

Restricted Materials 2020

What do you need to do in 2020?

Presented by:
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VP Consulting Services



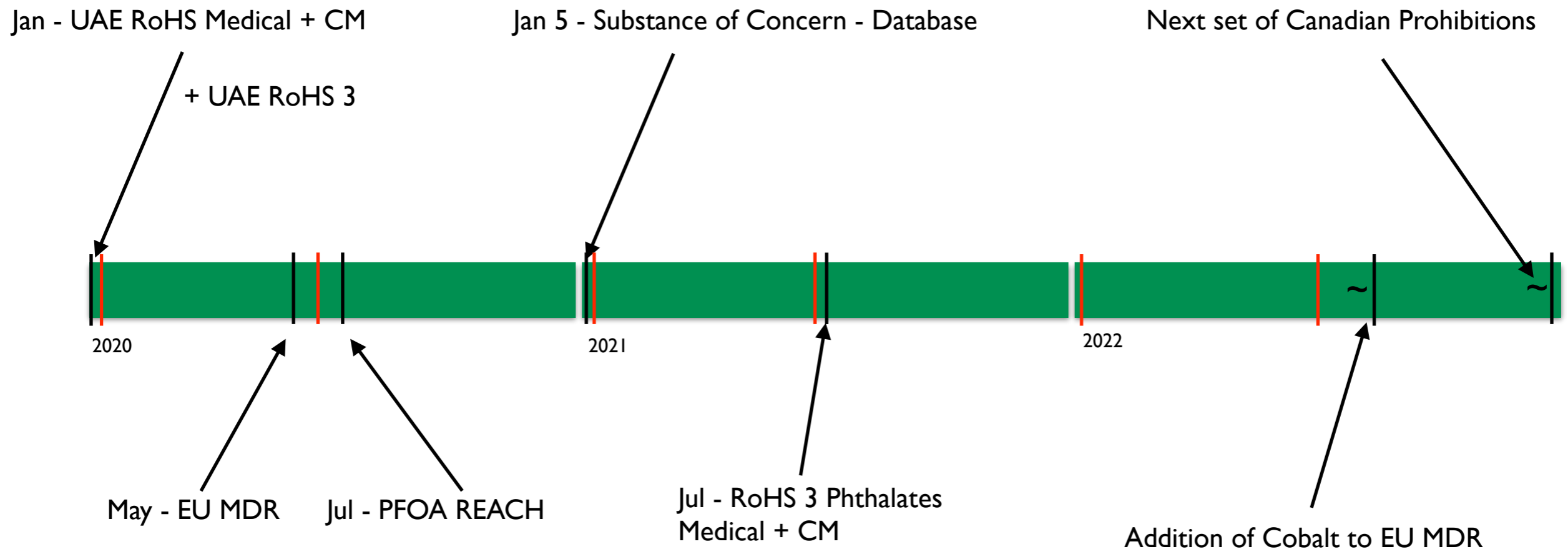
Overview - Agenda - REACH SVHC Database

- Introduction
- 2020 - 2022 Deadlines
- SCIP Database
 - Reminder
- REACH SVHCs
 - Updating declarations and high risk chemicals
- REACH / POP Restrictions
 - PFOA restriction in 2020
- EU MDR
 - CMR I / EDC Compliance
- RoHS 3
 - Medical devices, and monitoring and control
- Canadian Prohibition
 - Upcoming Canadian restrictions
- Q&A



