

Candidate List Substances in Articles: duties of suppliers of articles

3rd workshop on REACH Regulation
and its impact on space sector

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Summary

- ECHA at a glance
- Substances in articles under REACH
 - Duties of suppliers of articles & article definition
 - Candidate List substances
 - Some clarifications and recommendations
- SCIP database

ECHA at a glance

Working for the safe use
of chemicals



What is the European Chemicals Agency?

- EU Agency operating in Helsinki since 2007
- We implement European legislation related to chemicals
- 650 staff from 28 countries



Our competences:

Data management

Assessment of chemicals

Risk management of chemicals

Impact analysis of chemicals

Working with EU chemicals legislation

- **REACH** – Registration, evaluation, authorisation and restriction of chemicals (2007)
- **CLP** – Classification, labelling, packaging (2009)
- **BPR** – Biocidal products (2013)
- **PIC** – Prior informed consent (import and export) (2014)
- **POPs** – Persistent organic pollutants (2018)
- **OEL** – Occupational safety limits (2019)
- **Waste** – Waste Framework Directive (2018)



Our mission:

We, together with our partners, work
for the safe use of chemicals

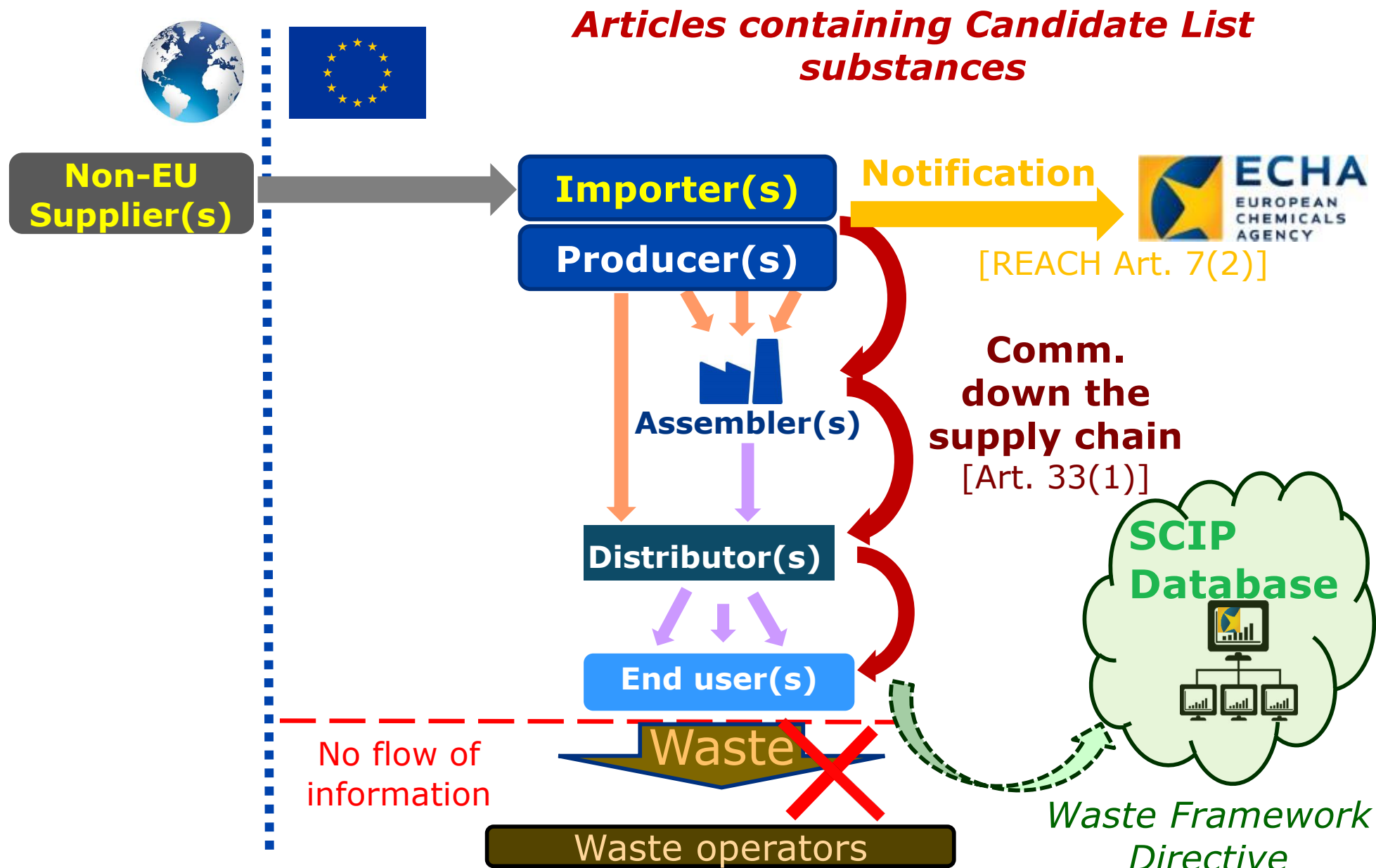
Substances in Articles (SiA) under REACH



Duties of suppliers of articles & article definition



What does REACH foresee?



