

# Managing New US Federally Restricted Substances

TSCA 5 PBTs and EPA SNUR on perfluoralkyl substances

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# Overview - Agenda -

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- Introduction
- Upcoming Deadlines
- TSCA
  - Legal basis
  - Substances
  - Deadlines and restrictions
- US EPA LC-PFAC
  - Rules and scope
  - Long chain versus short chain
- Q&A

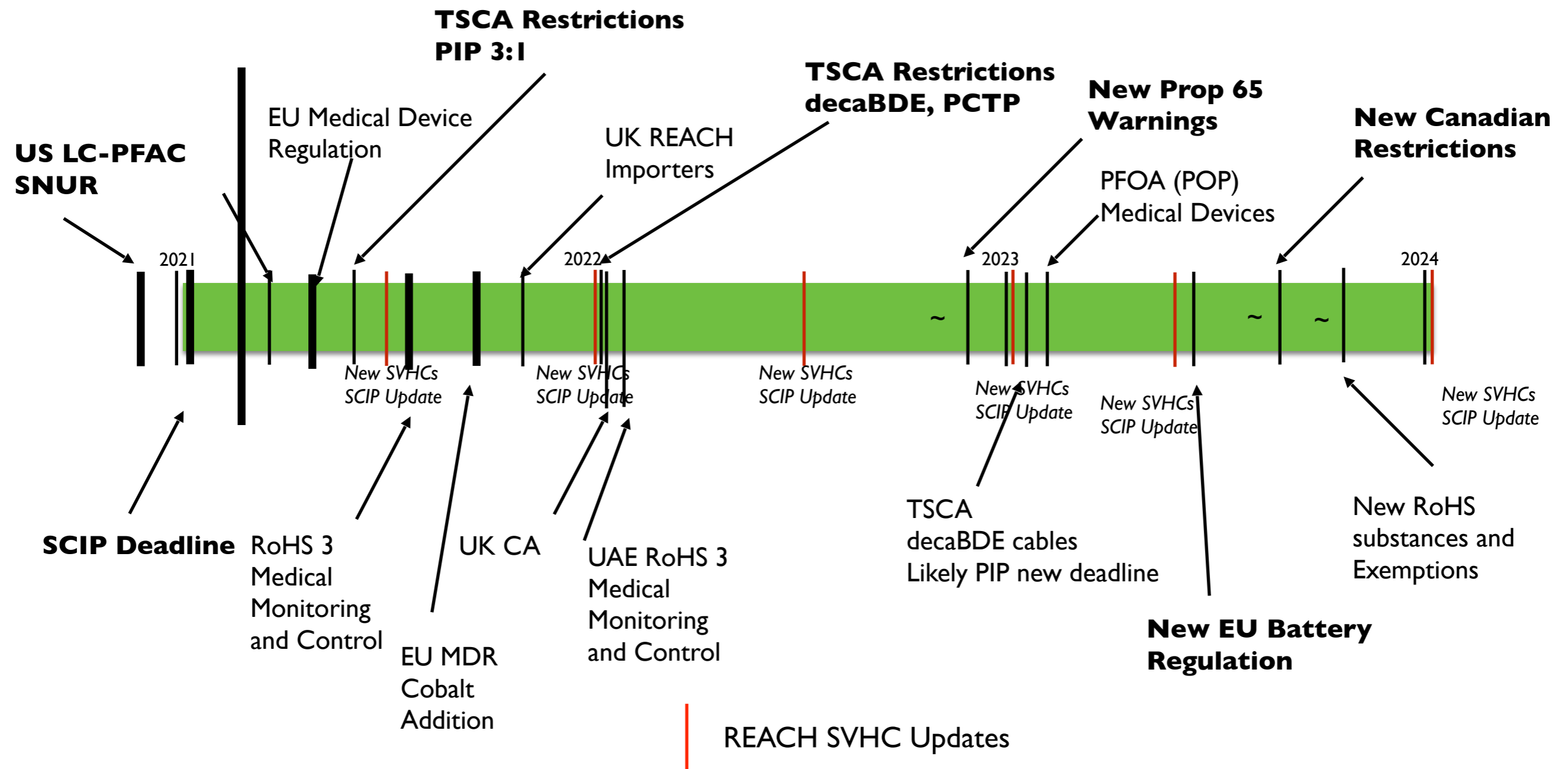


Webinar is 50 minutes with 10  
minutes of Q&A  
(hopefully)



