

Global PFAS Regulation

US, EU, and Canada

Presented by:
Bruce Calder
VP Consulting Services



Overview - Agenda -

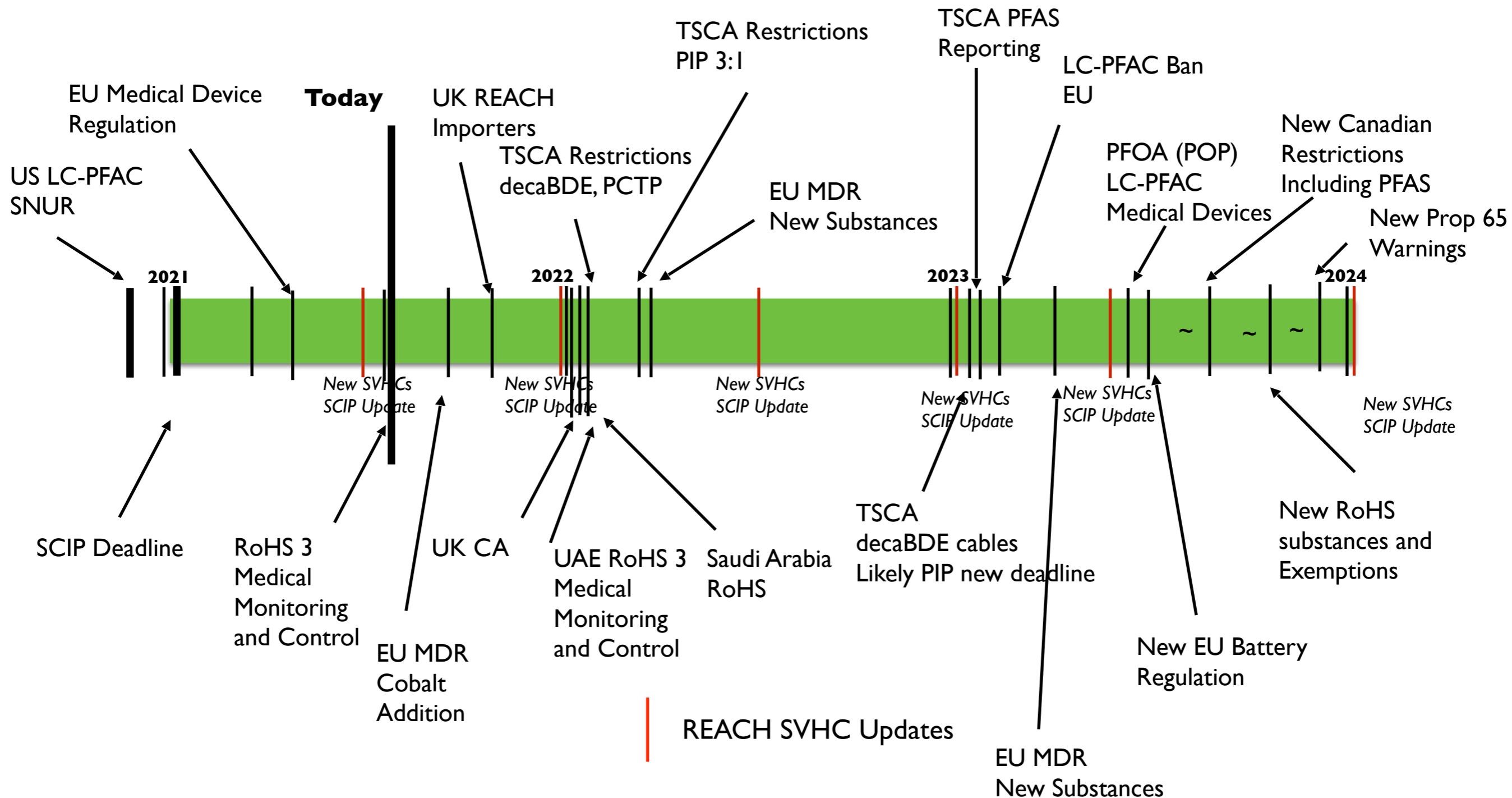
- Upcoming Deadlines
 - General
 - PFAS
- PFAS
 - Overview
 - High risk materials
- US PFAS Regulation
 - TSCA
 - LCPFAC
 - Proposed PFAS
 - California Proposition 65
- EU PFAS Regulation
 - POP (PFOA)
 - REACH (LC-PFAC)
 - + proposed broad restriction
- Canadian
 - Canadian Prohibition of Certain Toxic Substances
- Compliance strategies



Webinar is 50 minutes with 10
minutes of Q&A
(hopefully)

Restricted Materials

Upcoming Deadlines

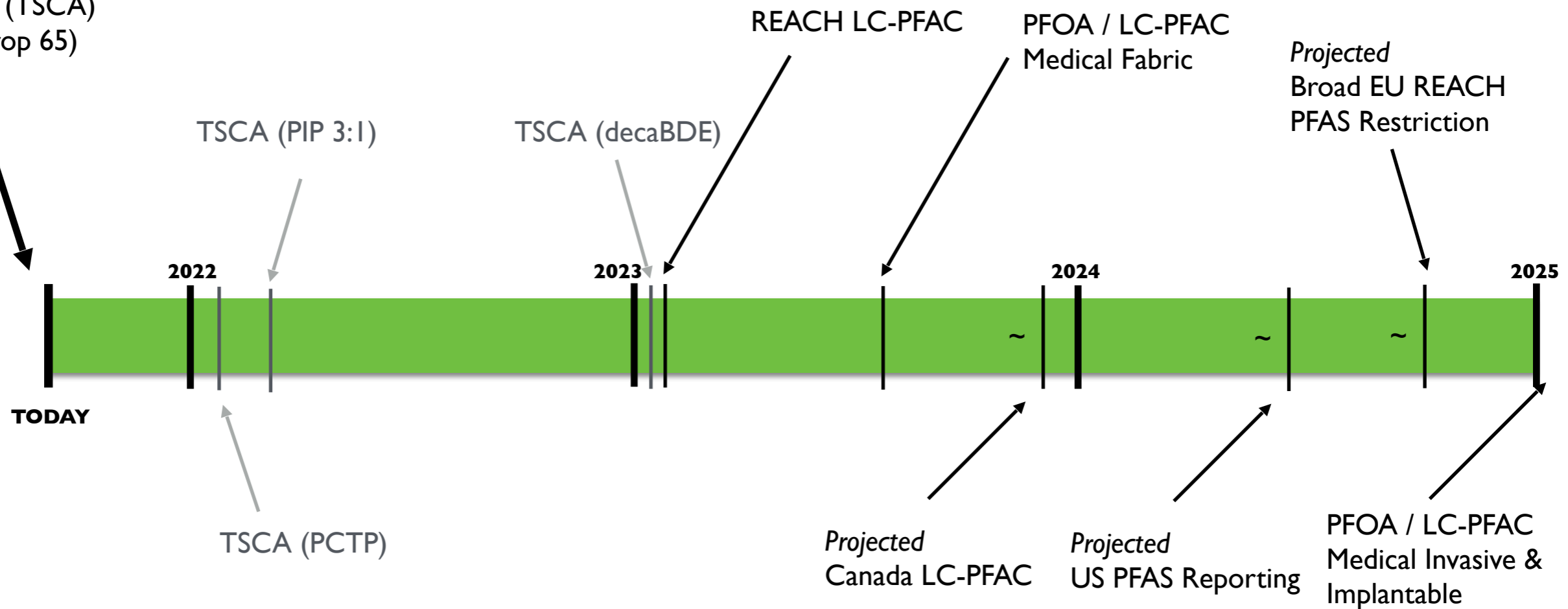


... not to mention REACH SVHC updates every six months and Prop 65 every year.

