenX Chemicals) | 10 | | |

## More than Half of States Considering Restricting PFAS

Dozens of states have enacted restrictions on dangerous PFAS in recent years, and 28 states are expected to consider legislation addressing the use of various forms of the chemicals this year. Some states are restricting all unnecessary uses of the chemicals, banning them from multiple product categories, including materials used for cooking or food packaging or requiring disclosure of PFAS levels in products.

### States Proposing PFAS Restrictions for 2023




Source: "Analysis of State Legislation Addressing Toxic Chemicals and Materials," Safer States, Feb. 6, 2023, p. 5, https://tinyurl.com/383p5ha9


# Thank You!

***Questions???***

# Industry Perspective on PFAS Reporting and Compliance

Presenter: Diana Rondeau,

Director Global Product Compliance

November 13, 2023

IDEXX

# Agenda

**Objective: Explain our successes and challenges in identifying PFAS in our Supply Chain**

1. IDEXX Overview
2. IDEXX Global Product Compliance Efforts
3. Available PFAS Testing Methods
4. Q&A

# Who IDEXX is and what we do?

# IDEXX's mission is to enhance the health and well-being of pets, people and livestock.


- Our global headquarters is in Maine, where ~3,000 out of our ~11,000 employees are based.
- 90% of our R&D and manufacturing occurs in Maine.
- The products we design and produce in Maine are exported to ~175 different countries and territories.
- We are driven by a desire to contribute to something bigger than ourselves and to make a positive social impact on a global scale.
- Our products are subject to comprehensive regulation by U.S. and international agencies. These include the FDA, USDA, EPA and EU REACH among others.

# Water

“Clean, safe drinking water is something no person should have to worry about. We partner with community organizations around the globe to help make water safety a reality. We can all take pride in this work.”
*Emily Frawley,*
*Product Manager*

*Our tests are relied on throughout Maine to ensure access to safe drinking water.*

- World-wide, more than 2.5 billion people rely on IDEXX water safety tests.
- We are a global leader in microbiological water testing.
- We offer solutions for drinking water, wastewater, on-premise and recreational water.

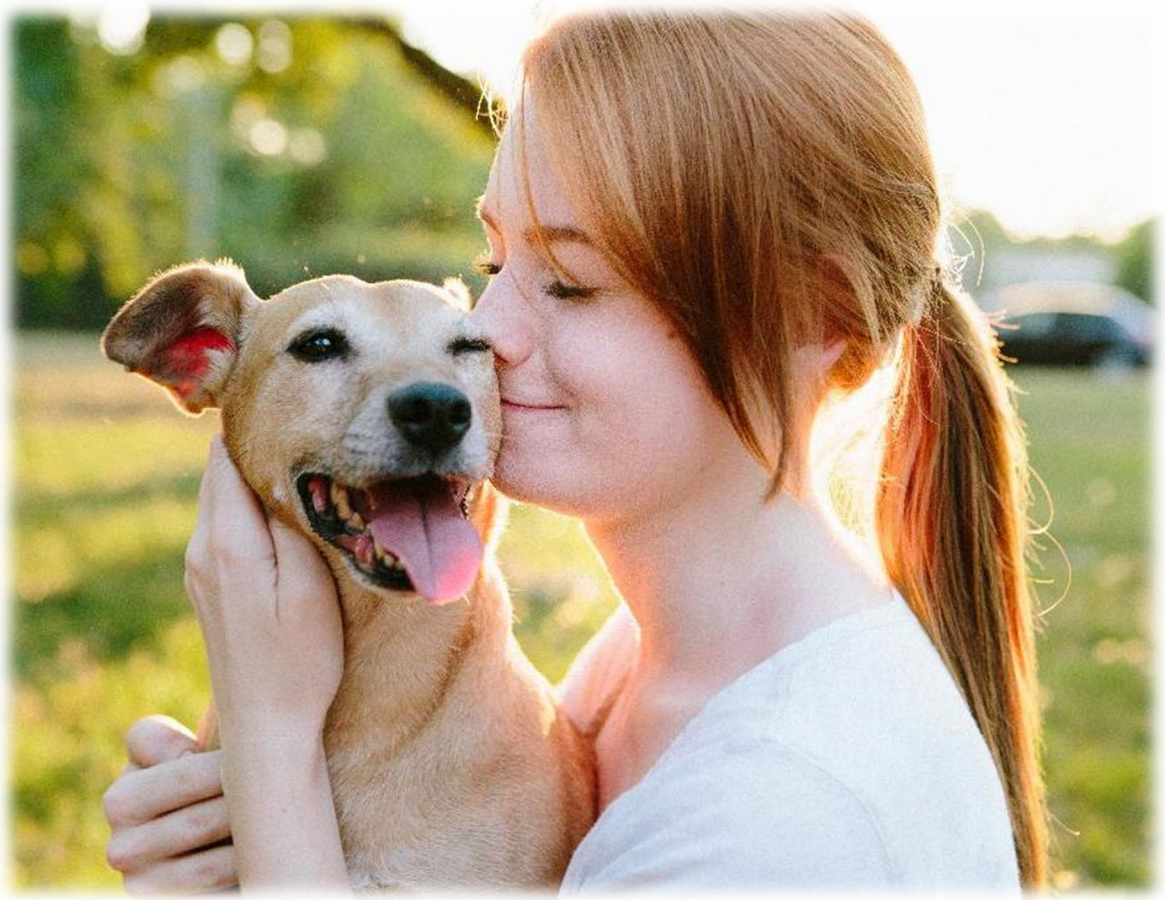
# Livestock, Poultry and Dairy (LPD)

