Claigan
Less Journey. More Results.

Claigan Webinar
Looking ahead to 2022

Presented by:
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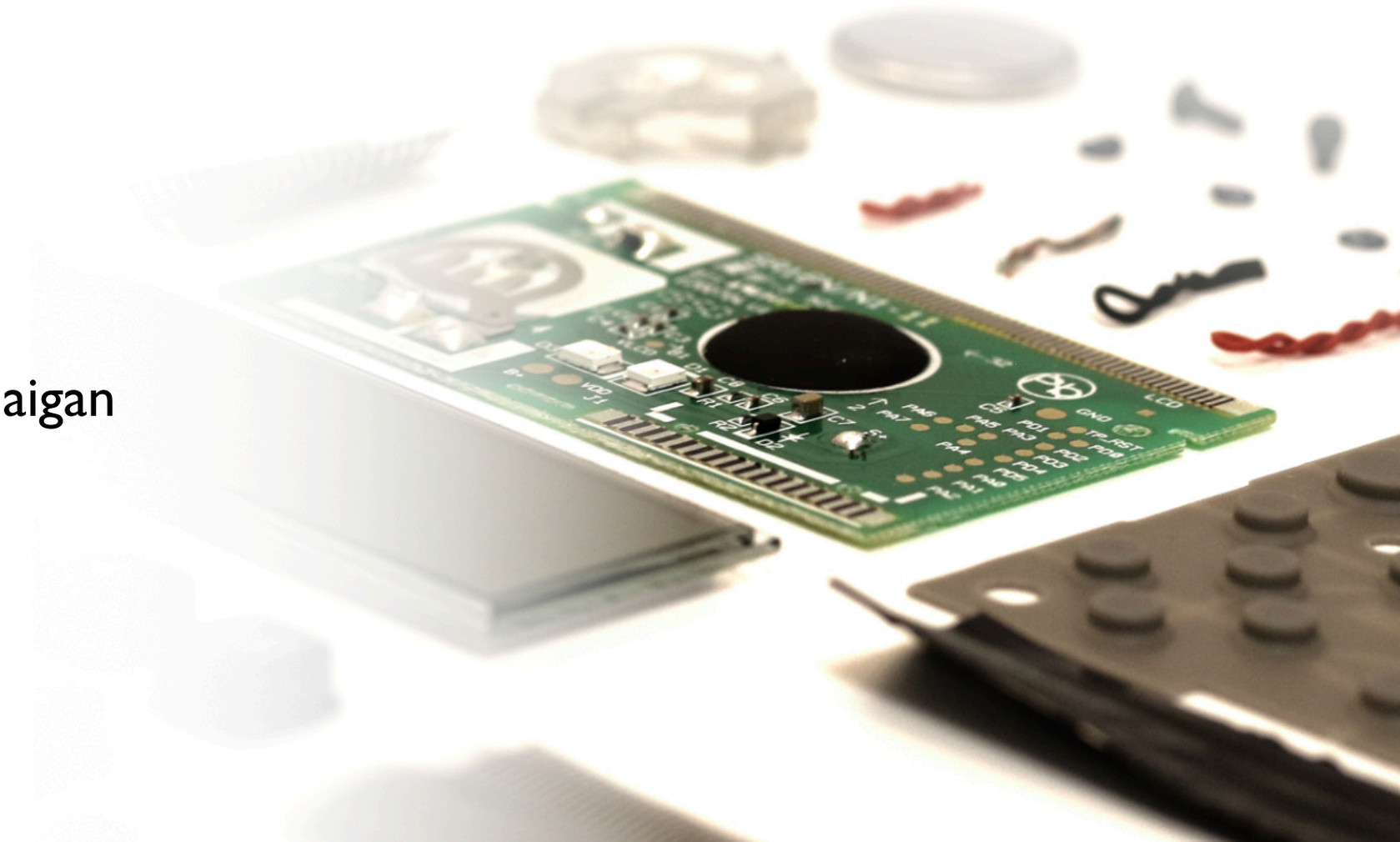
VP Consulting Services at Claigan