PFAS Deadlines

Already in place (2021)

- EU
- PFOA (POP)
- PFOS (SVHC)
- US
- LC-PFAC (TSCA)
- PFOA (Prop 65)



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What are PFAS (**P**er- and **P**oly-**f**luoroalkyl **S**ubstances)

- **Per**fluoroalkyl substances
 - More commonly referred to as PFAS
 - Building blocks of many water proof coatings
 - Processing aid for manufacturing of fluoropolymers
 - **Longer chain** perfluoroalkyl substances are **bioaccumulants**
 - Examples - PFOA, PFOS
- **Poly**fluoroalkyl substances
 - Fluorinated polymers
 - Such as PTFE, FKM, FEP, PVDF

Perfluoroalkyl Substances (PFAS) - Chain Length

Fig. 1

PFOS Family

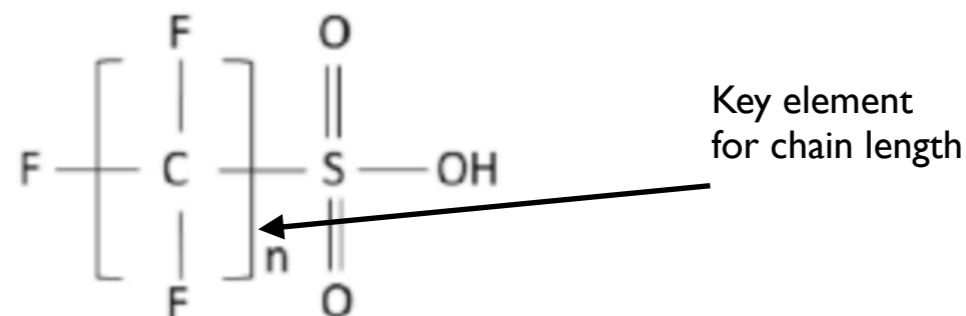
Perfluoroalkane sulfonic acids

Long-chain: $n \geq 6$

Short-chain: $n < 6$

Example short-chain representative:

PFBS ($n = 4$)



PFOA Family

Perfluoroalkyl carboxylic acids

Long-chain: $n \geq 7$

Short-chain: $n < 7$

Example short-chain representatives:

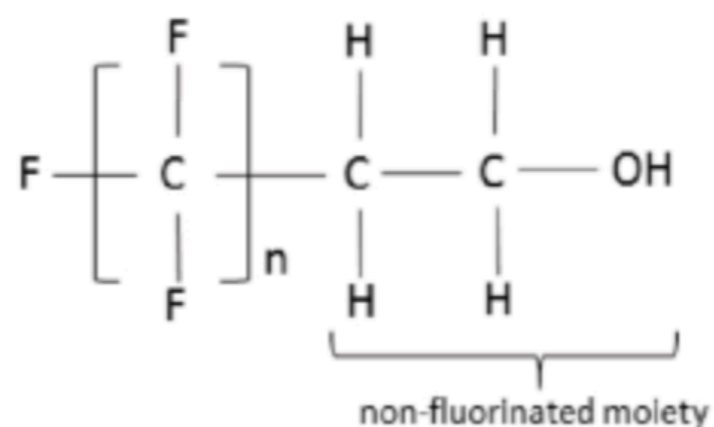
PFBA ($n = 3$), PFHxA ($n = 5$)



Example of short-chain precursors

4:2 fluorotelomer alcohol ($n = 4$)

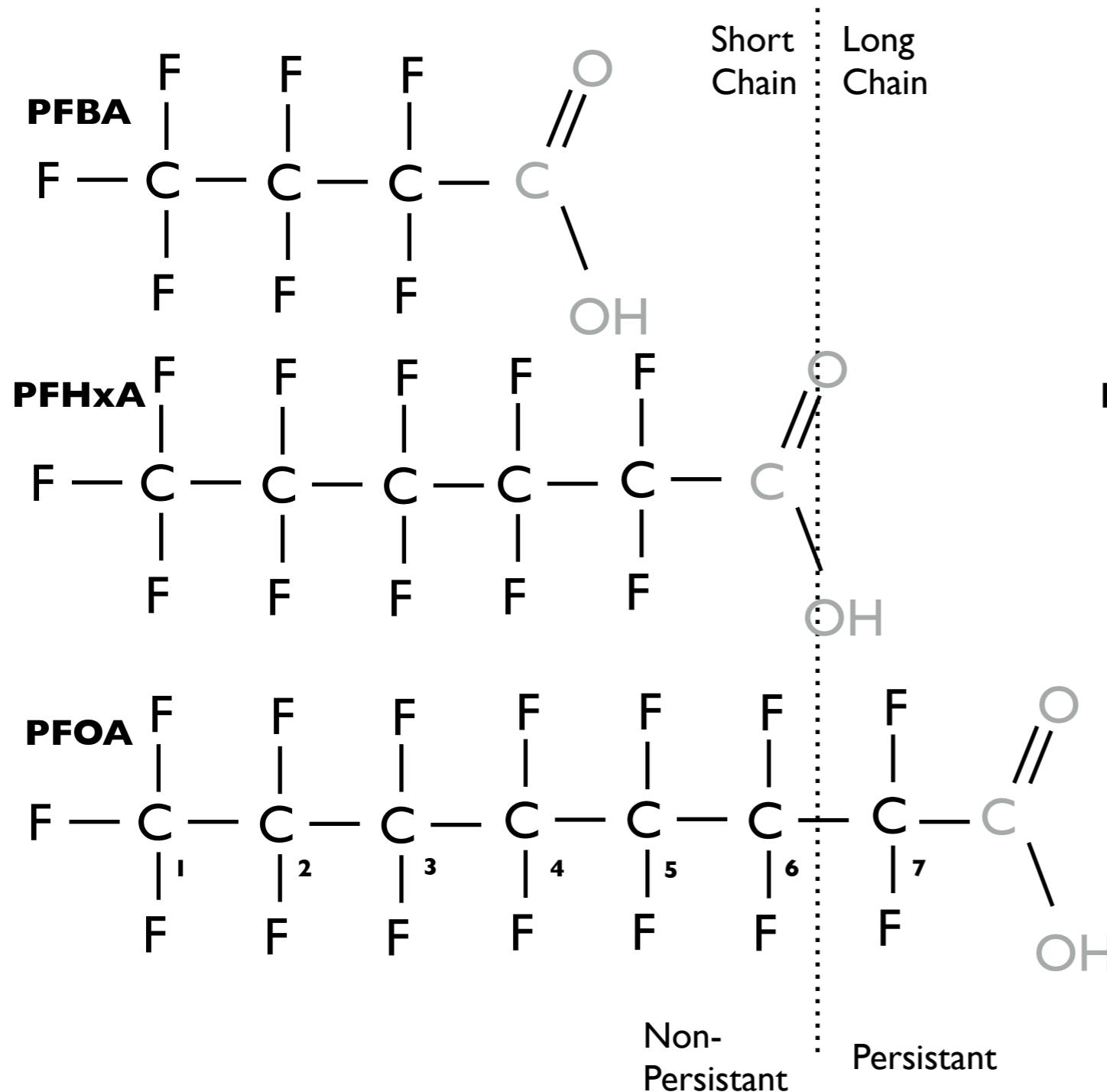
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Perfluoroalkyl Substances (PFAS)

