

SCIP Updates

Update ECHA Guidance from July 2020
+ 4 New REACH SVHCs

Presented by:
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Overview - Agenda - SCIP Database Requirements Update - July

- Intro
- SCIP Updates
 - Representative Article Approach
 - Simplified SCIP Notification (SSN)
 - Software changes (August)
- New REACH SVHCs (June 2020)
 - 4 new REACH SVHCs
- SCIP Compliance Process
- Q&A



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

Claigan - What do we need to quote?

- **Laboratory testing**

- Email us picture or weblink of product to info@claigan.com

- **Monthly / Quarterly Updates**

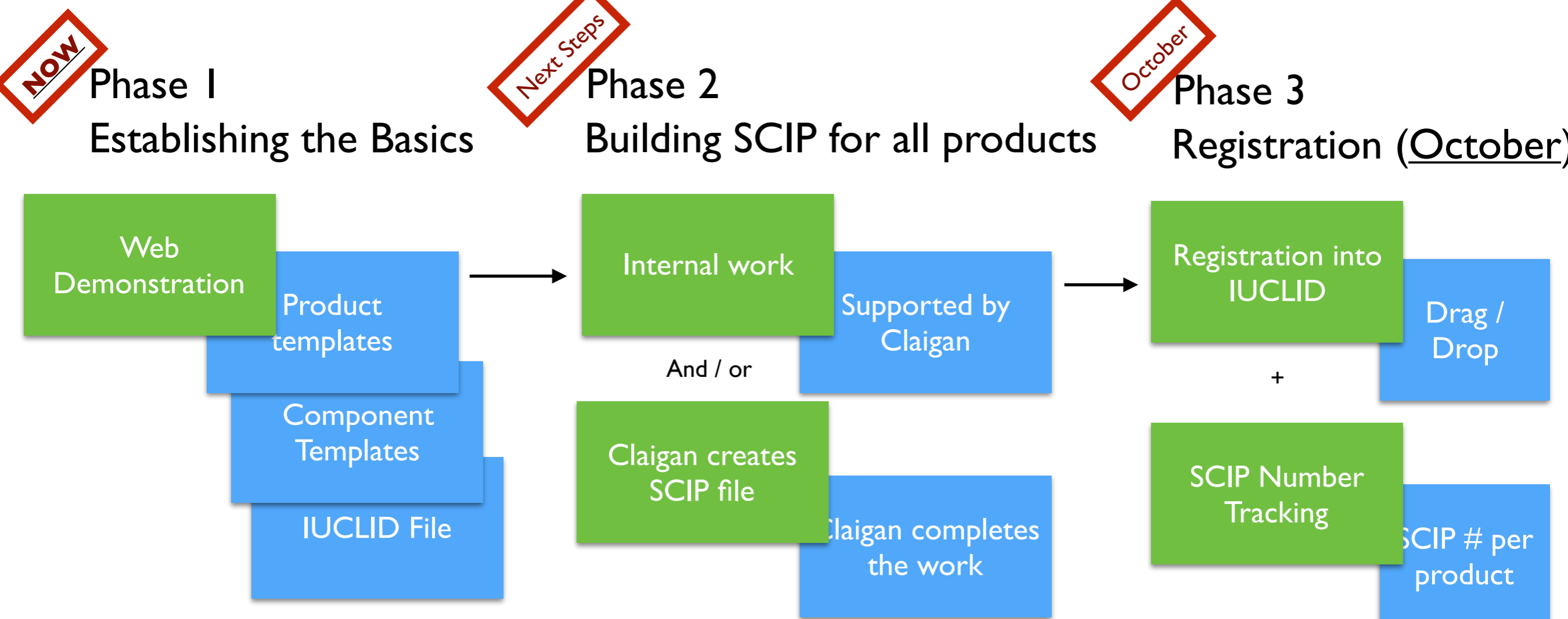
- Email us at info@claigan.com

- **SCIP Web Demonstration and Template**

- Email us at info@claigan.com



Claigan Practical Version (SCIP Process)



Explanation of Rules
 Explanation of Process
 Evaluation of representative product
 Creation of product template (excel)
 Creation of component templates (excel)
 Creation of IUCLID file for a product

Creating the necessary SCIP files
 Practical approach
 Create base product declarations
 Create variations based on differences
 Claigan and you have the same process
 Very interchangeable solution depending on internal resources

Drag / drop submission into IUCLID
 Tracking
 SCIP number per product
 To be able to send a single file to requesting customers

(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 - Available
 - V0b Version - August 2020
 - V1 - October 2020

SCIP Database - EU Deadline

- **Reminder**
- **Deadline**
 - January 5 2021
 - Less than 6 months away.



Update July - SCIP

- Representative article approach
 - Allowed by ECHA
 - Declaring the worst reasonable case for a product or product line
 - Using generic component for groups of components with the same attributes (SVHCs and materials)
- Simplified SCIP Notification (SSN) requirements
- New version of SCIP in August

Representative Article Approach

- Variation of what is sometimes also referred to as ‘worst case’ reporting.
 - Consists in the ‘worst’ possible combination of potential components and subcomponents containing Candidate List substances in a given complex object and reported in the SCIP notification under the umbrella of a ‘fictitious’ complex object.

