

# Upcoming Materials Restrictions

Deadline landscape 2020 to 2023

Presented by:  
Bruce Calder



# Overview - Agenda - Upcoming Restricted Materials Compliance

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- Introduction
- SCIP Database
  - Requirements
  - SSN Notification
- China VOC
  - Overview and requirements
- EU MDR
  - CMRs and EDCs
- UK CA
  - UK CE mark and REACH
- US Perfluorinated Substances Notification
- New Canadian Restrictions
- New Prop 65 Substances
- Q&A



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

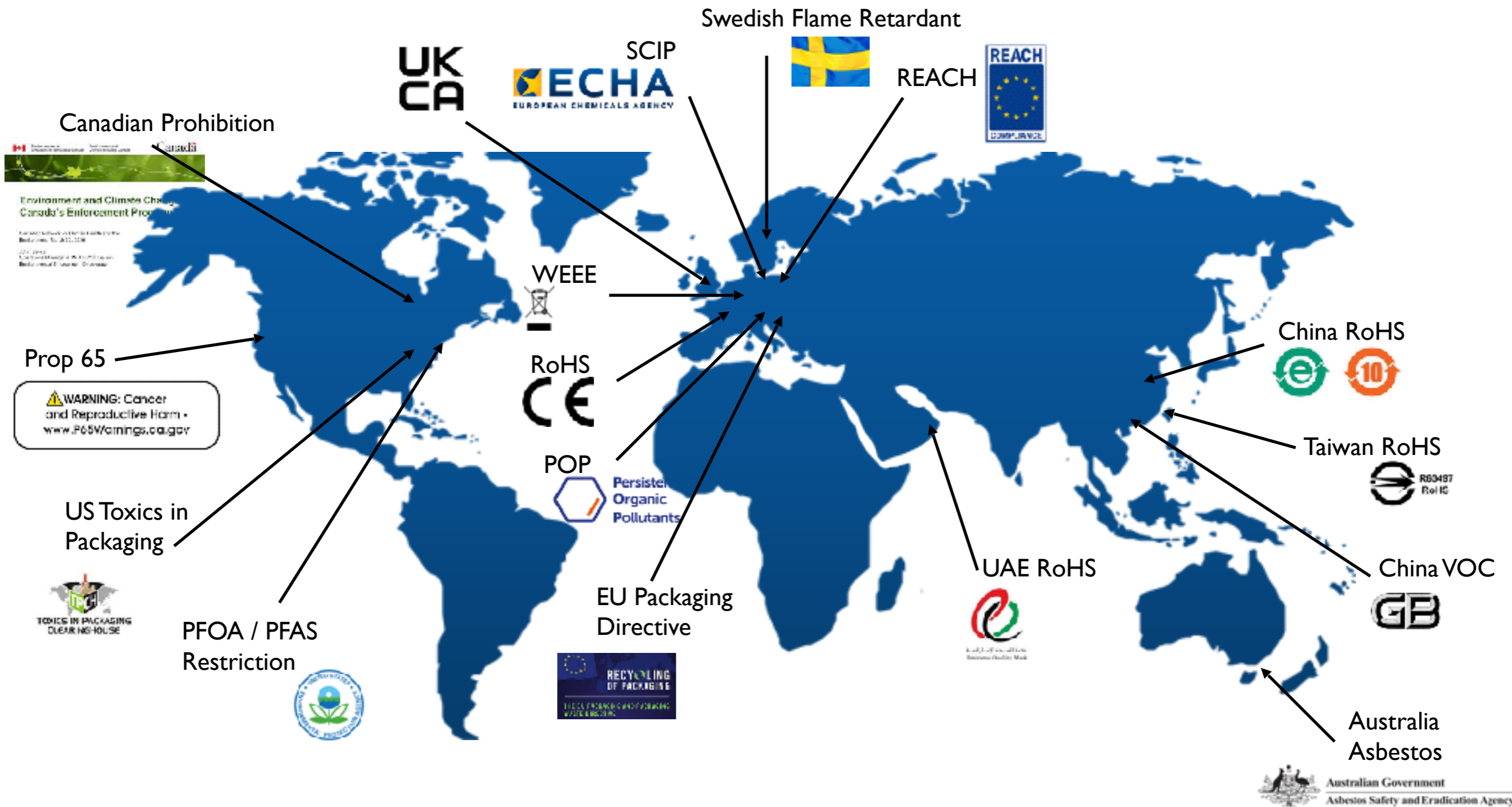
# Claigan - What do we need to quote?

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- **Laboratory testing**
  - Email us picture or weblink of product to [info@claigan.com](mailto:info@claigan.com)
- **Monthly / Quarterly Updates**
  - Email us at [info@claigan.com](mailto:info@claigan.com)
- **SCIP Web Demonstration and Templates**
  - Email us at [info@claigan.com](mailto:info@claigan.com)