*Our livestock diagnostic tests are used by veterinarians and farmers across Maine to ensure product safety and animal health.*

- Over the last ten years, nearly 1.1 billion IDEXX livestock diagnostic tests have been sold around the globe.
- We are innovation driven, with 36 livestock tests launched since 2015.
- Our tests support an abundant and healthy food supply.

"Healthy animals need fewer antibiotics and produce less waste, reducing environmental impacts and contributing to sustainable livestock production systems."
*Christoph Egli,*
*Product Marketing*

# Companion Animal Group (CAG)



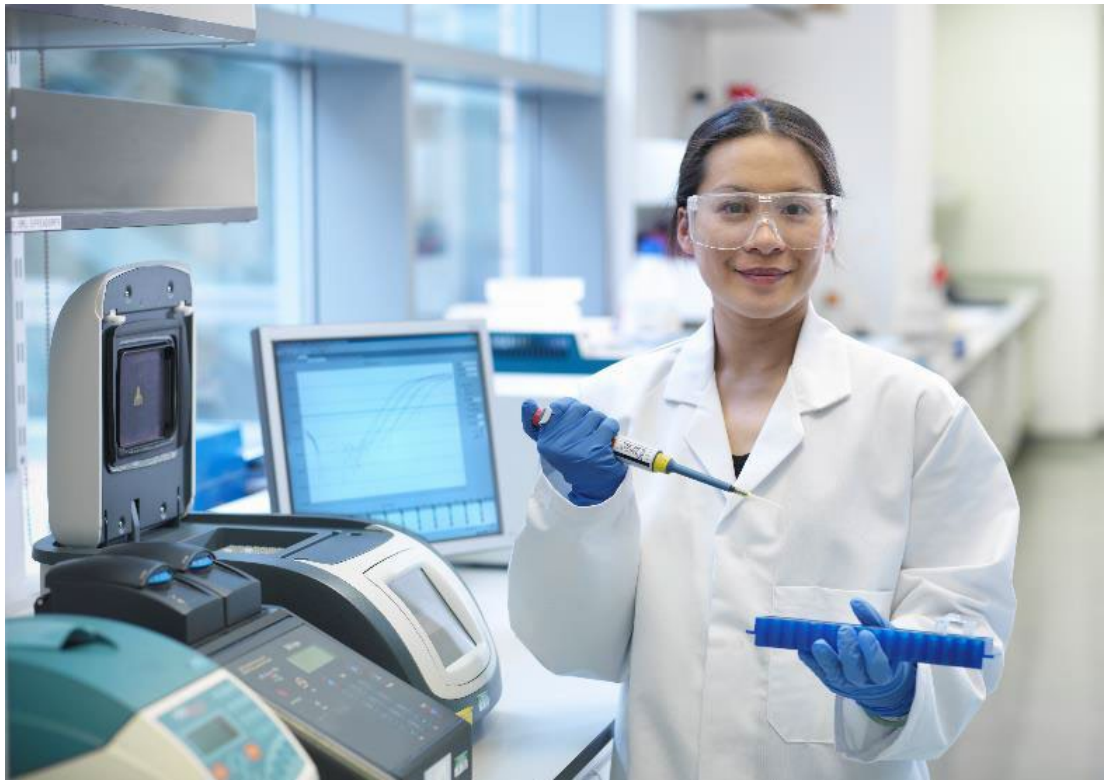
*Veterinarians and pet owners across Maine rely on IDEXX to help pets lead fuller lives.*