Representative Article Approach

- Articles in complex objects with different Candidate List substances in their composition are reported individually in the SCIP notification under a generic identification for those complex objects ('fictitious' complex object inserted in the hierarchical tree of components and sub-components).
- The component grouping done by Claigan
 - Brass component (Pb)
 - Heat shrink (Dechlorane Plus)

Location

- Lots of examples of identifying locations in guidance
 - Parts in sub assemblies
- Recommendation only
 - No rules
 - Not binding
- Component grouping
 - Allowance of component grouping removes the location requirement

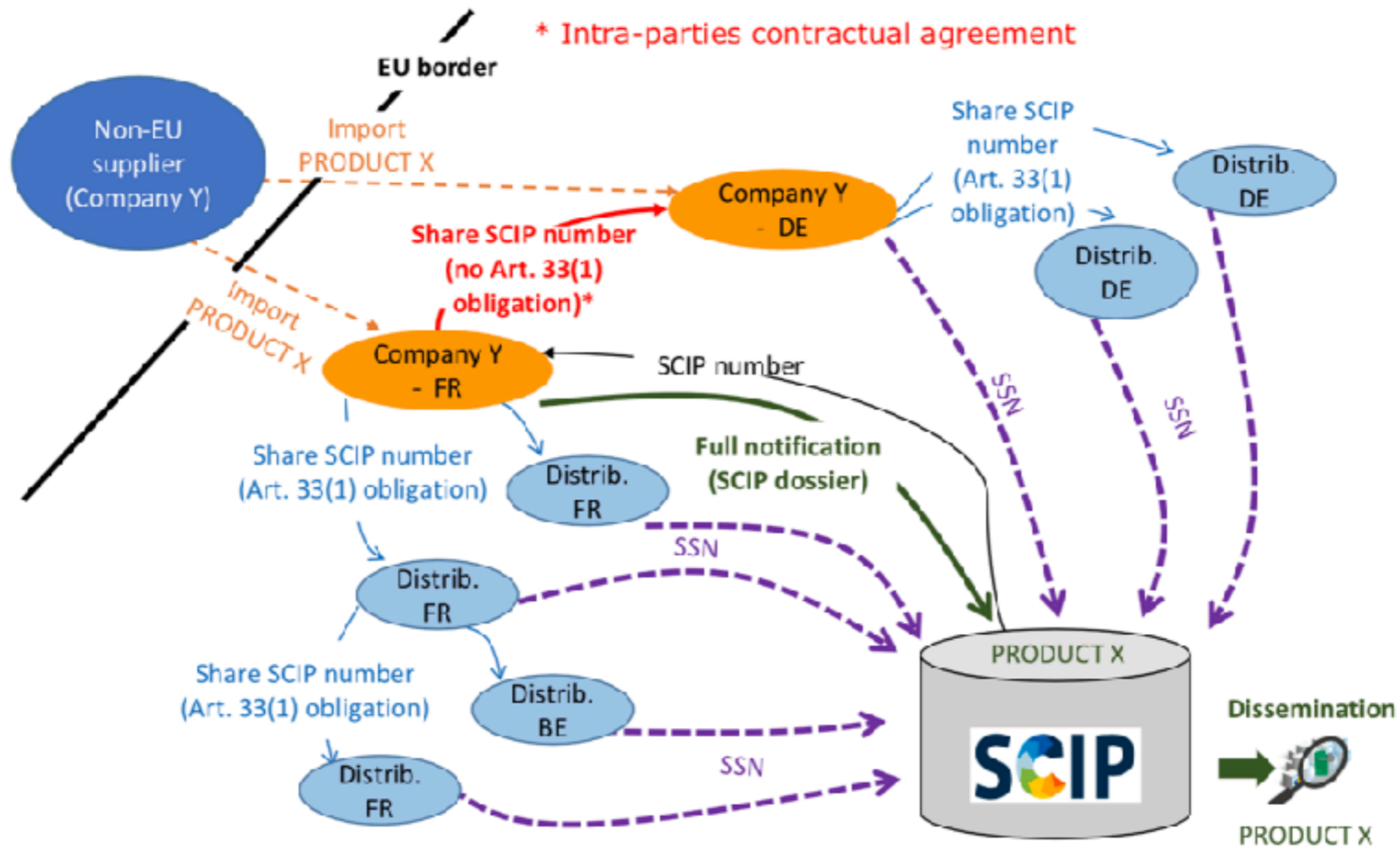
Distributor Responsibility

- Simplified SCIP Notification (SSN)
 - Guidance includes details on distributor simplified notification
- Distributor definition
 - Not well defined.
 - Does not include retailers of consumer products

Distributor Responsibility



Extension of the SSN (2)

