Latest Updates in Chemicals Management in the EU

Seminar & Workshop on the Latest Trends in Chemical Substances Management in the EU

Tokyo, Japan

14 September 2020

Jukka Malm
Deputy Executive Director
European Chemicals Agency

The European Chemicals Agency

- EU Agency operating in Helsinki since 2007
- Implementing several European legislations related to chemicals
- 650 staff from 28 countries
- Funding partly from fees, partly from EU subsidy

Our competences:

- **Data management**
- **Assessment of chemicals**
- **Risk management of chemicals**
- **Impact analysis of chemicals**

Chemicals legislations managed by ECHA

REACH
Registration
Evaluation
Authorisation

All chemicals ≥ 1 tonne per year

CLP
Classification
Labelling
Packaging

All chemicals and mixtures

United Nations standards

BPR
Biocides

Active substances and biocidal products

PIC
Prior Informed Consent

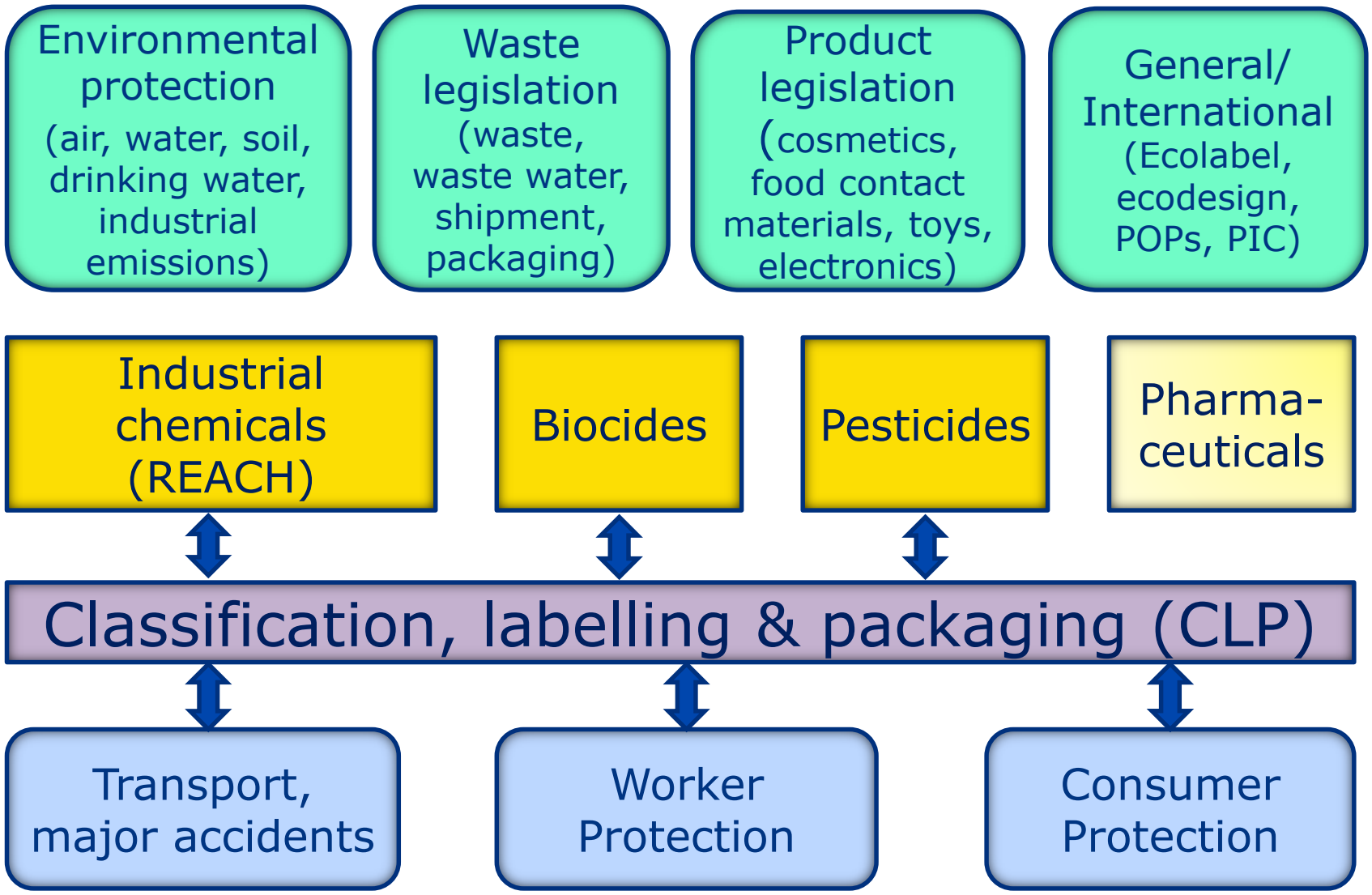
Import/export of certain hazardous chemicals

Rotterdam Convention

Several new work areas, e.g.