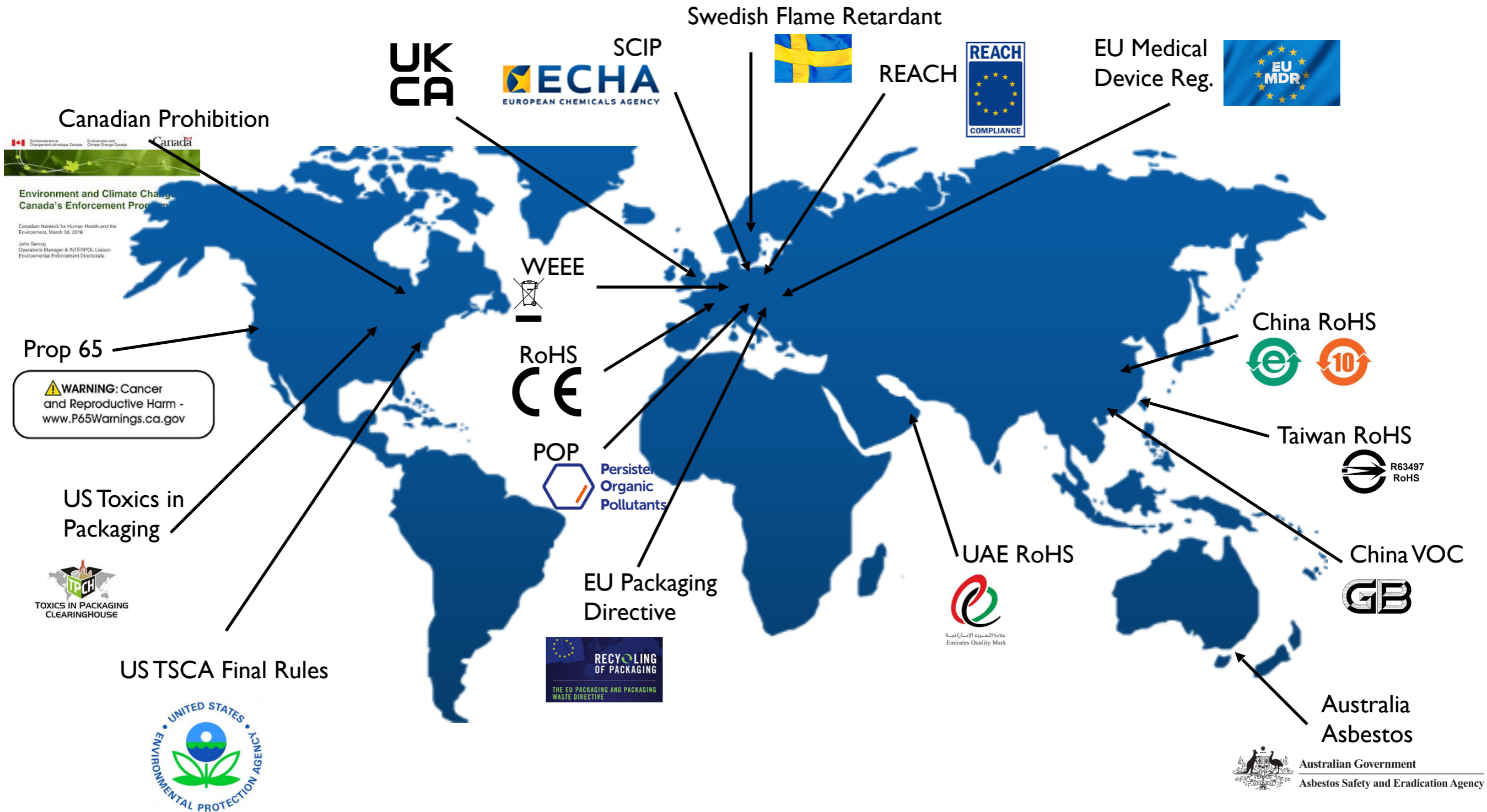
# Restricted Materials

## Upcoming Deadlines



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

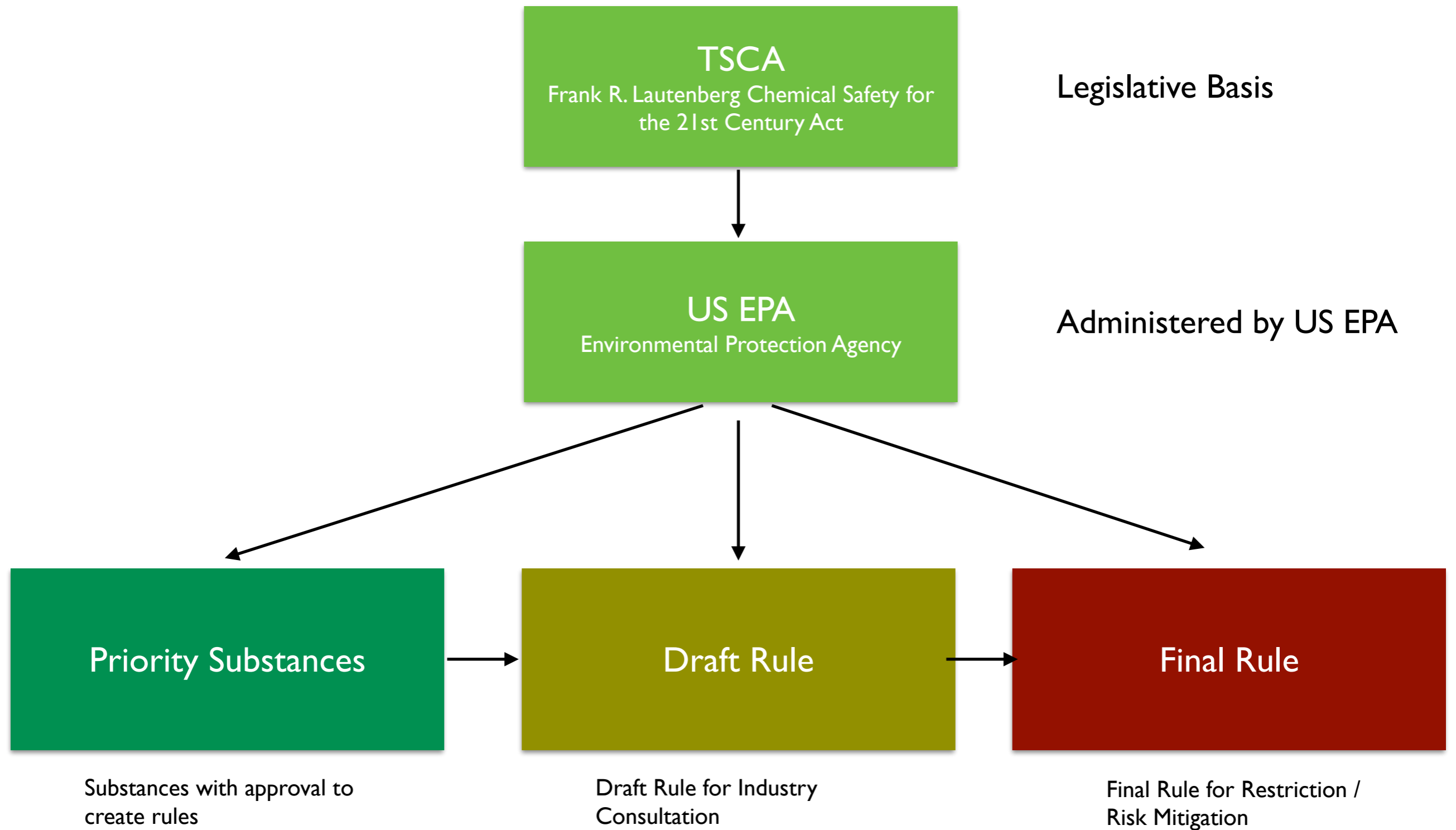
# Global Restricted Materials Requirements



Compliance with each is MANDATORY to sell in each jurisdiction



# US Federal Chemical Legislation



# EPA (TSCA) Restricted Substances

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- EPA published restrictions on five (5) substances
  - 2,4,6-TTBP (732-26-3) 2,4,6-Tris(tert-butyl)phenol
  - **DecaBDE** (1163-19-5) Decabromodiphenyl ether
  - **PCTP** (133-49-3) Pentachlorothiophenol
  - **PIP (3:1)** (68937-41-7) Phenol, isopropylated, phosphate (3:1)
  - HCBD (87-68-3) Hexachlorobutadiene
  
- Application / Scope
  - Most are restrictions in article
    - Believed to be at the component level (part of an article)
  - Does not apply to FDA exempted products