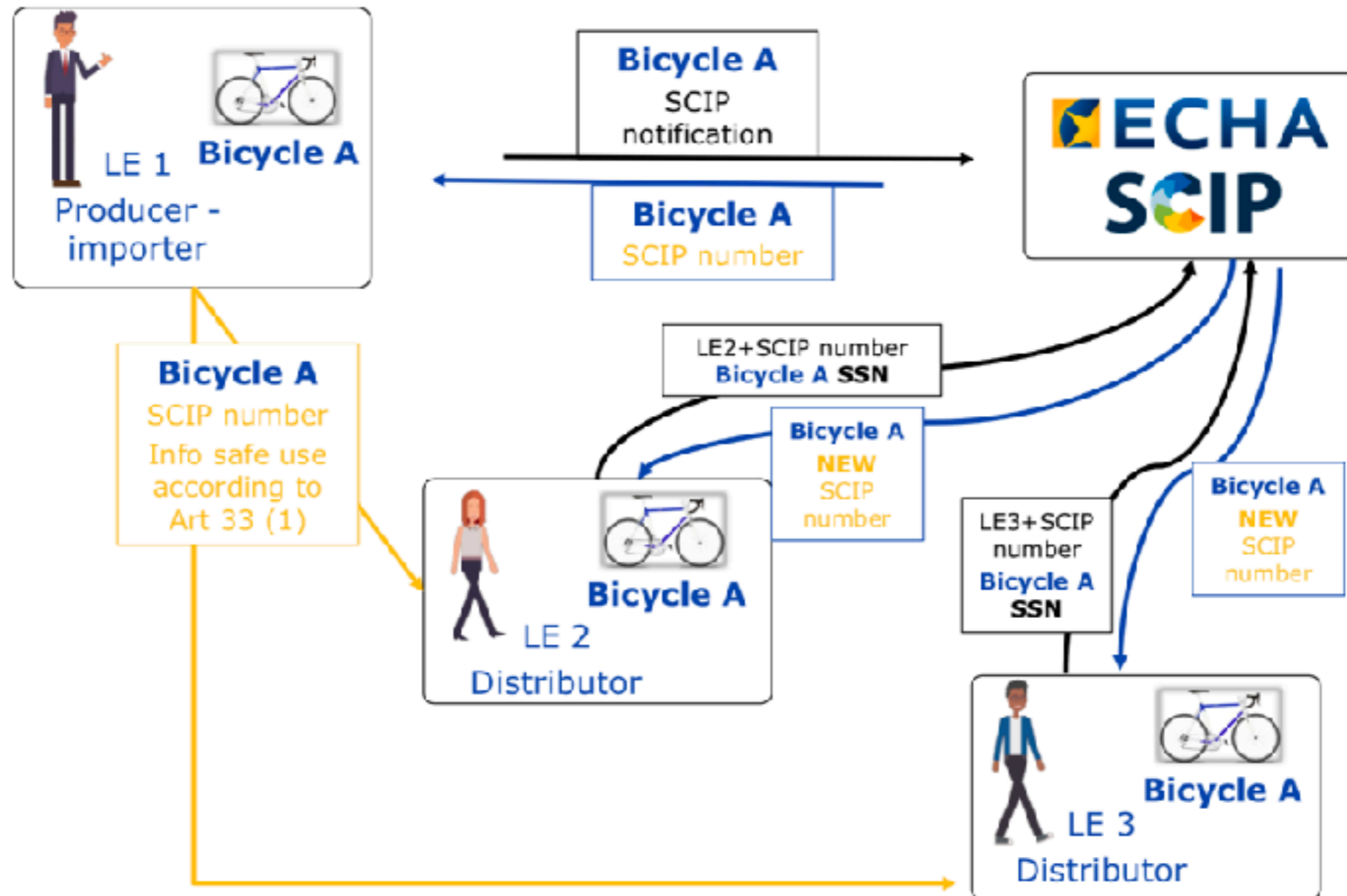


For each SSN submission, a new SCIP number is issued

Distributor Responsibility



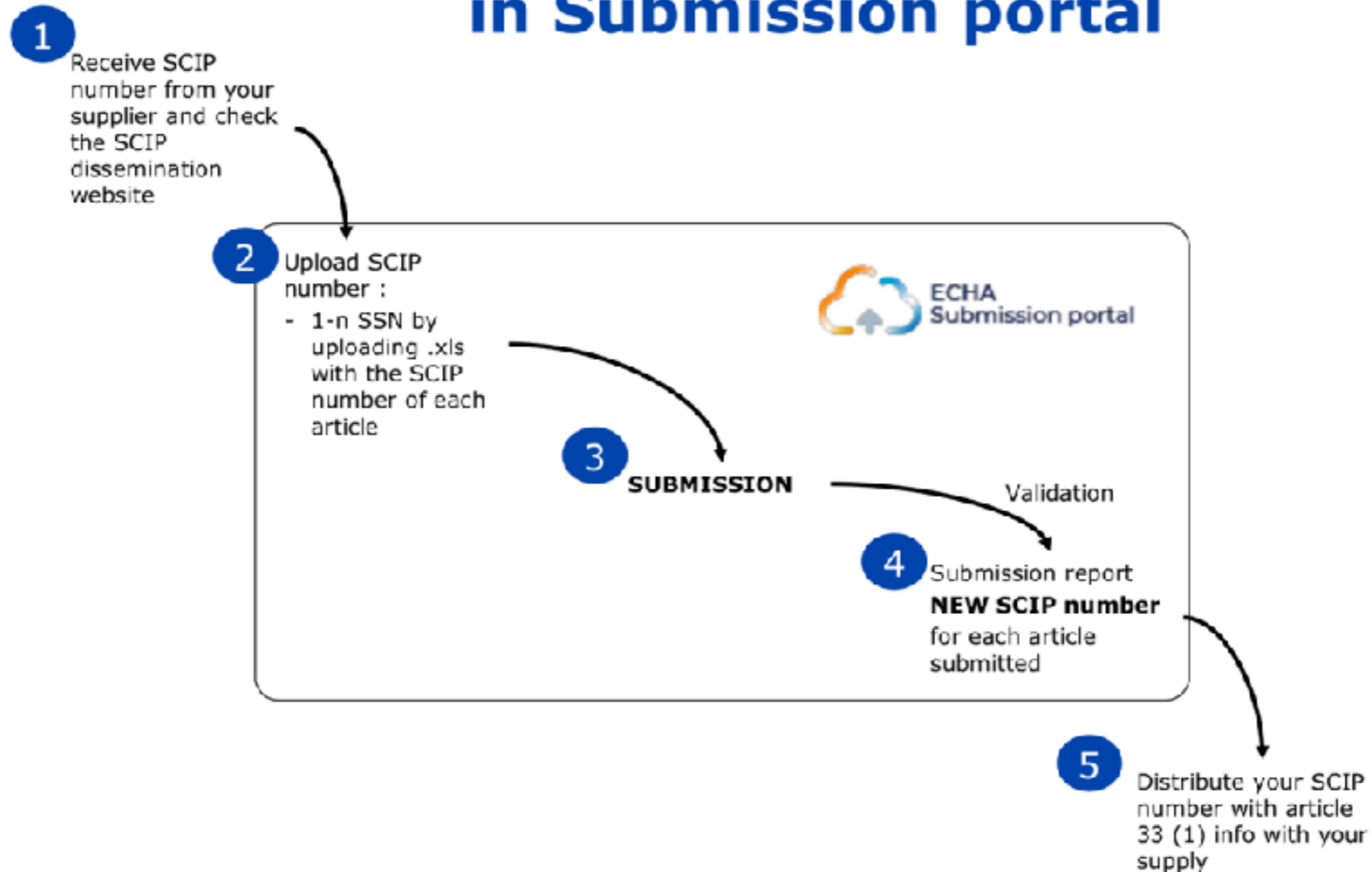
Simplified SCIP notification (SSN) overview