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

Upcoming Regulatory Deadlines



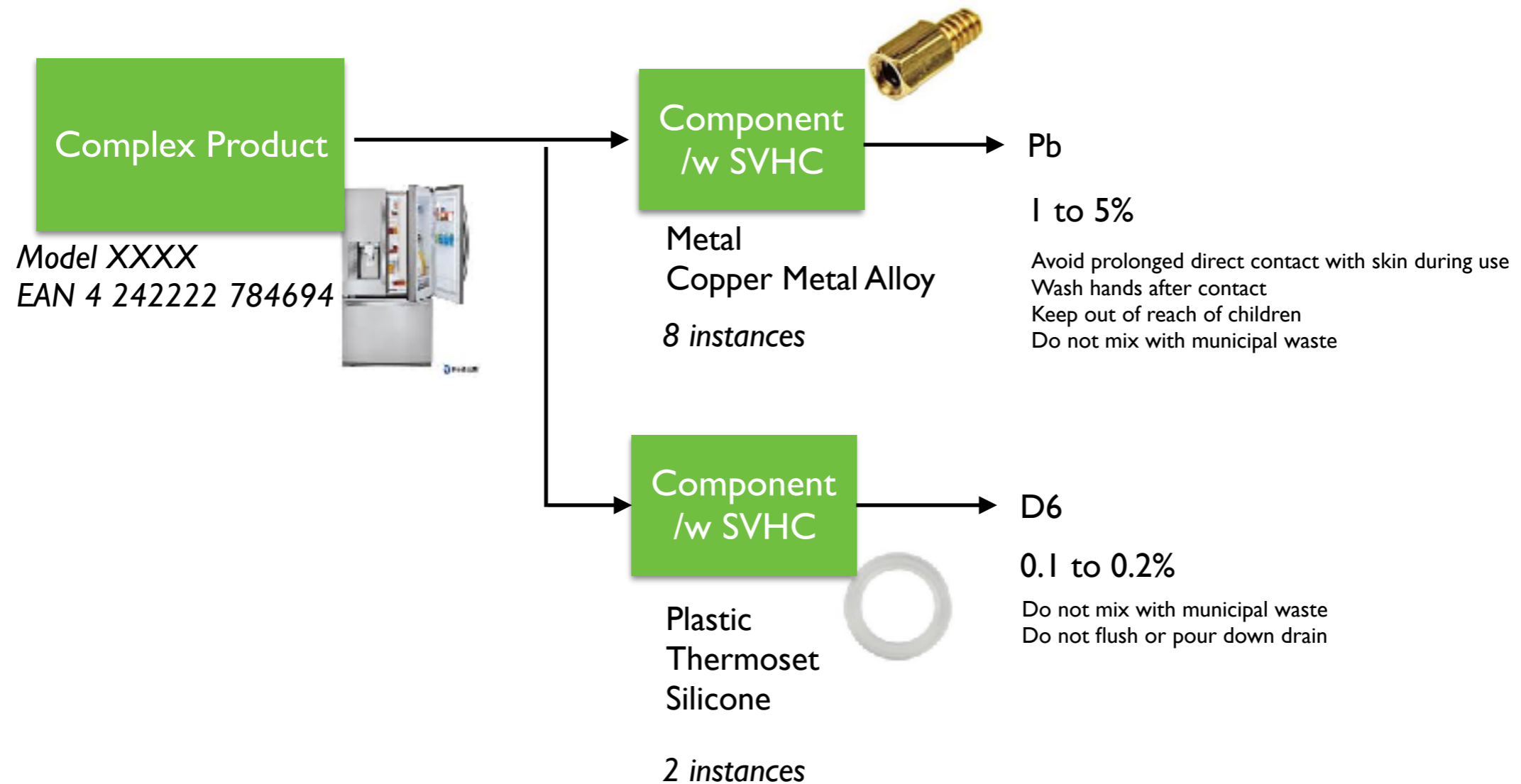
REACH SVHC Updates

(Formerly REACH SVHC Database)

- **Substances of Concern** In articles, as such or in complex objects (**P**roducts)
- Database
 - Manufacturers to register products and their SVHCs in products in IUCLID by Jan 5 2021
- Update
 - V0 Version - Start of 2020
 - V1 Version - October 2020

Substance of Concern Database - Clairigan

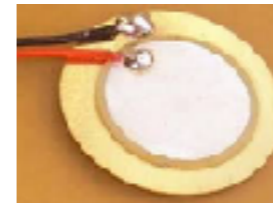
Example - with safe use



Some Specific Impacts

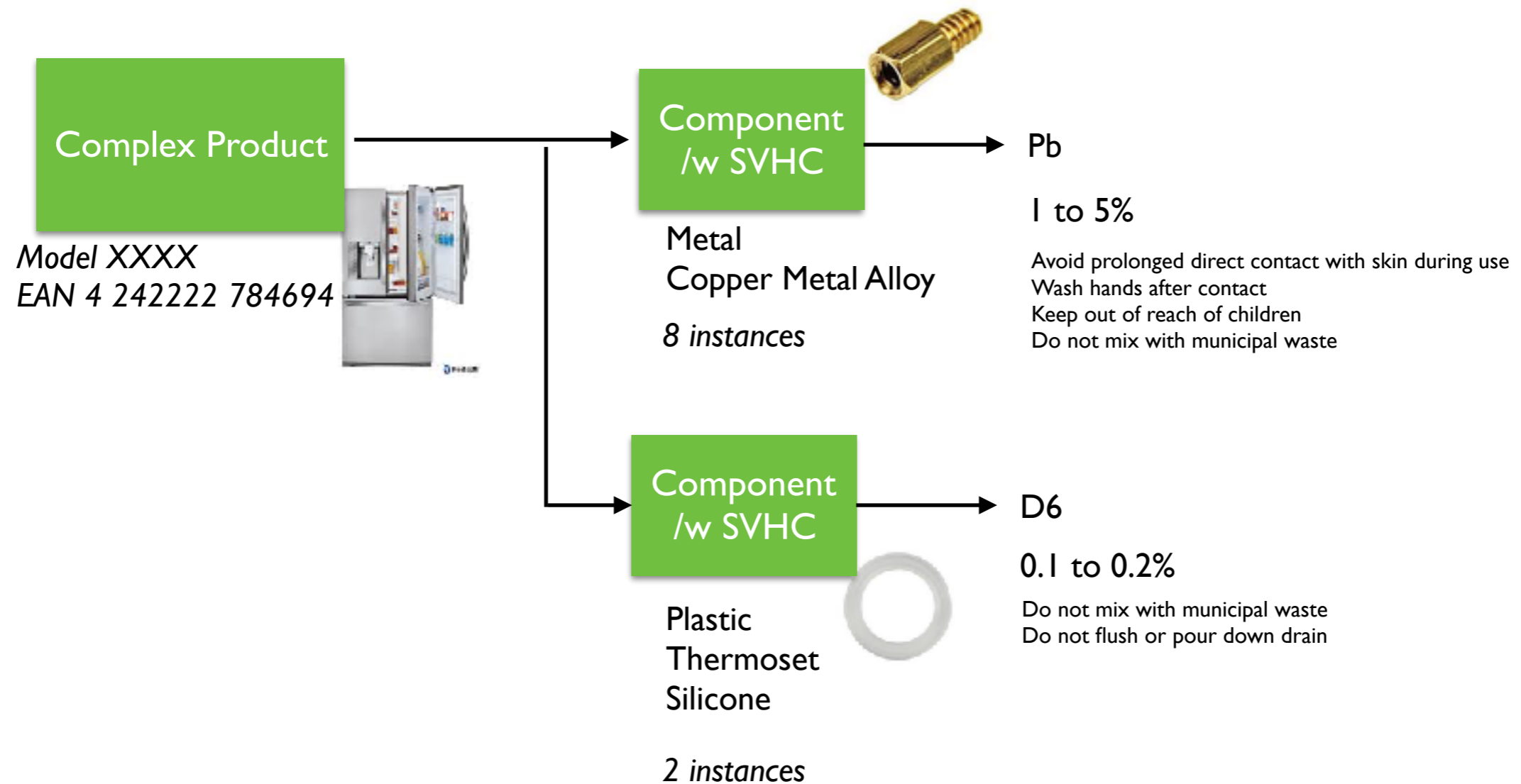
- Common components which will require product registration in SCIP database

- Pb metal (brass, aluminum, steel alloys)
- Wires and Cables (phthalates and SCCP)
- PVC, neoprene, or nitrile rubber gaskets (phthalates)
- Buzzers / transducers (PZT)
- DMAC (Kapton & Spandex)
- MOCA (Cast Polyurethane)
- D4, D5, D6 (silicone)
- EGDME (Button cell battery)
- ADCA (Closed Cell Foam)
- TNPP (all plastics)
- Polycarbonate (PFBS)