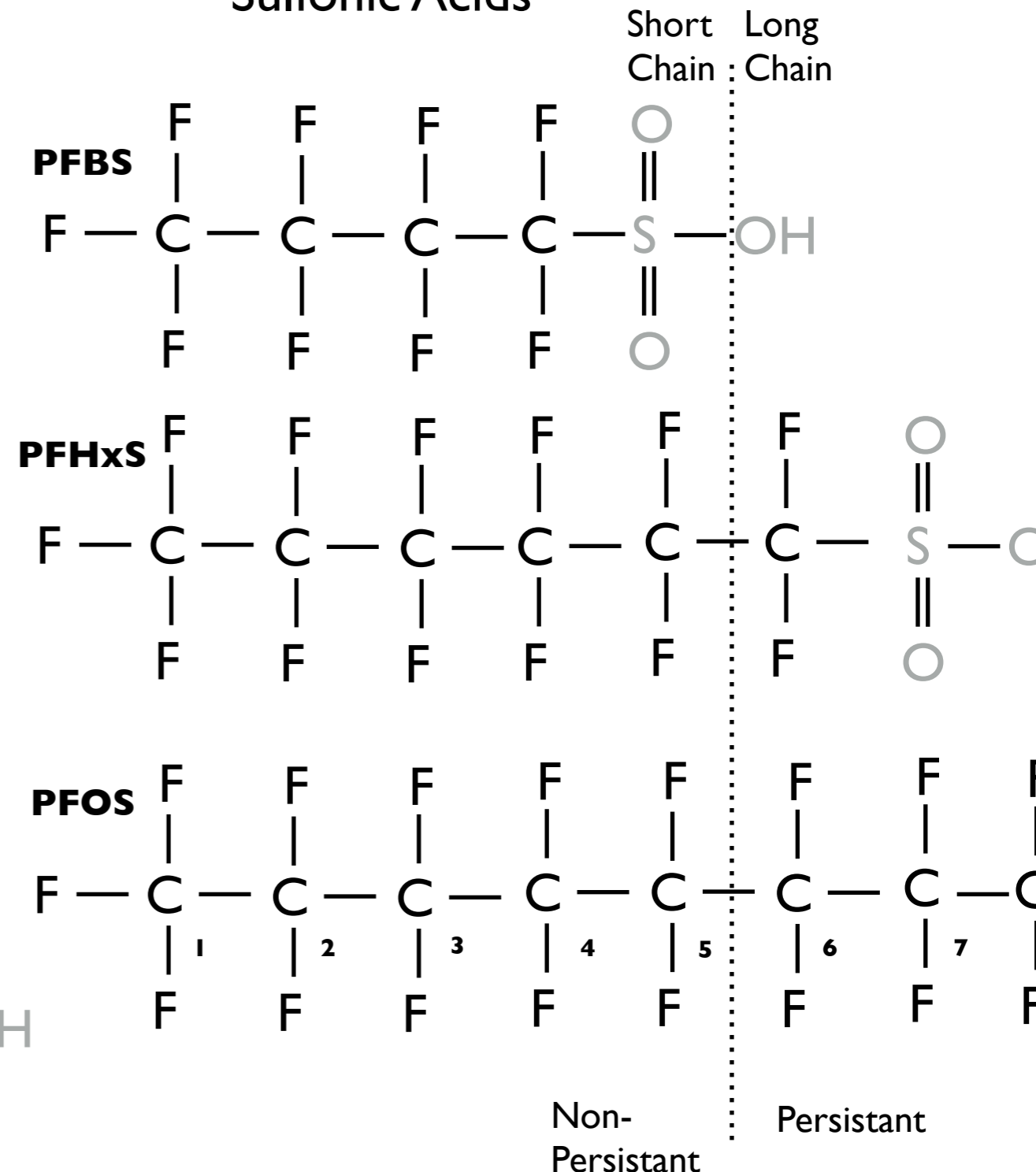
Perfluorinated carboxylate chemicals

Carboxylic Acids



Perfluoroalkyl sulfonate chemicals

Sulfonic Acids

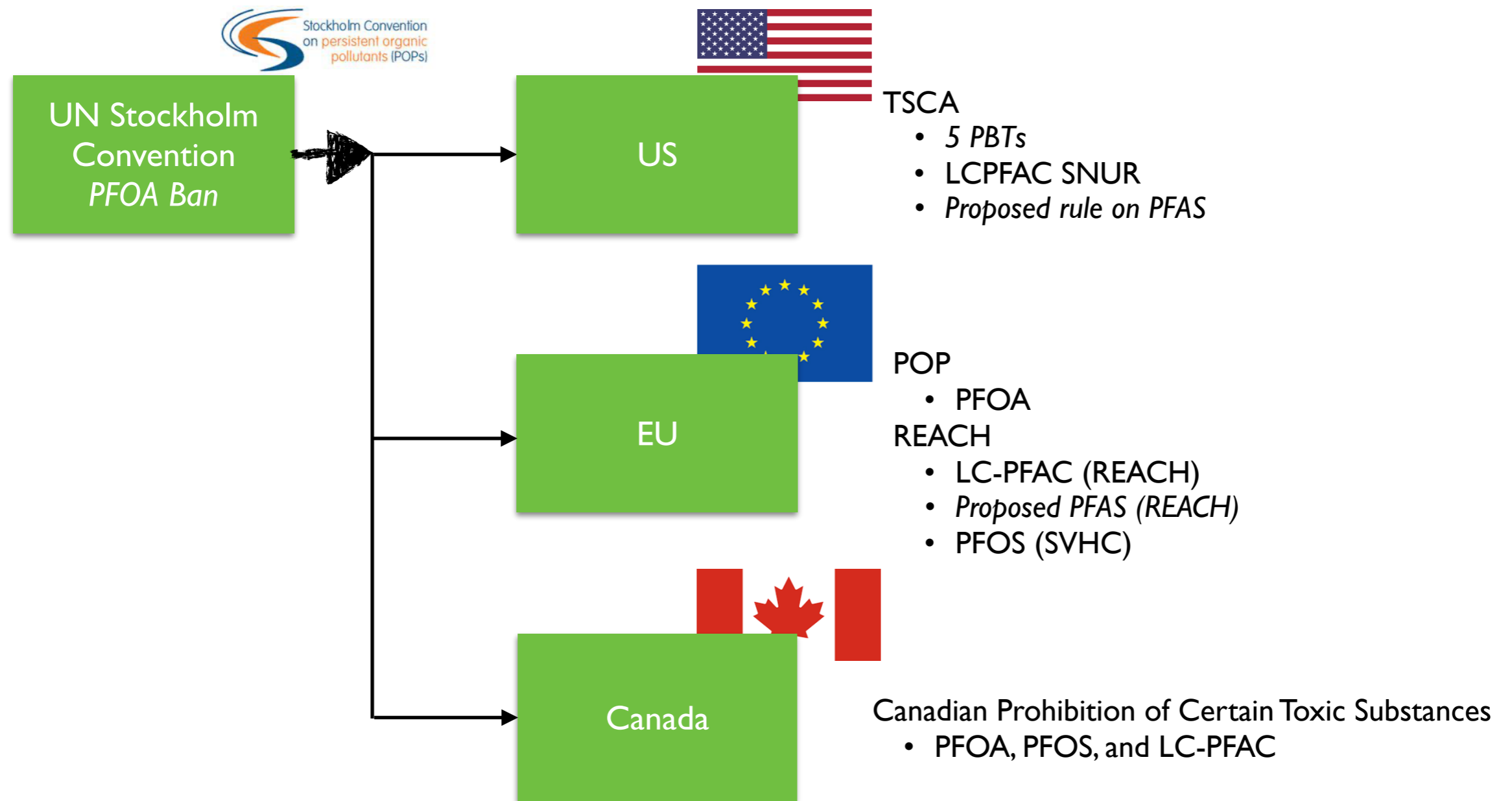


High Risk Uses PFAS

- LC-PFAC common locations fluoro coatings
 - fabric
 - membranes
 - steel mesh screens
 - silicone touch pads
 - Non-stick food contact surfaces
 - High durability touchscreen
 - Lithium Ion Batteries (electrode binder)
- Plus fluoropolymers (PTFE, FKM, FEP, etc.)

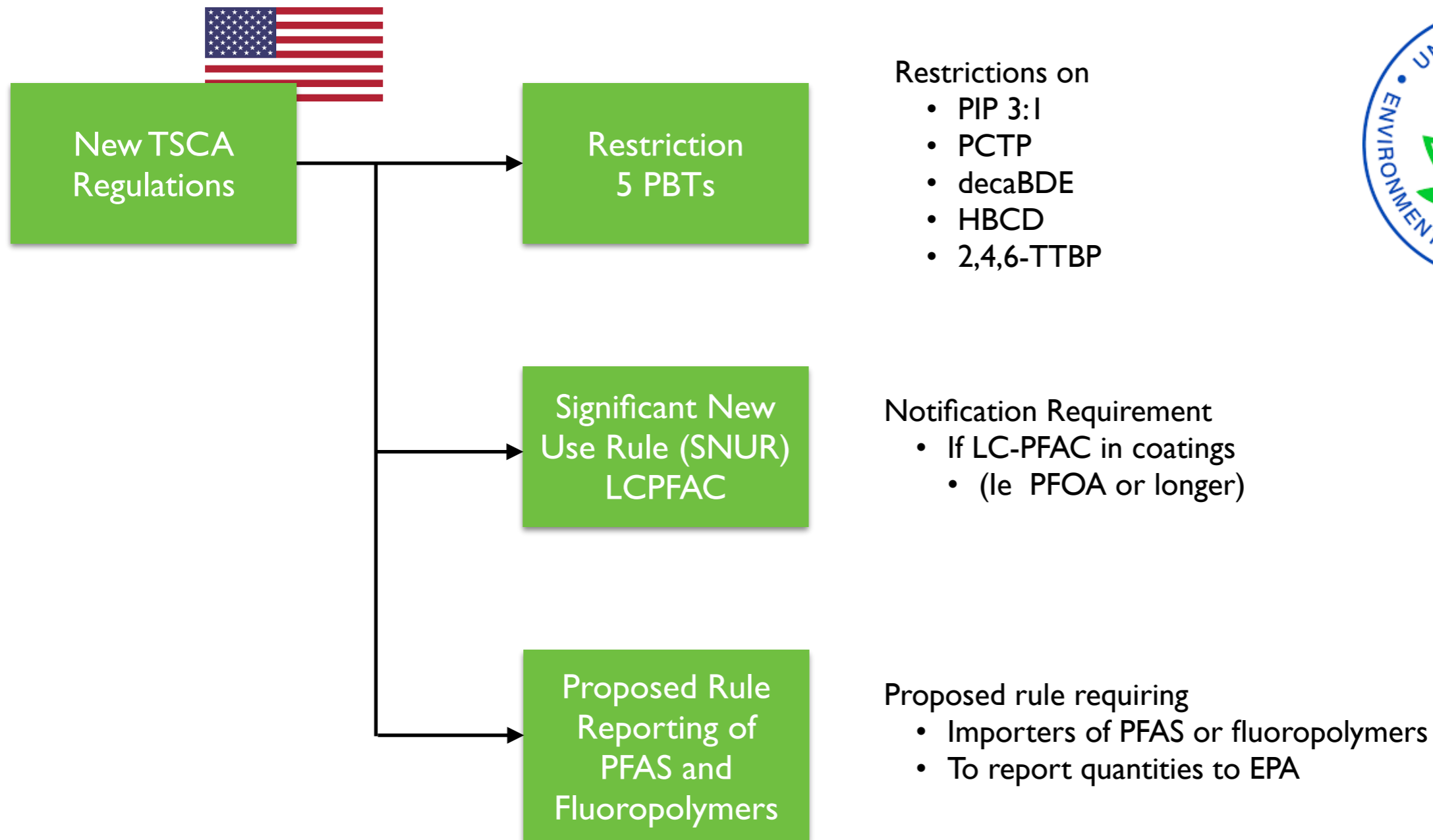


PFAS Regulation



+ other jurisdictions have emerging PFAS regulations

New US TSCA Regulations

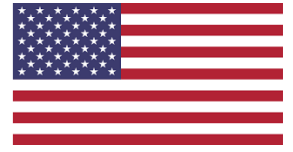


Does not apply to medical devices

US Perfluorinated Substances SNUR Notification



- Long-chain perfluoroalkyl carboxylate (LCPFAC) chemical substances
 - Require notification to EPA if
 - a subset of LCPFAC chemicals imported as part of a surface coating on articles
- In effect - September 25 2020
 - Does not include FDA regulated products (ie. medical devices)
- <https://www.federalregister.gov/documents/2020/07/27/2020-13738/long-chain-perfluoroalkyl-carboxylate-and-perfluoroalkyl-sulfonate-chemical-substances-significant>



US LC-PFAC Requirements

- Substance under scope of notification (SNUR) in coating of articles
 - LCPFACs
 - long-chain category of perfluorinated carboxylate chemical substances with perfluorinated carbon chain lengths equal to or greater than seven carbons and less than or equal to 20 carbons
- Scope
 - Coatings on articles (coatings on physical products)

US LC-PFAC Requirements Coatings



- *From original guidance*
- What is a surface coating
 - A coating is a material applied in a thin layer to a surface as a protective, decorative, or functional film. The term “coating” often refers to paints such as lacquers or enamels, but also refers to films applied to other materials including, but not limited to, paints, varnishes, sealants, adhesives, inks, maskants, and temporary protective coatings