SSN - Distributor Flow



Simplified SCIP notification in Submission portal



Distributor Responsibility

Practical Ramifications

- Implementation
 - Current guidance
 - Very unlikely to survive scrutiny
- Until then distributors would be required to
 - acquire SCIP # for each product they sell,
 - submit the # under their ID in IUCLID, and
 - collect their SCIP # for each submitted SSN

IUCLID / SCIP Update

- August
 - New version of IUCLID / SCIP
 - SSN system (distributor)
 - SCIP #s
 - Updated REACH SVHC list package
 - Dossier validation

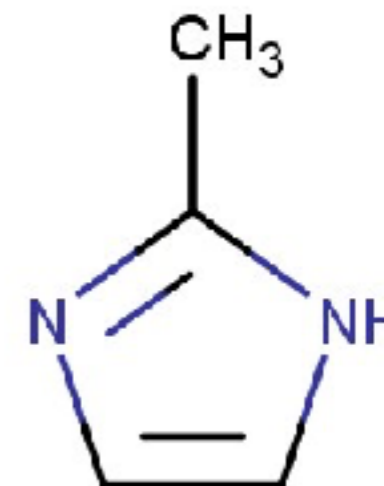
Four (4) New REACH SVHCs

- Four (4) new REACH SVHC
 - 1-vinylimidazole
 - 2-methylimidazole
 - Butyl 4-hydroxybenzoate
 - Dibutylbis(pentane-2,4-dionato-O,O')tin
- Referred to EU Commission for further review
 - Resorcinol

2-methylimidazole

**Low Risk
of presence >0.1% w/w**

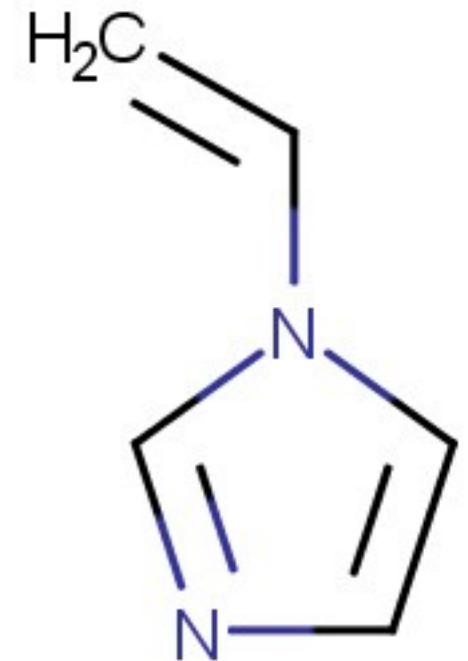
- Details
 - EC # 211-765-7
 - Believed Cat 1b Reproductive Toxin
- Uses
 - Used as a pre-cursor to make nitroimidazole antibiotics
 - Intermediate
 - Low volume substances (10+ tonnes per annum into EU)
- Status
 - Agreed by to be SVHC