Substance of Concern Database - ClaiGAN

Example - with safe use



Complex Article Example Spreadsheet



Identifiers	Article Name	MH-400	XH-700
	Company		
	Product IUCLID #		
Product IUCLID #	UPC Code		
	Article Category	853710.91 Industrial Controllers	853710.91 Industrial Controllers
	Production in European Union	No	No
Safe Use Instructions	Safe use instruction (s)	See component safe use instructions	See component safe use instructions
	Brand		
	Model		
<i>optional</i>	image (filename)		
Linked article	Linked article 1	<u>Brass Component (external)</u>	<u>Brass Component (external)</u>
	# of occurrences of article 1		3
	Linked article 2	<u>Brass Component (internal)</u>	<u>Brass Component (internal)</u>
	# of occurrences of article 2		2
	Linked article 3	<u>PZT Buzzer</u>	<u>PZT Buzzer</u>
	# of occurrences of article 3		1
	Linked article 4	<u>Twist Tie</u>	<u>Twist Tie</u>
	# of occurrences of article 4		1
	Linked article 5	<u>Silicone Seal</u>	<u>Silicone Seal</u>
	# of occurrences of article 5		1
	Linked article 6	<u>Polyimide film</u>	<u>Polyimide film</u>
	# of occurrences of article 6		3
	Linked article 7	<u>High temp solder</u>	<u>High temp solder</u>
	# of occurrences of article 7		0
	Linked article 8	<u>External Plastic Component</u>	<u>External Plastic Component</u>
	# of occurrences of article 8		0
	Linked article 9	<u>Flexible Circuit Board</u>	<u>Flexible Circuit Board</u>
	# of occurrences of article 9		0
	Linked article 10	<u>Heat Shrink</u>	<u>Heat Shrink</u>
	# of occurrences of article 10		0
	Linked article 11	<u>Button Cell Battery</u>	<u>Button Cell Battery</u>
	# of occurrences of article 11		0
	Linked article 12	<u>Neoprene Component</u>	<u>Neoprene Component</u>
# of occurrences of article 12		0	

Internal Components - Examples Spreadsheet



Identifiers	Article Name	Brass Components (External)	Brass Component (Internal)	PZT Buzzer
Product IUCLID #	Part number			
	Article Category	7419 99 30: Other articles of copper (including chain and parts thereof under 7419 10 and other articles under 7419 99) but not including metal castings under 7419 91 00	7419 99 30: Other articles of copper (including chain and parts thereof under 7419 10 and other articles under 7419 99) but not including metal castings under 7419 91 00	8518200: Electric-sound or visual signalling apparatus (for example, bells, sirens, indicator panels, burglar or fire alarms), other than those of heading 8512 or 8530 - Other apparatus
	Production in European Union	unwilling to disclose	unwilling to disclose	unwilling to disclose
Safe Use Instructions	Safe use instruction (s)	Avoid prolonged direct contact with skin during use Wash hands after contact Keep out of reach of children Do not mix with municipal waste	Avoid prolonged direct contact with skin during use Wash hands after contact Keep out of reach of children Do not mix with municipal waste	Avoid prolonged direct contact with skin during use Wash hands after contact Keep out of reach of children Do not mix with municipal waste
<i>optional</i>	Location	External	Internal	Internal
Concern Element	Candidate List Version	2019/07	2019/07	2019/07
	Candidate List Entry / Substance	Lead EC# 231-100-4 CAS# 7439-92-1	Lead EC# 231-100-4 CAS# 7439-92-1	Lead titanium zirconium oxide EC# 235-727-4 CAS# 12626-81-2
	Concentration range	≥ 1.0% w/w and < 10.0% w/w;	≥ 1.0% w/w and < 10.0% w/w;	≥ 20.0% w/w and < 100% w/w;
	Material category	Metal > Copper Metal Alloy	Metal > Copper Metal Alloy	Ceramic > Piezo

Data Gathering - REACH SVHC

Accuracy



- Claigan has tested >200,000 parts / products for SVHCs
- Supplier declared SVHC in part
 - <50% of the time, the SVHC is actually in the part
 - i.e. SVHC is not there most of the time
- Claigan measured SVHC > 1,000ppm in part
 - >40% of the time, supplier unaware
 - i.e. Undeclared SVHC

Recommendations - SCIP Database

- Recommendations
 - Start now!
 - It will take a lot longer than you think to put everything together to do a SCIP submission
 - Don't panic. But don't let it slip
 - Lots of mis-information out there. The work is straight forward but there is work to do
 - Work with an expert
 - When things are complicated and new, everyone tries to sell you something
 - We (Claigan) are the experts.
 - We are not sales people, we are restricted materials experts
 - We are in for the long haul, not the sales commission for the month

Updating REACH SVHC Declarations

- In 2020, REACH SVHC declarations need to be updated to include 2019 REACH SVHCs
 - Jan 15 2019 list (6 substances)
 - Jul 16 2019 list (4 substances)
- Key substance
 - TNPP

Tris(4-nonylphenyl, branched and linear) phosphite (TNPP) with \geq 0.1% w/w of 4-nonylphenol, branched and linear (4-NP)

- Details

**High Risk
of presence of TNPP
>0.1% w/w**

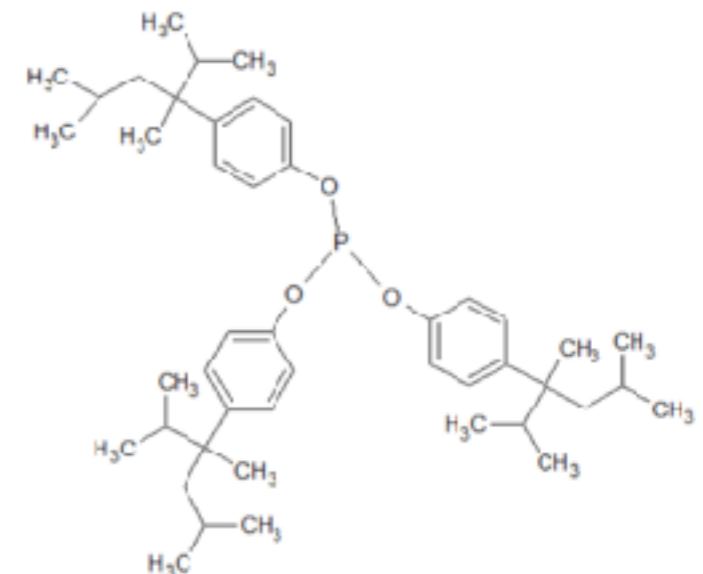
- EC # -
 - Phenol, 4-nonyl, phosphite (3:1) (CAS 3050-88-2)
 - Phenol, p-isononyl-, phosphite (3:1) (CAS 31631-13-7)
 - Phenol, p-sec-nonyl-, phosphite (CAS 106599-06-8)
- Endocrine disruptor (environment)
- 4-NP
 - TNPP decomposed quickly to 4-NP (SVHC)
 - Plastics using TNPP often end up with more 4-NP than TNPP

