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Claigan Webinar
New EU and US PFAS Restrictions

Presented by:
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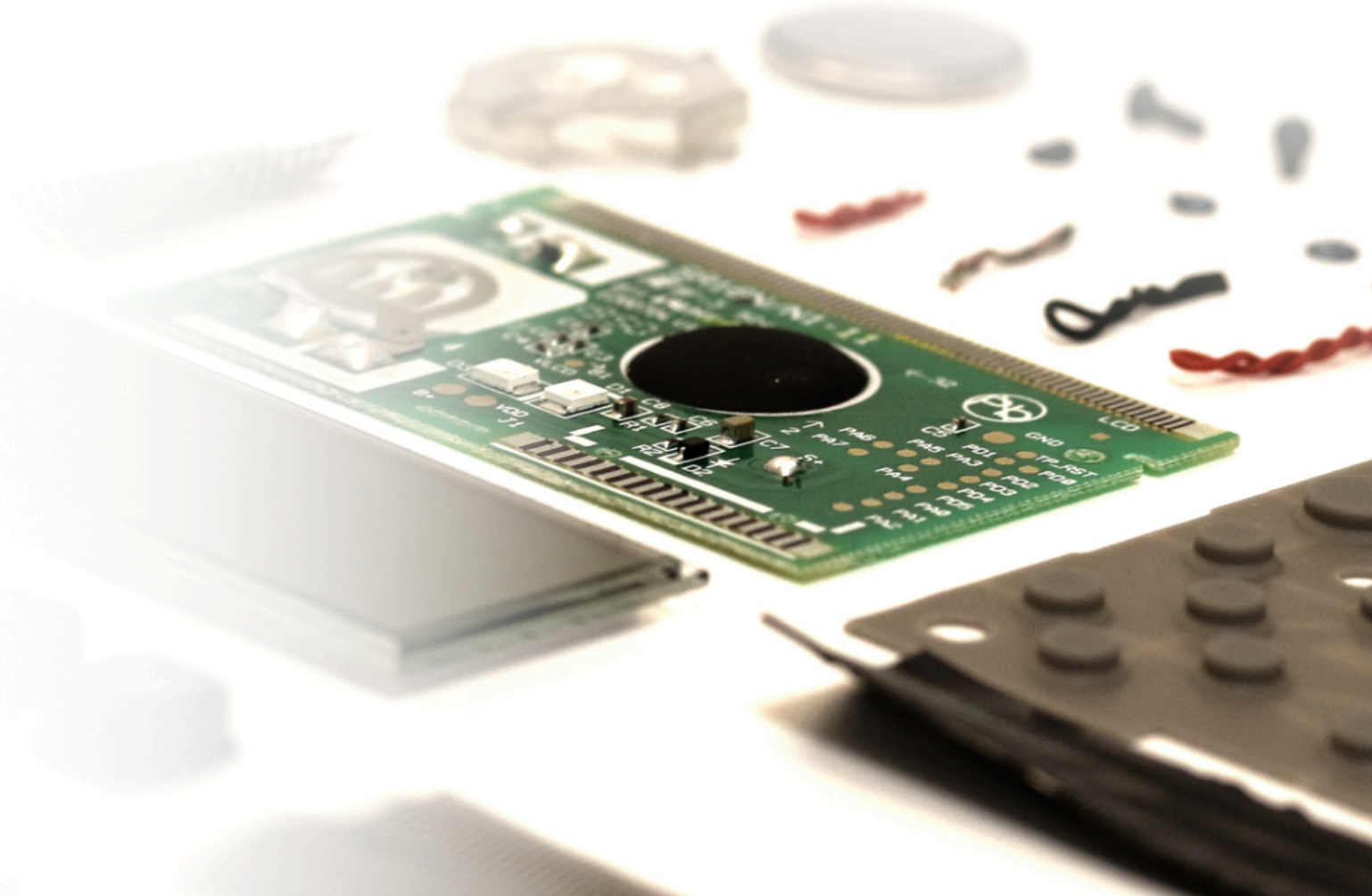
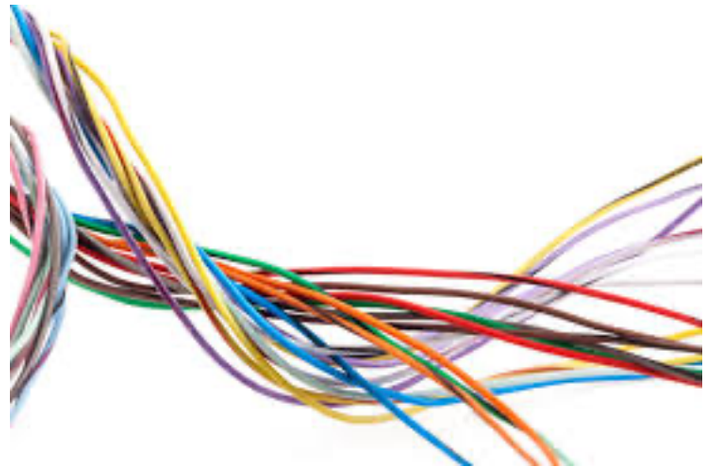
VP Consulting Services at Claigan

February 15, 2023

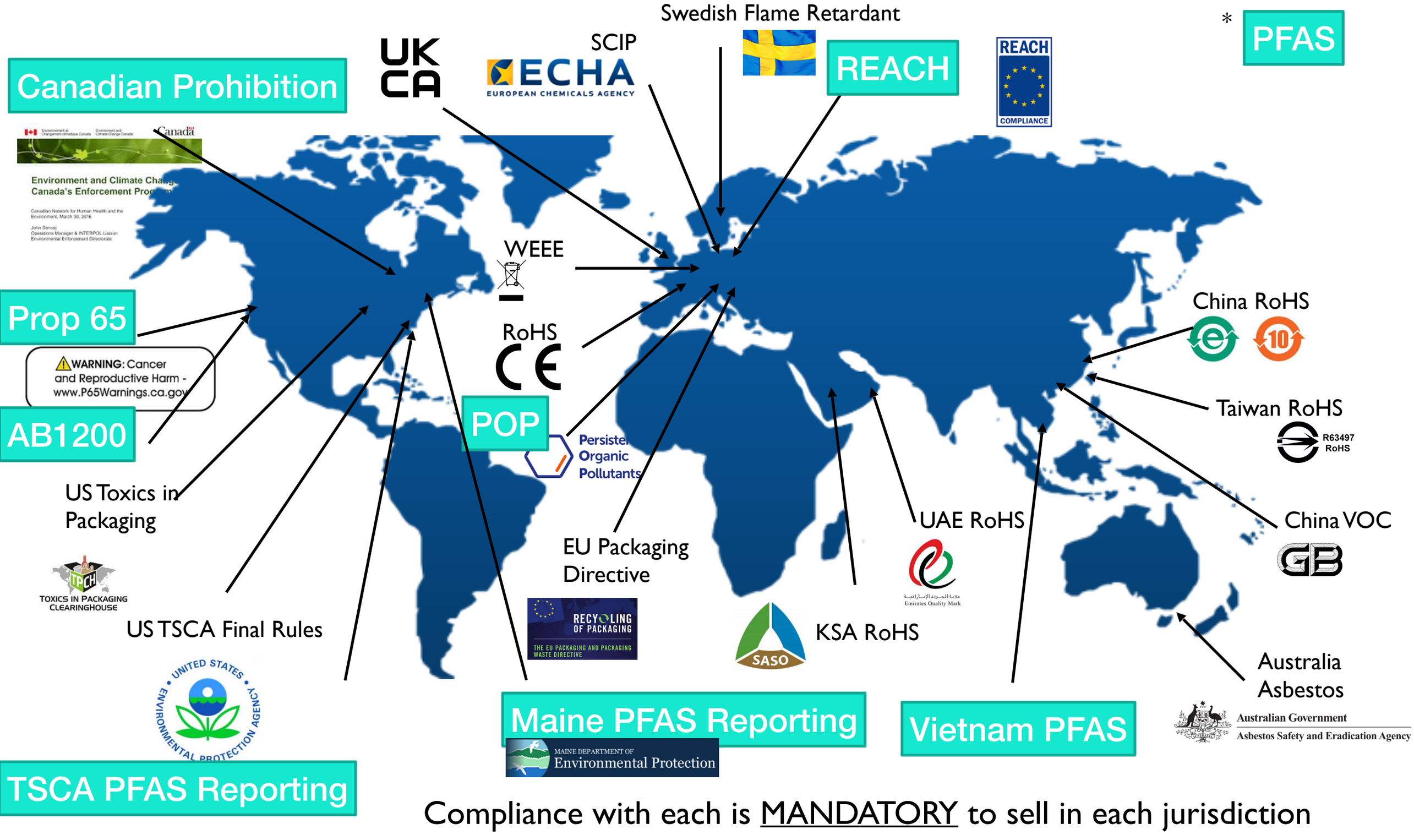


Overview - Agenda

- PFAS Regulation Global
- Fluoropolymers in a typical electronic product
- PFAS restriction summary
- EU restrictions
  - PFOA family
  - Proposed REACH PFAS Restriction
- US Restrictions
  - AB1200
  - Prop 65
- PFAS uses in electronics
- Finding your PFAS
- Q&A