    - ie. medical devices
  - Subject to a 60 day pause / review by new US administration

# EPA (TSCA) Restricted Substances

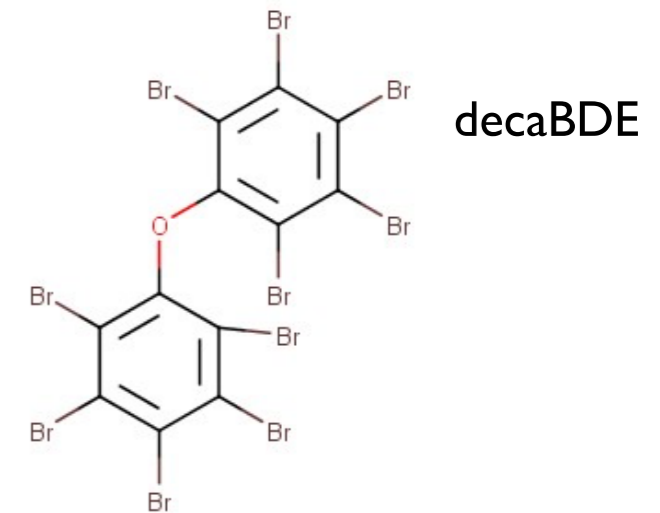
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- March 8, 2021 actions
  - 60-day comment period on all five restrictions
  - 180-day 'no action assurance' on PIP 3:1
- <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/public-comment-period-pbt-rules-and-no-action-assurance>

# EPA (TSCA) Restricted Substances

## Decabromodiphenyl ether (DecaBDE)

- Restriction
  - Restricted in articles (and chemicals)
  - Concentration limit unclear (0.1% would be a default)
- Deadline
  - General - Jan 6 2022
  - Wire and Cable - Jan 6 2023
- High risk materials
  - Thin flame retarded plastics such as heat shrink and nylon connectors
- Final Rule
  - 2020-28686.pdf ([govinfo.gov](https://www.govinfo.gov))