- Uses

- TNPP is common antioxidant to
 - stabilise light coloured thermoplastics

- Notes

- High volume substance used in thermoplastics
 - HDPE, LLDPE, SBR, ABS, PVC



Note on previous SVHCs

- Meanwhile, don't forget
- Key SVHCs in 2018 (July 2018 list)
 - Pb
 - D4/D5/D6

New REACH SVHC

Pb (powder and massive)

- Details
 - Lead (Pb)
 - EC # (231-100-4)
 - Toxic to reproduction
 - Very common uses
- Uses
 - Pb in brass, aluminum, steel, high temp solder
 - *RoHS exemptions 6a, 6b, 6c, and 7a*
 - *does not include leaded glass (7ci etc). Different chemical*
- Concentration
 - Well above 0.1% w/w

High Risk

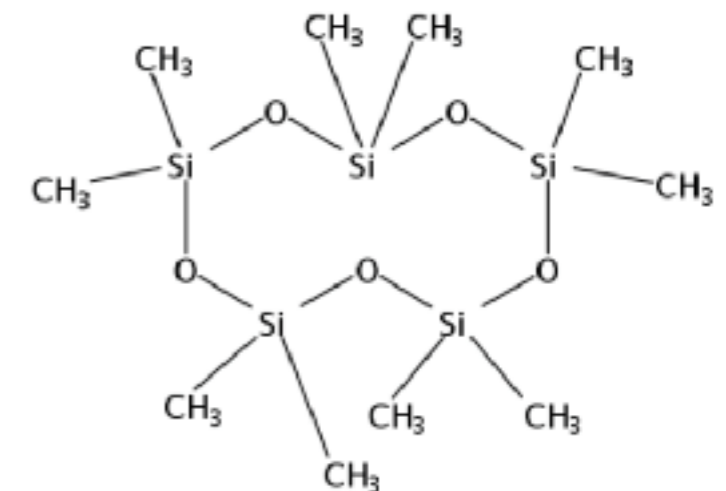
June REACH SVHC Update

D4, D5, D6 - cyclosiloxane

- Details
 - octamethylcyclotetrasiloxane (D4) (EC 209-136-7)
 - decamethylcyclopentasiloxane (D5) (EC 208-764-9)
 - dodecamethylcyclohexasiloxane (D6) (EC 208-762-8)
 - Very persistent and very bioaccumulative (PBT and vPvB)
- Uses
 - cosmetics
 - deodorants, sunblocks, hair sprays, and skin care
 - **Silicone rubber**
- Concentration
 - Listed at 10,000 ppm in some silicone SDSs

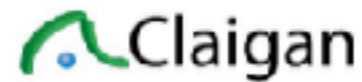
High Risk

540-97-6	Dodecamethylcyclohexasiloxane	$\geq 0,5 - < 1$	Persistent, bioaccumulative and toxic (article 57d) Very persistent and very bioaccumulative (article 57e)
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Claigan Summary Document

Monthly / Quarterly Update Customers



Claigan Environmental Inc.
4043 Corling Avenue, Suite 123
Kanata, ON, Canada, K2K 2A4

July 16 2019 Addition of SVHC

Risk assessment of potential presence in physical products of the four (4) REACH SVHC substances added to the EU Candidate List for Authorisation on July 16 2019.

Substance	Risk	Justification	Materials of Risk
2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid, its salts and its acyl halides	Low risk	Perfluorinated salt. Would not be present in physical products over 0.1% w/w	n/a
2-methoxyethyl acetate	Low risk	Solvent for formulation of paints. Solvents would be trace residual in paint whose weight contribution is measured over the mass of the surface it was painted on. No reasonable expectation to be in products over 0.1% w/w.	n/a
4-tert-butylphenol (PTBP)	Low risk	Polymer chain terminator for polycarbonate. Like BPA, it would be fully reacted into the polymer and any trace residual monomer would not be reasonable expected to be over 0.1% w/w.	n/a
Tris[4-nonylphenyl, branched and linear] phosphite (TNPP) with ≥ 0.1% w/w of 4-nonylphenol, branched and linear (4-NP)	High Risk	Anti-oxidant for light coloured plastics. Phenolic antioxidants are still commonly used, however TNPP is generally replaced by similar unregulated substance. However, there is a reasonable chance that TNPP or its degradation product 4-NP would be present.	All light coloured plastics