- We are a global leader in point-of-care and reference laboratory diagnostic testing.
- Our four decades of innovation have resulted in healthier pets and happier pet owners.
- We offer the most complete and advanced menu of differentiated diagnostic tests.
- We partner with our customers in Maine and around the world to advance veterinary standards of care.

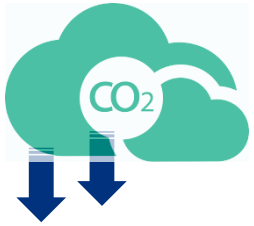
# Opti Medical Systems

*OPTI Medical Systems' analyzers are used in emergency rooms and intensive care units in more than 100 countries to aid in critical care diagnoses.*

- OPTI specializes in the design and manufacturing of point of care and laboratory diagnostics for human medicine.
- In early 2020, OPTI launched its OPTI® SARS-CoV-2 RT-PCR Covid test and partnered with DHS in operating Maine's COVID testing laboratory.



# Environmental Sustainability is Fully Integrated in Our Strategy




**Reduce our operational impact by 38% by 2030**
Includes gas (GHG) emissions (Scope 1 & 2)[3,4]

Source **100% renewable electricity** by 2030[4]

## 2021 Initiatives Highlights

### Sustainable Packaging

**U.S. Cold Consumables Shipping**

**~ 330k lbs**

Polystyrene foam anticipated to be avoided per year[2]

### Product Stewardship

**New Catalyst SDMA test**

**44%**

Reduction in packaging material and transition to 100% recycled cardboard[2]

### Promoting Circularity

**Single Swap Service Program**

**50%**

Reduction in packaging requirements avoiding 76k shipments per year[2]

[2] Data from the 2021 Corporate Responsibility Report
[3] Emissions target is based on 2021 data as baseline. Target aligned with United Nations Paris Agreement's goal of limiting warming to 1.5 degrees Celsius
[4] Goal as stated in the 2021 Corporate Responsibility Report