When do duties apply?

Supply chain communication



AND



> 0.1% w/w

Notification to ECHA



AND



> 0.1% w/w

AND



> 1 tpa

Article definition under REACH

Article

An **object** which during production is given a **special shape, surface or design** which determines its **function** to a greater degree than does its **chemical composition**.



Function

(**What it does (result)**, **not** how it does it)

Physical form

- Shape
- Surface
- Design

Chemical composition

- Chemical charact.
- Physicochemical charact.
- Other physical charact. resulting from the chemistry of the object's material(s)

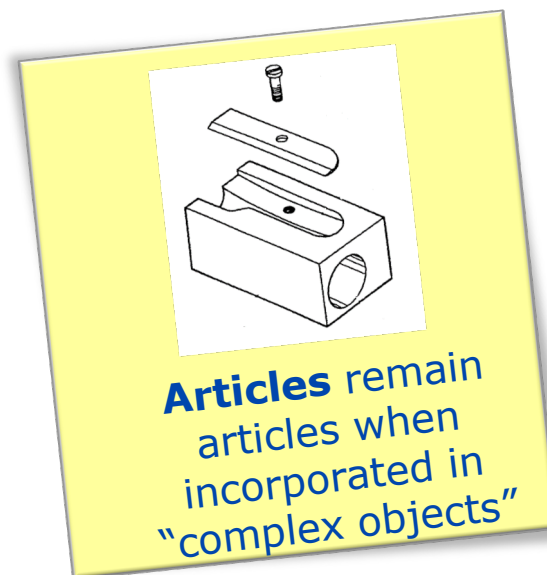
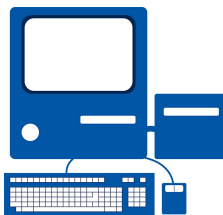
Article & Complex object

Article



Complex Object

Articles are assembled
together into
"Complex objects"