December 15 2021

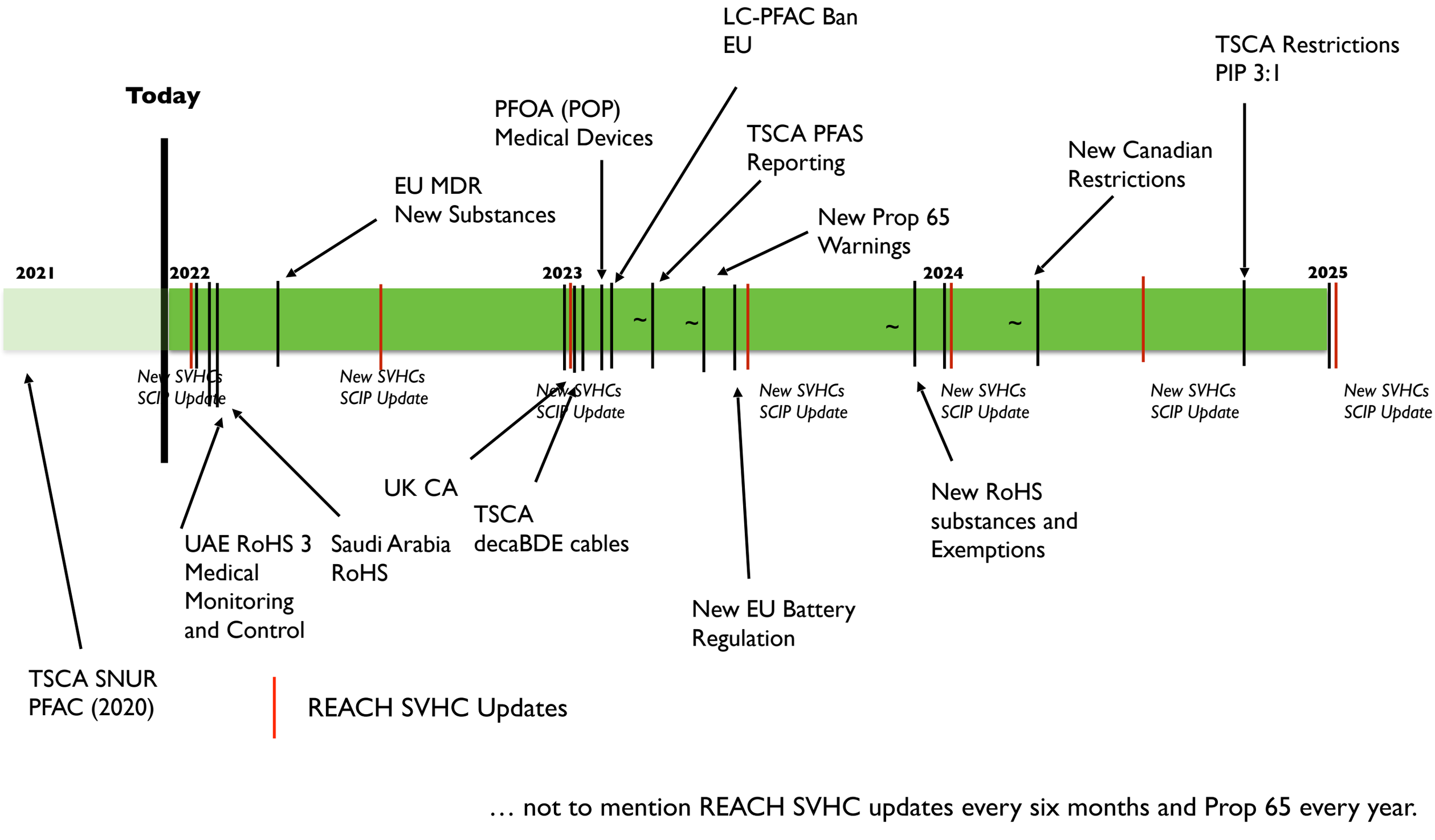


Overview - Agenda

- Introduction
- Upcoming deadlines
- 2022
  - California Proposition 65
  - REACH Restrictions
  - REACH SVHC
  - SCIP
  - RoHS
  - Saudi Arabia RoHS
  - Canadian Prohibition
  - TSCA
  - EU MDR
  - EU Battery Directive
- Q&A