# IDEXX Global Product Compliance Programs

# IDEXX invests heavily in technology solutions, platforms and people to enable our compliance efforts

## Primarily used for electronic and mechanical components

EPA list identifies

**430** unique CAS

OECD list identifies

**~4,700** unique CAS

Software also allows ability to survey suppliers and store supplier data

## Primarily used for reagent formulations

*Requires full details of purchased formulations*

**10 of 2,000 3E** lists are PFAS regulated lists

## Electronics sector submits chemical data

**~100,000** electronic suppliers submit data

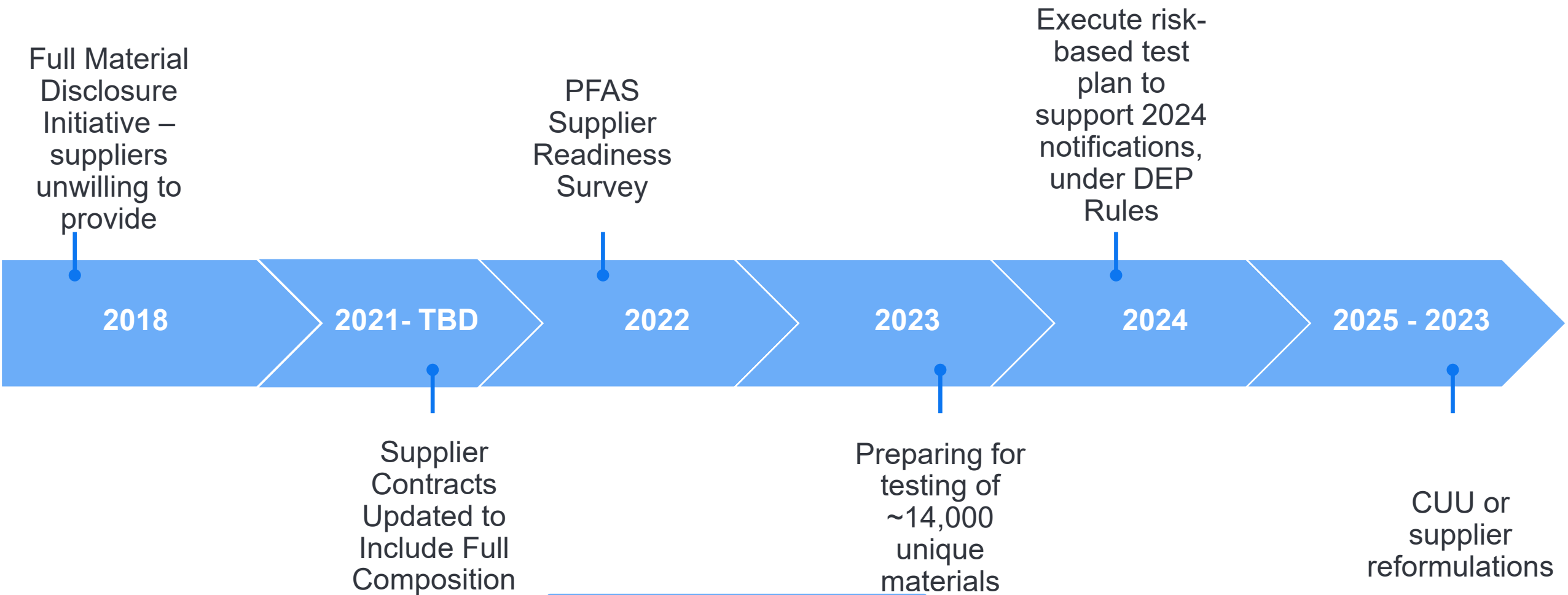
*Used to source all electronic components*