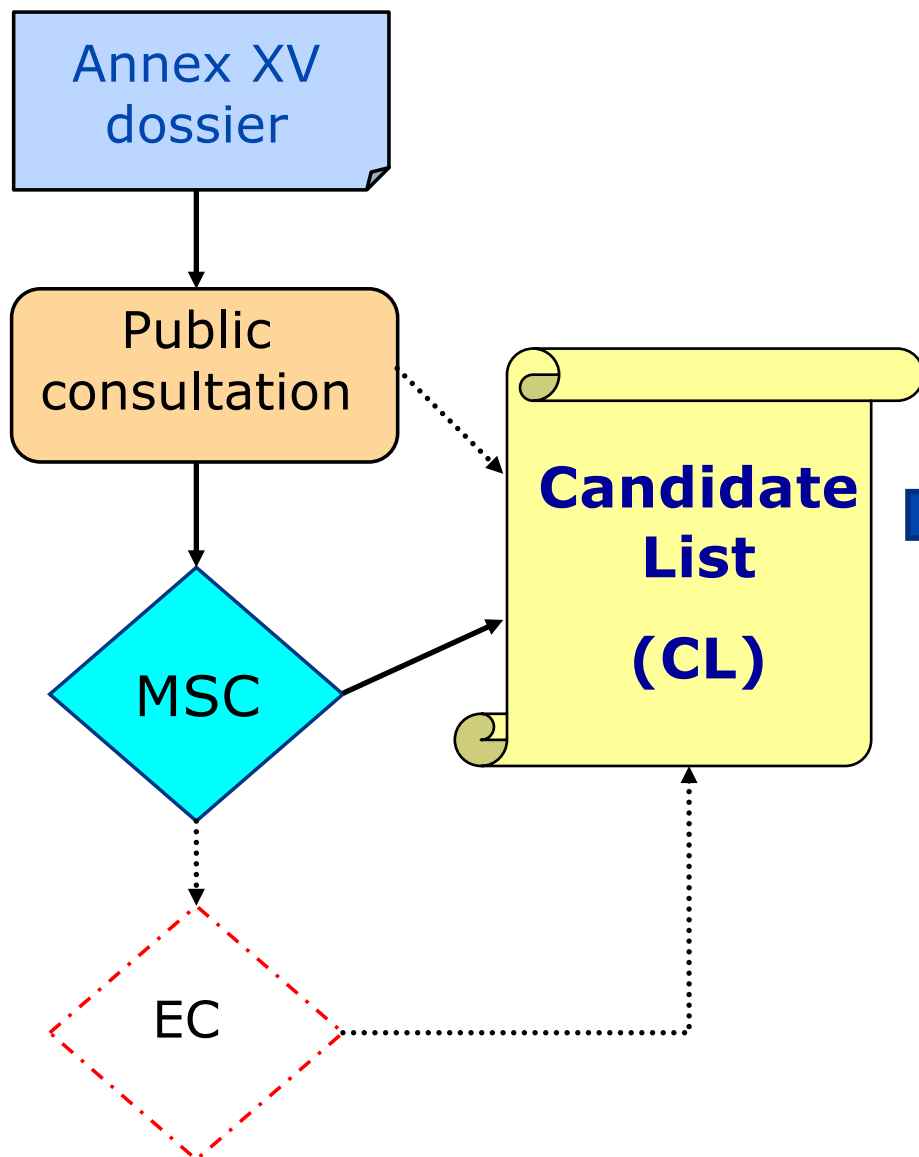
Candidate List substances



Article 57 :

- (a)-(c) Substances meeting the criteria for classification as **CMRs** category 1A or 1B;
- (d)-(e) Substances which are **PBTs** or **vPvBs** (REACH Annex XIII)
- (f) Substances identified on a case-by-case basis, for which there is scientific evidence of probable serious effects that cause an equivalent level of concern (**ELoC**) as CMRs or PBT/vPvB substances;

Procedure laid down in Art. 59



ECHA's website
(official source)

Candidate List of substances of very high concern for Authorisation
(published in accordance with Article 59(10) of the REACH Regulation)

Notes:

- Authentic version:** Only the Candidate List published on this website is deemed authentic. Companies may have immediate legal obligations following the inclusion of a substance in the Candidate List on this website including in particular Articles 7, 31 and 33 of the REACH Regulation.
- Numerical identifiers:** Each candidate list entry covers both anhydrous and hydrated forms of a substance. The CAS number shown in an entry is typically for the anhydrous form. Hydrated forms of the substance identified by other CAS numbers are still within the scope of the entry.
- Other numerical identifiers:** For those entries with "-" in the EC number and CAS number columns, a non-exhaustive inventory of EC and/or CAS Registry numbers describing substances or groups of substances considered to fall within the scope of the Candidate List entry is included, where practicable possible. This information can be accessed through the "Details" button of the selected entry.

FURTHER INFORMATION

- More information about Candidate List of Substances of Very High Concern for Authorisation
- Data on Candidate List substances in articles
- Reasons for inclusion

See a problem or have feedback?

Filter the list

Substance name	EC No.	CAS No.	Date of inclusion	Reason for inclusion	Decision	EUCLED database
2,3,3,3-tetrafluoro-2-(hexafluoroisopropoxy) propionic acid, its salts and its esters including any of their individual isomers and combinations thereof	-	-	16/07/2019	Equivalent level of concern having probable serious effects to human health (Article 57(f) - human health) Equivalent level of concern having probable serious effects to the environment (Article 57(f) - environment)	ED/7/2019	Details
2-methoxyethyl acetate	203-772-9	110-49-6	16/07/2019	Toxic for reproduction (Article 57(c))	ED/7/2019	Details
4-tert-butylphenol	202-679-0	98-54-4	16/07/2019	Endocrine disrupting properties (Article 57(f) - environment)	ED/7/2019 EU/2019/1194	Details
Tris(4-nonylphenyl, branched and linear) phosphite (TRPP) with a 0.1% w/w of	-	-	16/07/2019	Endocrine disrupting properties (Article 57(f) - environment)	ED/7/2019	Details








<https://echa.europa.eu/candidate-list-table>

- Currently contains 201 entries;
- Updated twice per year (June/July & December/ January).