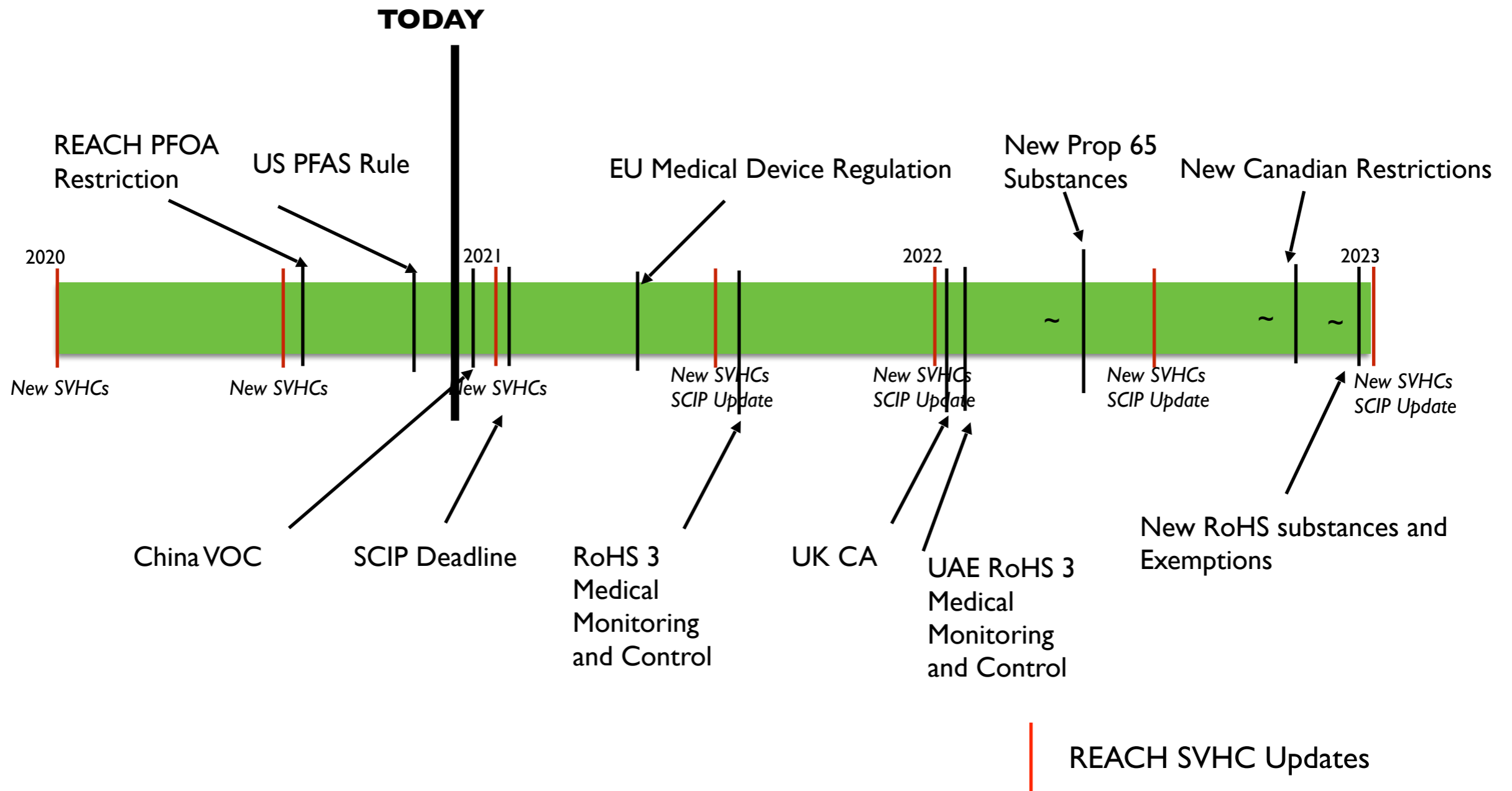


# Global Restricted Materials Requirements



Compliance with each is MANDATORY to sell in each jurisdiction

# Longer Term Regulatory Deadline



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

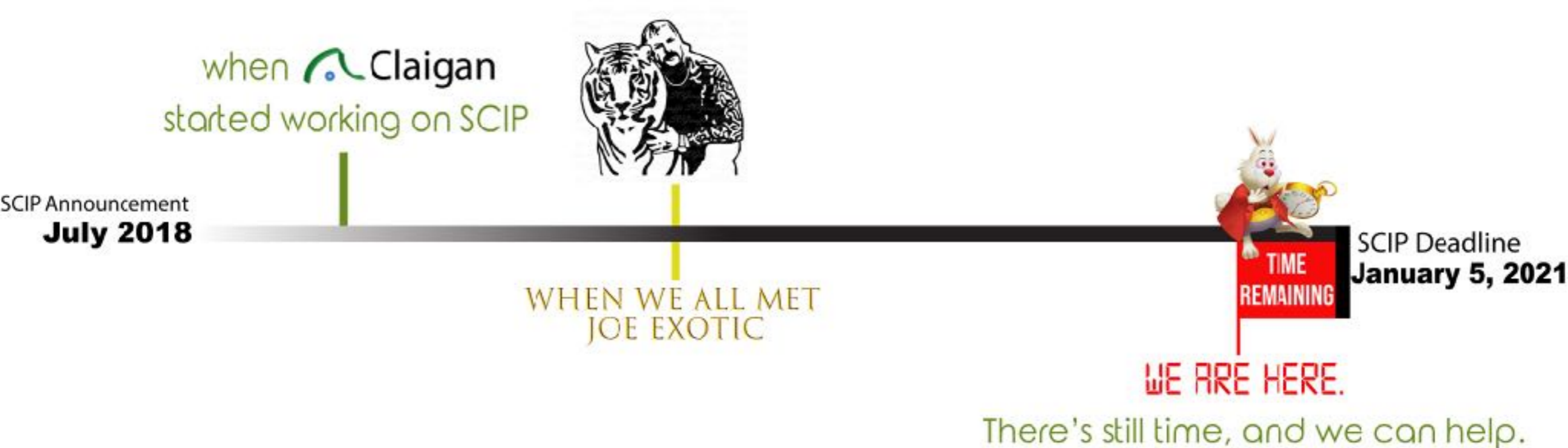
## (Formerly REACH SVHC Database)

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- **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 - Available
  - V0b Version - Updated August 2020. To be released in October
  - V1 - End of October 2020

# SCIP Database - EU Deadline

- **Reminder**
- **Deadline**
  - January 5 2021
  - Less than 3 months away.



# Substance of Concern Database - Claigan

## Product Declaration



Complex Product



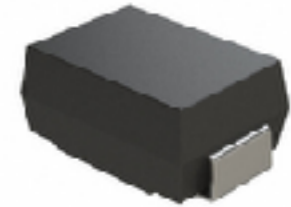
Component /w SVHC

metal - lead (and alloys of) - lead alloy

24 instances

Pb  
0.1% to 100%

Do not take apart  
Do not mix with municipal waste



Component /w SVHC

Metal - brass  
30 instances

Pb  
1 to 10%

Avoid prolonged direct contact with skin during use  
Wash hands after contact  
Keep out of reach of children  
Do not mix with municipal waste



Component /w SVHC

Rubber and elastomers - silicone rubber  
15 instances

D6  
0.1 to 0.3%

Do not mix with municipal waste  
Do not flush or pour down drain



Other declarables

- + Pb (Al)
- + EGDME (Battery)
- + Decl+ (Heat shrink)
- + Pb (Steel)
- + Cd (Relays)
- + Moca (PU)
- + PbO (Pots)
- + TNPP (Film)
- + UV-328 (LCD)

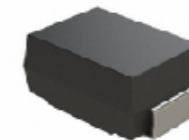


# SCIP - Templates - Building Blocks

## Product Template



4	3	2
Material	Wood Frame	Stainless Steel Coffee Maker, 12-Cup
Primary Author	ABC (General Product Code)	MM110 07113
Material Type		
Company	KLINGLUB	
Product UIC ID	Product UIC ID	
	Material Group	05011 - 10000: Barrels, Tanks or Oil, Water, or Gas
	Production in Europe Unit	10
Self-use Instruction	See use instruction (3)	See component self-use instructions
Supplier	Manufacturer	Distributor/Container Item is in the list of ADM's suppliers. Distribution Unit may have more or less of each RUC if S/C components from other base.
System	Material	
System	Image (3D view)	
Linear Article	Linear Article 1	Basic Component
	# of occurrences of article 1	2
	Linear Article 2	Special Feature
	# of occurrences of article 2	2
	Linear Article 3	Block Component
	# of occurrences of article 3	4
	Linear Article 4	Material Component
	# of occurrences of article 4	3