## Regulation monitoring technology solution

**73,000+ regulations**

- 30+ knowledge partners
- 23 languages
- 200+ countries

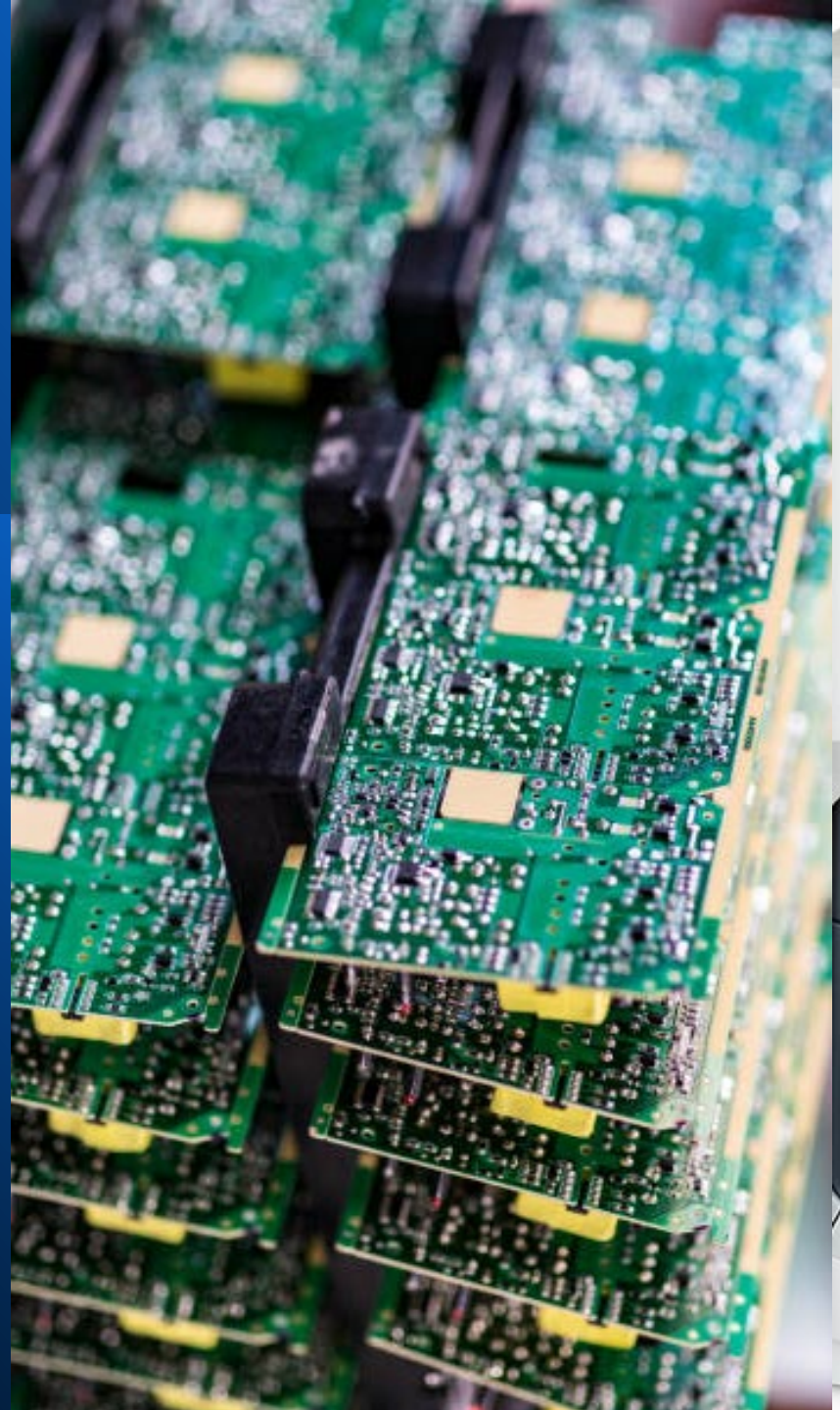
# IDEXX PFAS Discovery Journey



IDEXX Chemistry Analyzer has 1,200 unique parts

- Supplier information indicates 24 components may have PFAS
- Suppliers have not provided information that we have requested on the remaining 1,176 components

Numerous suppliers have cited concerns about releasing trade secret information to us regarding their components



# Despite significant efforts and ongoing investments over a period of years, knowledge gaps from our supplier network continue.

*IDEXX has and will continue to invest heavily in efforts to gain knowledge about components (PFAS included) in our supply chain.*

*This effort started over five years ago and we continue to-*

- Invest in technology and information databases
- Negotiate and extract information from suppliers
- Utilize external testing, as well as developing our own, internal testing methods to fill in knowledge gaps.


We estimate that we have PFAS information on approximately 1% of our ~14,000 individual components necessary to manufacture our products.

# Test Methods

# When required, IDEXX relies on its internal capability and commercial laboratories meeting high standards to test our electronic components.

While the Maine statute only allows for commercially available testing methods, IDEXX employs numerous organic chemists and has access to technologies that allows us to make risk assessments.

**IEC** - The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies. The labs that test electronic components use IEC methods.

**ISO 17025-** Further, we only utilize laboratories meeting this standard. Meeting this standard is a general requirement for independent laboratories to demonstrate the competence of testing and calibration laboratories.

- It is a world-wide accreditation standard and the highest available to testing and calibration laboratories.
- In most countries, ISO/IEC 17025 it is required to demonstrate technical competency necessary for accreditation.
- In many cases, suppliers and regulatory authorities will not accept test results from non- accredited laboratories.

# In the absence of supplier information, only some testing methods exist, and they won't always satisfy the requirements of Maine's statute.

**Targeted testing necessary to provide the data required by Maine's statute is not technically feasible in all circumstances-**

1. Existing, commercially available methods are only available for ~50 PFAS compounds.
2. The most common technology is Liquid Chromatography Mass Spectrometry (LC-MS/MS)
3. Detecting elements at trace levels requires Inductively Coupled Plasma Mass Spectrometry (ICP-MS)

# In the absence of a targeted testing method, other methods exist for determining the presence of fluorine which could indicate the presence of PFAS.

## Total Fluorine

Potential for contamination from ionic (inorganic) materials

- Water contains fluoride, which can interfere
- Method is used by some labs to screen complex products and identify when to do targeted testing

## Total Organic Fluorine

Method was developed to monitor impact to the environment and is not designed to test complex products.