- Individual substances

Substance name 	EC No. 	CAS No. 	Date of inclusion 	Reason for inclusion 	Decision	IUCLID dataset	
2-methoxyethyl acetate <small>expand / collapse</small>	203-772-9	110-49-6	16/07/2019	Toxic for reproduction (Article 57c)	ED/71/2019		
4-tert-butylphenol	202-679-0	98-54-4	16/07/2019	Endocrine disrupting properties (Article 57(f) - environment)	ED/71/2019 EU/2019/1194		
Diazene-1,2-dicarboxamide (C,C'-azodi (formamide)) (ADCA)	204-650-8	123-77-3	19/12/2012	Respiratory sensitising properties (Article 57(f) - human health)	ED/169/2012		
Dibutyltin dichloride (DBTC)	211-670-0	683-18-1	19/12/2012	Toxic for reproduction (Article 57c)	ED/169/2012		

- Group entries






Substance name 	EC No. 	CAS No. 	Date of inclusion 	Reason for inclusion 	Decision	IUCLID dataset	
1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo [12.2.1.16,9.02,13.05,10]octadeca-7,15-diene ("Dechlorane Plus"™) covering any of its individual anti- and syn-isomers or any combination thereof	-	-	15/01/2018	vPvB (Article 57e)	ED/01/2018		
4-Nonylphenol, branched and linear, ethoxylated substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof	-	-					

ECHA provides support to identify members of a group entry

Candidate List group entries

Example 1: 1,6,7,8,9,14,15,16,17,17,18,18-

Dodecachloropentacyclo[12.2.1.16,9.02,13.05,10]octadeca-7,15-diene ("Dechlorane Plus"TM)

EC No.: -	CAS No.: -	EC Number 236-948-9	
Reason for inclusion			vPvB (Article 57e)
Date of inclusion		CAS Number 13560-89-9	15/01/2018
Decision		135821-74-8	 ED/01/2018
IUCLID dataset		135821-03-3	 SiA_Dechlorane_Plus_en.i6z
Support document			 Non-exhaustive_list_numerical_identifiers_dechlorane_plus.pdf  svhc_msc_support_document_dechlorane_plus.pdf
Response to comments			 svhc_msc_rcom_dechlorane_plus_pub_.rtf
Remarks			

Example 1: 1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo[12.2.1.16,9.02,13.05,10]octadeca-7,15-diene ("Dechlorane Plus"TM)

✓ Group members

This group of substance has the following member substances:

Name	EC / List no.	CAS no.	Association
1,6,7,8,9,14,15,16,17,17,18,18-dodecachloropentacyclo[12.2.1.16,9.02,13.05,10]octadeca-7,15-diene	236-948-9	13560-89-9	Expert judgement
rel-(1R,4S,4aS,6aS,7S,10R,10aR,12aR)-1,2,3,4,7,8,9,10,13,13,14,14-dodecachloro-1,4,4a,5,6,6a,7,10,10a,11,12,12a-dodecahydro-1,4:7,10-dimethanodibenzo[a,e]cyclooctene	-	-	Expert judgement
rel-(1R,4S,4aS,6aR,7R,10S,10aS,12aR)-1,2,3,4,7,8,9,10,13,13,14,14-dodecachloro-1,4,4a,5,6,6a,7,10,10a,11,12,12a-dodecahydro-1,4:7,10-dimethanodibenzo[a,e]cyclooctene	-	-	Expert judgement

The identification of group members by "**Expert Judgement**" can come from:

- Support document to the (MSC) decision
- Non-exhaustive list
- Specific inquiries submitted to ECHA

Example 2: 4-Nonylphenol, branched and linear, ethoxylated

▼ Group members

This group of substance has the following member substances:

The identification of group members from “**Official source**”

Name	EC / List no.	CAS no.	Association
2-[2-[2-[2-(4-nonylphenoxy)ethoxy]ethoxy]ethoxy]ethanol	230-770-5	7311-27-5	Official source
2-[2-(4-nonylphenoxy)ethoxy]ethanol	243-816-4	20427-84-3	Official source
26-(nonylphenoxy)-3,6,9,12,15,18,21,24-octaoxahexacosan-1-ol	247-816-5	26571-11-9	Expert judgement
20-(4-nonylphenoxy)-3,6,9,12,15,18-hexaoxaicosan-1-ol	248-743-1	27942-27-4	Official source
Nonylphenol, ethoxylated	500-024-6	9016-45-9	Official source