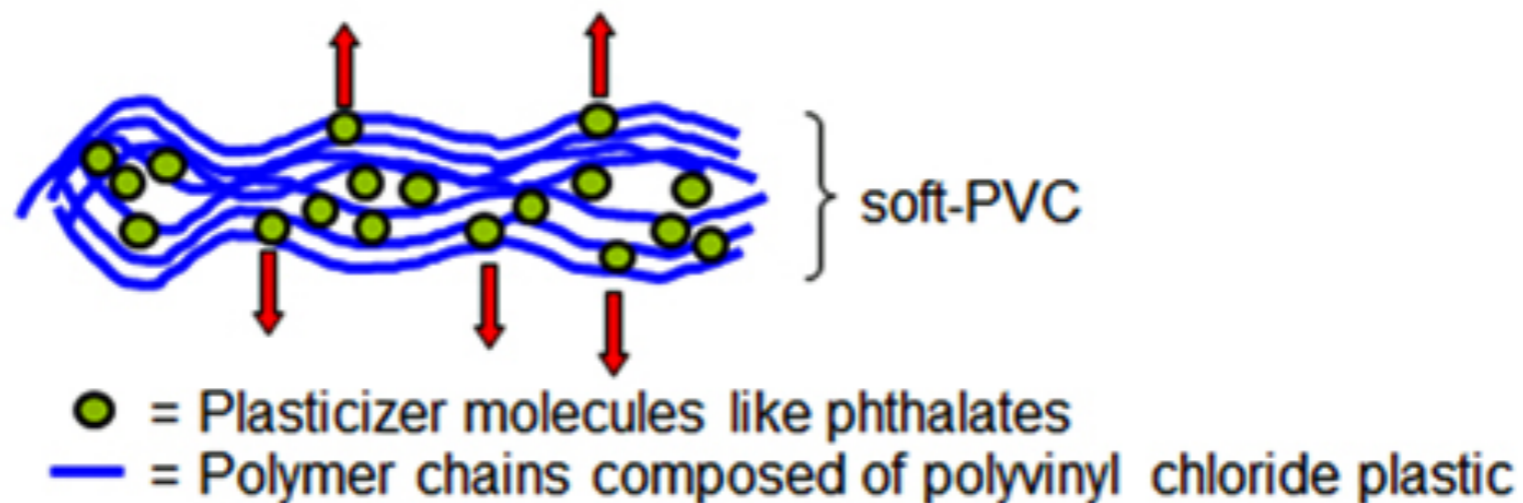
This risk is based on a reasonable technical review of the current chemical, EU information, and other publicly available data. It may not include unforeseen or unpublished uses. The risk is based on whether or not there is any reasonable expectation for it to be potentially present in physical products above 0.1% w/w in any component.

EU RoHS Recast

- CE marking directive
- EU RoHS 3 (phthalates) (2015/863) - *Amended*
 - DEHP, BBP, DBP, DIBP banned at 1,000 ppm
 - Deadline -
 - Most products - July 21 2019
 - Medical, IVD, monitoring and control - July 21 2021

Where are phthalates used?

- Rigid plastics
 - example - PVC
- Phthalates create flexibility
 - by getting in between the vinyl chloride strands and forcing them apart
 - leading to weaker forces of attraction
 - creating fluidity (flexibility)



High Risk Materials

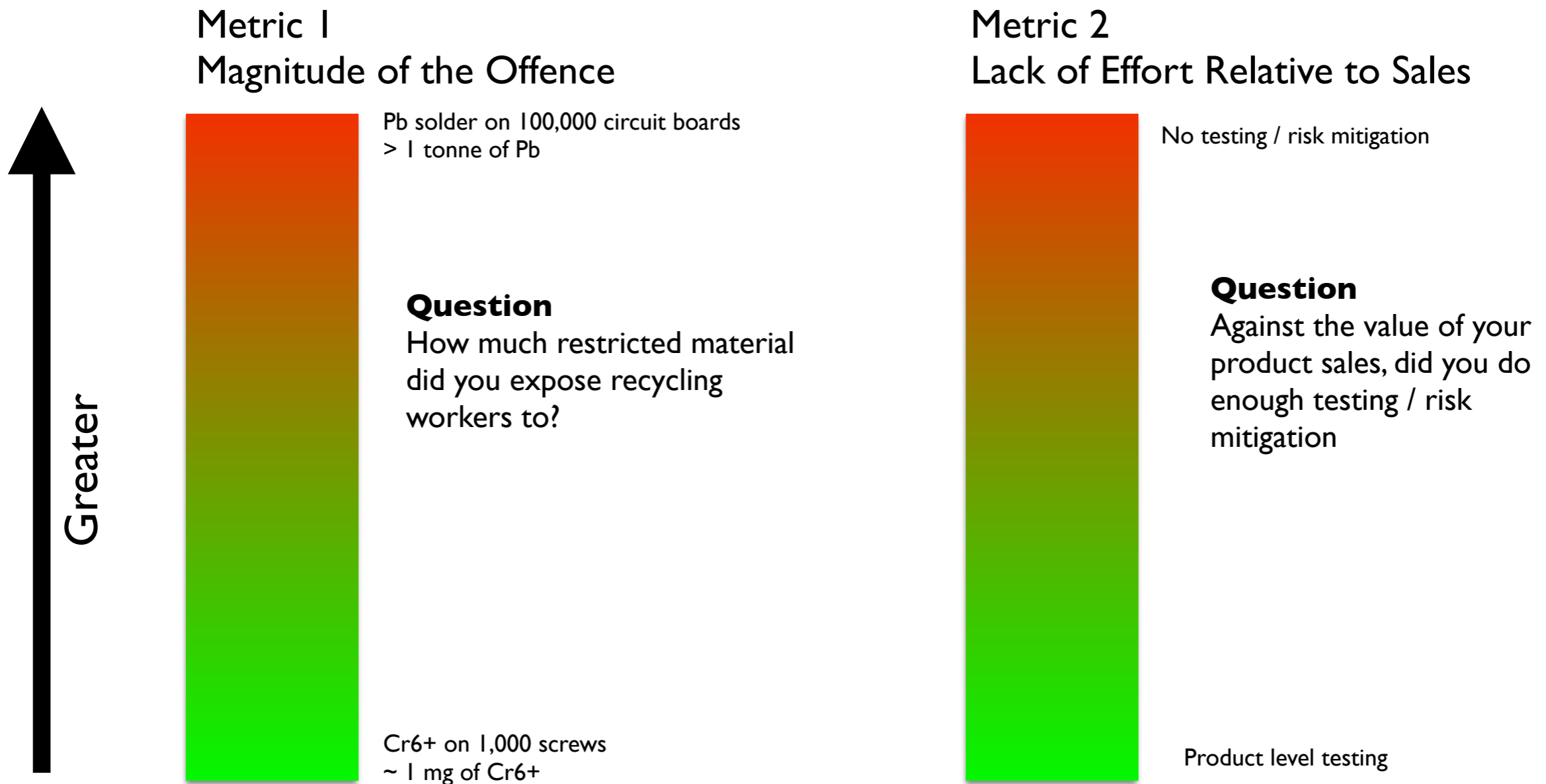
- Principal high risk materials
 - Flexible PVC
 - Neoprene
 - Nitrile rubber
 - SBR rubber
 - Adhesives
- Concentrations
 - 1,000 to 300,000 ppm

High Risk Components

- Typical high risk components
 - wires and cables
 - strain relief
 - o-rings, gaskets
 - sealed radial bearings
 - motor belts
 - stickers (PVC)
 - soft rubber components
 - synthetic leather
 - soft covers



Enforcement Metrics



Risk Mitigation - Enforcement

- Very important question that occurs in every non-self reported enforcement action
- Considering the value of your sales in our jurisdiction,
 - Could you and should you have done more testing?
- Note - by value, not by volume.