- Portal for notifications of hazardous mixtures to the national poison centres
- EU Nano Observatory
- EU Chemicals Legislation Finder
- Occupational Exposure Limits (OELs)
- POPs Regulation
- Database to track chemicals (Waste Framework Directive)

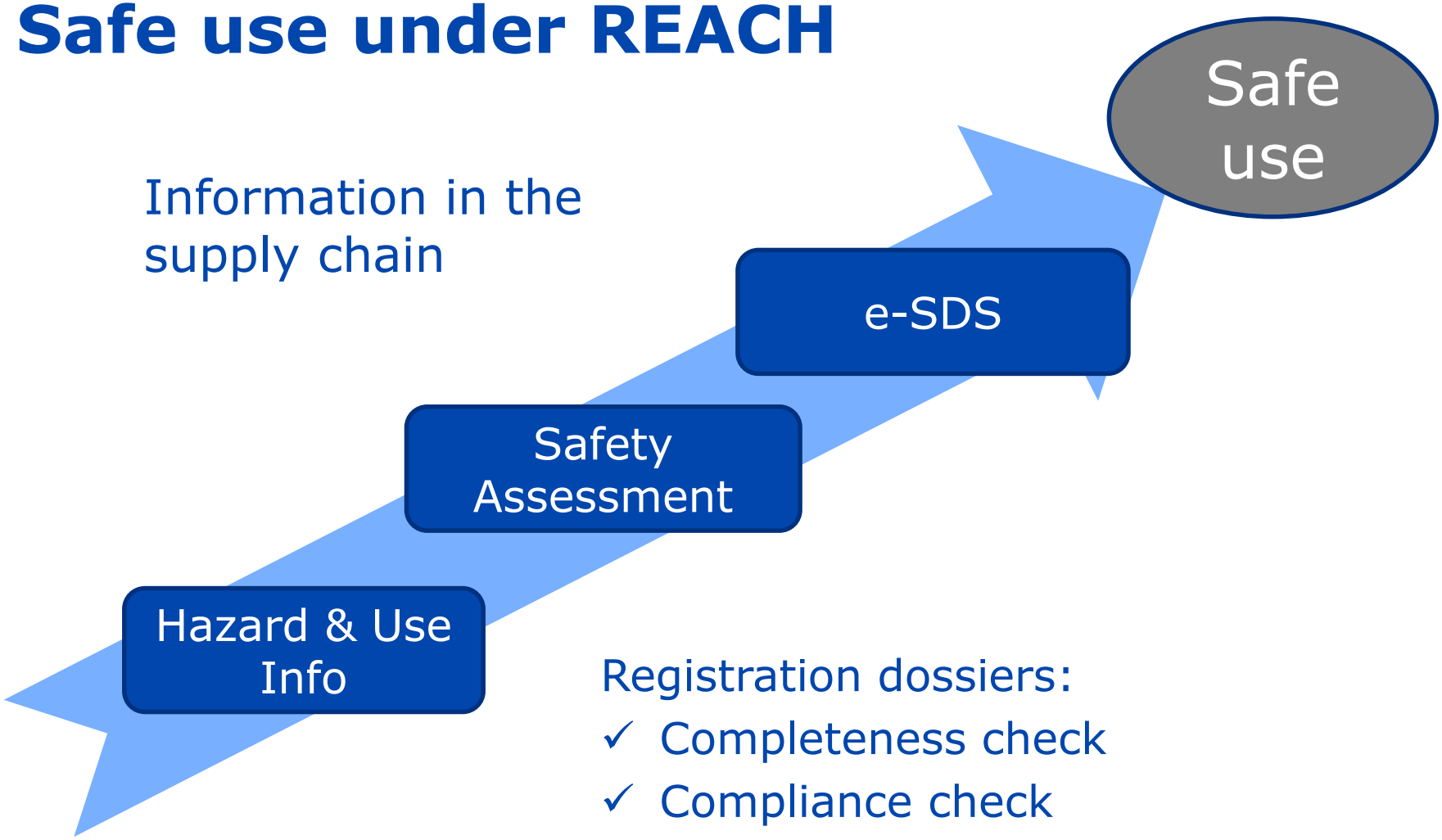
Chemicals Management in the EU
Simplified version