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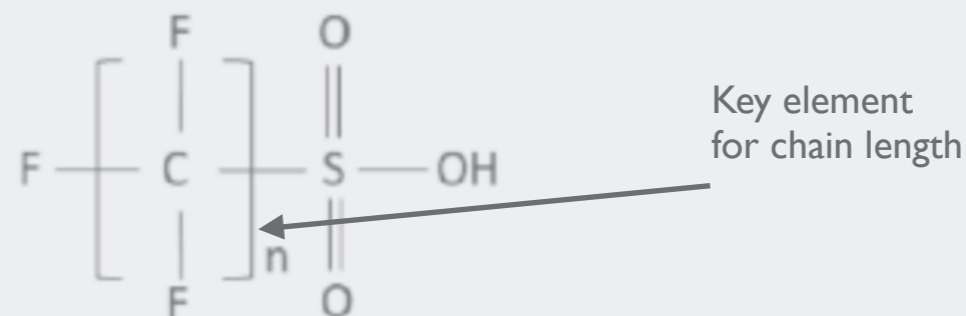
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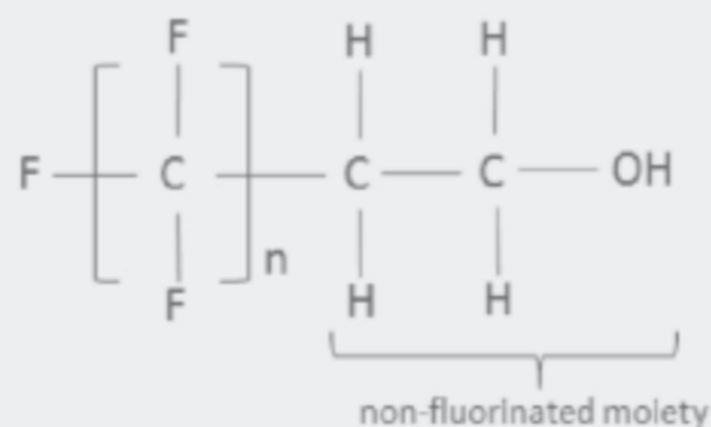
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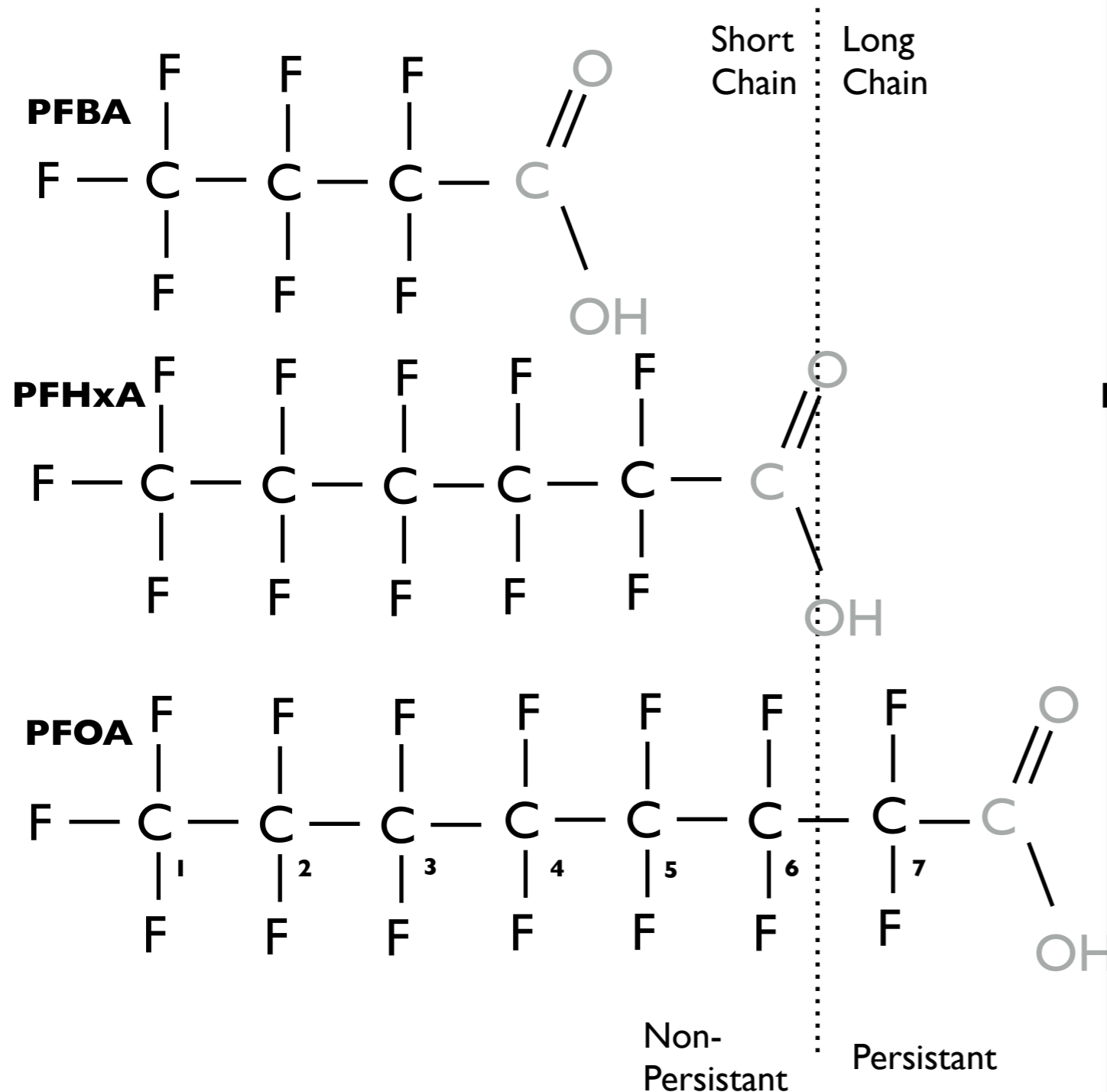