1-vinylimidazole

**Low Risk
of presence >0.1% w/w**

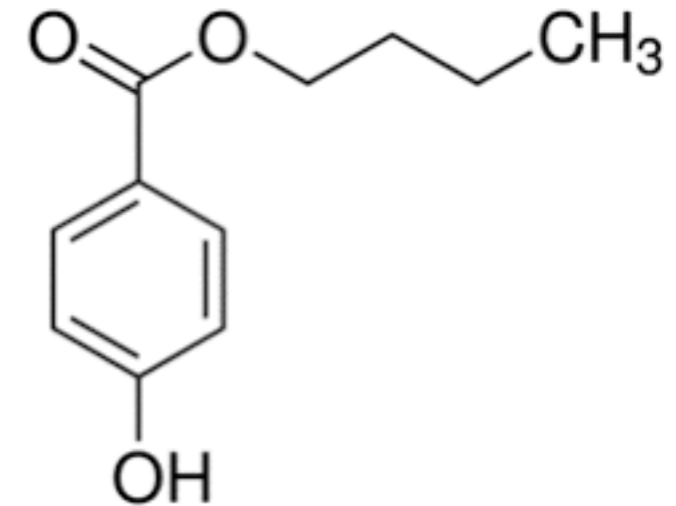
- Details
 - EC # 214-012-0
 - Cat 1b Reproductive Toxin
- Uses
 - Polymerization intermediate
 - Intermediate. Fully reacted in final product
 - UV lacquers, inks and adhesives
 - Below 1,000 ppm on final product
 - Low volume substances (1+ tonnes per annum into EU)
- Status
 - Agreed by to be SVHC



Butyl 4-hydroxybenzoate

- Details
 - EC # 202-318-7
 - Endocrine disruptor - human health
- Uses
 - Cosmetics and personal care products
 - Not used in articles
 - Uses to be revisited
- Status
 - Agreed by written motion (as SVHC)

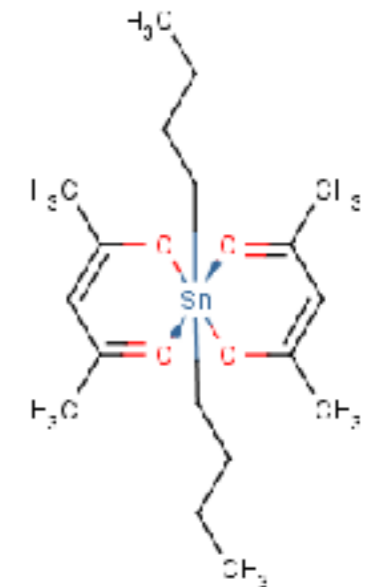
**Low Risk
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Dibutylbis(pentane-2,4-dionato-O,O')tin

**Low Risk
of presence >0.1% w/w**

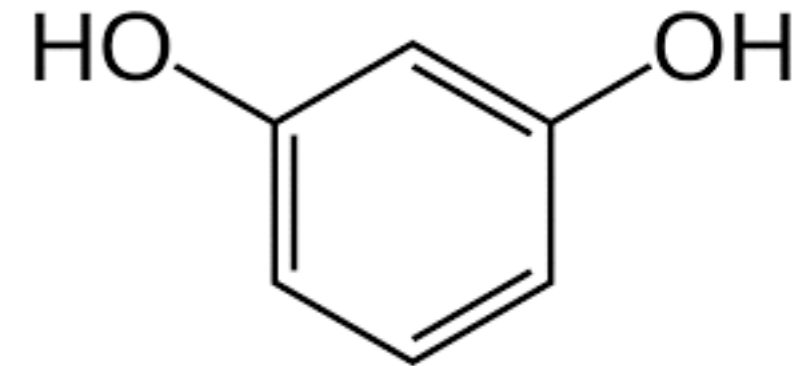
- Details
 - EC # 245-152-0
 - Cat Ib Reproductive Toxin
 - A dibutyltin
- Uses
 - Used in paint (but not 'consumed')
 - Catalyst
 - Stabilizer
 - Below 1,000 ppm in final product (paint on article)
 - Since it is a dibutyl tin, some companies will argue it can be in PVC,
 - But only in coatings
- Status
 - Agreed by written motion (as SVHC)



Resorcinol

- Details
 - EC # 203-585-2
 - Endocrine disruptor - human health
- Uses
 - Antioxidant in personal care products
 - Hair dye, eye lashes
 - Active ingredient in anti-acne cream
 - High volume use in rubber
 - Coating of aramid fibre reinforced rubber (car tires, conveyer belts, etc..)
 - To be re-visited on whether fully reacted
 - Intermediate in production of
 - UV stabilizers, Azo dyes
 - Wood adhesive (in combination with formaldehyde)
- EU MDR
 - Not otherwise regulated
 - Identification of EDC (human health) will add the substance to EU MDR

**Low Risk
of presence >0.1% w/w**



**Was not unanimous
Will not be SVHC in July**

SCIP Database - EU Deadline

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Complexity of SCIP (single product)

Guided dossier preparation 0

Substances 0

Mixtures 0

Article 61

Identifiers	Article Name	ABC Tracheostomy Tubes
Primary Article Identifier Type	reference number	ABC Tracheostomy Tubes
Primary Article Identifier Type	other:	Includes all /b series and /6 series
Company	IUCLID ID	
Product IUCLID #	Product IUCLID ID	
	Article Category	9018/90 - Instruments and appliances used in medical or veterinary sciences, nsa
	Production in European Union	No
Safe Use Instructions	Safe use instruction (s)	See components for safe use instructions
optional	Colour	
optional	Model(s)	
optional	image (filename)	
Linked article	Linked article 1	Brass Component
	# of occurrences of article 1	0
	Linked article 2	Silicone Component
	# of occurrences of article 2	6
	Linked article 3	Aluminum Component