Medical, and Monitoring and Control

- EU RoHS 3 (phthalates) (2015/863) - *Amended*
 - DEHP, BBP, DBP, DIBP banned at 1,000 ppm
 - Deadline -
 - Most products - July 21 2019
 - Medical, IVD, monitoring and control - July 21 2021
- Deadline approaching
 - Testing is the most effective method to ensure compliance
 - Contact Claigan for effective approaches for products

REACH Restriction

New

- Substance restrictions
 - from the former Dangerous Substances Directive
 - Directive 76/769/EEC as of 1 June 2009
 - Article 67 of REACH Regulation (annex 17 list)
- Requirement
 - A range of material restrictions in substances
 - Examples
 - Cd in plastics, Ni and PAHs in prolonged human contact, PFOA
- Current summary of restrictions (Annex 17 list)
 - <https://echa.europa.eu/substances-restricted-under-reach>

REACH Article 67 - PFOA

Moving to EU POP

- Restriction in regular products (July 2020)
 - Currently in REACH 67. Moving to EU POP
 - **25 ppb**
 - Commonly in PTFE (teflon), PVDF, FEP, FKM
 - “fluorinated polymers”
 - All products in scope
 - Extended time line (under proposed EU POP)
 - (d) invasive and implantable medical devices, until 4 July 2025;
 - plus a few other specialized uses

EU Medical Device Regulation (EU MDR)

- Regulation (EU) 2017/745
 - EU Medical Device Regulation
- Justification and Labeling of Cat I CMRs and EDCs
- In effect
 - May 26 2020
 - *With extensions for products still under medical device directive (MDD) certificates*

Section 10.4 Substances

- 10.4.1. Design and manufacture of devices
- 10.4.2. Justification regarding the presence of CMR and/or endocrine-disrupting substances
- 10.4.3. Guidelines on phthalates
- 10.4.4. Guidelines on other CMR and endocrine-disrupting substances
- 10.4.5. Labelling

Design and manufacture of devices

- Devices, or those parts thereof, or those materials used therein that:
 - *are invasive and come into direct contact with the human body,*
 - *(re)administer medicines, body liquids or other substances, including gases, to/from the body, or*
 - *transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body,*
- shall only contain the following substances in a concentration that is above 0,1 % w/w where justified
 - Category I CMRs
 - Endocrine disrupting chemicals

Data Gathering - EU MDR

- Pros
 - May work sometimes
- Cons
 - Limited supplier data
 - Significant supplier data inaccuracies
 - Very slow
 - Generally ineffective

Testing - EU MDR

- Pros
 - Relatively fast
 - Consistent timeline
 - Accurate
 - Provides confidence
 - Works all the time
- Cons
 - Requires physical sample
 - Very limited number of labs with effective process
 - Can be costly but only for a smaller number of parts

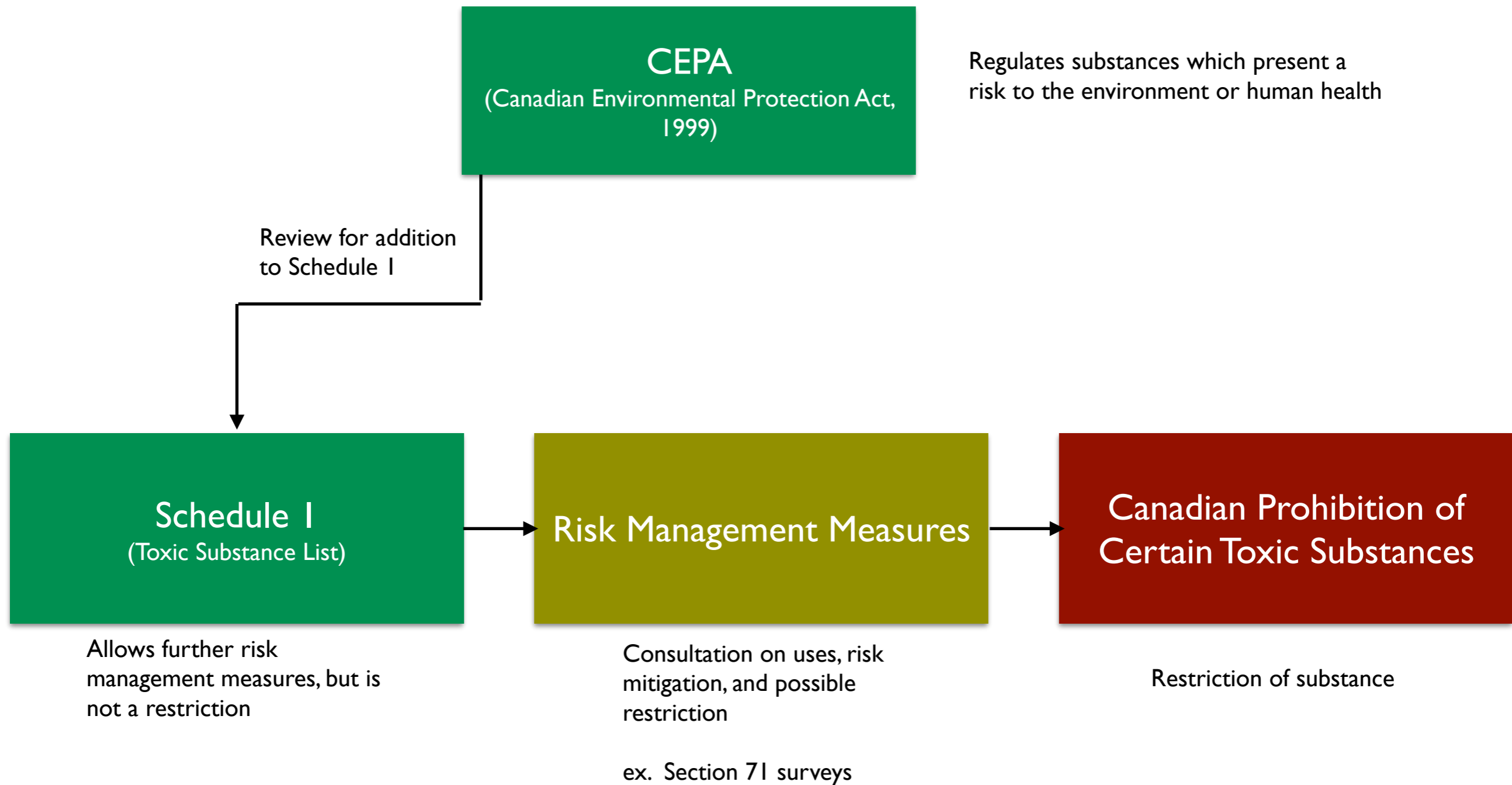
EU Medical Device Regulation (EU MDR)