# EPA (TSCA) Restricted Substances

## Pentachlorothiophenol (PCTP)

- Restriction

- Restricted in articles (and chemicals)
  - 1% limit

- Deadline

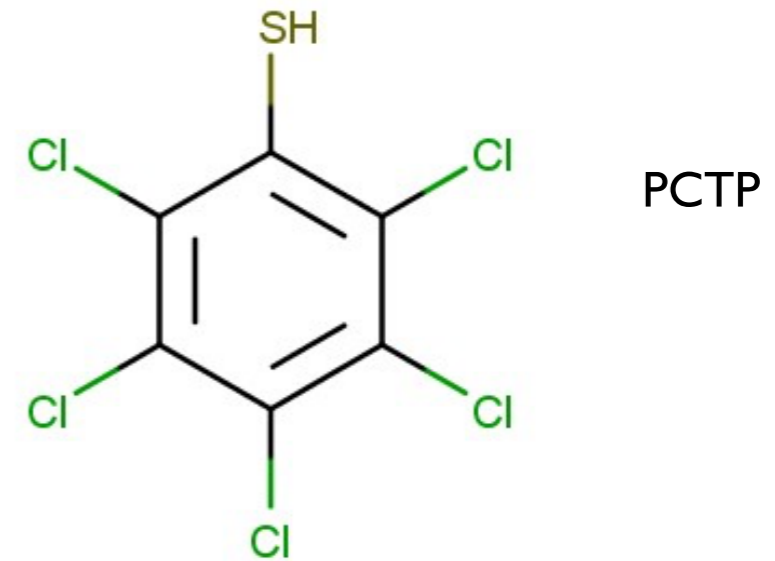
- January 6, 2022

- High risk materials

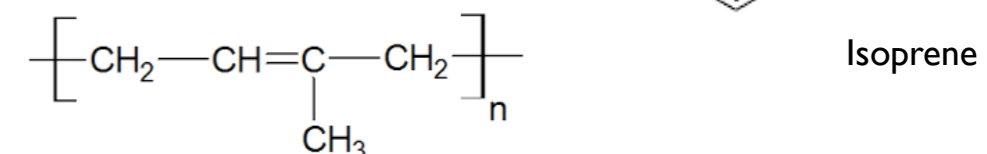
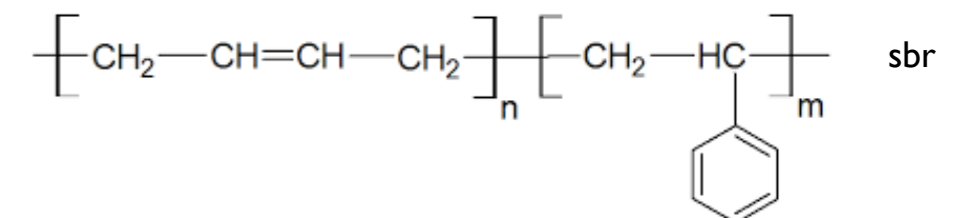
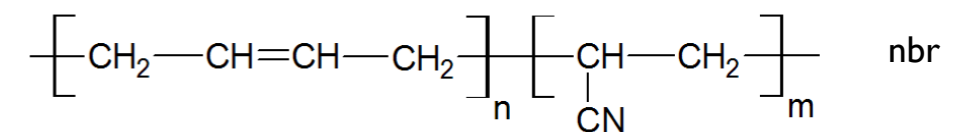
- Vulcanizer
- Butadiene (ex. nbr, sbr) or isoprene rubbers

- Final Rule

- 2020-28689.pdf (govinfo.gov)



Butadiene

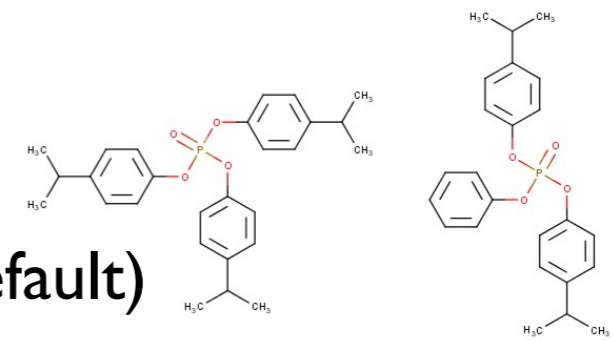


# EPA (TSCA) Restricted Substances

## Phenol, isopropylated, phosphate (3:1) PIP (3:1)

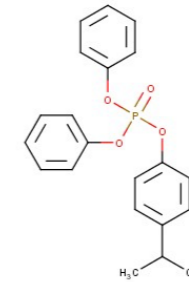
- Restriction

- Restricted in articles (and chemicals)
- Concentration limit unclear (0.1% would be a default)



- Deadline

- Originally - March 8 2021
- No action assurance - September 4 2021



PIP 3:1

- High risk materials

- Flame retarded PVC, polyurethane foam, and BPA epoxies
- Polyurea flame retarded lubricant (allowed)