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

Restricted Materials
Constant Deadlines



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

New Proposition 65 Warnings

- New warnings text
  - New rules for warnings

- Timeline
  - New draft version available now
    - In consultation until January 14
  - Final version ~March 2022
  - In effect ~March 2023

- Timeline
  - https://oehha.ca.gov/proposition-65/crnr/notice-modification-text-proposed-regulation-title-27-california-code-3

New Proposition 65 Warnings Where to Start….

- Warnings
  - Requires the identification of
    - One reproductive toxin (if one is present), and
    - One carcinogen (if one is present)
  - For both short and long form warnings

- Substance(s) to be identified can be a single substance that is both a carcinogen and a reproductive toxin
  - ex. Lead or DEHP

New Proposition 65 Warnings
Long Form vs Short Form

- Short form
  - Can only be used IF
    - The total surface area of the label available for consumer information is 12 square inches or less, and;
    - The packaging cannot accommodate the full length warning, and;
    - The entire warning may not be in a type set smaller than the largest type set used for other consumer information on the product (and in no case smaller than 6 point type)

New Proposition 65 Warnings Substance Identification

- Substance Identification
  - Requires the identification of
    - One reproductive toxin (if one is present), and
    - One carcinogen (if one is present)
  - For both short and long form warnings

- Substance(s) to be identified can be a single substance that is both a carcinogen and a reproductive toxin
  - ex. Lead or DEHP

New Proposition 65 Warnings
New Options for Warnings

- Warning options
  - First phrase after warning can now be any of the following
    - **WARNING:** or
    - **CA WARNING:** or
    - **CALIFORNIA WARNING:**
  - For both short and long form warnings

WARNING:

CA WARNING:

CALIFORNIA WARNING:

New Proposition 65 Warnings
Long Form Warning

- Warning options
  - Triangle with exclamation point
  - One of the WARNING header
    - **WARNING** or
    - **CA WARNING:** or
    - **CALIFORNIA WARNING:**
  - "This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to www.P65warnings.ca.gov"
    - (With 'including chemicals' being removable if only one chemical)

CALIFORNIA WARNING: This product can expose you to Lead which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to www.P65warnings.ca.gov.

New Proposition 65 Warnings
Short Form Warning

- Warning options
  - Triangle with exclamation point
  - One of the 3 WARNING headers
  - Either
    - "Cancer risk and Reproductive harm from [name of chemical] exposure - www.P65warnings.ca.gov." or
  - "Exposes you to [name of chemical], a carcinogen and reproductive toxicant - www.P65Warnings.ca.gov."
  - (With slightly different variations in two chemicals, or the one chemical is only a carcinogen or only a reproductive toxin)

CA WARNING: Cancer risk and Reproductive harm from DEHP exposure - www.P65warnings.ca.gov.

Or

CA WARNING: Exposes you to DEHP, a carcinogen and reproductive toxicant - www.P65Warnings.ca.gov.

Updated RoHS Exemptions

- Most major RoHS exemptions are currently in the renewal process
  - Annex III
    - 4a, 4f, 6a, 6a1, 6b, 6b1, 6b2, 6c, 7a, 7c1, 7c2, 8b, 8b1, 13a, 13b, 13b1, 13b2, 13b3, 15, 15a, 18b, 18b1, 29, 32, 34
  - Annex IV
    - 1, 1a, 1b, 1c, 2, 3, 5, 11, 12, 13, 14, 15, 17, 18, 20, 26, 27, 29, 31a, 39

- New text for exemptions expected
  - Longer and more specific while keeping the main uses

- Timeline
  - Publication - 2022
  - In effect - ~2023/2024

RoHS Exemption Renewal Exemption 7(a)

- Pb in High Temp Solder
- Consultation
  - https://rohs.exemptions.oeko.info/index.php?id=359

- Summary
  - OEKO proposes significant rewording of exemption
  - Industry disagrees with the very complicated re-wording of exemption