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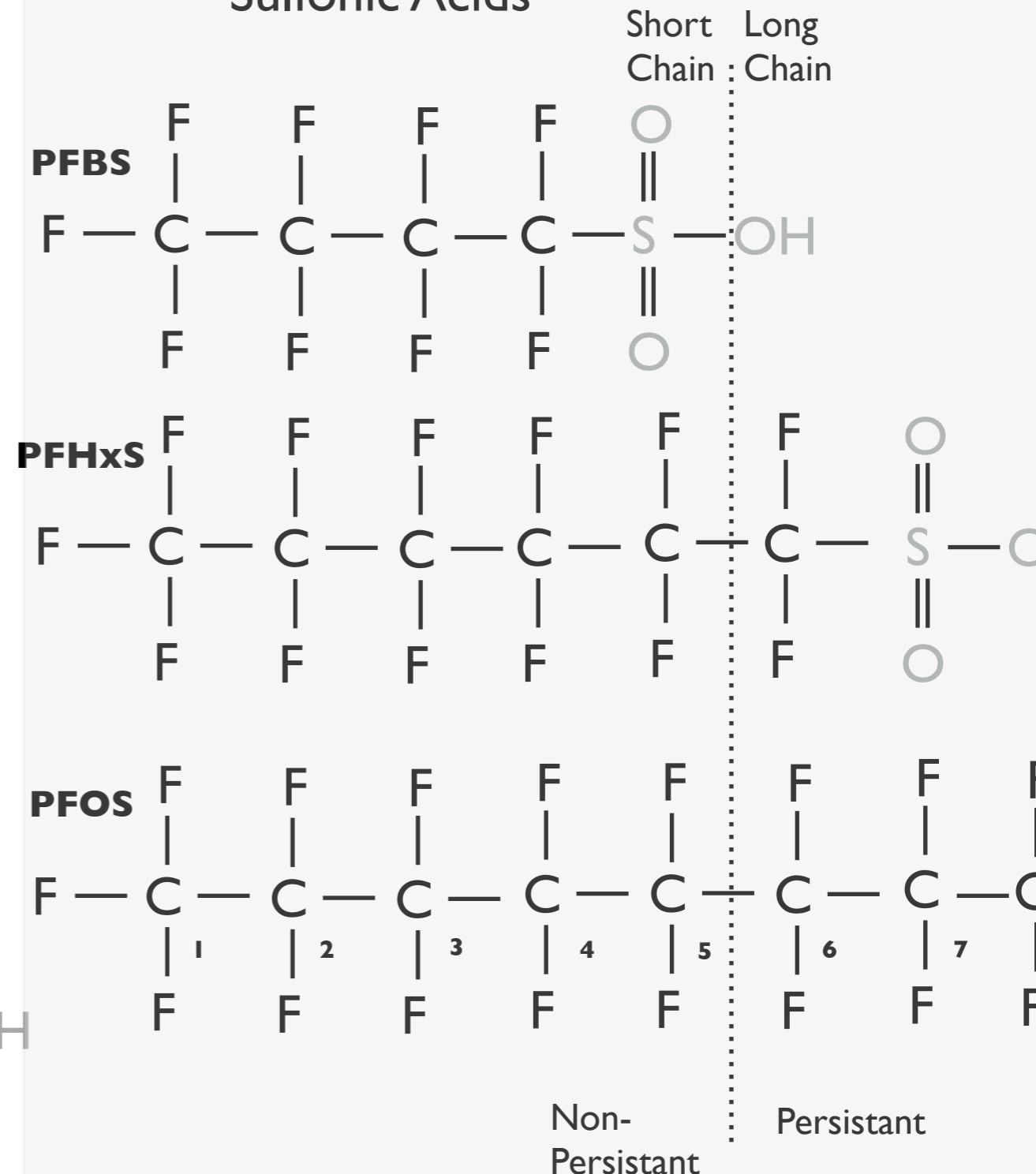
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Perfluoroalkyl sulfonate chemicals

Sulfonic Acids



New Proposed US Rule PFAS and Fluoropolymers

- NEW Proposed reporting requirements US
 - New proposed rule
 - <https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0549-0001>
 - Does not apply to medical devices
- Proposed
 - Reporting of any PFAS or fluoropolymers in articles and/or coatings in products since Jan 2011
 - Data gathering only
 - Still in consultation

New Proposed US Rule PFAS and Fluoropolymers



- Substances under scope
 - Initial review
 - **Standard PFAS** (perfluoroalkyl substances)
 - Carboxylates (ex. PFOA)
 - Sulfonates (ex. PFOS)
 - Fluoroalcohols
 - And **fluoropolymers**
 - Under the line "3. Fluoro polymer (for example, polymers made from tetrafluoroethene (C₂F₄), hexafluoropropene (C₃F₆) and/or halotrifluoroethene (C₂F₃halo))"
 - PTFE (fluoropolymer made from C₂F₄)
 - FKM (fluoropolymer made from C₃F₆)
 - Still in consultation (strong industry push back)
 - Industry comments due - August 27, 2021
 - Text

New REACH Restriction LC-PFAC - High Risk Materials

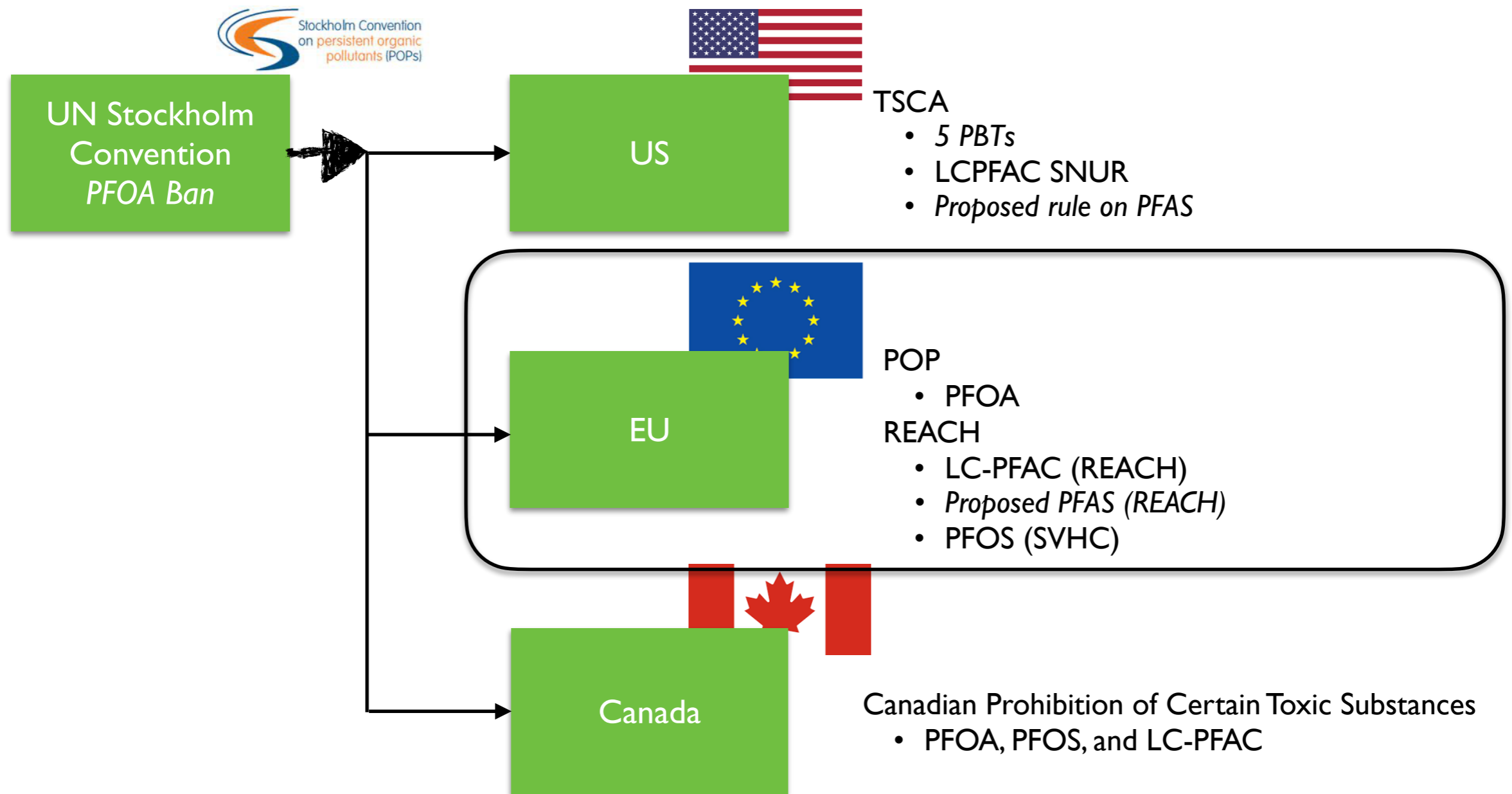
- LC-PFAC common locations of fluoro coatings
 - Fabric
 - Membranes
 - Steel mesh screens
 - Silicone touch pads
 - Non-stick food contact surfaces
 - High durability touchscreen
 - Lithium Ion Batteries (electrode binder)
- Plus fluoropolymers (PTFE, FKM, FEP, etc.)