Pb in Steel

Dechlorane Plus in Heat Shrink

EGMDE in Button Cell Batteries

Pb in High Temp Solder

Pb in Brass

## Component Templates

# Distributor Responsibility

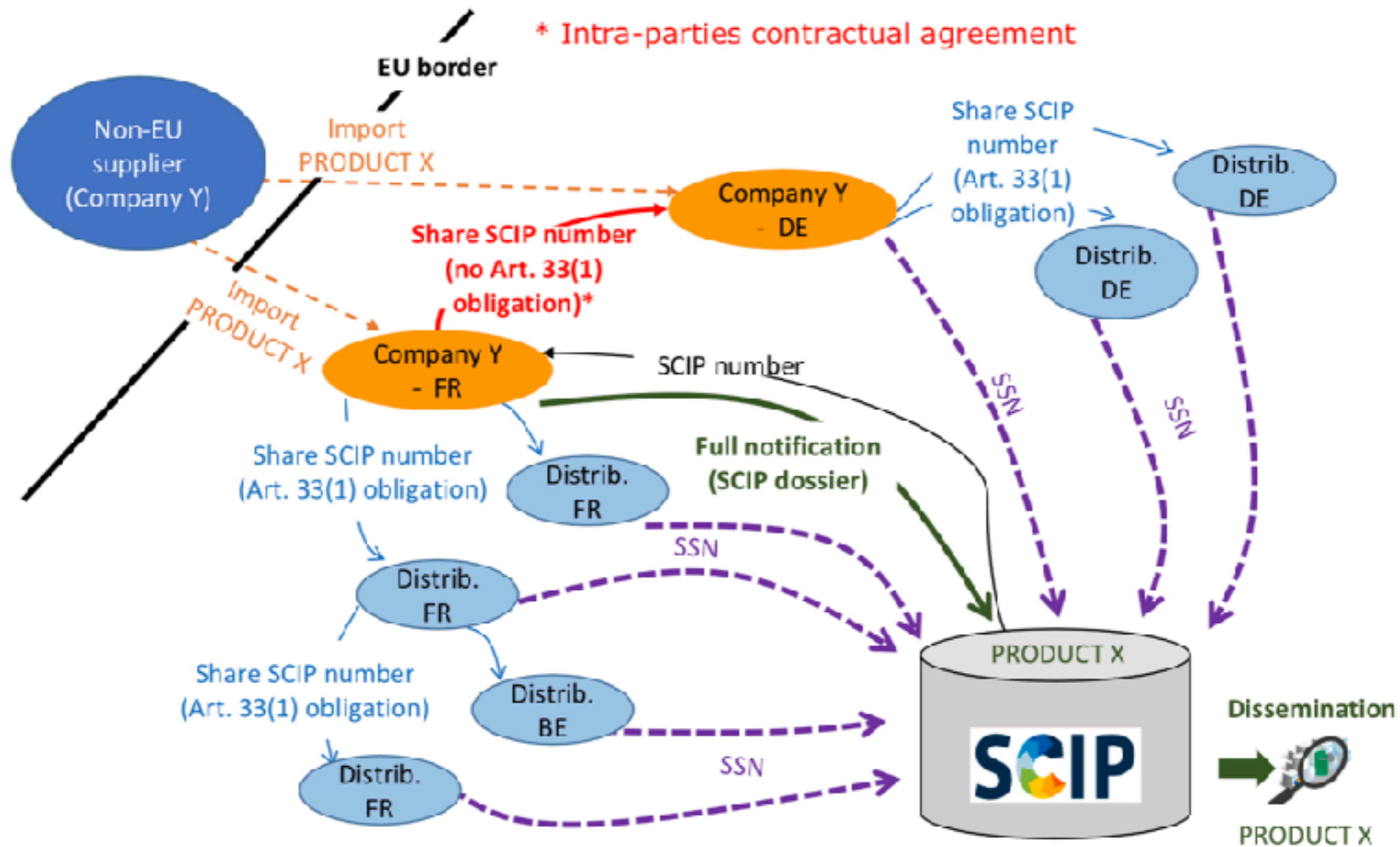
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- Simplified SCIP Notification (SSN)
  - Tools to refer to SCIP data already submitted to ECHA
- Providers of products in the EU that are not the original manufacturer or importer
  - Manufacturer is the brand owner of the product being placed on the market

# Distributor Responsibility



## Extension of the SSN (2)



For each SSN submission, a new SCIP number is issued

# SSN - Options

[Search](#) | [Upload & submit](#) | [Create dossier online](#) | [Simplified SCIP notification](#)

## Upload and submission of simplified SCIP notifications in bulk

Bulk Upload

Please upload information on the articles you wish to notify using an excel file including in each row

- A SCIP number (mandatory information)
- An Article name (optional)
- A Primary article identifier type (optional)
- A Primary article identifier value (optional)

ⓘ Please note that only Excel files are allowed to be uploaded and, currently, only simplified SCIP notifications can be submitted



Drop file to upload

or

Browse

Single Upload

## Individual submission of a simplified SCIP notification

Please enter the SCIP number of the article you wish to notify and click "Submit" to send your Simplified SCIP notification

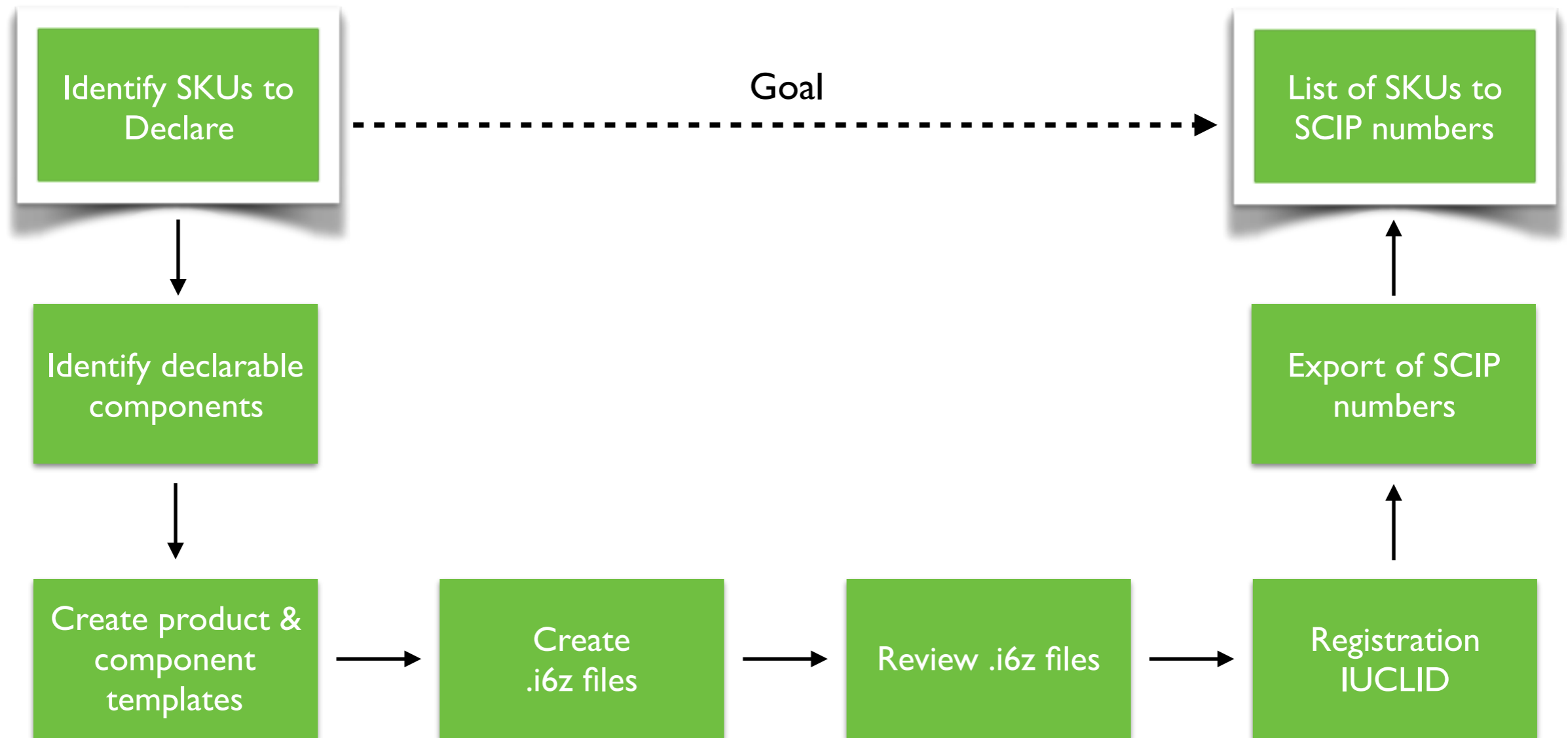
ⓘ Only one SCIP number can be submitted at a time.