Dashboard > Articles > Example Article

Example Article
f29f7823-e9d3-43c5-98c6-06eca90ae9fa

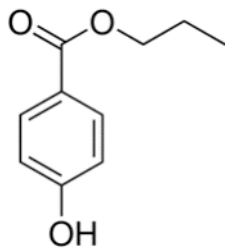
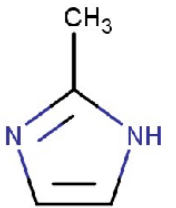
Submission Type:

Example Article
UUID: f29f7823-e9d3-43c5-98c6-06eca90ae9fa

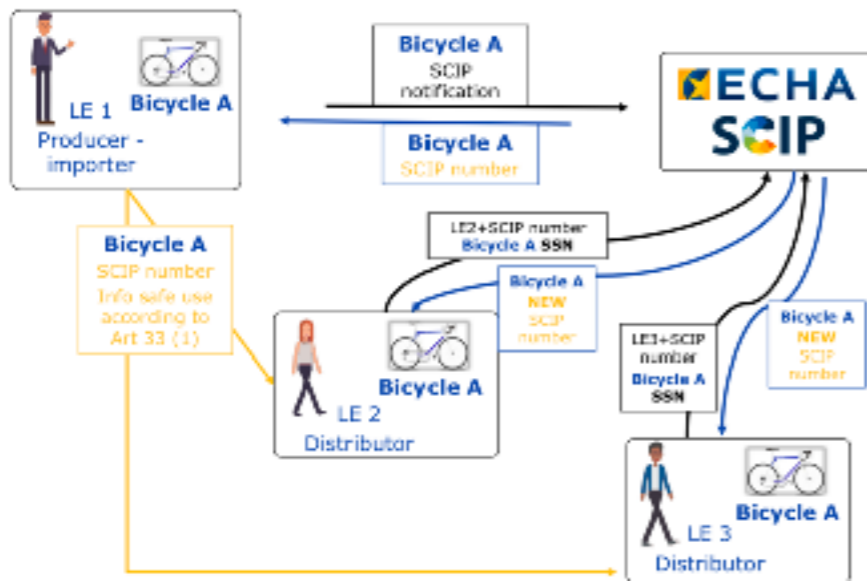
Complex object component(s)

Complex object component(s) + New item

- Article
Heatshrink | reference number | HS01
Number of units
10
- Article
High Temp Solder | reference number | HTS01
Number of units
40
- Article
Aluminium Component | reference number | ACS1
Number of units
3