- Used to monitor levels of TOF in water to inform on relative improvements
- Applicable for food packaging, some paper and textiles

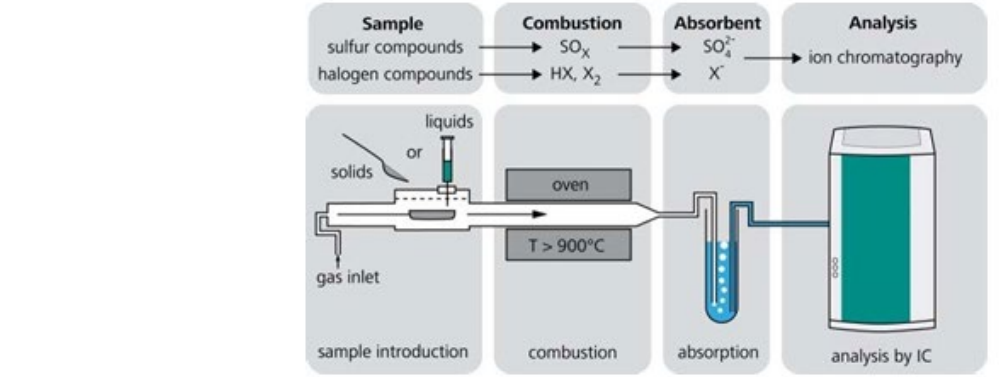
## FTIR

Fourier Transform Infra-Red Spectroscopy can be used for certain materials but not all

- Plastics
- PVC

Lab reports Total Fluorine as ‘there is a possibility that the total fluorine content does not come from PFAS. Retesting on individual PFAS is recommended to determine the compliance to the requirement’.

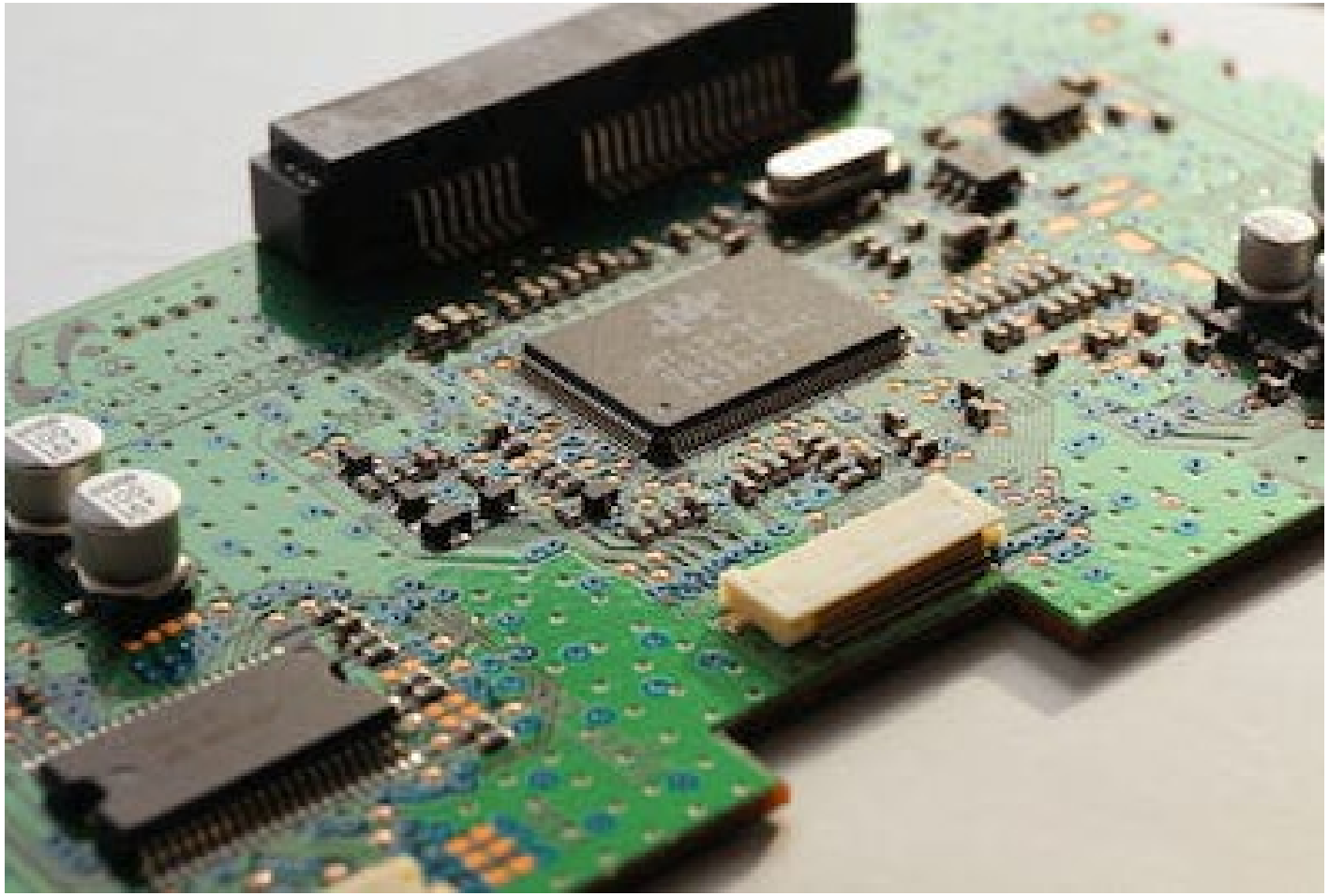
Total Organic Fluorine methods require converting solids to liquid and depending on the solvents, we need to carefully consider evaporation of the organic phase. **We could unintentionally remove organic fluorine, resulting in a false negative.**