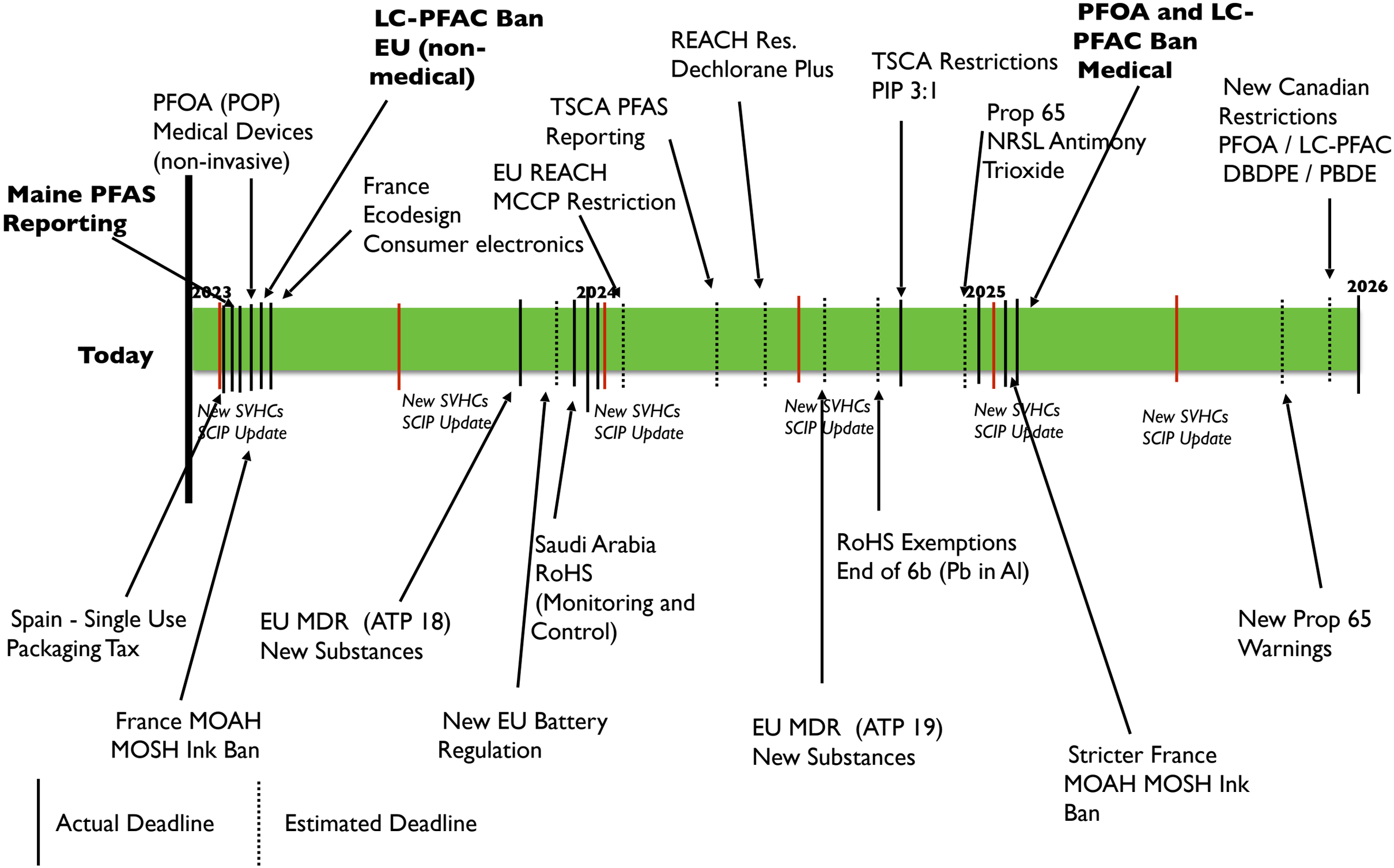


Global Restricted Materials Requirements Focus on PFAS



Compliance with each is <u>MANDATORY</u> to sell in each jurisdiction

Restricted Materials
Constant Deadlines



PFAS Legal Action - in 2021/2022

Litigation over 'forever chemicals' is growing: Is your company the next defendant?

Companies Face Billions in Damages as PFAS Lawsuits Flood Courts

DuPont, Chemours, Cortiva reach accord to split $4 billion in expenses to face potential liabilities over PFAS chemicals

Posted on Jan 26, 2021

Prop 65 PFAS Notices Increasing In Number

The PFAS litigation landscape – already involving PFAS manufacturers and purchasers of PFAS-containing fluoropolymers and firefighting films – is in the process of expanding, which is putting new companies and new industries in the spotlight, a process that may be accelerated by regulatory developments at the federal level.

Where are your fluoropolymers?

- **Average electronic product**
  - 5 to 10 fluoropolymer parts per product

Fluoropolymer mold release agent
~3 to 5 parts per product

Solid fluoropolymer parts
~1 to 2 per product

Fluoropolymer coating
Strain relief and wires inside cable

Fluoroelastomer
~1 to 2 per product

+ Fluorocoating on textile carrying case

Note - medical devices and laboratory products have 2X fluoropolymer parts per product

Where are your fluoropolymers?

- **Industrial products**
  - 2 to 15 fluoropolymer parts per product

Solid fluoropolymer parts
~1 to 5 per product

Fluoropolymer mold release agent
~1 to 4 parts per product

PTFE Tape
~1 to 2 per product

Fluoropolymer coating
Strain relief inside wiring

PTFE Grease
~1 to 2 per product

Fluoroelastomer
~1 to 4 per product

Globally
Principle PFAS Restrictions

- Restricted (PFOA and longer)
  - EU (+related non-EU related countries. Ex. Switzerland)
  - California (Proposition 65) - warning

- Planned Restrictions
  - Canada (Canadian Prohibition) - PFOA and longer
  - Vietnam - Date TBD (at 1ppm) - PFOA and longer
  - EU REACH Restriction - PFHxS
  - **Proposed EU REACH PFAS Restriction - broad ban**
  - Maine - 2030 (general PFAS ban)
    - *But, really a deadline for federal pre-emption*
    - *Any ban is expected to be sector specific*

Globally
Very Use-Specific PFAS Restrictions

- California
  - Food contact packaging - All PFAS
  - PFAS in juvenile products

- Maine
  - PFAS in carpets

- EU
  - PFOS in at 1,000 ppm (irrelevant number for articles)

EU PFAS Restrictions Current

- **Current**
  - *PFOA banned at 25 ppb*
    - *And substances that degrade into PFOA (260 ppb)*

- **Near term**
  - ***Feb 25 2023 –*** *LCPFAC (longer versions of PFOA) banned at 25 ppb*
  - ***July 25 2025 –*** *LCPFAC (invasive/implantable medical devices)*

- Cannot have PFOA or longer in a component above regulated limit

- No specific declaration or other paperwork requirement

REACH Restriction

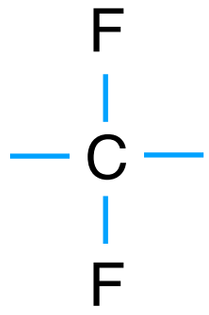
- REACH Restriction Annex 68
  - LC-PFAC Restriction February 25 2023