SCIP number

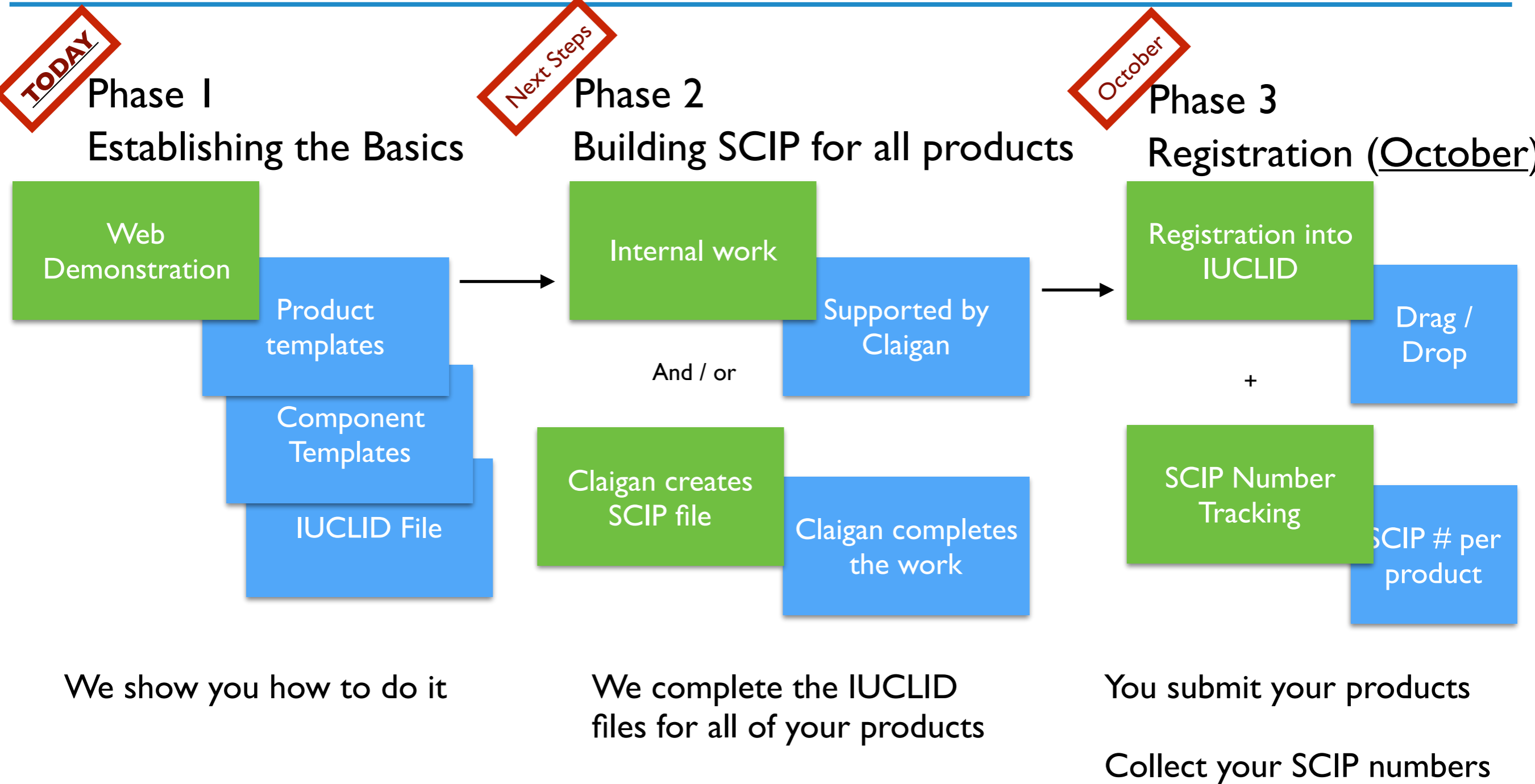
Submit

# SCIP Outputs (Simplified)

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# Claigan Practical Version (SCIP Process)