Some clarifications and recommendations



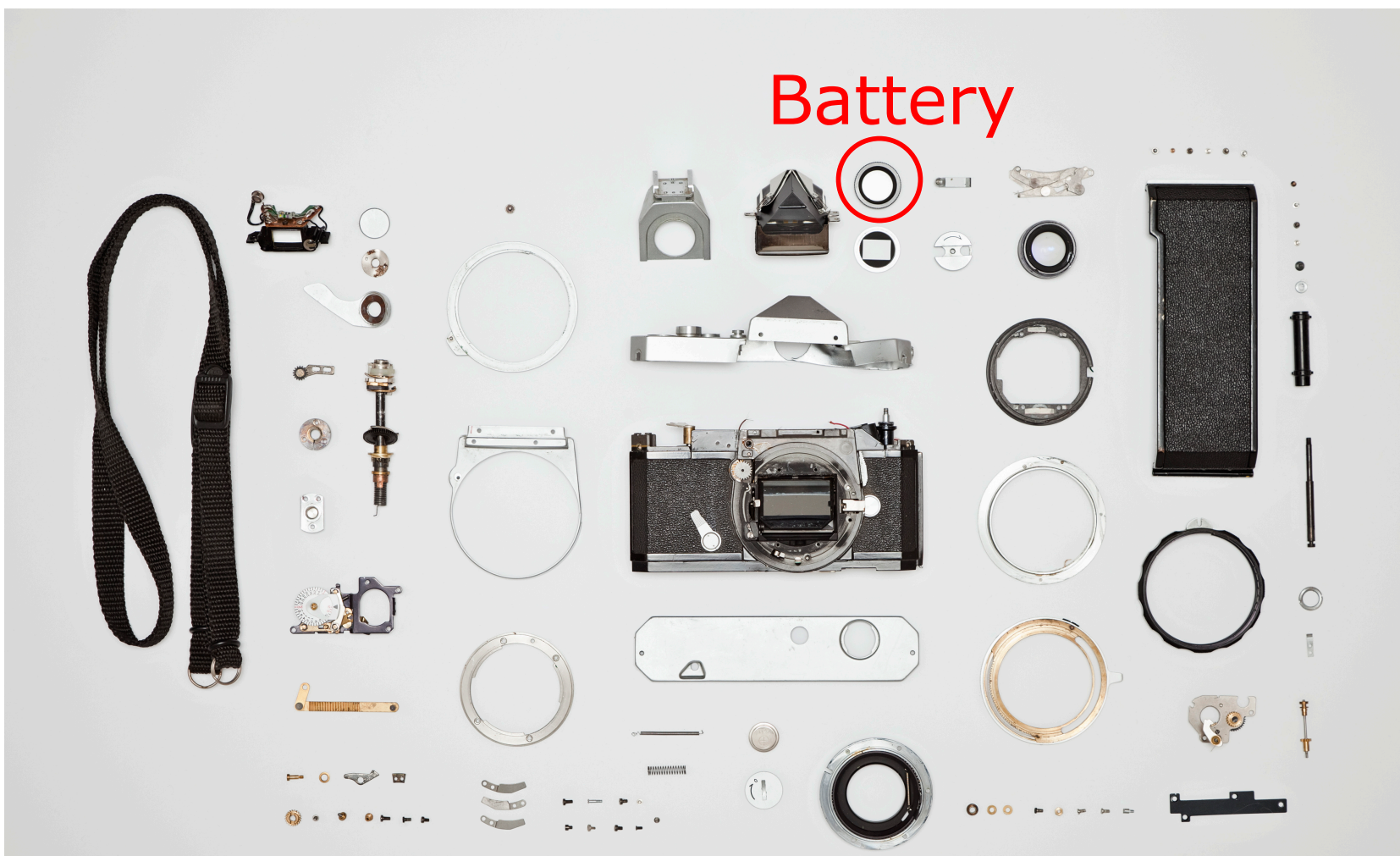
Communication of information for complex objects



The information to be communicated down the supply chain must:

- identify the **components (articles)** that contain Candidate List substances
- contain the identification of the substances in each component
- contain any other information needed to ensure the safe use of the article

The information to be communicated down the supply chain must follow each component (or “sub-assembly”) as placed on the market



If during the service life of a complex object, there is the replacement of a component, the communication obligation applies for that component (article), provided that it contains a Candidate List substance

“Long projects”

Production/assembling of units (complex objects) during long periods



ECHA aims at ensuring the transparency and predictability of regulatory activities for a given substance or group of substances:

E.g.