Entry Nº	Substance name	Conditions[3]	Effective Date[3]
68	C9-C14 PFCAs[1], their salts and C9-C14 related substances[2] [1] Linear and branched perfluorocarboxylic acids of the formula CnF2n+1-C(= O)OH where n = 8, 9, 10, 11, 12, or 13. [2] Any C9-C14 PFCA-related substance having a perfluoro group with the formula CnF2n+1- directly attached to another carbon atom, where n = 8, 9, 10, 11, 12, or 13. Any C9-C14 PFCA-related substance having a perfluoro group with the formula CnF2n+1- that it is not directly attached to another carbon atom, where n = 9, 10, 11, 12, 13 or 14 as one of the structural elements. The following substances are excluded from this designation: • CnF2n+1-X, where X = F, Cl, or Br where n = 9, 10, 11, 12, 13 or 14, including any combinations thereof, • CnF2n+1-C(= O)OX' where n> 13 and X'=any group, including salts.	Shall not be manufactured or placed on the market as substances on their own	25 February 2023
		Shall not be used or placed on the market in: a) another substance, as a constituent; b) A mixture; c) an article, Exception: • The concentration in the substance, mixture or article is < 25 ppb for the sum of C9-C14 PFCAs and their salts or < 260 ppb for the sum of C9-C14 PFCA-related substances. Some derogations include, within others: • The concentration limit shall be 10 ppm for the sum of C9-C14 PFCAs, their salts and C9-C14 related substances where they are present in a substance to be used as transported isolated intermediate for the manufacturing of fluorochemicals with a perfluoro carbon chain length of less than or equal to 6 atoms.	25 February 2023 This deadline changes depending on the use. Main applications include, within others: 4 July 2023: Textiles or oil- and water-repellency for the protection of workers from dangerous liquids that comprise risks to their health and safety. 4 July 2025: Invasive and implantable medical devices. 25 August 2028: Can coating for pressurized metered-dose inhalers. 31 December 2023: Semiconductors on their own and/or semiconductors incorporated in semi-finished electronic equipment. For semiconductors used in spare or replacement parts for finished electronic equipment placed on the market before 31 December 2023, it shall apply from 31 December 2030.

PFAS Simplified - Part I

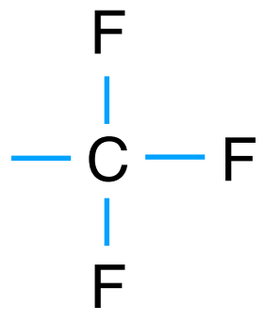
- **What is a PFAS?**
  - Has a fluorinated methylene or methyl group.

Fully Fluorinated Methylene



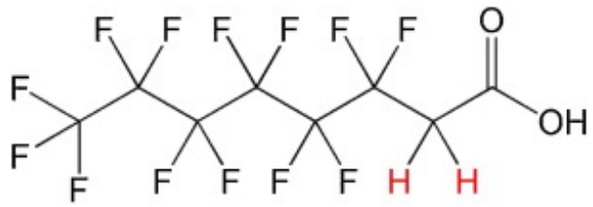
And/or

Fully Fluorinated Methyl

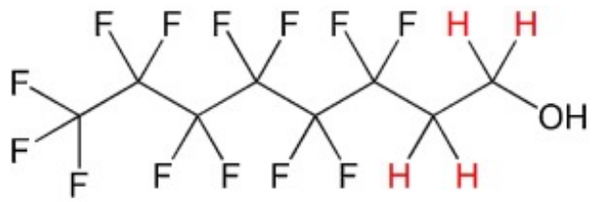


PFAS Simplified - Part 2

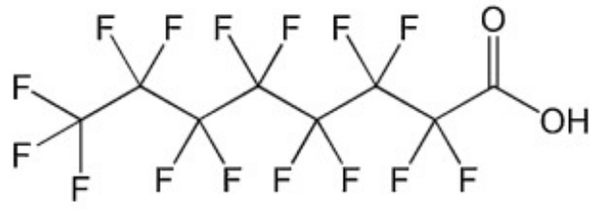
- **Non-Polymer PFAS**
  - Non-repeating PFAS (non-polymer)