US (California) - Proposition 65

- August 2021:
 - Three hundred eighty-one (381) notices
- PFOA
 - Prosecutions (6 total)
 - Mineral water
 - Makeup concealer X3
 - Ski wax
 - Dental floss
 - Coatings and mineral water only.

PFAS Regulation



Current PFAS Regulation

PFOA and PFOS

- PFOA
 - Banned at 25 ppb under EU POP Regulation
 - Already in effect
 - Medical devices
 - Medical textiles July 4 2023
 - Medical invasive and implantable July 4 2025
 - REACH SVHC at 1,000 ppm (low risk)
- PFOS
 - REACH SVHC at 1,000 ppm (low risk)

New REACH Restriction LC-PFAC

- Ban on long chain perfluorocarboxylic acids
 - Linear and branched perfluorocarboxylic acids containing 9 to 14 carbon atoms in the chain ('C9-C14 PFCAs')
 - February 23 2023
- Restrictions
 - 25 ppb
 - Very similar to PFOA ban (PFOA is 8 carbon atoms)
 - This is 9 carbon atoms and longer
- Details -
 - <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021R1297>

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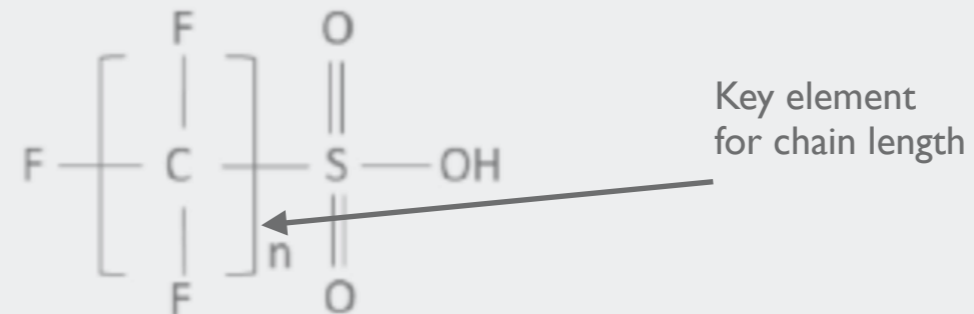
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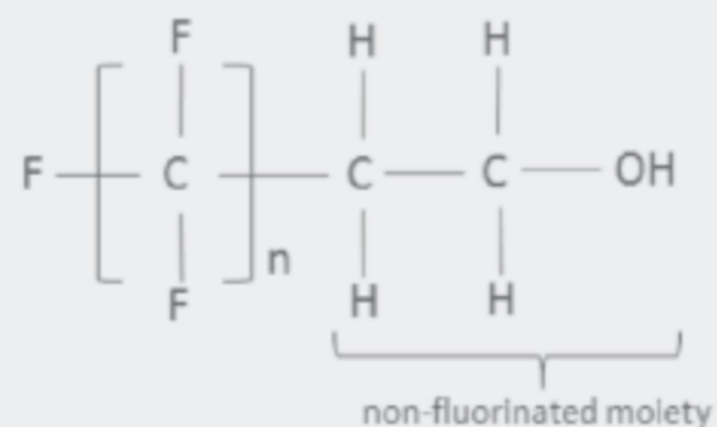
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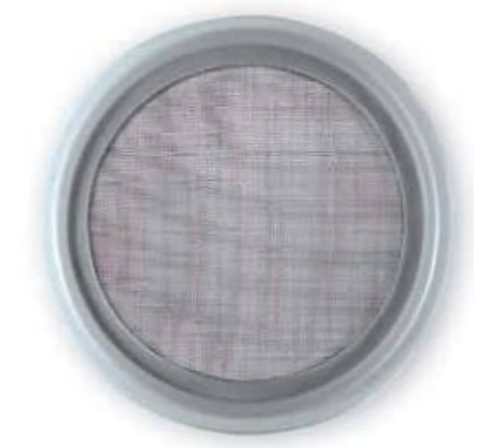


New REACH Restriction LC-PFAC

- Timelines
 - Deadline - Feb 25 2023
 - Medical textiles - July 4 2023
 - Invasive and implantable devices - July 4 2025

New REACH Restriction LC-PFAC - High Risk Materials

- LC-PFAC common locations of fluoro coatings
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- Plus fluoropolymers (PTFE, FKM, FEP, etc.)