Main actors

Providing data	Industry gathers information and makes sure risks are managed
Evaluation	ECHA and Member States screen and check the data and request more if needed
Risk management	European Commission, with support of ECHA and Member States, applies EU-wide risk management measures

Safe use under REACH

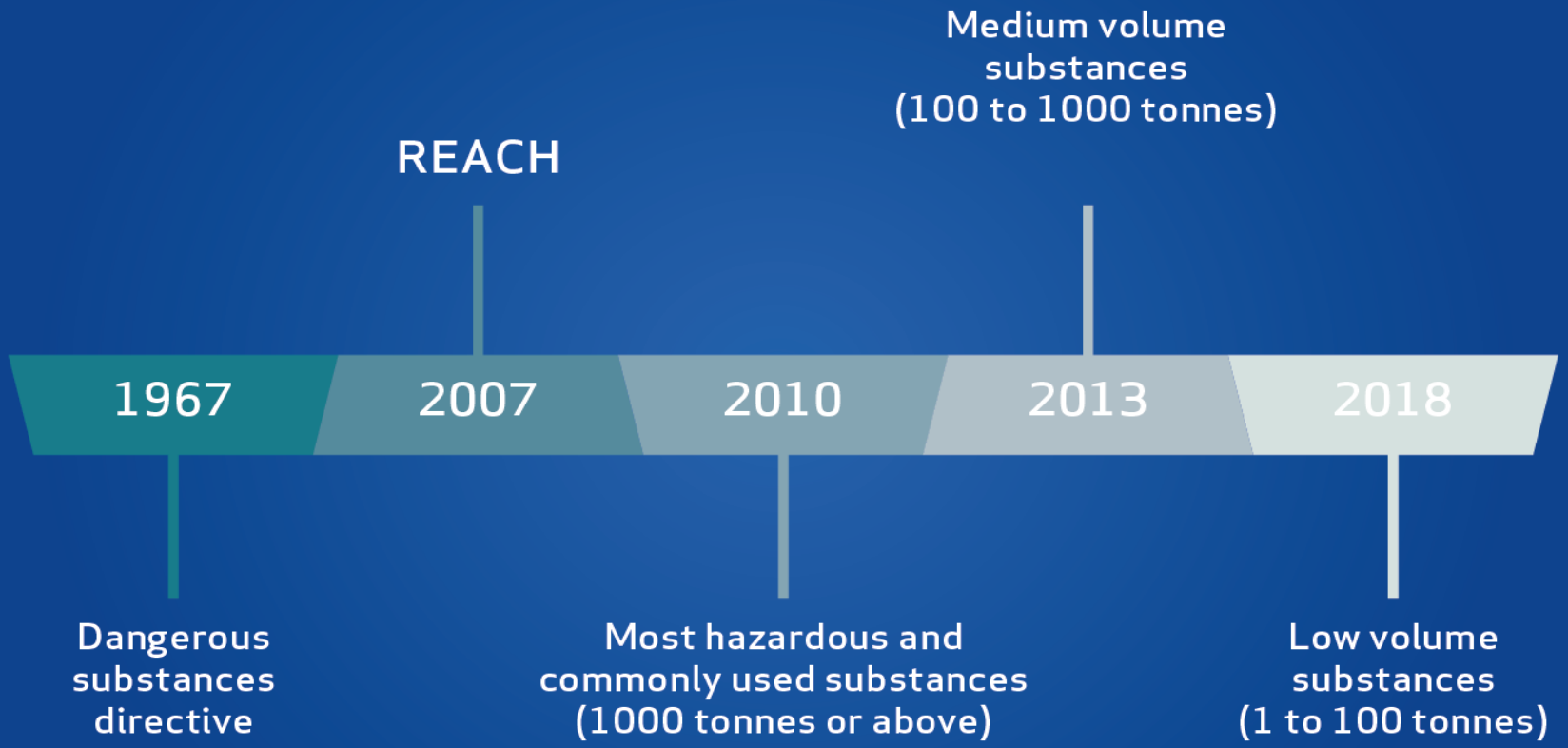


Registration dossiers:

- ✓ Completeness check
- ✓ Compliance check

All substances > 1 tpa now registered

- 23 000 substances - 100 000 registration dossiers
- Can be searched via ECHA website



More data on chemicals than ever before

209
substances of very high concern

600
risk management proposals

2200
substances checked for compliance

23 000
substances registered under REACH

145 000
substances classified under CLP

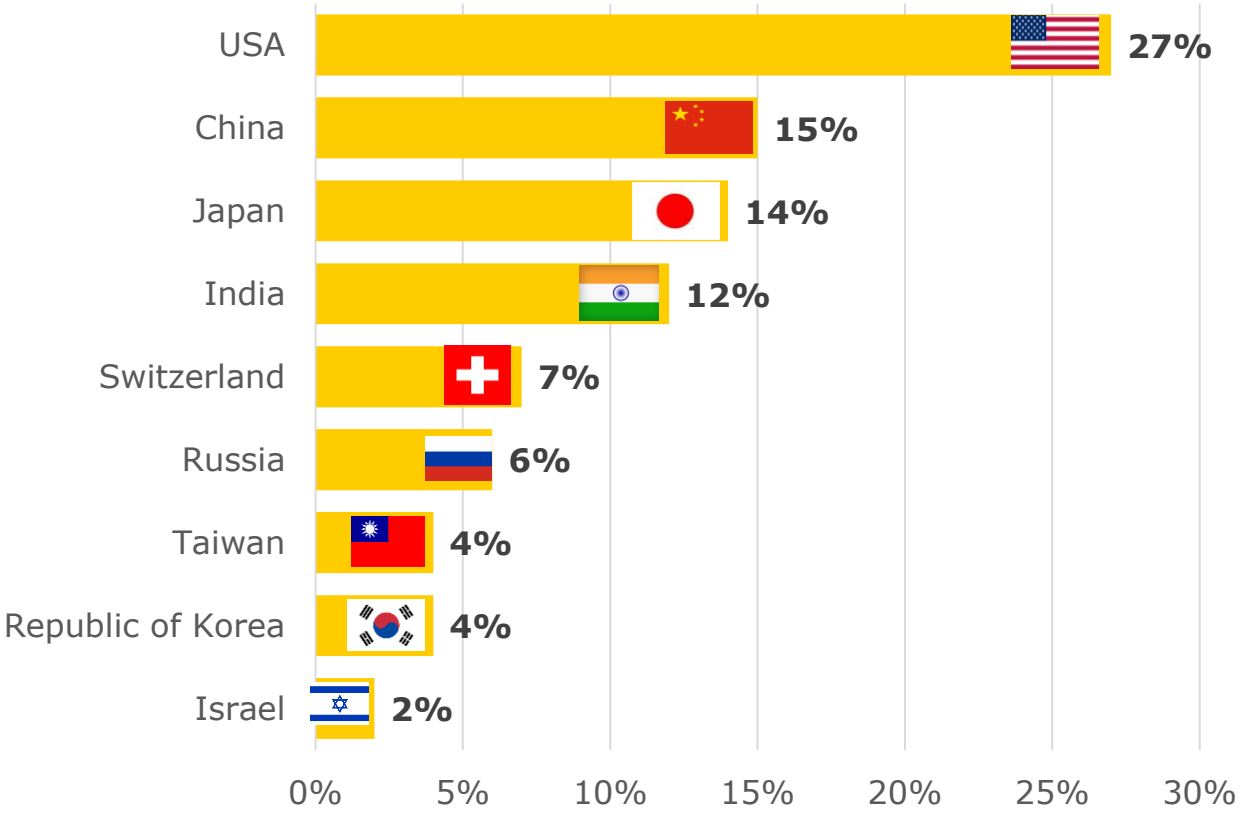
>2 million
study summaries on chemical properties and effects

Visit our regulatory chemicals database – largest in the world

- Information on hazards and safe use of **140 000** chemicals
- 24 000 daily users

echa.europa.eu

REACH registrations - Top 10 non-EU countries



Understanding registration information

- Registrations are prepared by companies, the data is owned by them
  - Data quality is not systematically reviewed by authorities
- Most of the data is publically available
  - N.B. intellectual property rights of data owners
- ECHA prepares decisions requesting further testing and information
  - Dossier and substance evaluation
- Data can be consulted via ECHA website and OECD eChemPortal