6:2 FTCA

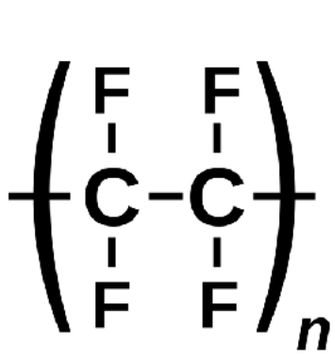


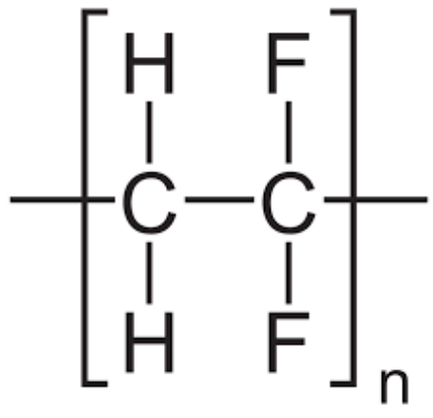
6:2 FTOH



PFOA

- **Polymer PFAS**
  - Repeating chains





Carboxylate and Sulphonic Non-polymer PFAS

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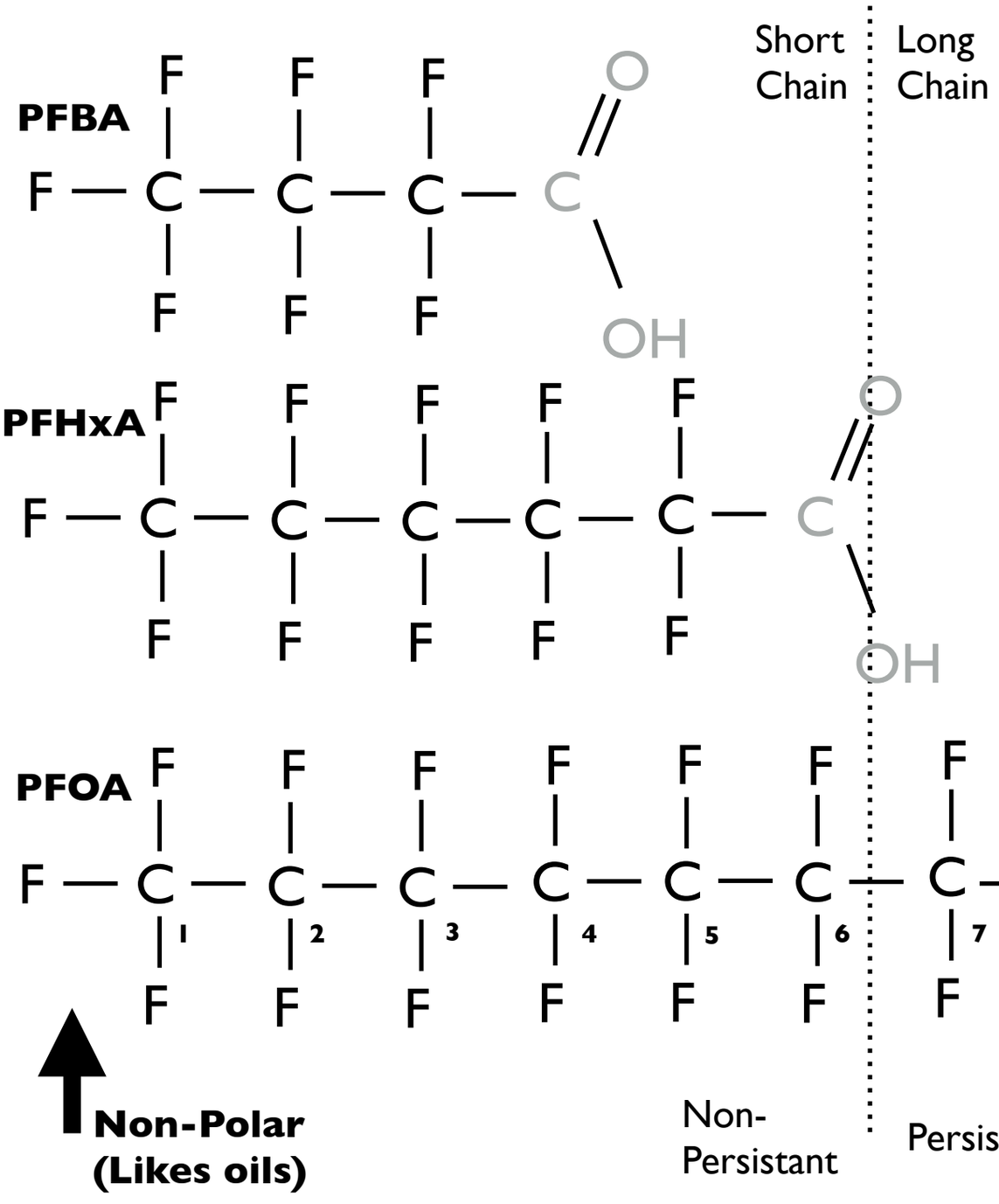
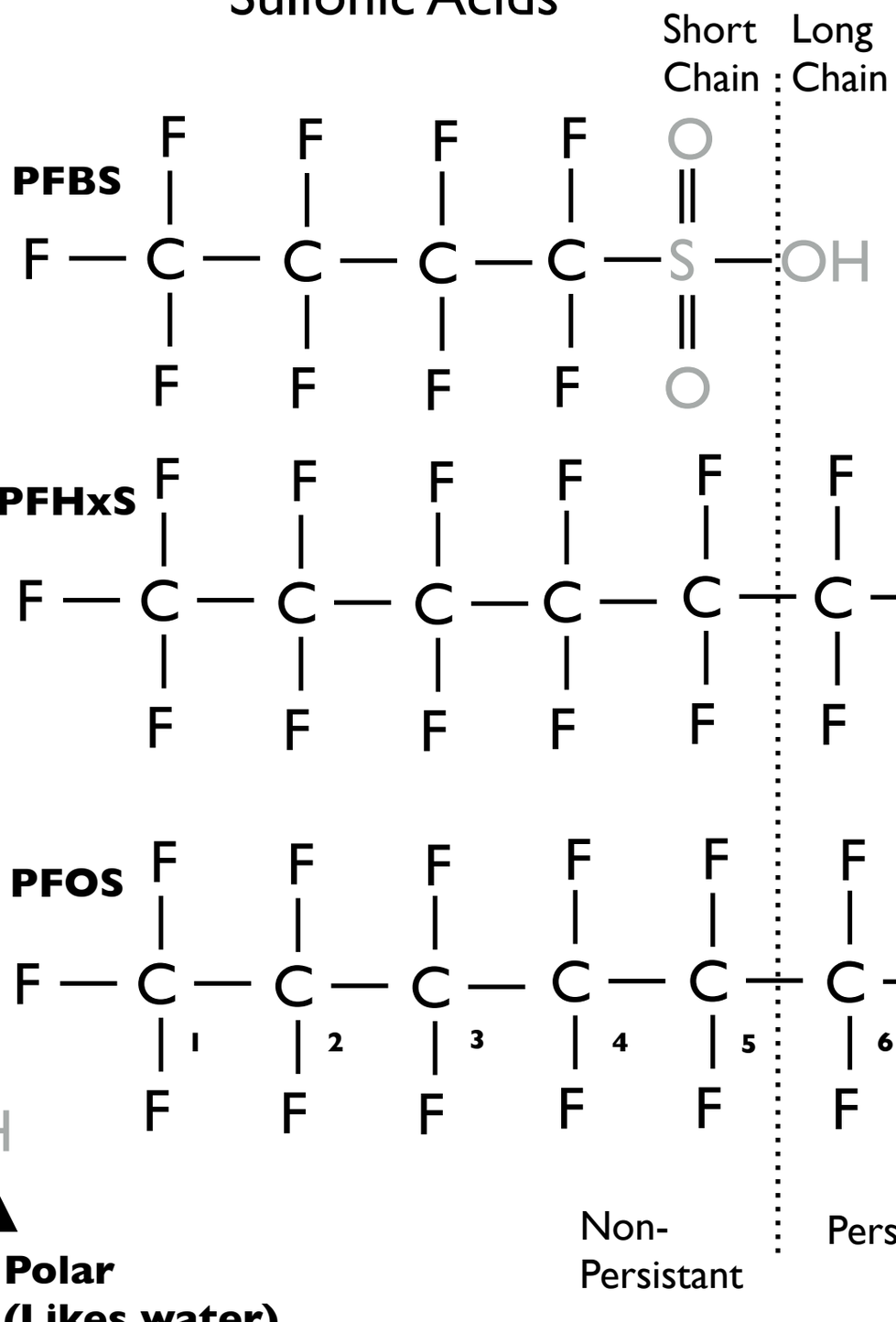
Perfluorinated carboxylate chemicals

Carboxylic Acids

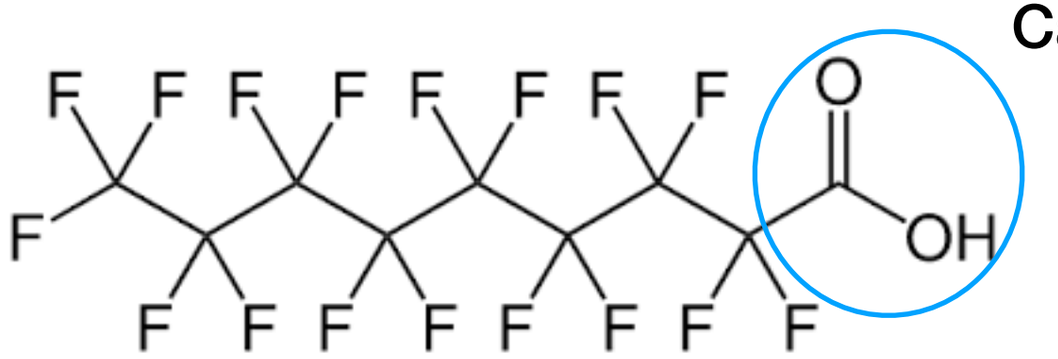


Perfluoroalkyl sulfonate chemicals

Sulfonic Acids



Carboxylates (PFOA Family)

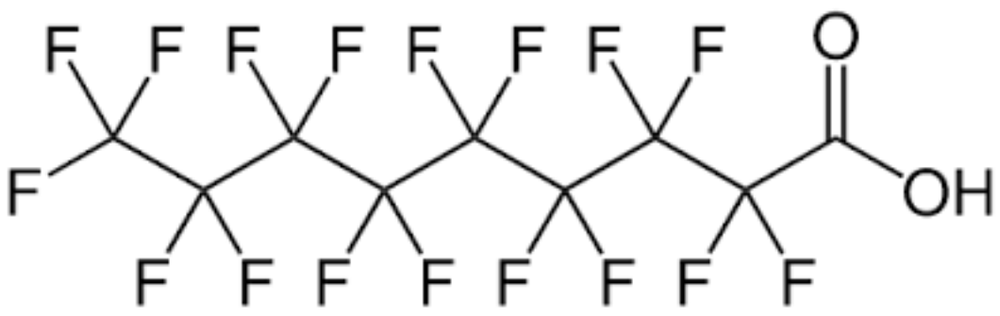


Carboxylate Group

Regulated at 25 ppb

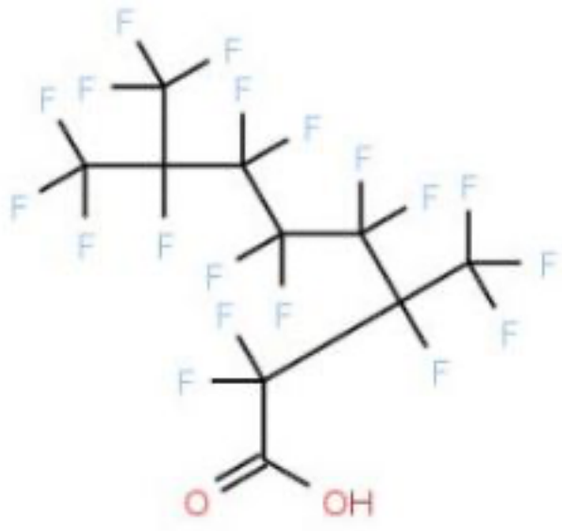
Note - ‘H’ can be Na, K, NH4, CH3 etc..