  - We are unlikely to see an impactful change in 7(a)
    - But there is a potential of detailed re-wording

Detailed Proposed Re-wording Exemption 7(a)

- Proposed by OEKO. Opposed by Industry
- Proposed re-wording

a. for internal interconnections in electrical and electronic components, i.e.

i) for die attach in power semiconductors with steady state or transient/impulse currents of 1 A or greater and/or blocking voltages beyond 200 V, or die edge sizes larger than 0.5 mm

ii) in components with steady state currents of more than 1 A and/or blocking voltages beyond 200 V other than die attach

iii) for other internal interconnections in electrical and electronic components excluding those in the scope of exemption 24

iv) in HID lamps and oven lamps

b. in solder balls for the attachment of ceramic BGA to the printed circuit board (second level interconnect)

c. for the attachment of components to printed circuit boards (second level interconnect) in high temperature plastic overmouldings (> 220 °C)

Detailed Proposed Re-wording Exemption 7(a) - continued

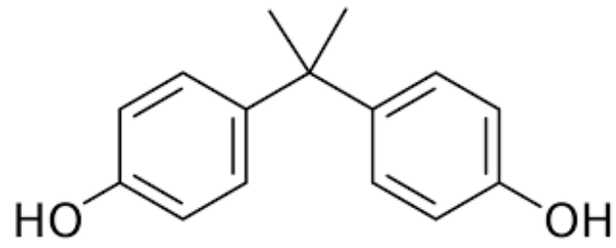
d.for mounting electronic components onto subassemblies (first level interconnect), i.e. modules or sub-circuit boards

e.as a hermetic sealing material between a ceramic package or plug and a metal case

f. other applications; expires on 1 January 2021 for EEE in cat. 1-7 and 10

New REACH Restriction
BPA

- 0.02% Restriction of BPA
  - Restriction of BPA at 200 ppm
  - No exemptions / exclusions yet in the text
  - Expected to be May 2022
  - Into effect likely 2024
  - High risk materials
    - ABS/PC blends
    - PVC
- Details -
  - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021R1297



REACH SVHC

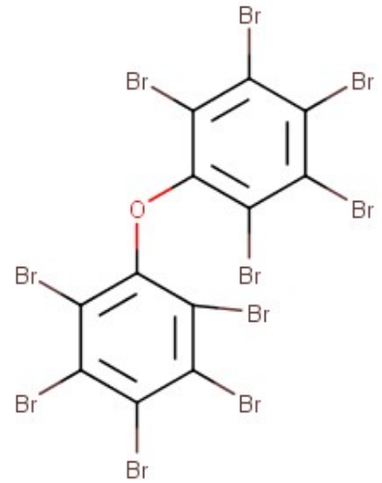
- Two REACH SVHC Updates
  - January Update
  - July Update
- Updates to SCIP
  - Updates expected to SCIP to address
    - Poor data quality
    - Brand control

EPA (TSCA) Restricted Substances

- EPA has 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

EPA (TSCA) Restricted Substances Decabromodiphenyl ether (DecaBDE)

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



decaBDE

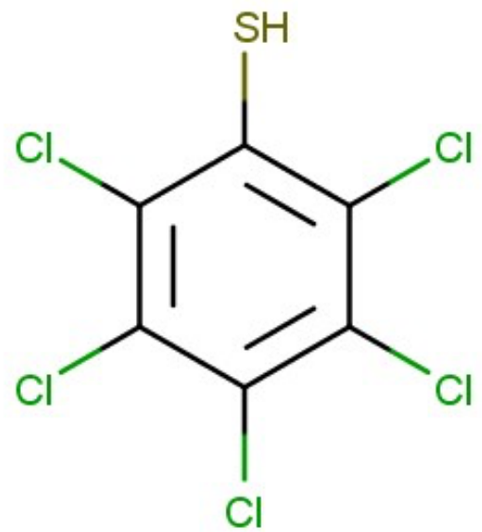
- Deadline
  - General - Jan 6 2022
  - Wire and Cable - Jan 6 2023