- Final Rule

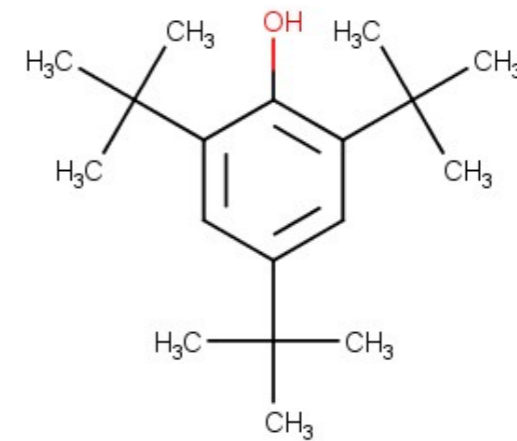
- [2020-28692.pdf \(govinfo.gov\)](#)

# EPA (TSCA) Restricted Substances

## 2,4,6-Tris(tert-butyl)phenol (2,4,6-TTBP)

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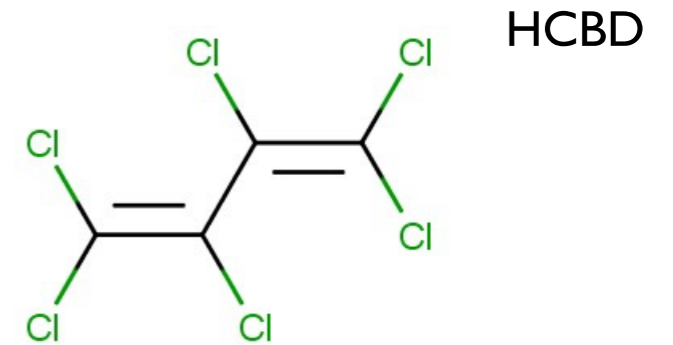
- Restriction
  - 0.3% in chemicals only
  - Not articles
- Deadline
  - 60 days after February 5 2021 (April 6 2021)
- High risk materials
  - Lubricants sold separately of articles
- Final Rule
  - [2020-28690.pdf \(govinfo.gov\)](#)



2,4,6-TTBP

# EPA (TSCA) Restricted Substances Hexachlorobutadiene (HCBD)

- Restriction
  - Restricted in articles (and chemicals)
  - Concentration limit unclear (0.1% would be a default)
- Deadline
  - March 8, 2021
- Low risk in articles
  - Intermediate of an intermediate (solvent of chlorine)
  - Also banned under EU POP Regulation
- Final Rule
  - [2020-28693.pdf](#) (govinfo.gov)



# US Perfluorinated Substances Notification

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- 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

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- 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)
- Guidance
  - [https://www.epa.gov/sites/production/files/2021-01/documents/final\\_lcpfac-snur\\_surface-coating-compliance-guide\\_0.pdf](https://www.epa.gov/sites/production/files/2021-01/documents/final_lcpfac-snur_surface-coating-compliance-guide_0.pdf)



# US LC-PFAC Requirements Coatings

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- 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

# US LC-PFAC Requirements

## Coatings - Scope

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- Subject to SNUR if it meets one of the following criteria
  - coating on any surface of an article that is in direct contact with humans or the environment during the article's normal use or reuse, whether the coating is oriented towards the interior or exterior of the article;
  - coating on any internal component, even if facing the interior of the article, if that component is in contact with humans or the environment during the article's normal use or reuse.

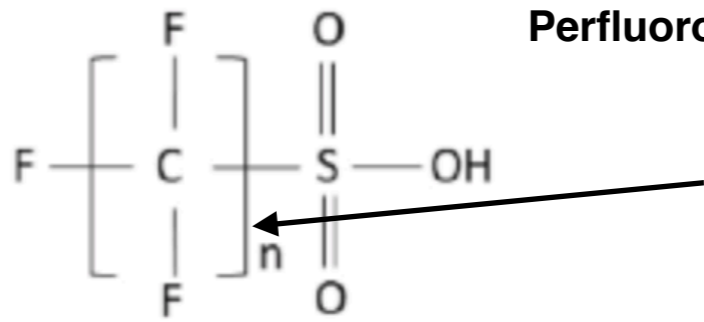
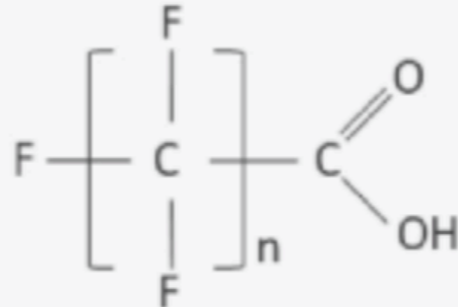
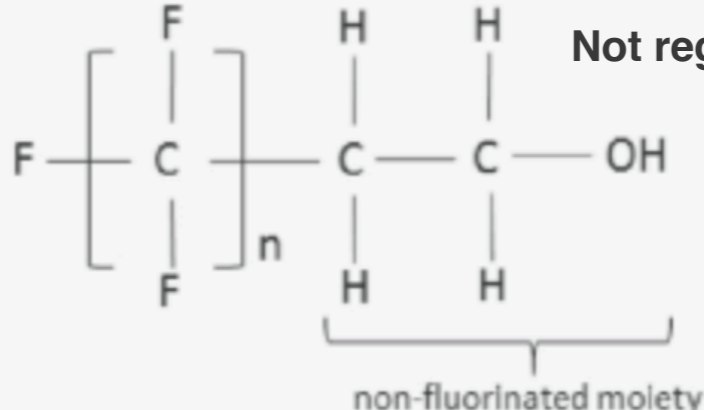
# Perfluoroalkyl Substances (PFAS) - Chain Length