Linear



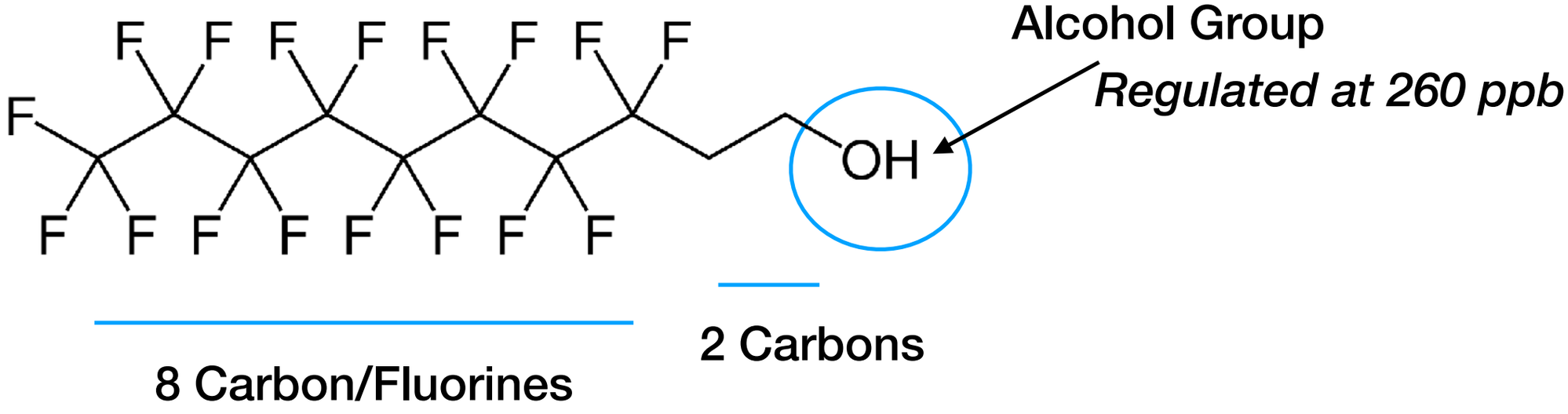
PFNA

Branched



PF-3,7 DMOA

Fluorotelomers (Degrades into PFOA)



8:2 FTOH

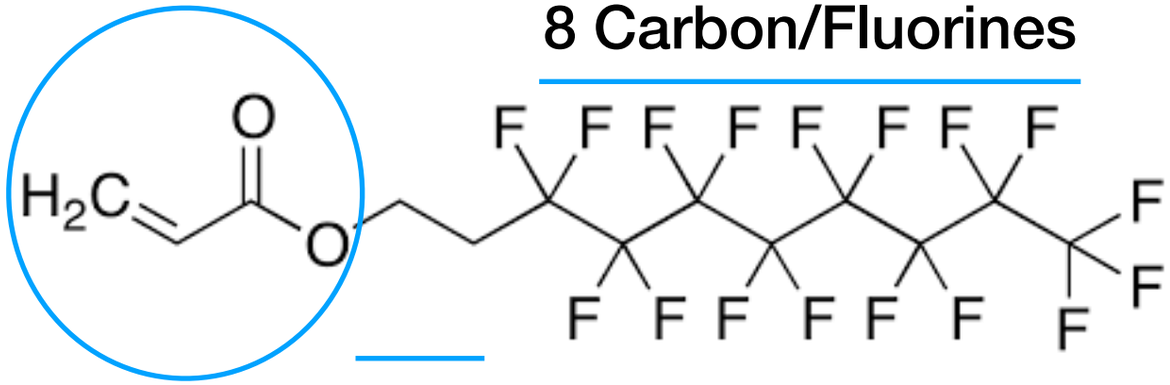
Uses - Generally an intermediate to fluoroacrylates or similar

Included in REACH because degraded into LC-PFAC

Fluoro-acrylates

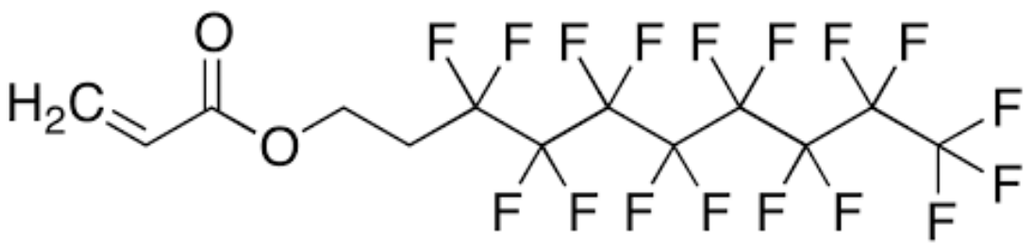
Acrylate Group

Regulated at 260 ppb



8:2 FTA

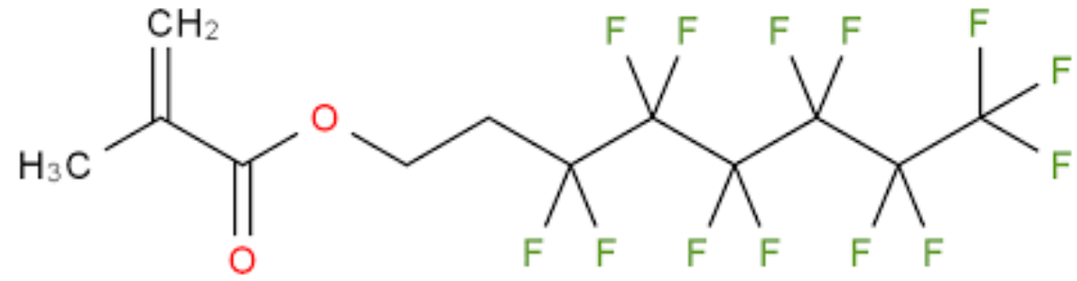
Acrylate



Acrylate

8:2 FTA

Methyl Acrylate



Methyl Acrylate

8:2 FTMA

EU PFAS Restrictions
Current - Non-polymer PFAS

- **Current**
  - *PFOA banned at 25 ppb*
    - *And substances that degrade into PFOA (260 ppb)*

- **Near term**
  - ***Feb 25 2023 –*** *LCPFAC (longer versions of PFOA) banned at 25 ppb*
  - ***July 25 2025 –*** *LCPFAC (invasive/implantable medical devices)*

- Cannot have PFOA or longer in a component above regulated limit

- No specific declaration or other paperwork requirement

Where to find non-polymer PFAS?

- **In polymer PFAS**
  - Non-polymer PFAS are not normally used on their own.
  - They are either
    - Manufacturing aids,
    - Ingredients, or
    - Degradation products
  - of a polymer PFAS

- **Find your polymer PFAS**
  - And you know where your non-polymer restricted PFAS can be

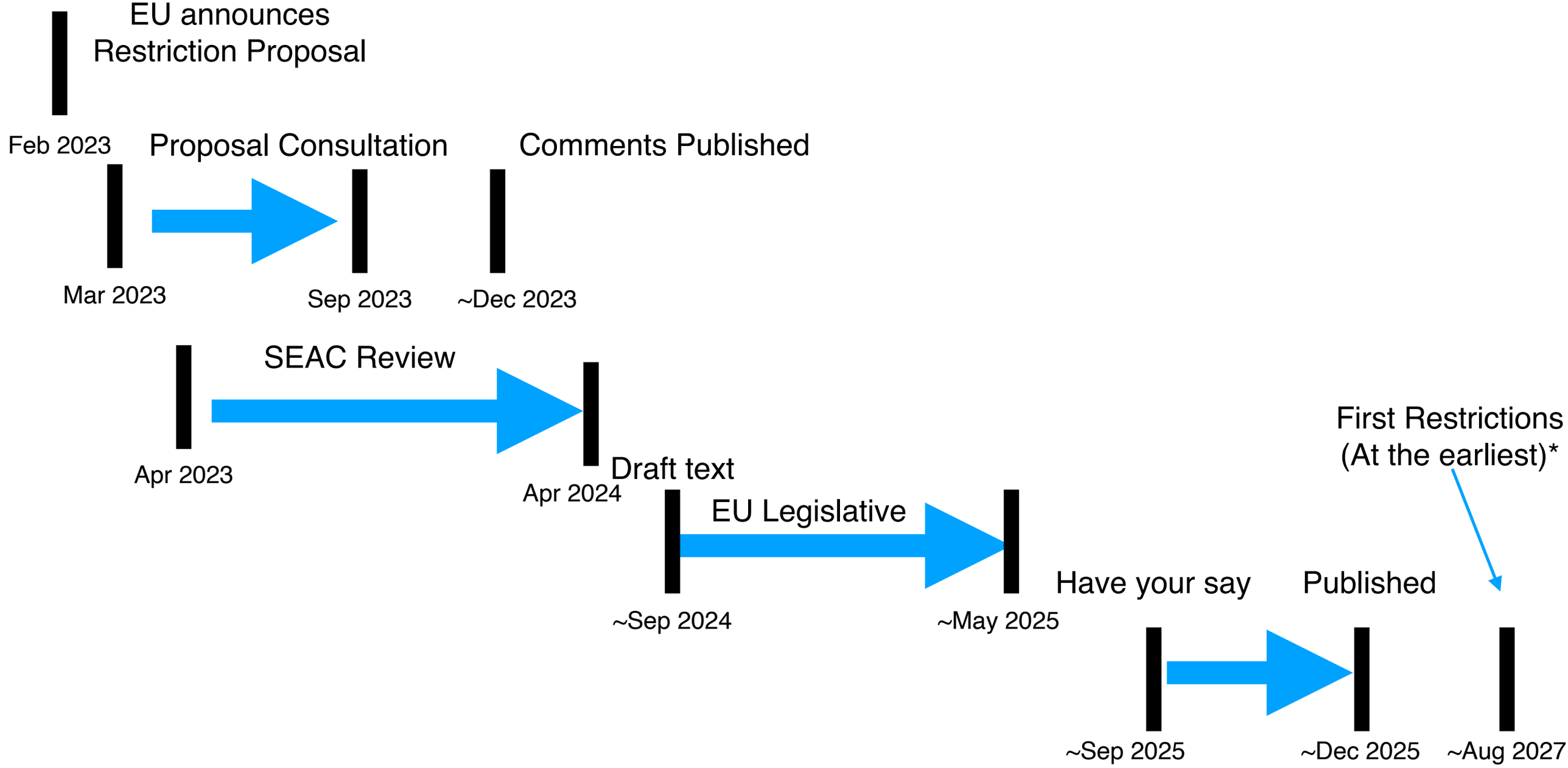
Proposed REACH Restriction Published - PFAS