- Regulation (EU) 2017/745
 - EU Medical Device Regulation
- Justification and Labeling of Cat I CMRs and EDCs
- In effect
 - May 26 2020

EU MDR - Cobalt

- Cobalt is being re-classified as a Cat I carcinogen
 - https://ec.europa.eu/info/law/better-regulation/initiatives/c-2019-7227_en
- Cobalt would be regulated under EU MDR by late 2021
- Stainless steel
 - Stainless steel commonly has Co between 0.1 and 0.2%
 - Which would require labelling and justification of most stainless steels under EU MDR
 - Lobbying ongoing by US and steel industry to exclude

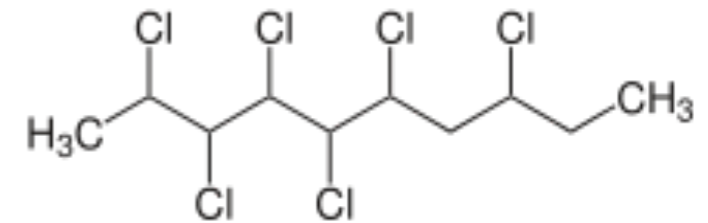
Canadian Chemical Regulation



Canadian

Prohibition of Certain Toxic Substances

- Currently restricted in articles (physical products)
 - Short Chain Chlorinated Alkanes (SCCAs)
 - Known as SCCPs in the EU and elsewhere
- Restricted
 - Regularly enforced by Environment Canada
 - ~1,500 ppm limit



Canada - Changes to Prohibition

- Canada is in process to change / add to the Prohibition of Certain Toxic Substances for the following chemicals
 - PFOA, PFOS, LC-PFCA
 - decaBDE
 - Hexabromocyclododecane (HBCD)
 - Dechlorane Plus (DP)
 - Decabromodiphenyl ethane (DBDPE)
- Firm dates and limits still in process
 - ie. Nothing final



Perfluorinated Salts and Acids

PFOA, PFOS, LC-PFCA

- Chemicals
 - Perfluorooctanoic acid (PFOA)
 - Perfluorooctanesulfonic acid (PFOS)
 - Long-Chain (C9–C20) Perfluorocarboxylic Acid (LC-PFCA)

- Restrictions

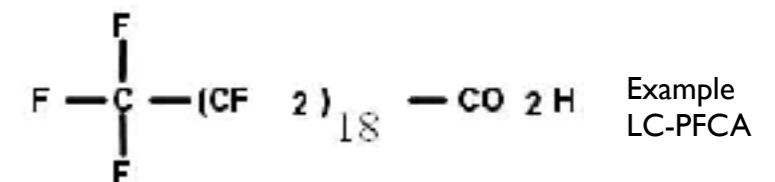
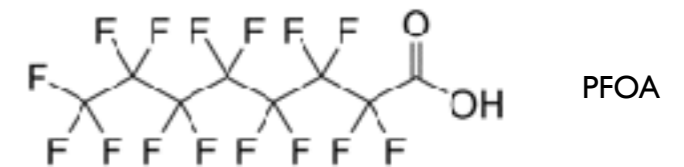
- Ban in manufactured items.
- Concentration?

- Timeline

- TBD (Restriction not published yet in Gazette)
 - *Likely 2020, with restriction in ~2022*

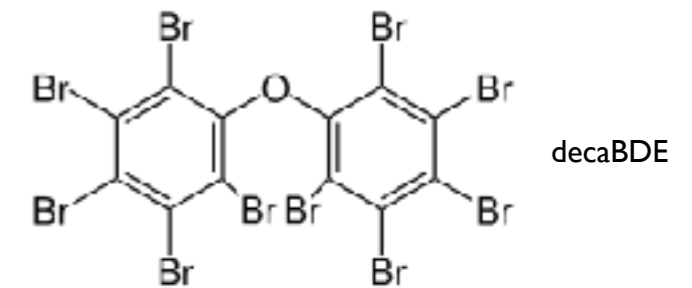
- Uses

- Water proof coatings
- Processing aid in fluoropolymers (ex. PTFE, FKM, FEP, PVDF)
- Makeup



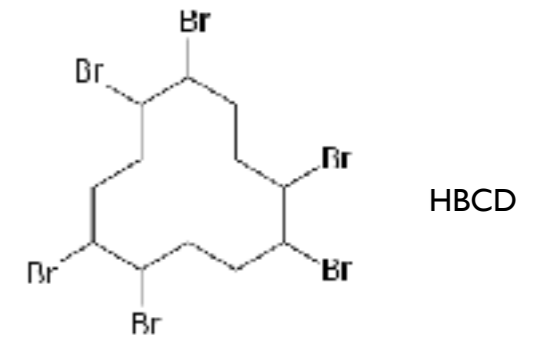
decaBDE

- Chemicals
 - Decabromodiphenyl ether (decaBDE)
- Restrictions
 - Ban in manufactured items. Likely at ~0.1%
- Timeline
 - TBD (Restriction not published yet in Gazette)
 - *Likely 2020, with restriction in ~2022*
- Uses
 - Flame retardant in thin plastics
 - Used with antimony trioxide as a synergist
- Regulation
 - EU RoHS