ECHA Simplified SCIP notification (SSN) overview

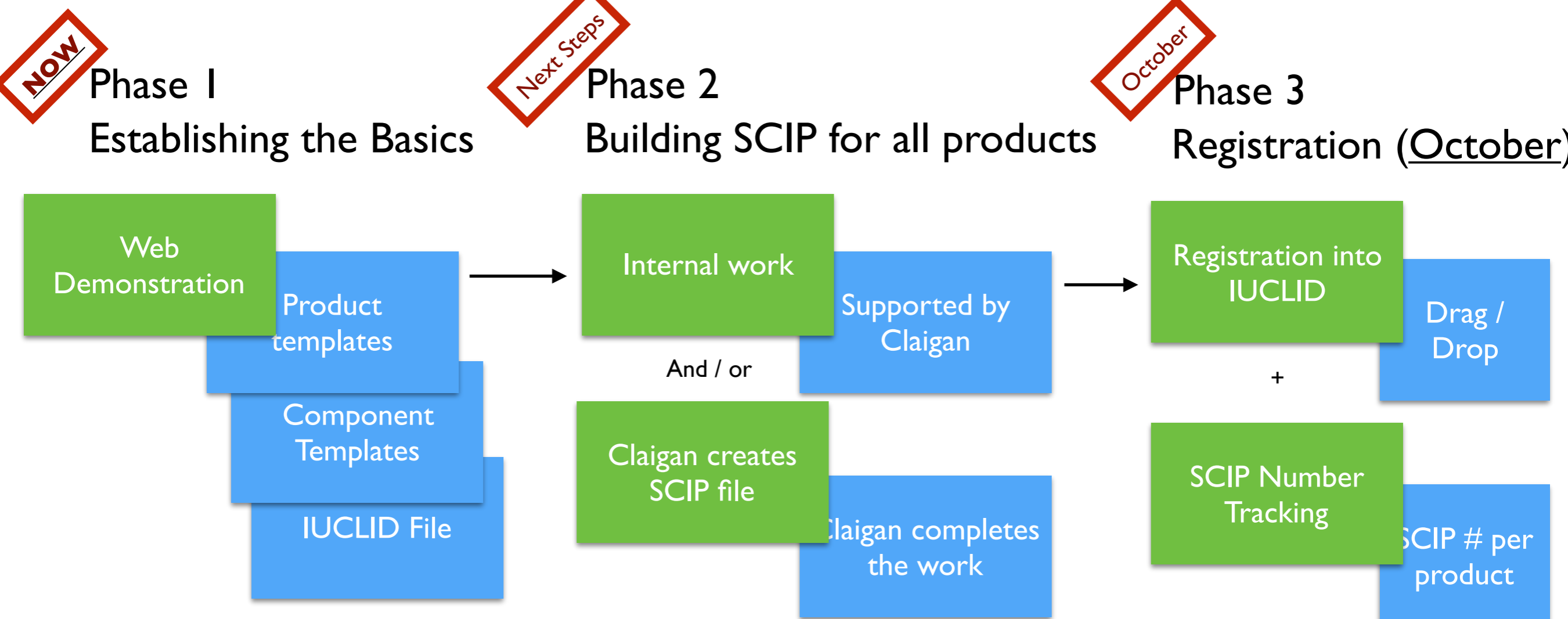


Fields	Silicone Component	Brass Component
Product IUCLID #		
Primary Article Identifier Type	reference number	HS01
Other Article Identifier Type	other:	HS01
	silicone washers, gaskets, seals, tubes, wires, o-rings, and similar silicone components	brass stand offs, connectors, tubing, springs, and other brass components
Article Category	9918/9001 - Plastics and articles thereof, primary and articles thereof > Plastics and articles thereof > Miscellaneous primary items	781899 - Base metals and articles of base metal > Copper and articles thereof > Other articles of copper > Other > Other
Production in European Union	unwilling to disclose	unwilling to disclose
Safe Use Instructions	Safe use instruction (s) Do not mix with municipal waste Keep out of water supplies and sewers	Avoid prolonged direct contact with skin during use Wash hands after contact Keep out of reach of children Do not swallow Do not mix with municipal waste
Concern Element	Candidate List version	2020/01
	Candidate List Entry / Substance	2020/01
	Dodecamethylcyclohexasioxane ECF# 203-762-8 CAS# 540-97-6	Lead ECF# 231-100-1 CAS# 7439-92-1
Concentration range	> 0.1% w/w and < 0.3% w/w	> 1.0% w/w and < 15.0% w/w
Material category	rubber and elastomers - silicone rubber	metal - brass

Data Gathering

- Nobody enjoys supplier data gathering
- Why?
 - Long (6+ months)
 - Expensive
 - Never works right
 - Very intangible for upper management
- Data gathering projects are what I would give to people I do not like

Claigan Practical Version (SCIP Process)