- On Feb 7 2023, the proposed REACH Restriction on PFAS was published
  - It is broadest proposed restriction ever

- Notes
  - Applies to non-polymeric and polymeric PFAS
  - This is the strictest the law could be. There is a lot of lobbying / consultation left
  - Restrictions start between 18 months and 13.5 years from Entry into Force of final version
    - Entry into Force (EIF) is generally 20 days after publication

Timeline for EU PFAS Ban

- EU is promoting that proposed ban will be broad
  - Proposed version to be presented February 7 2023



*Note - for some industries, such as medical invasive, restriction closer to ~2038

Two (2) PFAS Restriction Proposals

- Proposal 1
  - Ban all PFAS at 25 ppb

- Proposal 2
  - Ban all PFAS at 25 ppb /w a large number of longer timelines

Proposal 2
Proposed EU PFAS Restrictions

- **Details - Page 1**

- Summary
  - Articles and mixtures
  - 25 ppb / 250 ppb for non-polymeric PFAS
  - 50 ppm F for polymeric
- Out of scope (except reporting)
  - Pesticides / biocides
  - Pharmaceuticals

Column 1 Designation of the substance, of the group of substances or of the mixture	**Column 2** Conditions of restriction
Per- and polyfluoroalkyl substances (PFASs) defined as: Any substance that contains at least one fully fluorinated methyl (CF_3-) or methylene (-CF_2-) carbon atom (without any H/Cl/Br/I attached to it). A substance that only contains the following structural elements is excluded from the scope of the restriction: CF_3-X or X-CF_2-X', where X = -OR or -NRR' and X' = methyl (-CH_3), methylene (-CH_2-), an aromatic group, a carbonyl group (-C(O)-), -OR'', -SR'' or –NR''R'''; and where R/R'/R''/R''' is a hydrogen (-H), methyl (-CH_3), methylene (-CH_2-), an aromatic group or a carbonyl group (-C(O)-).	1. Shall not be manufactured, used or placed on the market as substances on their own; 2. Shall not be placed on the market in: a. another substance, as a constituent; b. a mixture, c. an article in a concentration of or above: i. 25 ppb for any PFAS as measured with targeted PFAS analysis (polymeric PFASs excluded from quantification) ii. 250 ppb for the sum of PFASs measured as sum of targeted PFAS analysis, optionally with prior degradation of precursors (polymeric PFASs excluded from quantification) iii. 50 ppm for PFASs (polymeric PFASs included). If total fluorine exceeds 50 mg F/kg the manufacturer, importer or downstream user shall upon request provide to the enforcement authorities a proof for the fluorine measured as content of either PFASs or non-PFASs. 3. Paragraphs 1 and 2 shall apply 18 months from entry into force of the restriction. 4. By way of derogation, paragraphs 1 and 2 shall not apply to a. active substances in biocidal products within the scope of Regulation (EU) 528/2012 b. active substances in plant protection products within the scope of Regulation (EC) 1107/2009 c. active substances in human and veterinary medicinal products within the scope of Regulation (EC) No 726/2004, Regulation (EU) 2019/6 and Directive 2001/83/EC Manufacturers and importers of the active substances referred to in points a) – c) shall submit to the Agency every two years the following information: i. the derogation that the intended use belongs to; ii. the identity and quantity of the active substance placed on the market

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Proposed EU PFAS Restrictions

- **Details - Page 2**

- Longer timelines for
  - Certain polymerization aids
  - PPE and related chemicals
  - Refrigerants
  - Cleaning fluids

Column 1 Designation of the substance, of the group of substances or of the mixture	**Column 2** Conditions of restriction
	The Agency shall publish on its website a summary of the submitted information referred to in points i) – ii) 5. By way of derogation, paragraphs 1 and 2 shall not apply to: a. polymerisation aids in the production of polymeric PFASs until 6.5 years after EIF. This derogation does not apply to the production of PTFE, PVDF and FKM. b. textiles used in personal protective equipment (PPE) intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I, Risk Category III (a) and (c), until 13.5 years after EiF; c. textiles used in personal protective equipment (PPE) in professional firefighting activities intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I, Risk Category III (a) - (m), until 13.5 years after EiF; d. impregnation agents for re-impregnation of articles referred to in paragraph 5b and 5c until 13.5 years after EiF; e. textiles for the use in filtration and separation media used in high performance air and liquid applications in industrial or professional settings that require a combination of water- and oil repellence until 6.5 years after EiF; f. refrigerants in low temperature refrigeration below -50°C until 6.5 years after EiF; g. refrigerants in laboratory test and measurement equipment until 13.5 years after EiF; h. refrigerants in refrigerated centrifuges until 13.5 years after EiF; i. maintenance and refilling of existing HVACR equipment put on the market before [18 months after EiF] and for which no drop-in alternative exist until 13.5 years after EiF; j. refrigerants in HVACR-equipment in buildings where national safety standards and building codes prohibit the use of alternatives; k. industrial precision cleaning fluids until 13.5 years after EiF; l. cleaning fluids for use in oxygen-enriched environments until 13.5 years after EiF;

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Proposed EU PFAS Restrictions

- **Details - Page 3**

- Long timelines cont.
  - Fire fighting foams
  - Diagnostic laboratory equipment
  - More refrigerants
  - Insulated gases
  - Lubricants for harsh environments
  - Calibration samples
- For further consultation
  - Textiles for automotive
  - Hard chrome plating
  - Foam blowing agents
  - Solvent in 3D printing
  - Propellants
  - Cultural paper
  - Heat transfer fluids for medical

Column 1 Designation of the substance, of the group of substances or of the mixture	**Column 2** Conditions of restriction
	m. clean fire suppressing agents where current alternatives damage the assets to be protected or pose a risk to human health until 13.5 years after EiF; n. diagnostic laboratory testing until 13.5 years after EiF; o. additives to hydraulic fluids for anti-erosion/anti-corrosion in hydraulic systems (incl. control valves) in aircraft and aerospace industry until 13.5 years after EiF; p. refrigerants in mobile air conditioning-systems in combustion engine vehicles with mechanical compressors until 6.5 years after EiF; q. refrigerants in transport refrigeration other than in marine applications until 6.5 years after EiF; r. insulating gases in high-voltage switchgear (above 145 kV) until 6.5 years after EIF s. lubricants where the use takes place under harsh conditions or the use is needed for safe functioning and safety of equipment until 13.5 years after EIF; t. calibration of measurement instruments and as analytical reference materials. *The following potential derogations are marked for reconsideration after the Annex XV report consultation:* u. [textiles for the use in engine bays for noise and vibration insulation used in the automotive industry until 13.5 years after EiF]; v. [hard chrome plating until 6.5 years after EiF]; w. [foam blowing agents in expanded foam sprayed on site for building insulation until 6.5 years after EiF]; x. [industrial and professional use of solvent-based debinding systems in 3D printing until 13.5 years after EiF]; y. [industrial and professional use of smoothing agents for polymer 3D printing applications until 13.5 years after EiF]; z. [propellants for technical aerosols for applications where non-flammability and high technical performance of spray quality are required until 13.5 years after EiF]; aa. [preservation of cultural paper-based materials until 13.5 years after EiF]; bb. [cleaning and heat transfer: engineered fluids for medical devices until 13.5 years after EiF];