- Identification of SVHCs
- Restrictions

Recommendations:

- Understand how substances of concern are addressed by authorities at the EU level

(<https://echa.europa.eu/substances-of-potential-concern>)

- Follow the public activities coordination tool (PACT): provides up-to-date information on the activities planned, ongoing or completed by ECHA and/or MSCAs for a given substance

(<https://echa.europa.eu/substances-of-potential-concern>)

Recommendations (cont.):

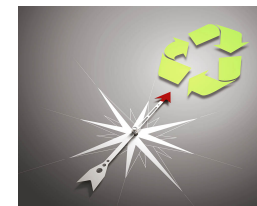
- Assess impacts on your “projects” based on information on which substances may be addressed by which formal risk management routes in the future
- Prepare for public consultations during any subsequent regulatory processes to present your case (potential impacts)
- Consider your best business strategy and take adequate actions
- Possible approaches to obtain the necessary information:
 - Use IT tools to transfer information and manage communication in the supply chains
 - Implement a quality management system and/or an alternative means of ensuring traceability of raw materials and articles compositions
 - Keep good communication with your suppliers
 - Draft suitable procurement and contract specifications

SCIP database of articles containing Candidate List substances



Revised Waste Framework Directive

(Directive 2008/98/EC (WFD), Articles 9(1)(i))



Any supplier of **articles** containing a **substance of very high concern** (SVHC) on the Candidate List above 0.1% w/w

EU producers & Importers

EU *assemblers*

EU distributors



From
5 January 2021

Need to submit info to ECHA



Sufficient information to allow safe use of the article

(Art. 33(1) REACH)

Reduce the content of hazardous substances in materials and products, including recycled materials

Push for **substitution** of substances of concern and **prevention** of (hazardous) waste generation



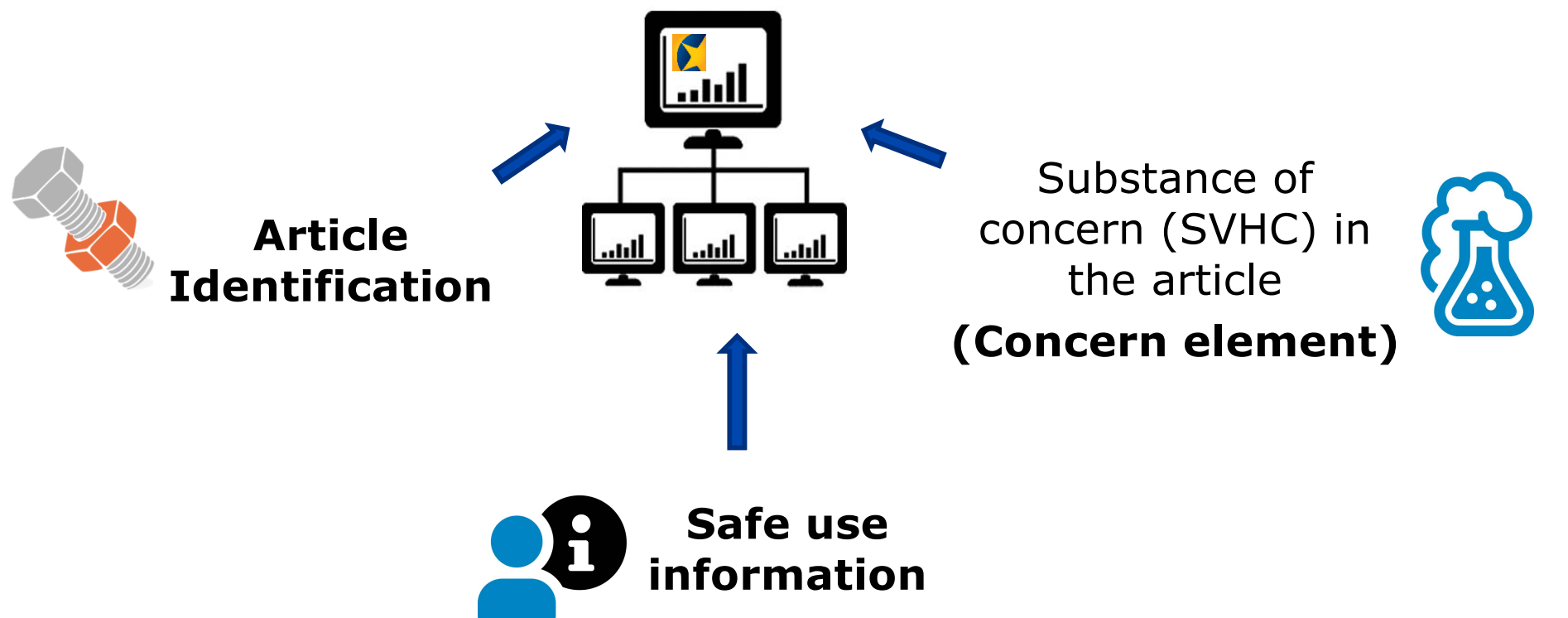
Contributing to a more circular economy: improve waste treatment operations