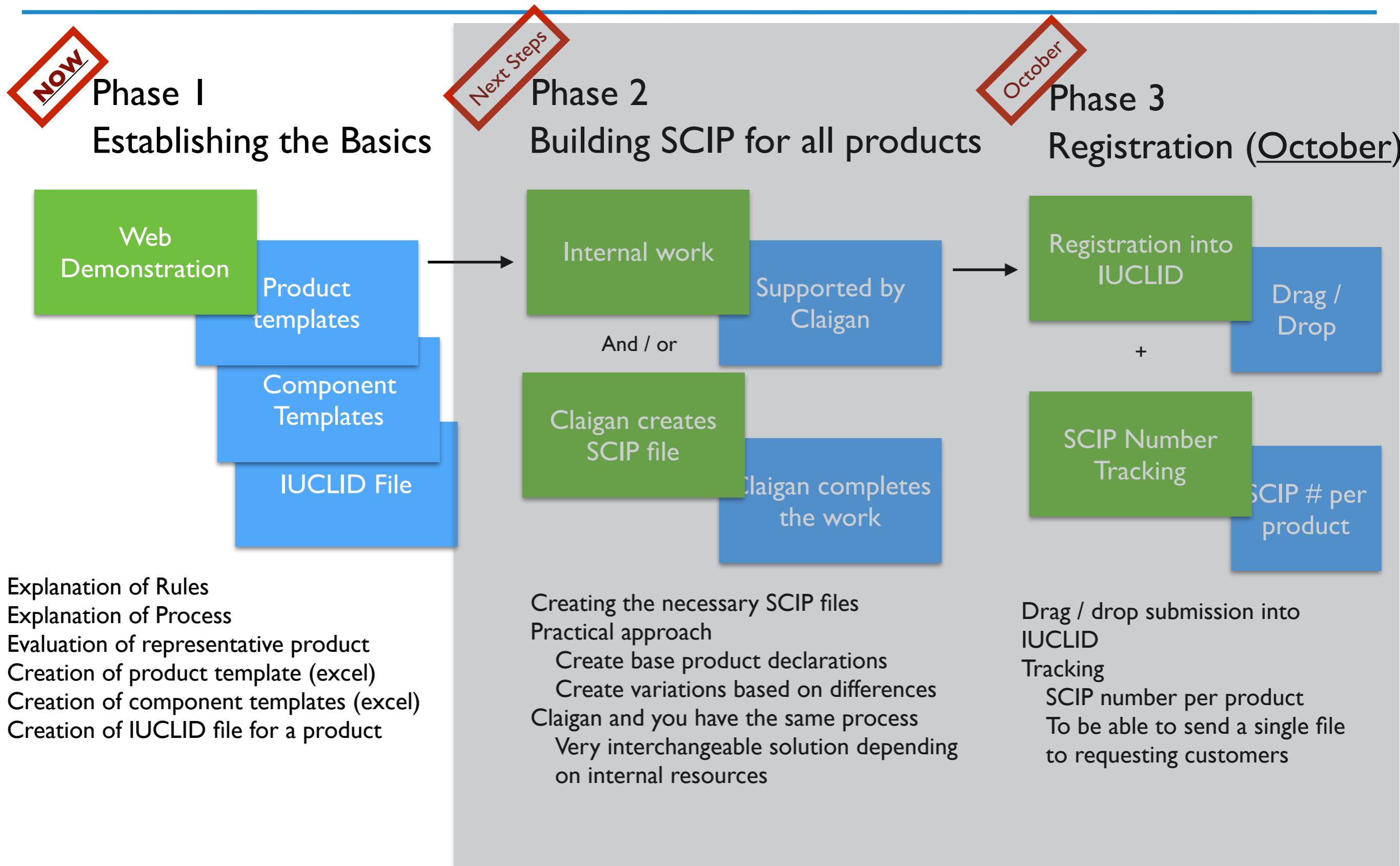


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SCIP - Now



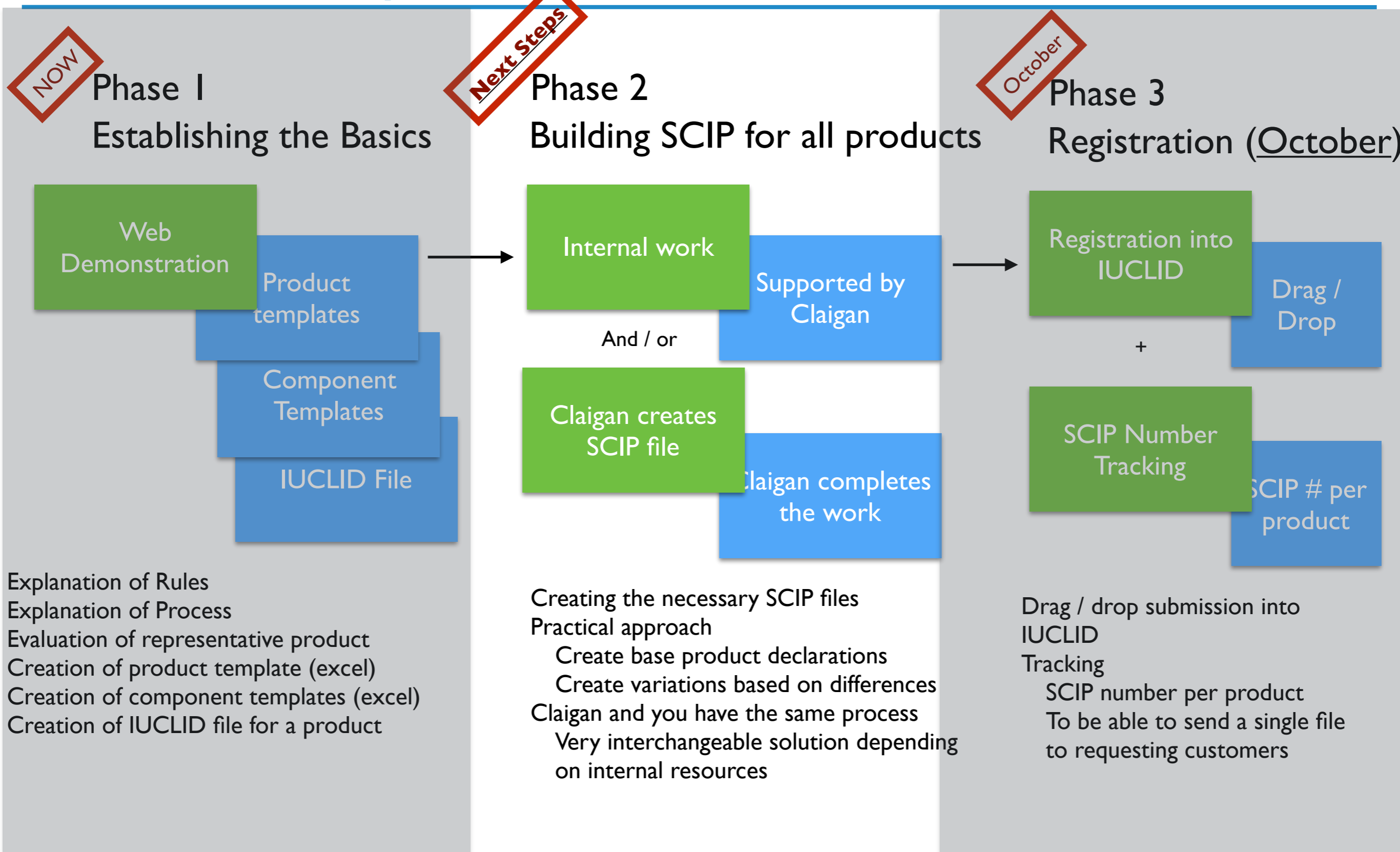
Overview - Agenda - SCIP

- Introduction
- SCIP Database
- Process
 - Structure
 - Product and component grouping
- Templates (excel)
 - Product templates
 - Component templates
- IUCLID

- Declaration for a number of product examples
 - Pb solder leads
 - High temp solder
 - PZT
- Declaration formats
 - Excel
 - IUCLID



Next Steps - SCIP Process



Best-in-Class Companies

Restricted Materials Compliance

- Legacy products
 - Supplier specification
 - Engineering evaluation
 - Test of representative units
- New products
 - Supplier specification
 - Testing all new products

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- **SCIP Web Demonstration and Templates**
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Q&A