# Claigan Practical Version (SCIP Process)

**TODAY**

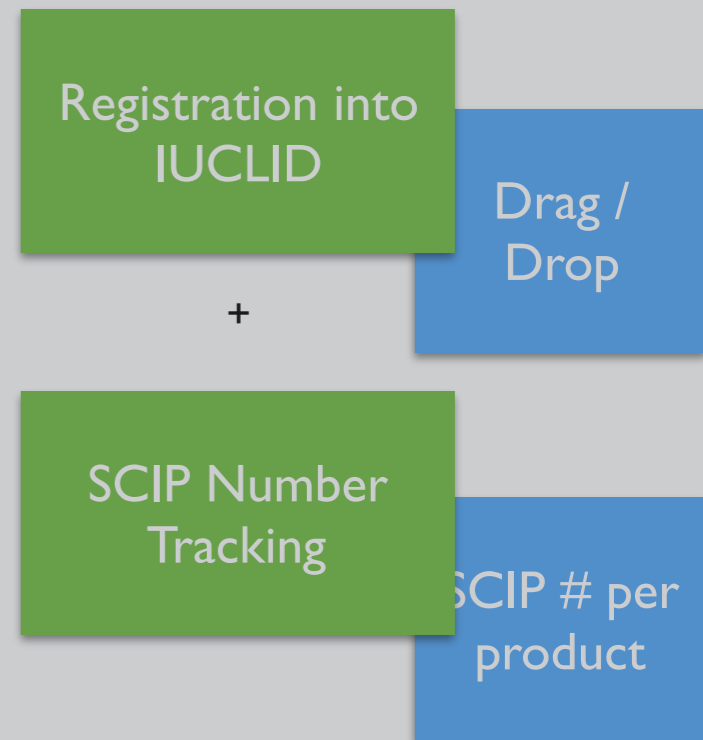
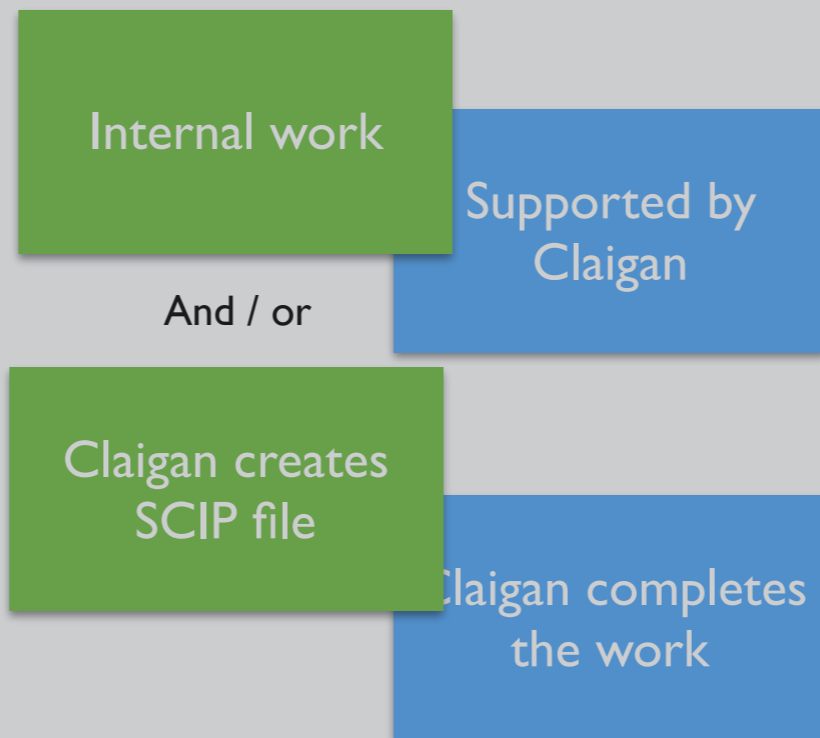
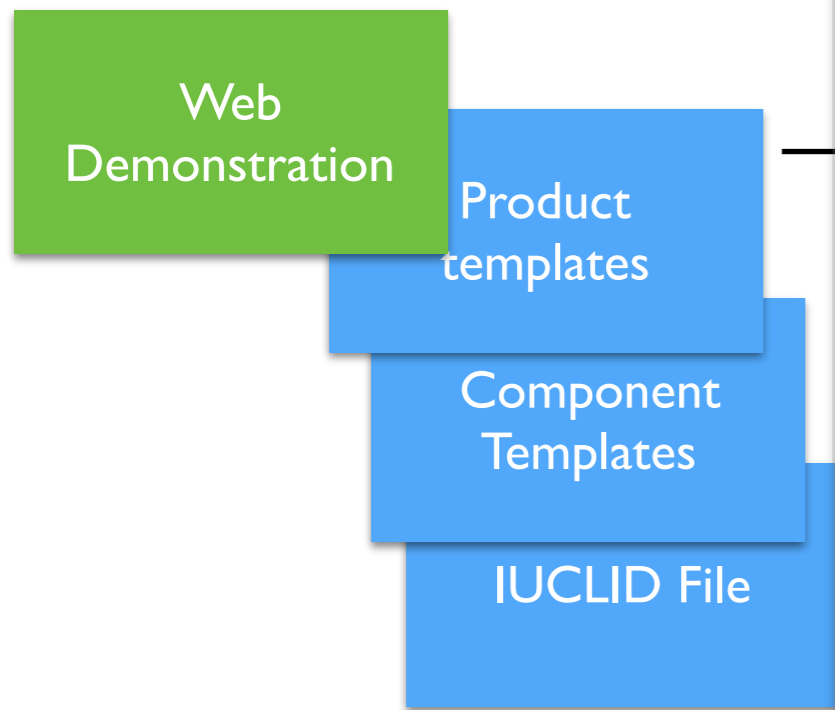
**Phase 1**  
Establishing the Basics

**Next Steps**

**Phase 2**  
Building SCIP for all products

**October**

**Phase 3**  
Registration (October)



We show you how to do it

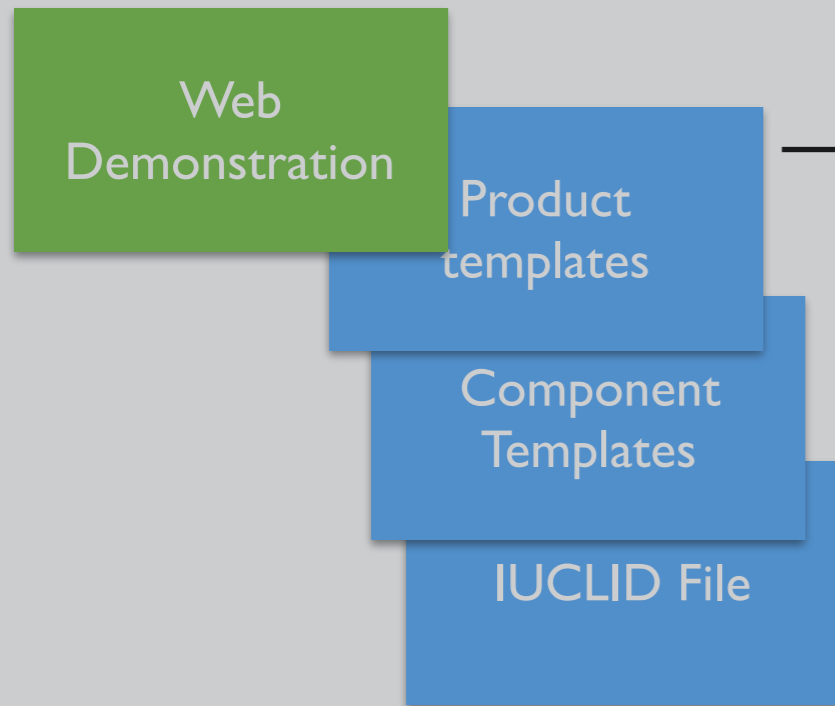
We complete the IUCLID files for all of your products