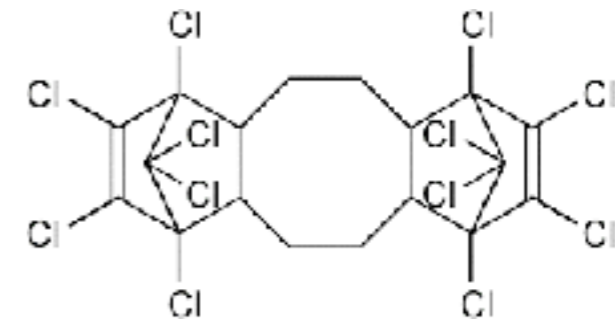
HBCD

- Chemicals
 - Hexabromocyclododecane (HBCD)
- Restrictions
 - Ban in manufactured items. Likely at ~0.1%
- Timeline
 - TBD (Restriction not published yet in Gazette)
 - *Likely 2020, with restriction in ~2022*
- Uses
 - Flame retardant in extruded (XPS) and expanded (EPS) polystyrene foam
- Regulation
 - EU REACH SVHC



Dechlorane Plus (DP)

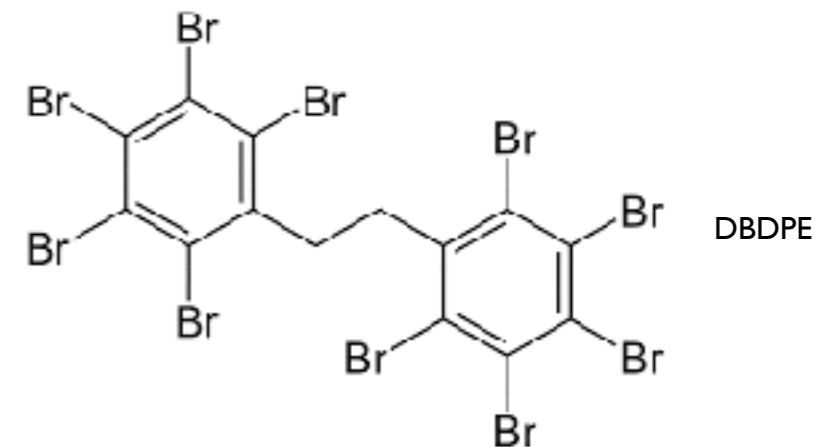
- Chemicals
 - Dechlorane Plus (DP)
- Restrictions
 - Ban in manufactured items. Likely at ~0.1%
- Timeline
 - Still in risk assessment
 - *More consultation to occur*
 - *Likely 2021, with restriction in ~2023*
- Uses
 - Flame retardant thin plastics
 - Nylon, polyolefin (heat shrink), EPDM
 - Regulation
 - EU REACH SVHC



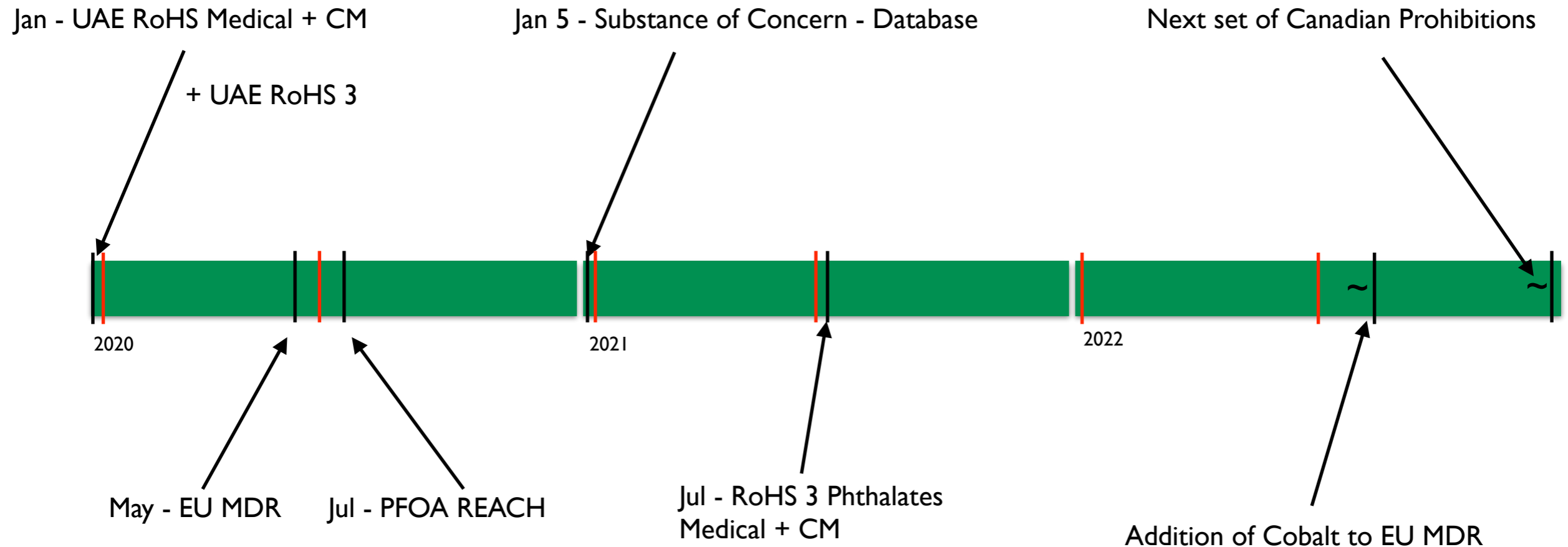
Dechlorane Plus

Decabromodiphenyl ethane (DBDPE)

- Chemicals
 - Decabromodiphenyl ethane (DBDPE)
- Restrictions
 - Ban in manufactured items. Likely at ~0.1%
- Timeline
 - Still in risk assessment
 - *More consultation to occur*
 - *Likely 2021, with restriction in ~2023*
- Uses
 - Flame retardant plastics (primarily thin plastics)
 - Common replacement for decaBDE (very common)
 - High risk materials are heat shrink and small connectors
 - Used with antimony trioxide (synergist)
 - Regulation
 - None



Upcoming Regulatory Deadlines



REACH SVHC Updates

Q&A