REACH Evaluation Action Plan

- Ambition: **ECHA to check 20% of REACH registrations by 2027 for compliance** (previous target 5%)
- 20% of registrations = around 30% of chemical substances on EU market
- **Two milestones**:
  - **End 2023** for substances in tonnage bands over 100 tonnes/year
  - **End 2027** for substances in the 1-100 tonnage bands/year
- Companies can expect more compliance checks

Updated requirements for nanomaterials

- REACH information requirements for registration have been amended to specify how to register substances in nanoform
  - characterisation of nanoforms (Annex VI)
  - the chemical safety assessment (Annex I);
  - registration information requirements (Annexes III and VII-XI); and
  - downstream user obligations (Annex XII).
- Apply as from 1 January 2020
- IUCLID was updated to facilitate registration of nanoforms in Autumn of 2019
- ECHA guidance on nanomaterials partly updated

Mapping the registered substances

- ECHA's goal is to conclude by the **end of 2020** for all substances registered above 100 tonnes per year whether they are:
  - of priority for regulatory risk management;
  - currently of low priority for further regulatory action; or
  - need more data for a judgement to be made.
- ECHA will draw similar conclusions for all remaining registered substances by the **end of 2027**.

Find out what is on our radar

- Substances of potential concern
  - Screening of substances is an ongoing process
  - We focus on substances that may need regulatory action -> risk management option analysis (RMOA)
    - Substances of very high concern (SVHC)
    - Persistent, bioaccumulative, toxic (PBT, vPvB)
    - Endocrine disruptors
  - Increased focus on grouping of substances
- See on ECHA website, e.g:
  - PACT – public activities coordination tool
  - Section ’addressing substances of concern’

Risk management: restrictions

- When unacceptable risks to humans or the environment have been identified
- Member State competent authorities can submit dossiers proposing restrictions (or European Commission asks ECHA to submit)
- ECHA prepares a scientific opinion, always preceded by a consultation on the proposal
- European Commission makes a decision
- Annex XVII of REACH lists all restrictions

27 ECHA opinions – 71 entries in REACH Annex XVII

Restriction proposals currently under consideration

- Calcium cyanamide
- 5 cobalt compounds
- Formaldehyde and formaldehyde releasers
- Microplastics
- D4, D5, D6 (siloxanes)
- Perfluorohexane sulfonic acid (PFHxS), its salts and related substances
- Skin sensitizing substances in textile, leather, hide and fur articles

Risk management: authorisation

- Substances of very high concern (SVHCs): CMRs, PBT/vPvB or 'equivalent concern'
- Identification by Member States (or European Commission instructing ECHA) onto the 'Candidate List'
- Some transferred onto the 'Authorisation List', Annex XIV
- Once on the Authorisation List, the substance can only be marketed or used after 'sunset date' if authorised by the European Commission who decides based on ECHA opinion

209 substances on Candidate List – 54 on Authorisation List –>300 ECHA opinions ->150 Authorisation Decisions

Classification and labelling – ECHA's role

- Establish and maintain C&L inventory
  - Self classification by industry
  - Over 6 million notifications covering more than 140 000 substances
- Harmonised C&L
  - Proposals by Member States or industry
  - Opinion by ECHA Risk Assessment Committee
  - Commission decision (Annex VI of CLP)

Ca. 400 ECHA opinions

SCIP database in a nutshell

SCIP = Database of
Substances of (very high) **C**oncern **I**n articles and **P**roducts

SCIP database context

EU action plan for the **Circular Economy**

Legal basis:

Waste Framework Directive (WFD)

SCIP

Establish and maintain a database

for info communicated down in the supply chain on **substances in articles**

SCIP database - Objectives

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

Target audiences

SCIP

Waste operators

Available info to
- ✓ *drive waste stream decisions*
- ✓ *support compliant re-use*
- ✓ *increase recycled materials*

Consumers and other interested parties

- ✓ *Empower informed choices*
- ✓ *Improve targeted disposal*

Authorities

- ✓ *SVHC monitoring to address regulatory actions*
- ✓ *Available info to support (waste) policy decisions*
- ✓ *Support enforcement*

When does the SCIP notification duty apply?