- High risk materials
  - Thin flame retarded plastics such as heat shrink and nylon connectors

- Final Rule
  - 2020-28686.pdf (govinfo.gov)

EPA (TSCA) Restricted Substances Pentachlorothiophenol (PCTP)

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

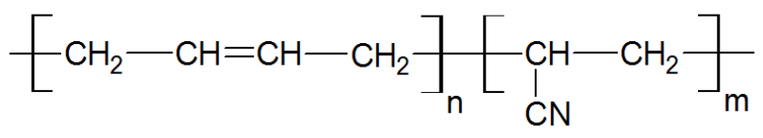


PCTP

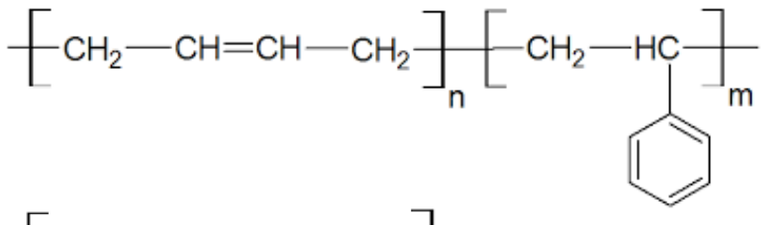
- Deadline
  - January 6, 2022 (restriction)
  - March 8 2021 (record keeping)

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

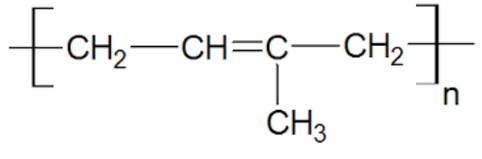
Butadiene



nbr



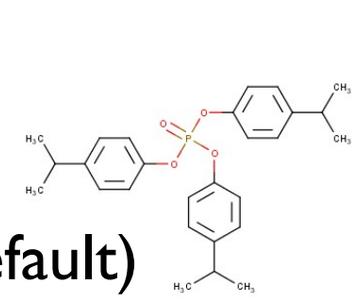
sbr

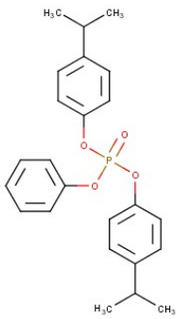


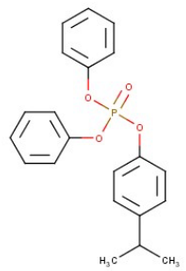
Isoprene

- Final Rule
  - 2020-28689.pdf (govinfo.gov)

EPA (TSCA) Restricted Substances
Phenol, isopropylated, phosphate (3:1) PIP (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
  - Updated Deadline - October 31 2024

- High risk materials
  - Flame retarded PVC, polyurethane foam, and BPA epoxies
    - Primarily halogen free flame retarded PVC

- Final Rule
  - 2020-28692.pdf (govinfo.gov)

TSCA - High Risk Materials

- PIP
  - Flame retarded thin plastics
    - ex. wiring, heat shrink, wire connectors, foam, flexible circuit boards, insulation sleeves
- PCTP
  - Butadiene based rubbers
    - Nitrile (nbr), sbr rubber, latex
    - ex. gaskets, seals

TSCA

- Next steps in risk management of high priority substances
  - https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/chemicals-undergoing-risk-evaluation-under-tsca

- Includes
  - DEHP, DBP, DIBP, D4, BBP and many others.