You submit your products

# Claigan Practical Version (SCIP Process)

**TODAY**

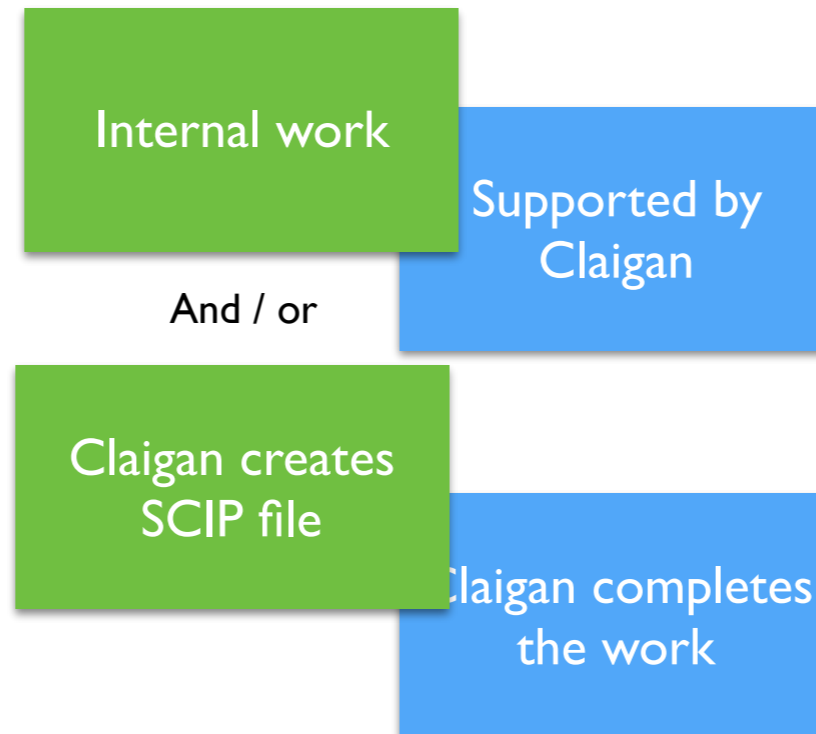
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Establishing the Basics



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**Next Steps**

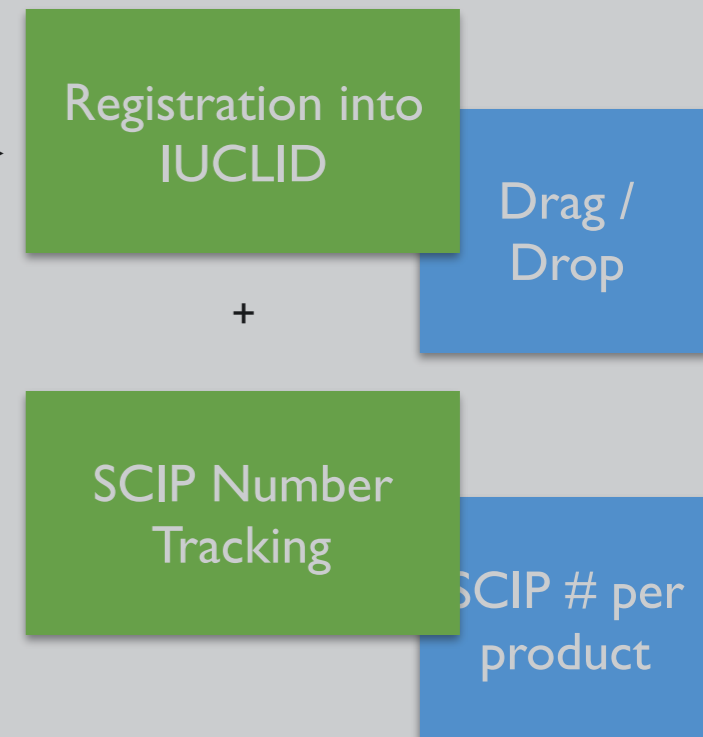
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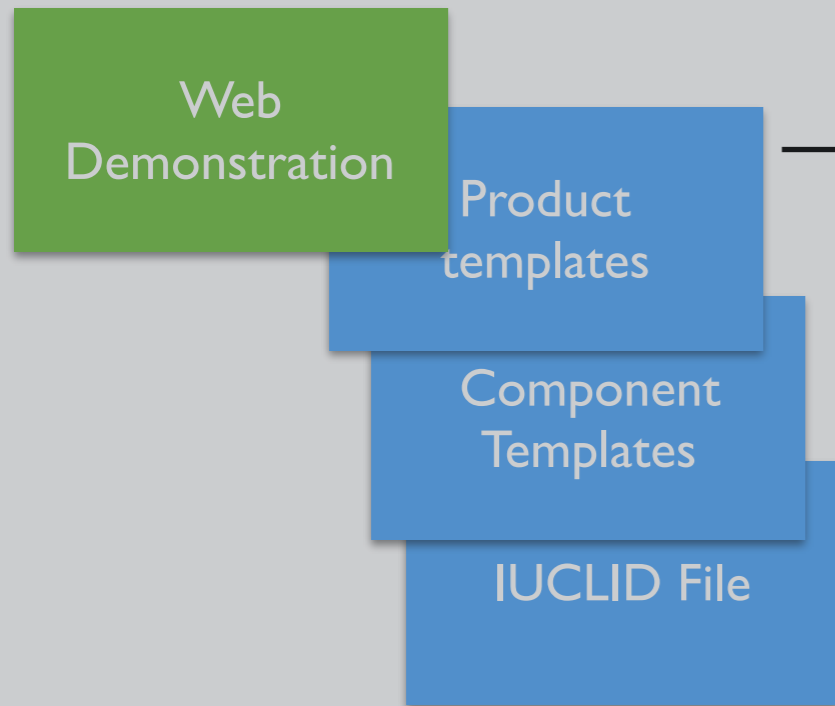
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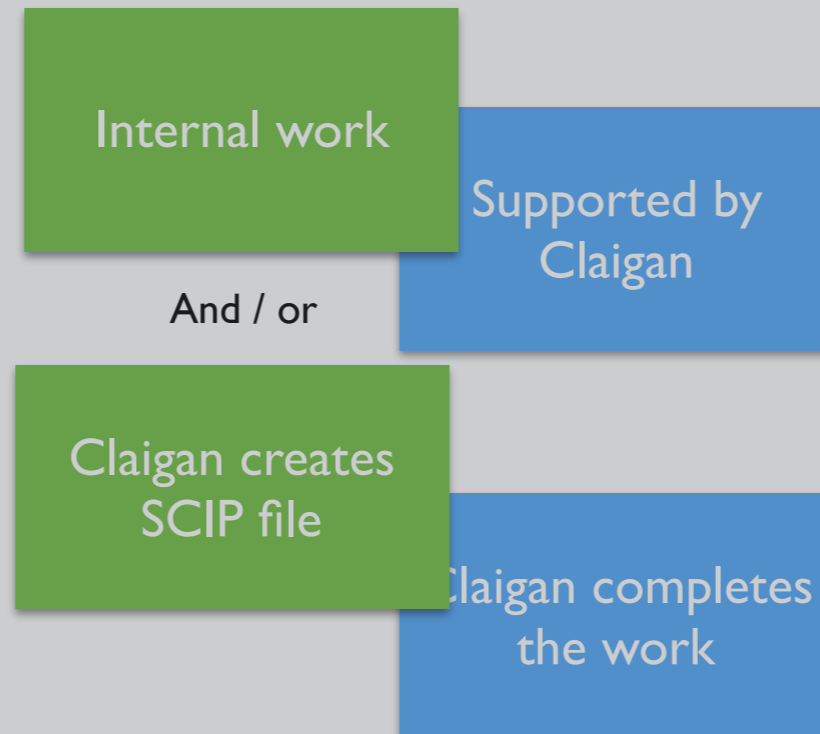
**Phase 1**  
Establishing the Basics