Substance of concern (SVHC)

0,1% w/w

Article

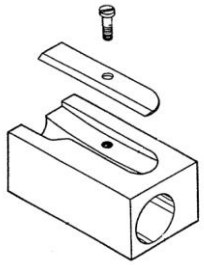
→ Duty to supply sufficient information to allow safe use of the article (Art. 33(1) REACH)

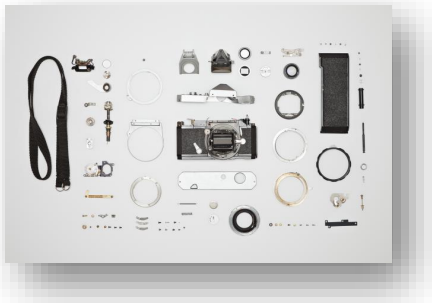
What is an Article in SCIP?

Article

Complex object

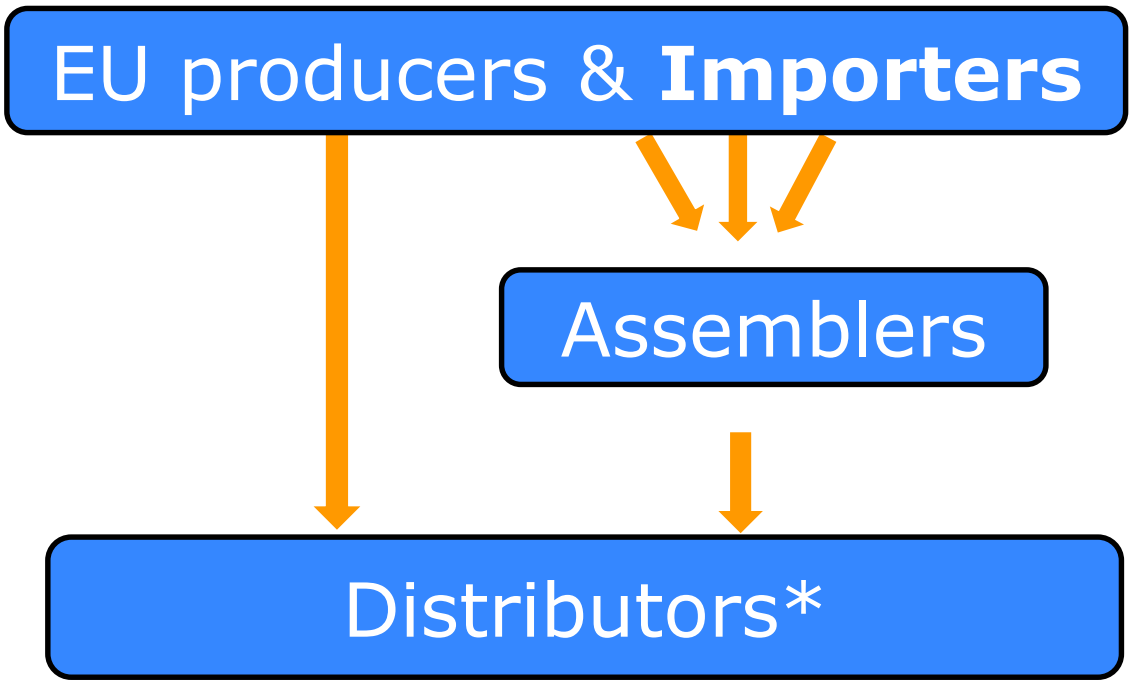
Articles remain articles when incorporated in “complex objects” (“O5A principle”)





Who needs to submit a SCIP notification?

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



* Except retailers that supply directly and exclusively to consumers

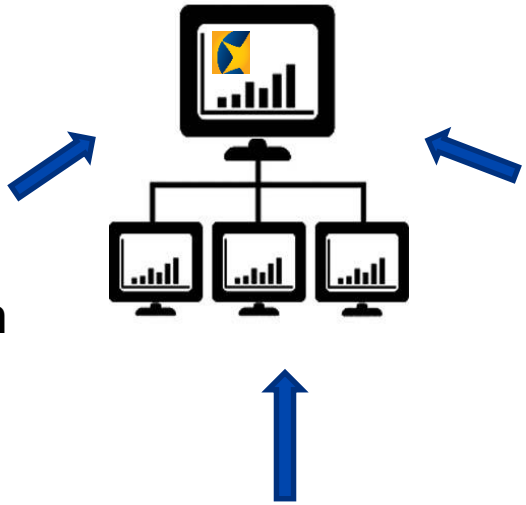
Non-EU suppliers

- Not allowed to submit SCIP notifications.

- Should support **importers** of their articles in the EU to fulfil their regulatory obligations, namely to submit SCIP notifications to ECHA.