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Proposed EU PFAS Restrictions

- **Details - Page 4**
- For further consultation cont.
  - Membranes for venting of medical devices
  - Semiconductor manufacturing
- Extended deadlines for
  - Food contacting
  - Medical implantable
  - Medical tubes and catheters
  - Metered dose inhalers
  - Fuel cells
  - Petroleum and mining industry
- All the above are marked for reconsideration plus
  - Contact lens
  - Medical packaging plus others

Column 1 Designation of the substance, of the group of substances or of the mixture	**Column 2** Conditions of restriction
	cc. [membranes used for venting of medical devices until 13.5 years after EiF]; dd. [use as refrigerants and for mobile air conditioning in vehicles in military applications until 13.5 years after EiF]; ee. [the semiconductor manufacturing process until 13.5 year after EiF]. 6. By way of derogation, paragraphs 1 and 2 shall not apply to fluoropolymers and perfluoropolyethers for the use in: a. food contact materials for the purpose of industrial and professional food and feed production until 6.5 years after EiF; b. implantable medical devices (not including meshes, wound treatment products, tubes and catheters) until 13.5 years after EiF; c. tubes and catheters in medical devices until 13.5 years after EiF; d. coatings of Metered Dose Inhalers (MDIs) until 13.5 years after EiF; e. proton-exchange membrane (PEM) fuel cells until 6.5 years after EiF; f. fluoropolymer applications in petroleum and mining industry until 13.5 years after EiF. *The following potential derogations are marked for reconsideration after the Annex XV report consultation:* g. [non-stick coatings in industrial and professional bakeware until 6.5 years after EiF]; h. [hernia meshes until 13.5 years after EiF]; i. [wound treatment products until 13.5 years after EiF]; j. [coating applications for medical devices other than Metered Dose Inhalers until 13.5 years after EIF]; k. [Rigid gas permeable contact lenses and ophthalmic lenses until 13.5 years after EiF]; l. [PCTFE-based packaging for medicinal preparations, medical devices and medical molecular diagnostics until 13.5 years after EIF]; m. [PTFE in ophthalmic solutions packaging until 13.5 years after EIF]; n. [packaging of terminally sterilised medical devices until 13.5 years after EIF]; o. [applications affecting the proper functioning related to the safety of transport vehicles, and

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Proposed EU PFAS Restrictions

- **Details - Page 6**

- <u>Reporting requirements</u>
  - Each year, PFAS information
- Site management plan
  - For allowed uses of fluoropolymers
- Note
  - Stricter PFAS legislation takes precedence

Column 1 Designation of the substance, of the group of substances or of the mixture	**Column 2** Conditions of restriction
	affecting the safety of operators, passengers or goods until 13.5 years after EiF]. 7. Manufacturers and importers of PFASs or PFAS containing articles as well as formulators of PFAS containing mixtures making use of any of the derogations according to paragraphs 5 b)-d) and f) – t) [and u), w)-ee)],and 6 b)-d) and f) [and h)-o)], shall from (EiF + 18 months) provide by 31 March of each calendar year a report to the Agency containing: i. the derogation that the intended use belongs to; ii. the identity and quantity of the substances placed on the market in the previous year. The Agency shall forward the information to the Commission by 30 June every year; 8. Without prejudice to paragraph 7, importers and downstream users of fluoropolymers and perfluoropolyethers making use of any of the derogations in paragraphs 5 or 6 shall establish a site-specific management plan which shall include: i. information on the identity of the substances and the products they are used in ii. a justification for the use; iii. details on the conditions of use and safe disposal. The management plan shall be reviewed annually and kept available for inspection by enforcement authorities upon request. 9. Paragraphs 1 and 2 shall apply without prejudice to the application of any stricter restrictions set out in this Annex or in other applicable Union legislation.

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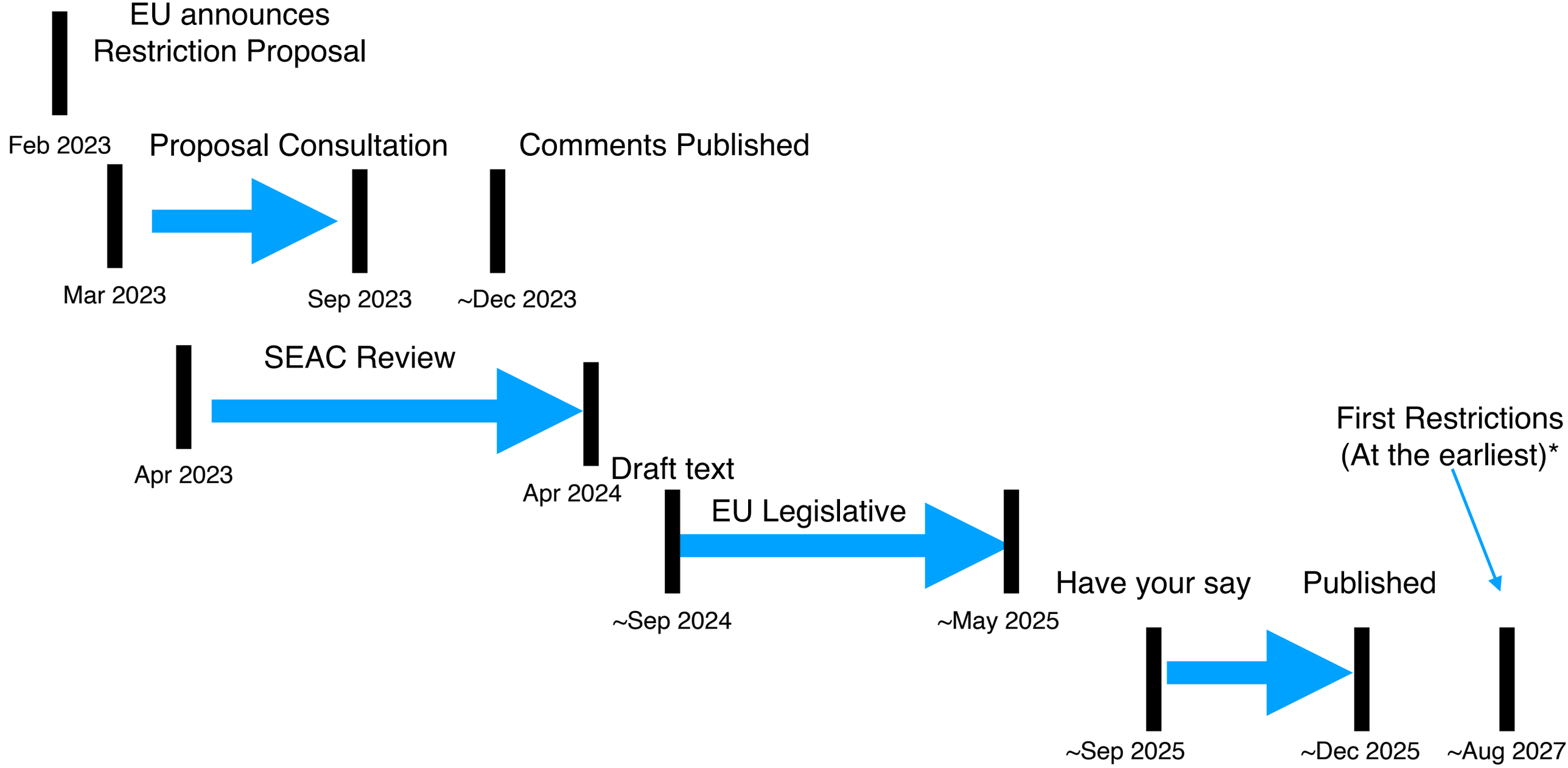
Timeline for EU PFAS Ban

- EU is promoting that proposed ban will be broad
  - Proposed version was presented February 7 2023



*Note - for some industries, such as medical invasive, restriction closer to ~2038

California Proposition 65

- **Restricted list includes the non-polymer PFAS's**
  - *PFOA*
  - *PFNA (Dec 31 2022)*
  - *PFDA (Dec 31 2022)*
  - *PFOS*

- **Prosecutions**
  - *26 so far. Mostly in 2022*

Maine Reporting Update

- **New draft reporting rule published Feb 14 2023**

- **Details**
  - Rules on grouping of products
    - Same customs codes
    - Same PFAS
    - Substantially the same quantity and use of PFAS

- Plus more details on costs, enforcements, and notification.