We show you how to do it

**Next Steps**

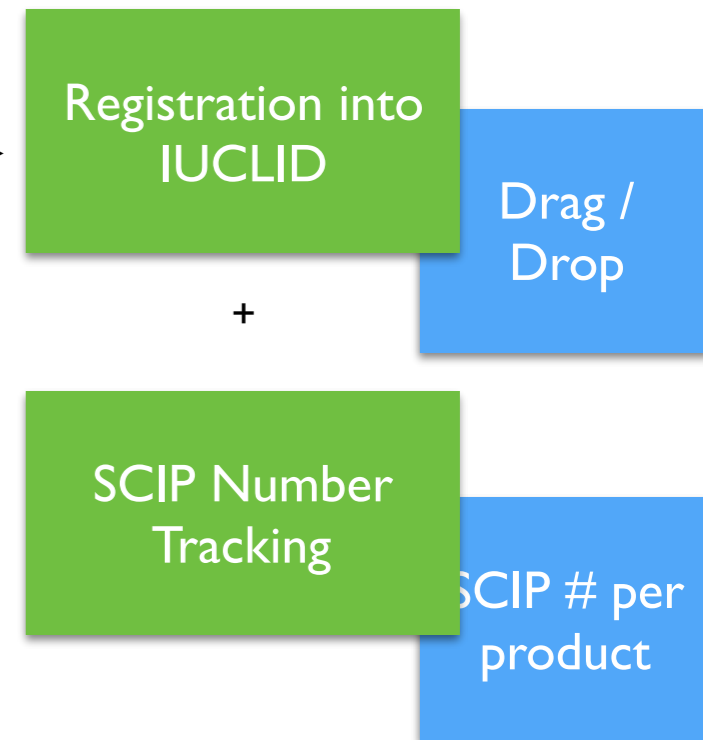
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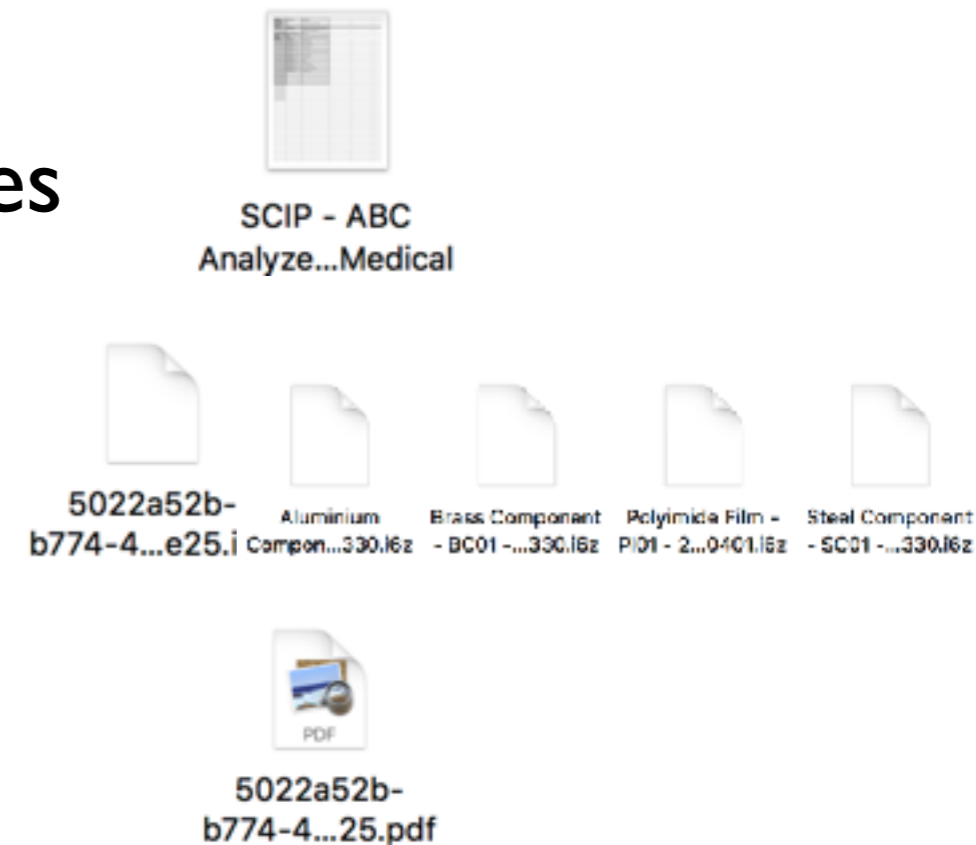
You submit your products

Collect your SCIP numbers

# Example Outputs - Engineering Evaluation

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- Outputs
  - Excel files /w component templates
  - IUCLID .i6z file
  - IUCLID .pdf



# Chinese VOC Restrictions

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- Coatings for electronic products
  - VOC restriction in coatings applied to electronic products (in China)
  - Standard - GB 30981-2020
- VOC limit for coating (pre-application)
  - 420 g/L VOC
  - Different for UV curable

Electronic and electrical coatings	Primer	≤420
	Paint	≤420
	Varnish	≤420

# Chinese VOC Restrictions

- UV (Radiation) Curable Coatings

**Table 4 – Limit Value Requirements for VOC Content in Radiation-Curable Coating**

Product Types	Application methods	Limit Values / (g/L)
Water-based	Spray	≤400
Water-based	Other	≤150
Non-water-based	Spray	≤550
	Other	≤200

- Deadline
  - Dec 1 2020

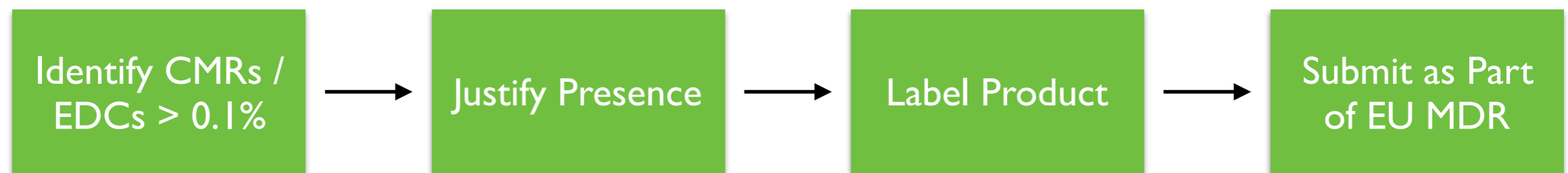
# EU Medical Device Regulation

## CMRs and EDCs

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- 10.4.1 - 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,
- Require to justify and label
  - Carcinogens, Mutagens, Reproductive Toxins (CMR) & Endocrine Disrupting Chemicals (EDCs)
  - >0.1% w/w