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- Polyfluorinated substances
  - Become more and more regulated
  - Examples
    - PFOA, PFOS
- In general
  - Long chain - persistent bioaccumulants - regulated
  - Short chain - not persistent bioaccumulants - not generally regulated
- Regulations (at least some long chain PFAS)
  - EPA (SNUR)
  - EU POP + REACH SVHC
  - Canadian Prohibition
  - And others being added

# Perfluoroalkyl Substances (PFAS) - Chain Length

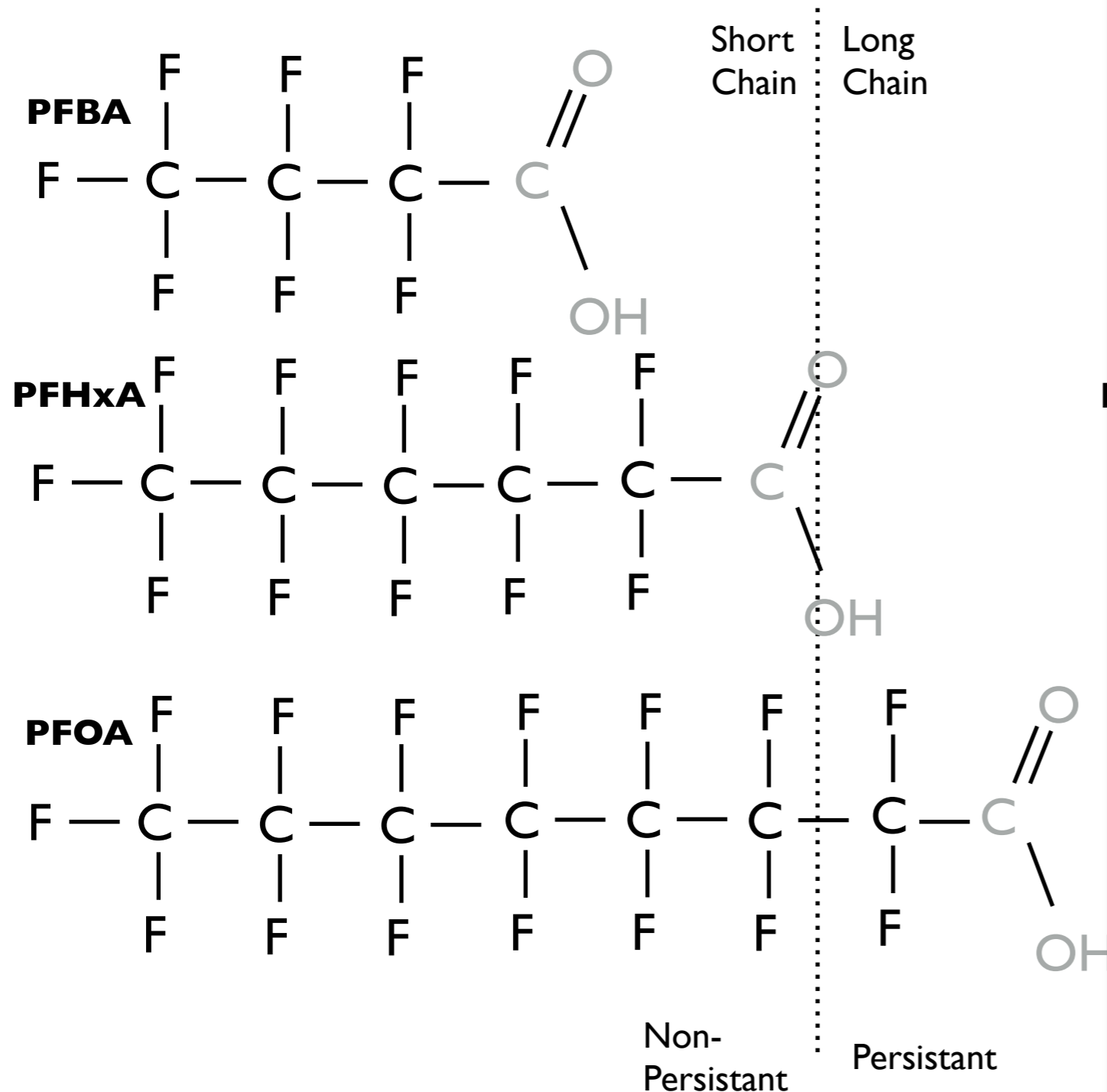
**Fig. 1**

<p>Perfluoroalkane sulfonic acids</p> <p>Long-chain: <math>n \geq 6</math> Short-chain: <math>n &lt; 6</math></p> <p>Example short-chain representative: PFBS (<math>n = 4</math>)</p>	<p style="text-align: right;"><b>Perfluoroalkyl sulfonate chemicals</b></p>  <p style="text-align: right;">Key element for chain length</p>
<p>Perfluoroalkyl carboxylic acids</p> <p>Long-chain: <math>n \geq 7</math> Short-chain: <math>n &lt; 7</math></p> <p>Example short-chain representatives: PFBA (<math>n = 3</math>), PFHxA (<math>n = 5</math>)</p>	<p style="text-align: right;"><b>Perfluorinated carboxylate chemicals</b></p> 
<p>Example of short-chain precursors</p> <p>4:2 fluorotelomer alcohol (<math>n = 4</math>) 6:2 fluorotelomer alcohol (<math>n = 6</math>)</p>	<p style="text-align: right;"><b>Not regulated yet</b></p>  <p style="text-align: center;">non-fluorinated moiety</p>