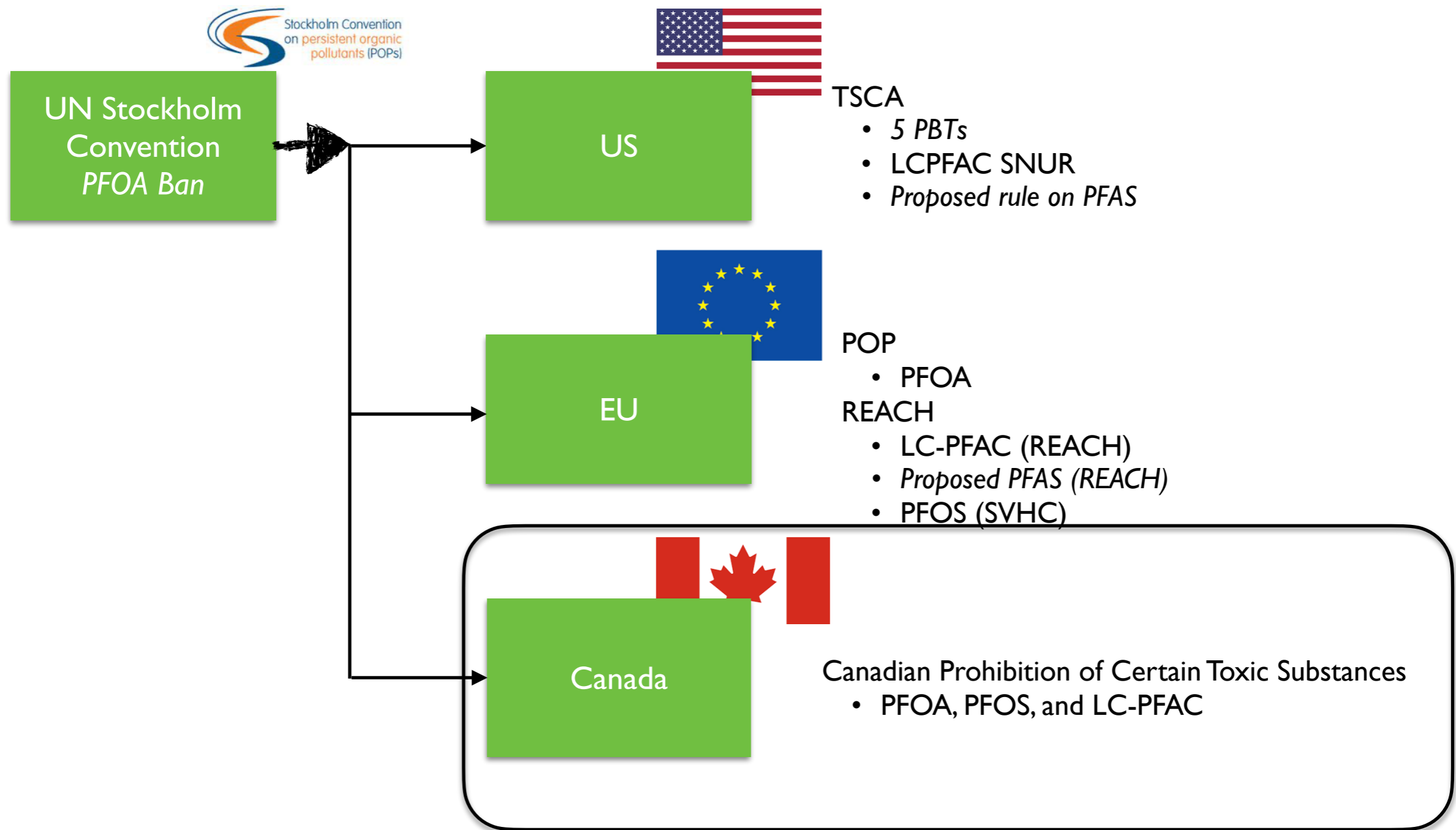


Proposed REACH Restriction All PFAS and Fluoropolymers

- Proposal stage
 - Intention to place restriction on PFAS
 - Initial data gathering includes PFAS and fluoropolymers
- Current stage
 - Data gathering on uses of PFAS and fluoropolymers in EU
 - At least a year away from a specific proposal
 - Unlikely to include fluoropolymers
- Details -
 - <https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18663449b>



PFAS Regulation



Prohibition - LC-PFAC

- Ban on long chain perfluorocarboxylic acids
 - Removal of exemption for LC-PFAC in articles
 - Expected to be published in 2021
 - Into effect ~2023 or later
- Restrictions
 - No threshold (likely to use 25 ppb as non-detect)
- Details -
 - <https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/proposed-amendments-certain-toxic-substances-2018-consultation/chapter-2.html#toc11>



PFAS Compliance Principle Options

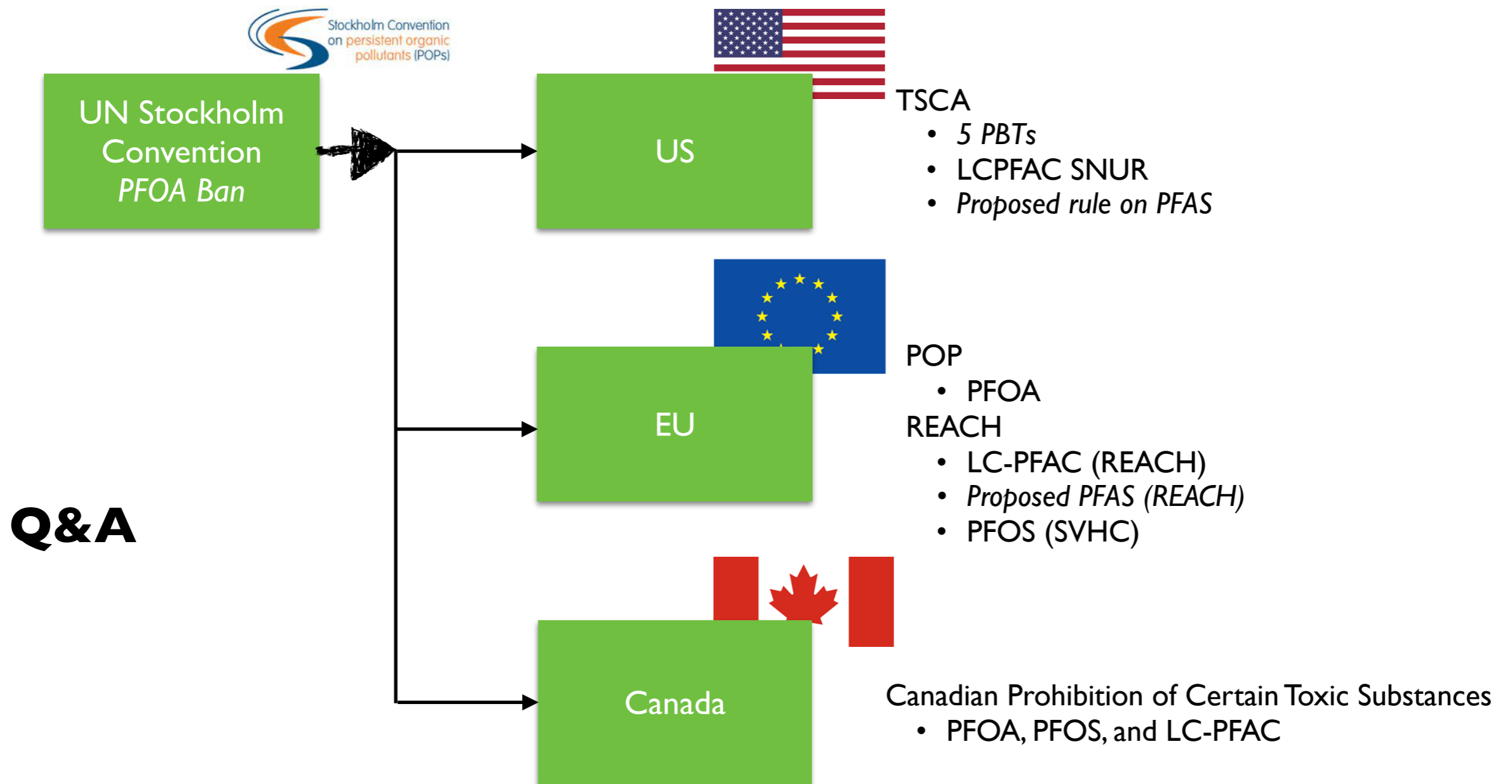
- Combining with other emerging restricted materials compliance
 - Testing high risk materials for TSCA PBT (ie. PIP 3:1) at the same time as LC-PFAC
 - For large diverse product lines
 - Short term - test representative parts to show due diligence
 - Long term - merge it in with the rest of your global compliance

PFAS Compliance

Common Industry Approach

- Choose representative products in each product family
 - Test high risk parts
 - Use the reports as due diligence
 - Expand testing or supplier work based on results
- Advantages
 - Less expensive, faster, and definitive
 - If positives are found, adjust compliance plan
- It is new for everyone. Definite and timely is better

PFAS Regulation



Q&A

+ other jurisdictions have emerging PFAS regulations