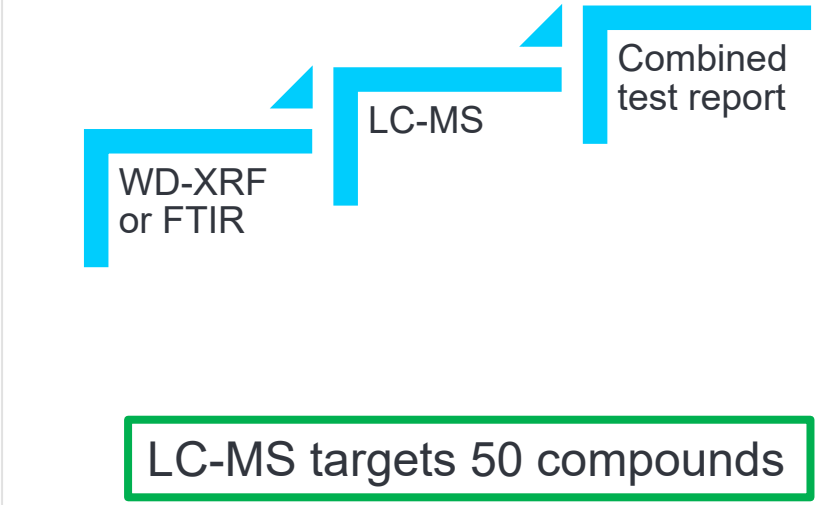




Source of visual: https://apps.nelac-institute.org/nemc/2021/docs/presentations/pdf/8-2-21-Polyfluoroalkyl%20Substances%20%28PFAS%29%20in%20the%20Environment-5.01-Gandhi.pdf