# Perfluoroalkyl Substances (PFAS)

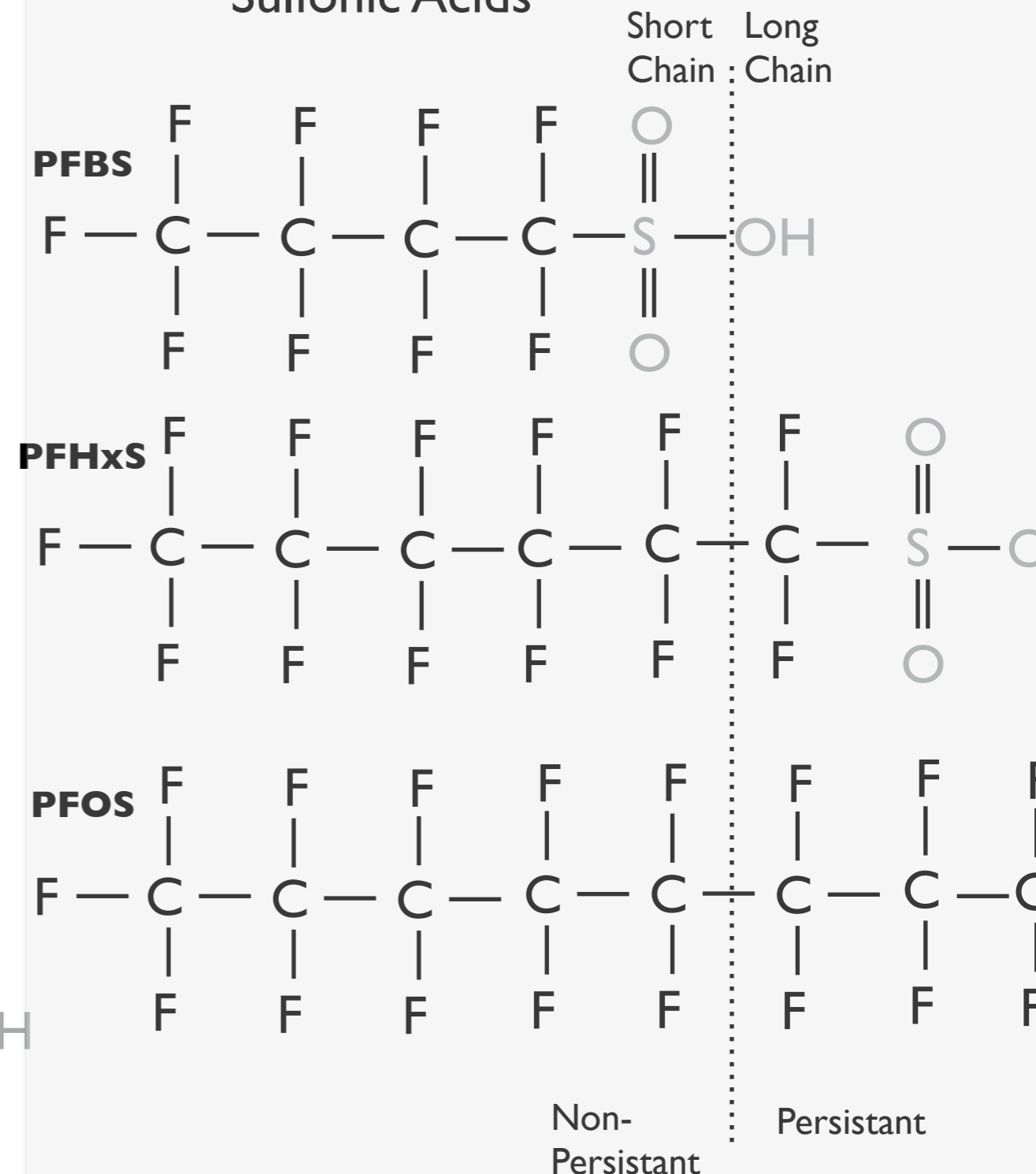
## Perfluorinated carboxylate chemicals

### Carboxylic Acids



## Perfluoroalkyl sulfonate chemicals

### Sulfonic Acids



# Perfluoroalkyl Substances (PFAS) High Risk Materials

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- Coatings
  - Fluoropolymer coatings (PTFE, FKM, PVDF, FEP)
  - Non-stick coatings
  - Water proof coatings
  - Plus ski wax and makeup
- Solid materials
  - (Not covered in EPA SNUR but under scope of EU POP)
  - Fluoropolymers (PTFE, FKM, PVDF, FEP)
- Firefighting foams
  - Not covered by the updated SNUR