Increase authorities' information basis on substances in articles



SCIP – Info requirements

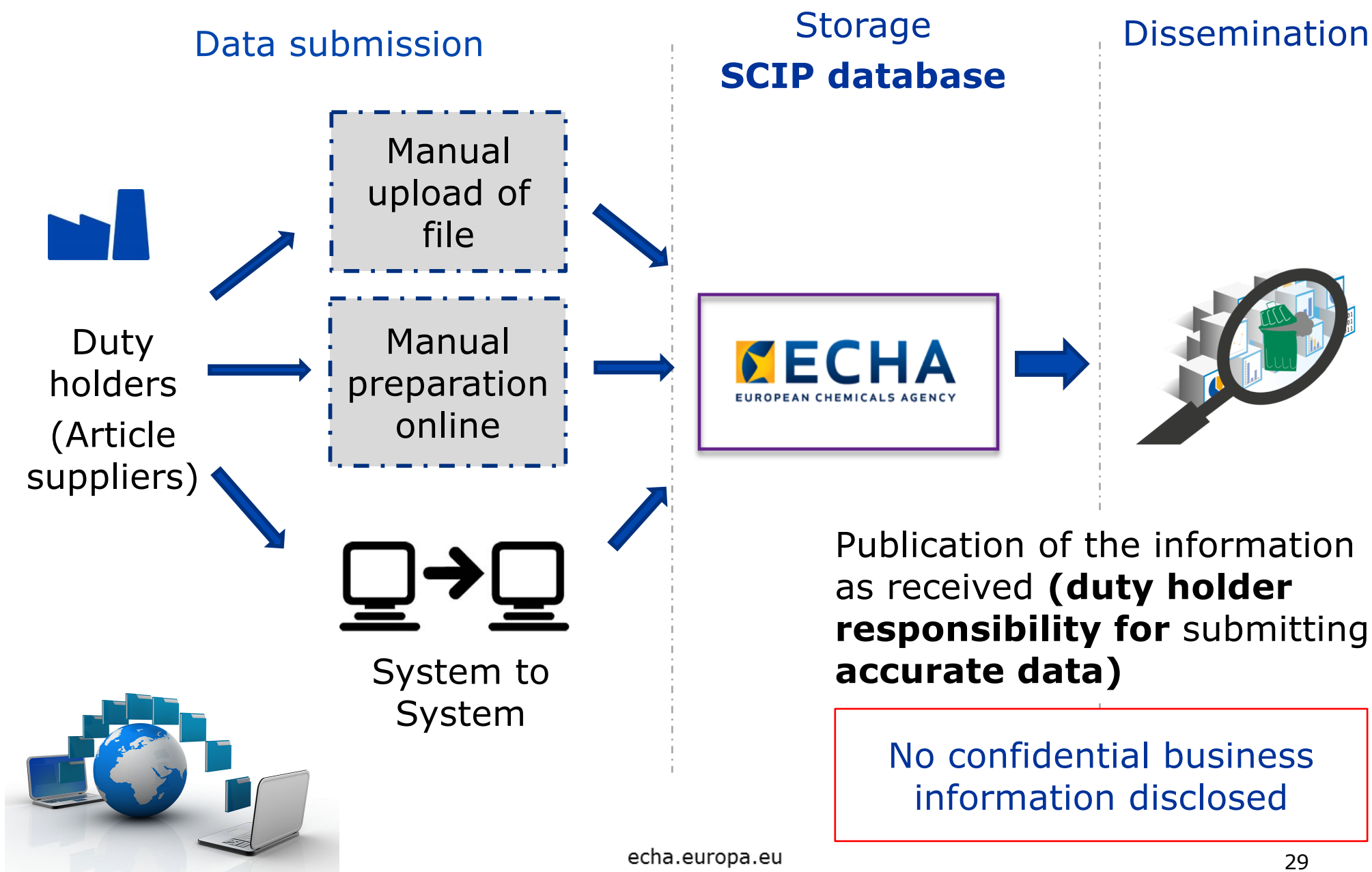


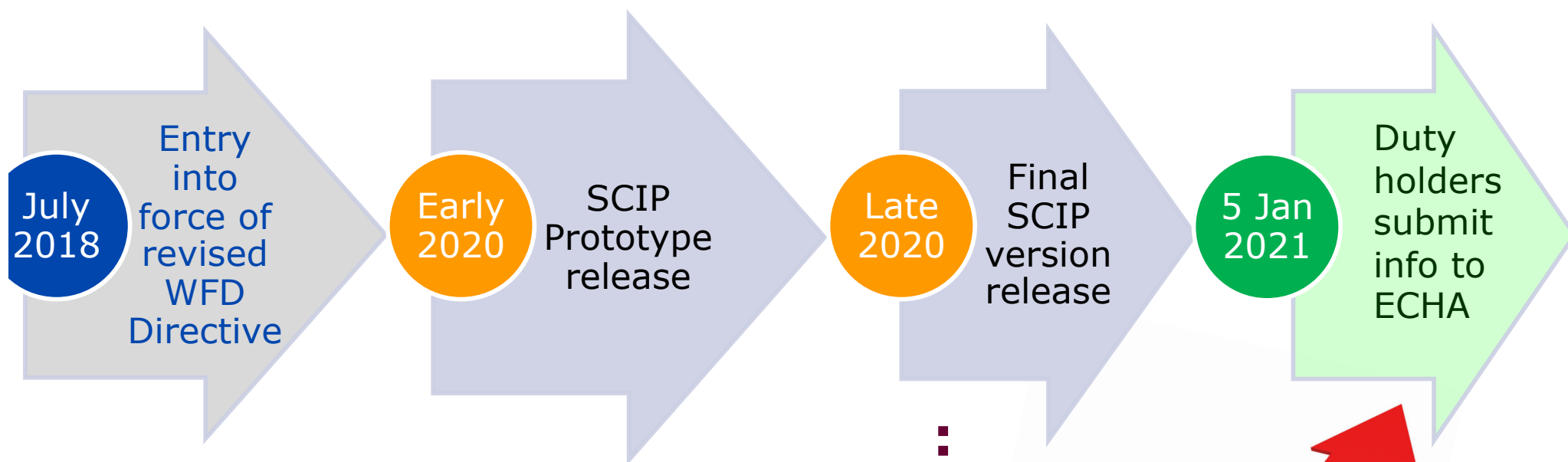
- *Identifiers*
- *Name*
- *Article category (TARIC/CN code)*

- *SVHC identifiers*
- *Concentration range*
- *Material category*

Detailed information requirements published on ECHA website

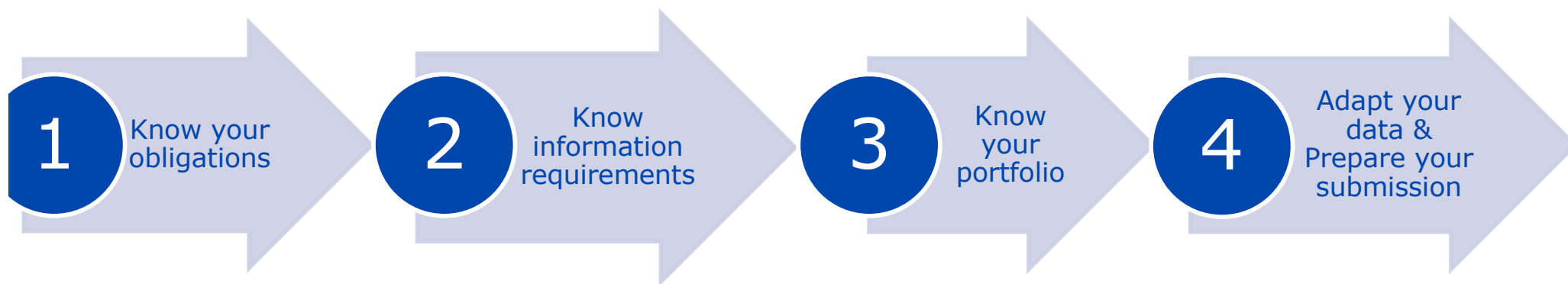
SCIP database flow





- SCIP IT user group just started
- Technical format for data submission to be published by end Oct. 2019 ("IUCLID" format)
- **SCIP workshop at ECHA on 12 November** (registration still open)

How to get prepared?





Articles with CL substance >0,1 % w/w


Duty holders:
Producers,
Importers,
"Assemblers" &
Distributors



Identification
Concern Element
Safe use info

ECHA Submission portal



System to System

Thank you!

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Where & When?

- At ECHA
- 12 November
- The workshop will be web streamed

Key issues

- State of play of the project and IT implementation of the SCIP database;
- break-out discussions on efficient notification procedures; and
- how to make the data available to waste operators and consumers.

Interested?

- Additional info and registration is available at [ECHA>Events](#)



Aims

- Engage the user community in the development of the system.
- Gather improvement ideas.
- Identify the areas where extra attention is needed in order to provide adequate support/guidance.

Activities

- IUCLID format revision
- IUCLID & S2S testing
- Additional working topics (e.g. reporting/dissemination, efficient notification procedures)

Members

- ~30 representing companies, associations and service providers.

Periodicity

- Monthly virtual meetings on 2019.
- Monthly- biweekly meetings expected 2020