06-096 DEPARTMENT OF ENVIRONMENTAL PROTECTION

-POSTING DRAFT-

Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances

SUMMARY: This Chapter details the notification requirements and sales prohibitions for new products and product components containing intentionally added Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS) pursuant to 38 M.R.S. §1614.

Maine Reporting Update Components

- There is some confusion in industry regarding this passage
  - Notifications are required only for products or product components offered for sale or distributed for sale in the State Maine. Product components that are incorporated into a complex product which are offered or distributed for sale in Maine are not subject to the notification requirement, even when information regarding the product components is provided as part of that product's notification submission.

- Default
  - The finished product manufacturer is responsible for notifying Maine regarding the parts contained, not the component supplier
    - Unless the component supplier also supplies those parts separately on the market in Maine.

What to do?

- **Find your PFAS polymers**
  - For reporting in Maine, US, and EU
  - For identifying parts with risk of non-polymer PFAS
  - Simplest method - Test for fluorine
    - **No fluorine, no fluoropolymer**

- **Test PFAS polymers**
  - For restricted non-polymer PFAS (PFOA), test your identified fluoropolymers

PFAS Compliance Process

Products

Claigan

Claigan

4 to 6 weeks

Reporting

Product	Air Samplers	Carrying Bags
Description	Professional air sampler for industrial gases	Carrying bags for air samplers
Purpose	PTFE tape is a polytetrafluoroethylene (PTFE) film tape commonly used in plumbing for sealing pipe threads. The tape is sold cut to specific widths and wound on a spool, making it easy to wind around pipe threads. Thread seal tape lubricates allowing for a deeper seating of the threads, and it helps prevent the threads from seizing when being unscrewed. The tape also works as a deformable filler and thread lubricant, helping to seal the joint without hardening or making it more difficult to tighten	Durable water repellent, or DWR, is a coating added to fabrics at the factory to make them water-resistant
PFAS	polytetrafluoroethylene (PTFE)	Fluorochemical Acrylate Copolymer
PFAS CAS#	9002-84-0	Undisclosed
Weight (g)	2.2 g	0.2 g

Restriction

Restrictions results
& Due Diligence

Where are your fluoropolymers?

- **Average electronic product**
  - 5 to 10 fluoropolymer parts per product

Fluoropolymer mold release agent
~3 to 5 parts per product

Solid fluoropolymer parts
~1 to 2 per product

Fluoropolymer coating
Strain relief inside cable

Fluoroelastomer
~1 to 2 per product

+ Fluorocoating on textile carrying case

Note - medical devices and laboratory products have 2X fluoropolymer parts per product

Where are your fluoropolymers?

- **Industrial products**
  - 2 to 15 fluoropolymer parts per product

Solid fluoropolymer parts
~1 to 5 per product

Fluoropolymer mold release agent
~1 to 4 parts per product

PTFE Tape
~1 to 2 per product

Fluoropolymer coating
Strain relief inside wiring

PTFE Grease
~1 to 2 per product

Fluoroelastomer
~1 to 4 per product

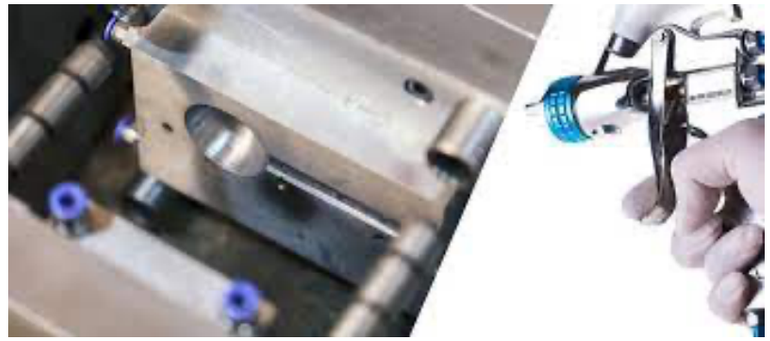
Surprise use of fluoropolymers

- **Very common unexpected uses of fluoropolymers**
  - Mold release agent for
    - Polyurethane foam
    - Polycarbonate molded parts

  - Strain relief inside cables
    - Coating on wires and separators in cables
      - To prevent friction

Mold Release Agents

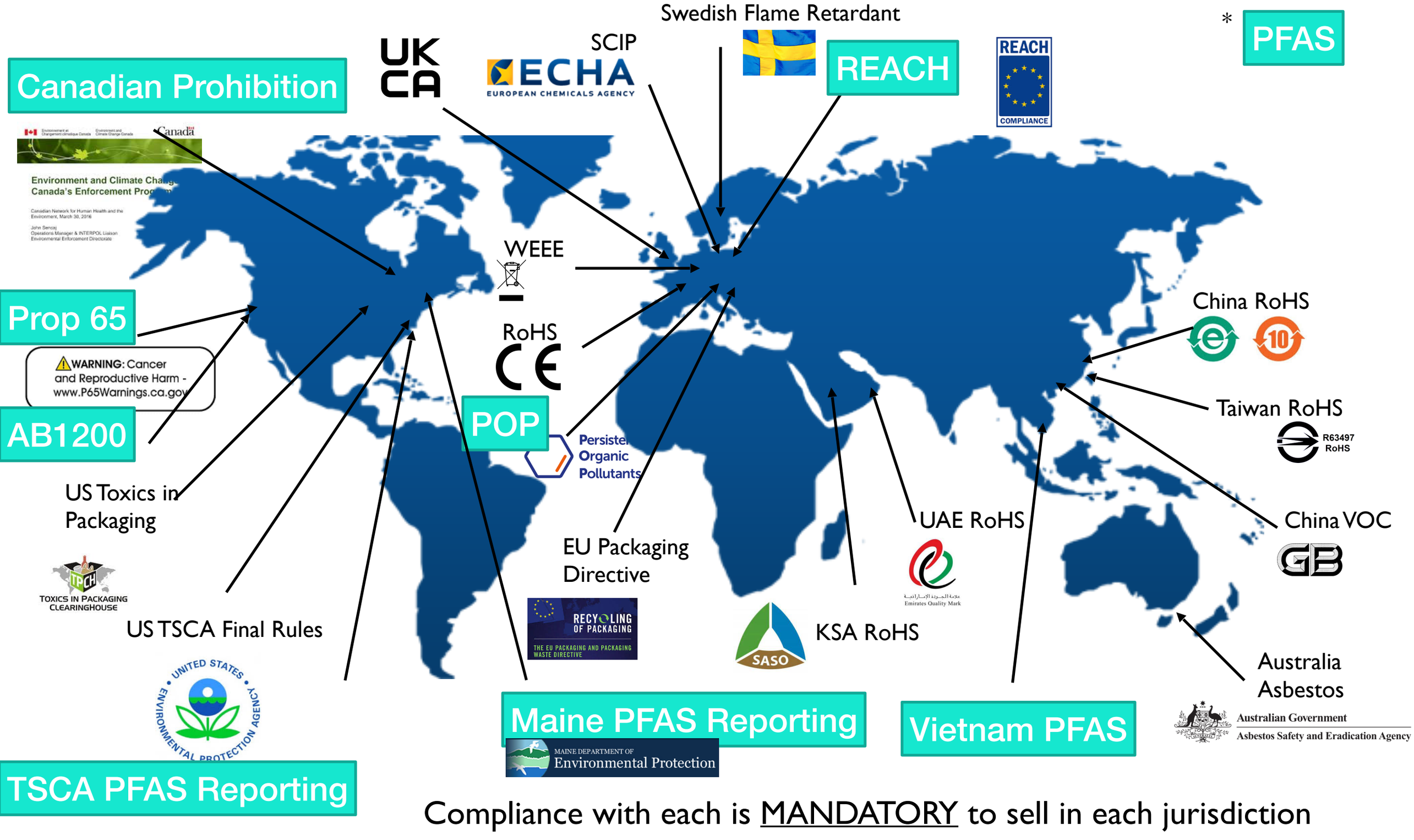
- **Very common in electronics and medical devices**
  - Generally a fluorosulphonate polymer
  - Common materials with release agent
    - Polyurethane foam (nearly 100%)
    - Polycarbonate parts



- **Regulations**
  - Not in scope of Maine PFAS reporting (not intentional)
  - Low risk of PFOA / LC-PFAC
  - High risk of sulphonates (future regulated)
  - Would be banned under EU PFAS Restriction

- **Note - supplier data would not identify it**

Global Restricted Materials Requirements Focus on PFAS



Compliance with each is <u>MANDATORY</u> to sell in each jurisdiction

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Q&A