- Asbestos
- 1-Bromopropane
- Carbon Tetrachloride
- C.I. Pigment Violet 29 (PV29)
- Cyclic Aliphatic Bromide Cluster (HBCD)
- 1,4-dioxane
- Methylene Chloride
- N-Methylpyrrolidone (NMP)
- Perchloroethylene
- Trichlorethylene (TCE)
- p-Dichlorobenzene
- 1,2-Dichloroethane
- trans-1,2- Dichloroethylene
- o-Dichlorobenzene
- 1,1,2-Trichloroethane
- 1,2-Dichloropropane
- Dibutyl phthalate (1,2-Benzene- dicarboxylic acid, 1,2- dibutyl ester)
- Butyl benzyl phthalate - 1,2-Benzene- dicarboxylic acid, 1- butyl 2(phenylmethyl) ester
- Di-ethylhexyl phthalate - (1,2-Benzene- dicarboxylic acid, 1,2- bis(2-ethylhexyl) ester)
- Di-isobutyl phthalate - (1,2-Benzene- dicarboxylic acid, 1,2- bis-(2methylpropyl) ester)
- Dicyclohexyl phthalate
- Di-isodecyl phthalate (DIDP) – (1,2-benzenedicarboxylic acid 1,2-diisodecyl ester)
- Di-isononyl phthalate (DINP) – (1,2-benzenedicarboxylic acid, 1,2-diisononyl ester)
- 4,4'-(1-Methylethylidene)bis[2, 6-dibromophenol] (TBBPA)
- Tris(2-chloroethyl) phosphate (TCEP)
- Phosphoric acid, triphenyl ester (TPP)
- Ethylene dibromide
- 1,3-Butadiene
- 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta [g]-2-benzopyran (HHCB)
- Formaldehyde
- Phthalic anhydride
- Octamethylcyclotetra- siloxane (D4)

ATP 15 and 16
Medical Devices

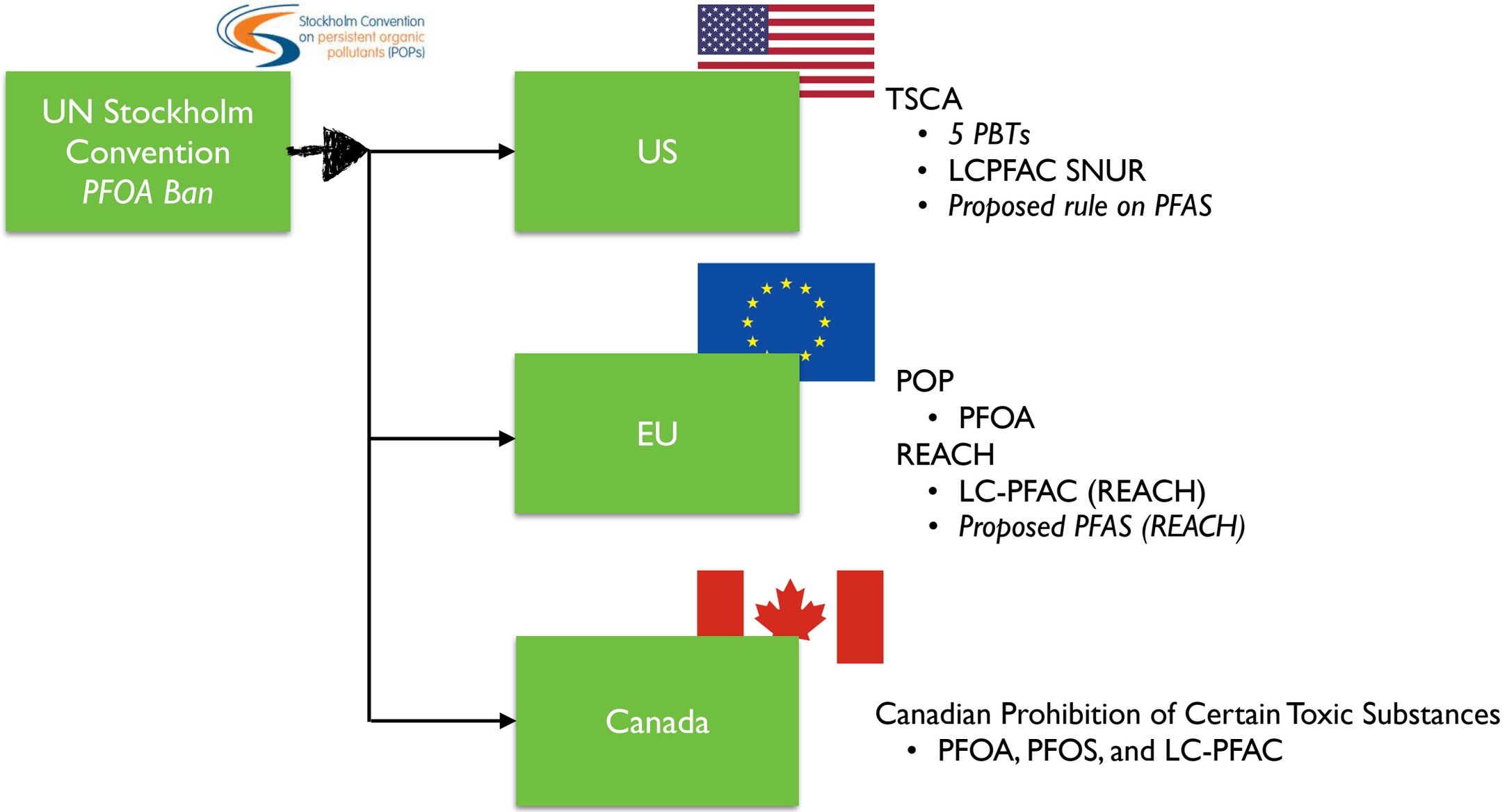
- Adaptation to technical progress (EU)
  - New cat 1 CMRs
  - Affects medical devices (fluid, gas, or invasive path)
- ATP 15
  - New substances in effect in March 2022
- ATP 16
  - New substances chosen for regulation
  - Timeline
    - New substances identified in 2022
    - Regulation in 2023