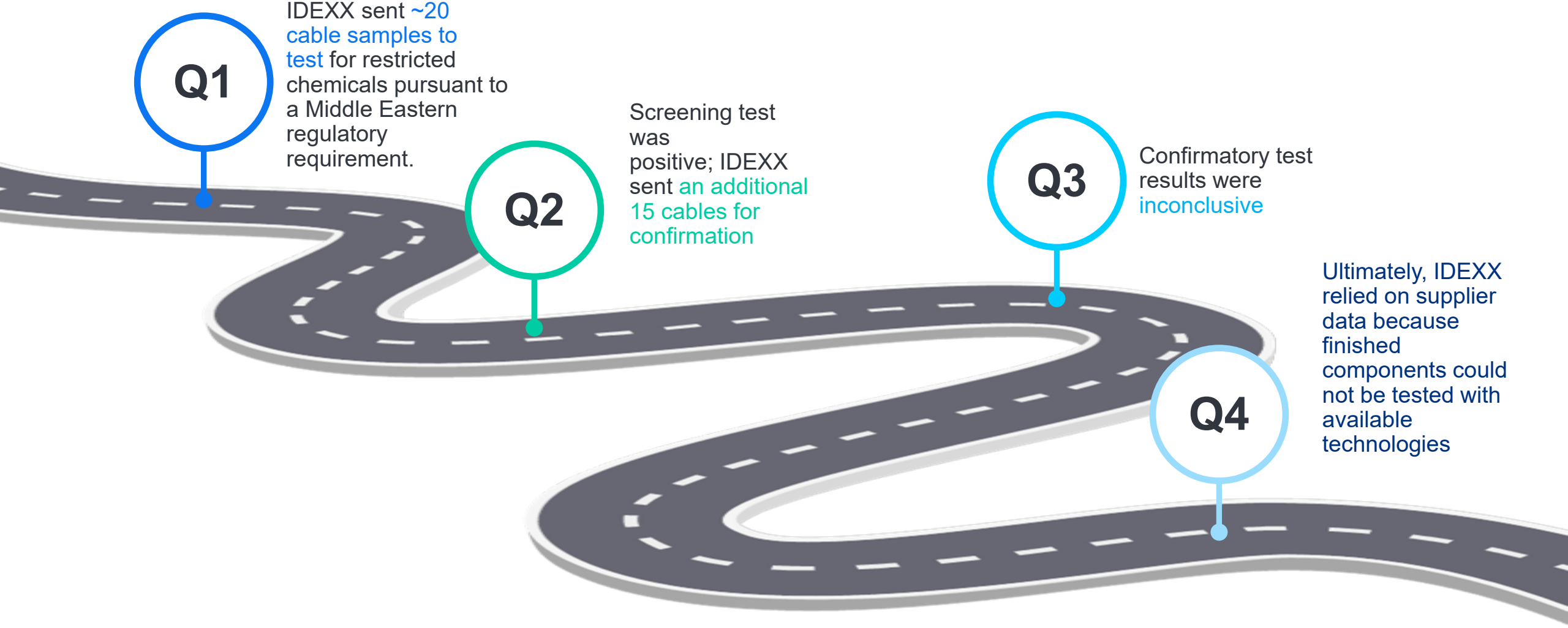
Our selected test labs will run a combination of tests to screen for fluorine. The reported results will provide any fluorine data on components of high concern for ***potential*** PFAS use within a circuit board. Targeted confirmation testing confirms only 50 compounds. We need clarity in the rulemaking to accommodate different methods for multiple parts under one finished product, as well as allowance to test only what is technically feasible.





# 2021 Case study:  Chemical testing of a single electronic component

Testing complex products is not simple or straightforward.



# In the absence of having full access to supplier information, IDEXX is evaluating testing options with accredited labs.

Our experiences to date, have resulted in a few key learnings-

- Testing on many material types can generate inconclusive results.
- Targeted testing on electronic components that would meet Maine's notification requirement can only be done for very limited (50 standard) number of the potential (~15,000) PFAS compounds.
- Timeframes to complete testing are difficult to determine, as each item must be sent before a quote and timeframe can be established.
- The material dictates the test methods that will be used.
- For complex parts, such as a circuit board, various methods will be applied using screening or technical knowledge.
- Based on current methods and lab capacity, we estimate it will take years to test all of our ~14,000 unique materials, with no guarantee of measurable results.

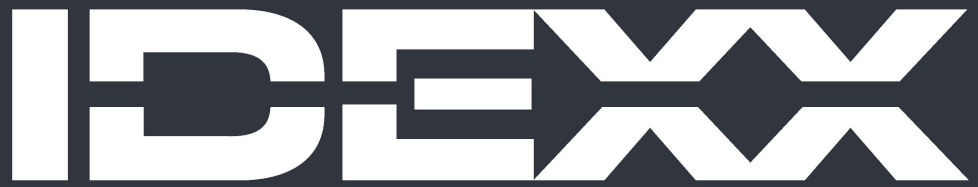
# Summary and Q&A

# Conclusion

- As you can see, we cannot determine exact concentrations for all complex materials.

- The alternative test option, Total Organic Fluorine, is not practical for all materials and is a screening tool that may generate false positives, at a rate that is unreliable for purposes of DEP policy making.

- If a notification requirement is desired, it has to allow for technical limitations and supplier research.  Adding safe harbor language, such as the EPA's 'known or reasonably ascertainable' is one such approach.


IDEXX