# EU Medical Device Regulation CMRs and EDCs Process



In invasive, fluid, or gas contacting materials

Commonly through testing

If required, justify presence over 0.1 % w/w

Label product with chemical

Submit as part of EU MDR technical file



# UK CE Marking

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- **UK Conformity Assessed**
- Replacement for CE mark (in the UK)
- Required to be with product by
  - Jan 1 2022
- Required to be on product by
  - Jan 1 2023
    - With the usual CE marking exceptions
- Currently the same compliance requirements as CE
  - But notified body registrations have to be transferred to UK

UK  
CA

# UK REACH

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- Chemical registrations need to be re-conducted in UK
  - If substance importation into UK above 1 tonne per annum
  - <https://www.gov.uk/guidance/how-to-comply-with-reach-chemical-regulations#tonnage-band-deadlines>



# UK REACH registration deadlines

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- Initially chemicals are grandfathered
- Deadlines for UK registrations
  - Oct 28 2023
    - 1,000 tonnes
    - 100 tonnes very toxic to aquatic
    - 1 tonne CMRs
  - Oct 28 2025
    - 100 tonnes
  - Oct 28 2027
    - 1 tonne

# US Perfluorinated Substances Notification

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- Long-chain perfluoroalkyl carboxylate (LCPFAC) chemical substances and PFOA
  - Require notification to EPA if
  - a subset of LCPFAC chemicals imported as part of a surface coating on articles
- In effect - September 25 2020
- <https://www.federalregister.gov/documents/2020/07/27/2020-13738/long-chain-perfluoroalkyl-carboxylate-and-perfluoroalkyl-sulfonate-chemical-substances-significant>

# US Perfluorinated Restrictions

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- Substance under scope of notification 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
  - PFOAs
- Looking at perfluorinated chemicals in coating
  - Generally water proof coatings

# Canada - Changes to Prohibition

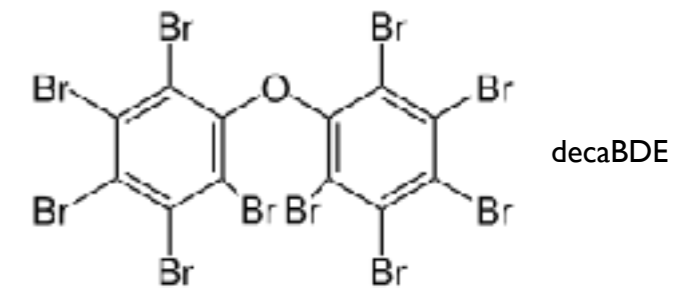
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- Canada is in process to change / add to the Prohibition of Certain Toxic Substances for the following chemicals
  - PFOA, PFOS, LC-PFCA
  - decaBDE
  - Hexabromocyclododecane (HBCD)
  - Dechlorane Plus (DP)
  - Decabromodiphenyl ethane (DBDPE)
- Projected timelines
  - Originally planned to be published Dec 2020 (delayed)
  - Into effect likely 2023

## decaBDE

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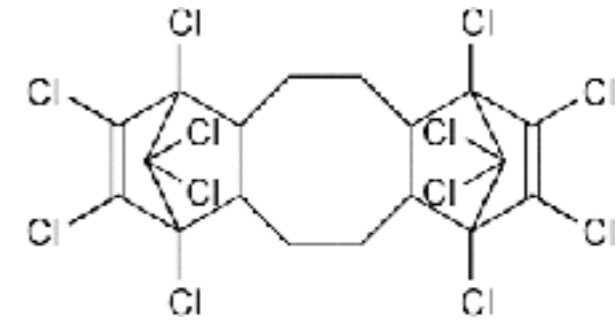
- Chemicals
  - Decabromodiphenyl ether (decaBDE)
- Restrictions
  - Ban in manufactured items. Likely at ~0.1%
- Timeline
  - TBD (Restriction not published yet in Gazette)
- Uses
  - Flame retardant in thin plastics
  - Used with antimony trioxide as a synergist
- Regulation
  - EU RoHS



## Dechlorane Plus (DP)

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

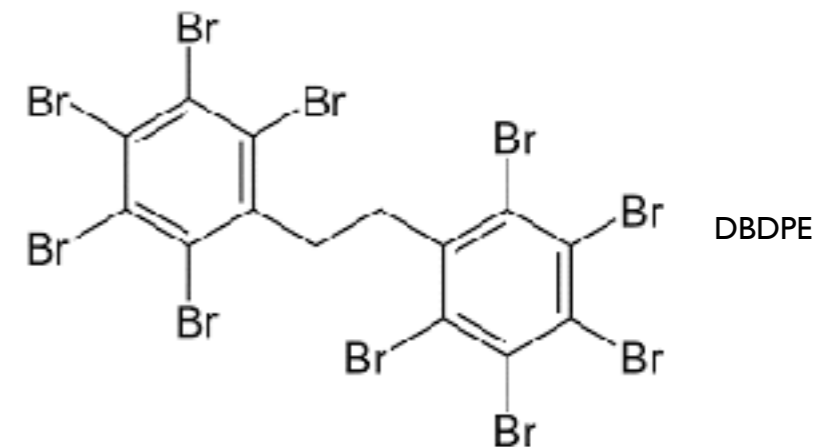


Dechlorane Plus

## Decabromodiphenyl ethane (DBDPE)

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



# New Prop 65 Substances Under Consultation

- **New Substances under consultation**

- Benzophenone-3
- Bisphenol S
- Diazinon
- Diethylphthalate
- Domoic acid
- Glyphosate and its salts
- Manganese
- Neonicotinoid pesticides
  - Acetamiprid
  - Clothianidin
  - Imidacloprid
  - Thiamethoxam
- Parabens
  - Butyl paraben
  - Isobutyl paraben
  - Methyl paraben
  - Propyl paraben
- Per- and polyfluorinated substances (PFASs)
  - Perfluorodecanoic acid (PFDA)
  - Perfluorohexanesulfonic acid (PFHxS)
  - Perfluorononanoic acid (PFNA)
  - Perfluoroundecanoic acid (PFUnDA)
- Titanium dioxide nanoparticles
- Vinpocetine
- Zearalenone





# New Prop 65 Substances Under Consultation - Key Substance

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- Key substance
  - Manganese
- Uses
  - Very common in steel and cast iron
- Listing basis
  - Reproductive toxin
  - Very good chance of becoming listed



# Claigan - What do we need to quote?

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- **Monthly / Quarterly Updates**
  - Email us at [info@claigan.com](mailto:info@claigan.com)
- **SCIP Web Demonstration and Templates**
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Q&A