PFAS Globally

- Further regulation of PFAS
  - Primarily LC-PFAC
  - But also we expect to see consultations / government data gathering on
    - Carboxylates
    - Sulfonates
    - Fluorotelomers
    - Fluoropolymers

- Countries
  - EU, US, Canada, China, South Korea, Japan, and others

PFAS Regulation



+ other jurisdictions have emerging PFAS regulations

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, LC-PFAC is 9+
- Details -
  - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021R1297

New REACH Restriction
LC-PFAC - Timelines

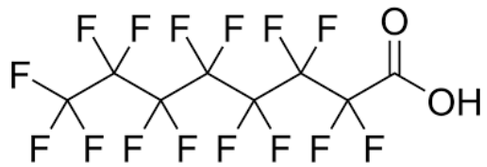
- Timelines
  - Deadline - Feb 25 2023
  - Medical textiles - July 4 2023
  - Invasive and implantable devices - July 4 2025

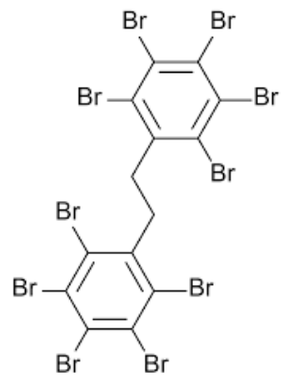
New REACH Restriction
LC-PFAC - High Risk Materials

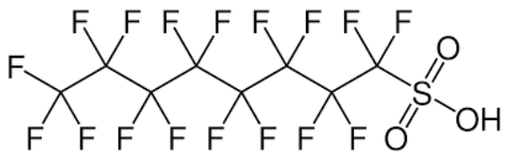
- LC-PFAC (25 ppb) common locations fluoro coatings
  - fabric
  - membranes
  - steel mesh screens
  - silicone touch pads
  - Non-stick food contact surfaces
  - High durability touchscreen
- Solid fluoropolymers
  - PTFE (Teflon), FKM (Viton), PVDF, FEP, etc.
  - Lithium battery cathodes

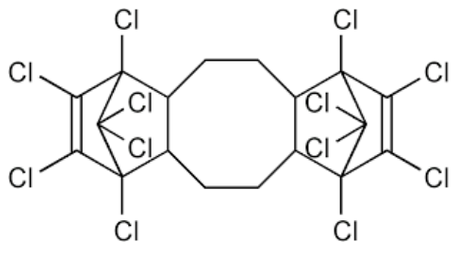
Canadian Prohibition of Certain Toxic Substances