# Claigan Approach

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- Representative testing
  - Testing sample high risk components from representative products
    - For TSCA and LC-PFAC
- Purpose
  - To provide baseline compliance for US TSCA and LC-PFAC
  - Within the practicality of time and cost

# Why Representative Testing

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- EPA acknowledges challenges of ‘complex durable goods’
  - Directly in the guidance
- Tangible compliance in a reasonable time / cost
  - Provides concrete and defensible data in weeks
- Most compliance in a reasonable time / cost
  - Provides concrete and defensible data in weeks

# Claigan TSCA Services

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Legacy Products  
(Product you already have)

## Claigan Rapid Approach

- Selecting and testing of representative high risk parts
- Screening for key substances
- Solved in weeks

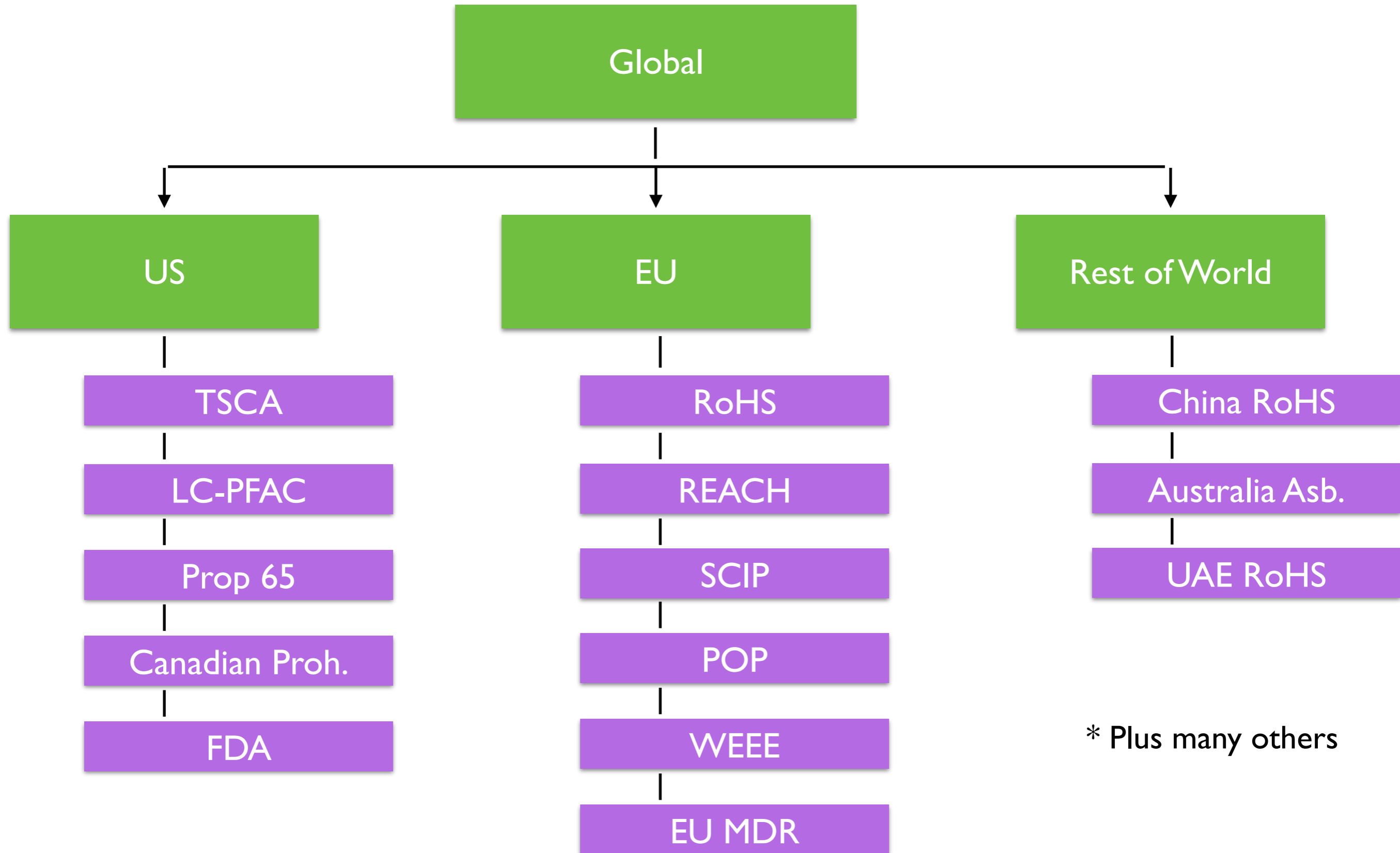
New Designs

## Comprehensive

- Testing of product to all requirements
- Screening for key substances
- Take advantage of overlapping requirements
- Solved conclusively in weeks not months



# Claigan Testing Global Product Compliance



# Claigan Approach

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- Representative testing
  - Testing sample high risk components from representative products
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Q&A