- Restriction of
  - PFOA
  - LC-PFAC
  - PFOS
  - DBDPE
  - Dechlorane Plus





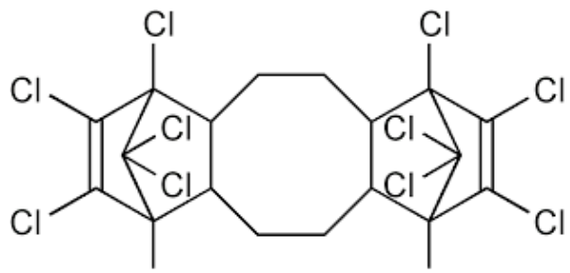




- Timeline
  - Publishing likely in early 2022
  - Restriction in 2024/2025 timeframe

Dechlorane Plus (DP)

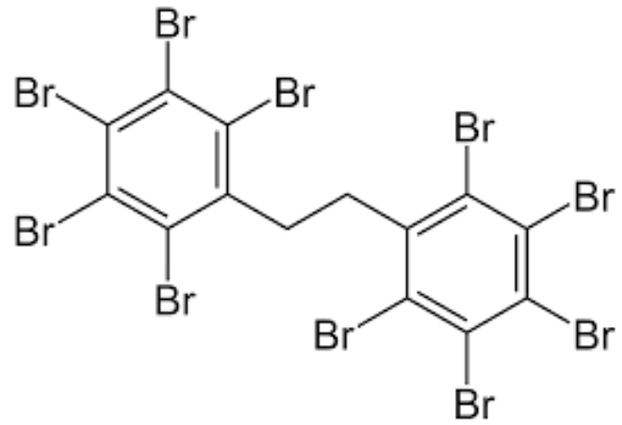
- Chemical
  - Dechlorane Plus (DP)
- Restrictions
  - Ban in manufactured items. Likely at ~0.1%
- Uses
  - Flame retardant thin plastics
    - Nylon, polyolefin (heat shrink), EPDM
- Currently regulated as
  - EU REACH SVHC



Dechlorane Plus

Decabromodiphenyl ethane (DBDPE)

- Chemical
  - Decabromodiphenyl ethane (DBDPE)
- Restrictions
  - Ban in manufactured items. Likely at ~0.1%
- Uses
  - Flame retardant plastics (primarily thin plastics)
    - Common replacement for decaBDE and TBBPA
    - High risk materials are **heat shrink** and small connectors
    - Used with antimony trioxide (synergist)
- Current regulated
  - Nowhere

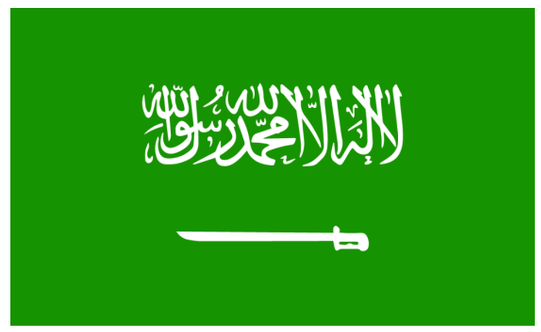


DBDPE

Saudi Arabia RoHS

- Technical Regulation published July 13 2021
  - Deadline January 5 2022 (but likely not enforced)

- Details
  - Finished products (not components)
  - Same substances as EU RoHS 2
  - Same IEC standards are EU RoHS (testing and conformity assessment)
  - Requires notified body approval
    - Usually through same process as UAE RoHS
      - ie. Testing of 3 critical components.
  - Saudi Arabia specific DoC
  - Does not include medical devices



Draft New EU Battery Regulation

- Draft EU Battery Regulation
  - Draft regulation
  - Draft annexes
  - First requirements targeting July 1 2023
- Updated requirements
  - Material restrictions
  - Carbon footprint (industrial and electrical vehicle)
  - Recycled metal content (industrial and electrical vehicle)
  - Durability
  - Removeability
  - QR Code
  - Conformity assessment provisions
    - Included notified body requirements

Summary & Q&A

- 2022
  - Going to be very busy…..

- Need Help?
  - Test your product? See Claigan
  - Need regulatory support? See Claigan