What information is required?

Article Identification



Substance of concern (SVHC) in the article

(Concern element)

Safe use information

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

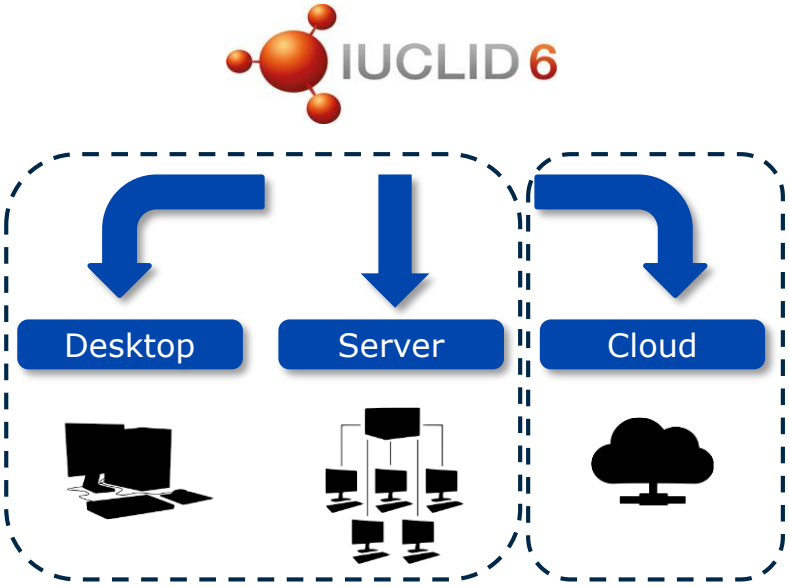
- *SVHC identifiers*
- *Concentration range*
- *Material category*

Detailed information requirements published on ECHA website

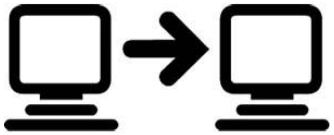
How to submit?

There are three ways to prepare the SCIP notifications

2. Offline in the company's own IT system

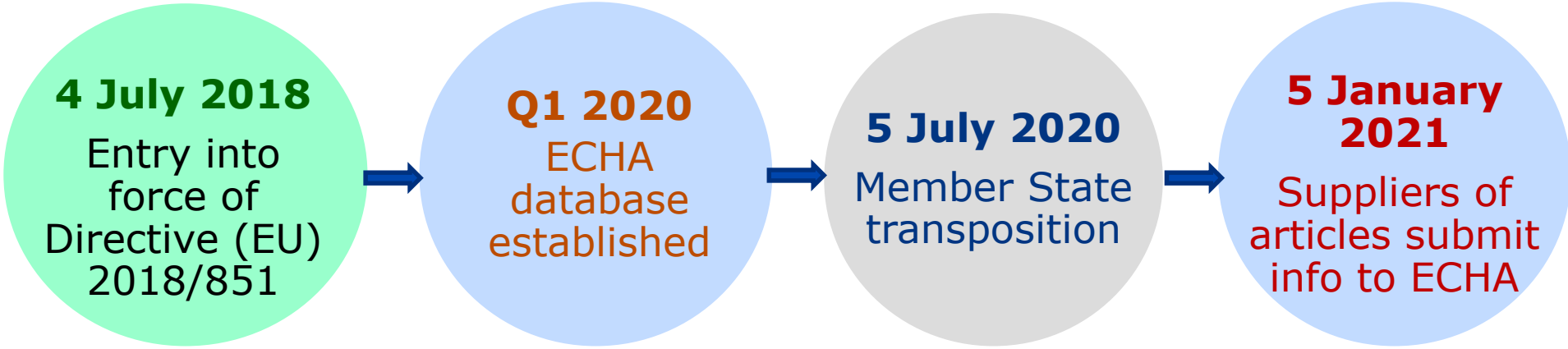


1. Online



3. System-to-System Service

Roles and milestones



- Establish a **database** + **Enable submission** of info by EU suppliers of articles
- Provide **access to the database** to "waste treatment operators", and to consumers (upon request)

MSs

- **Transpose** into national law
- **Enforce**

Where are we now?

SCIP prototype released on **17 February 2020**:

- Allows companies to get familiar with the tools to prepare and submit a SCIP notification.
- Allows users to provide feedback to further improve the tool

PROVIDE FEEDBACK

Contact ECHA

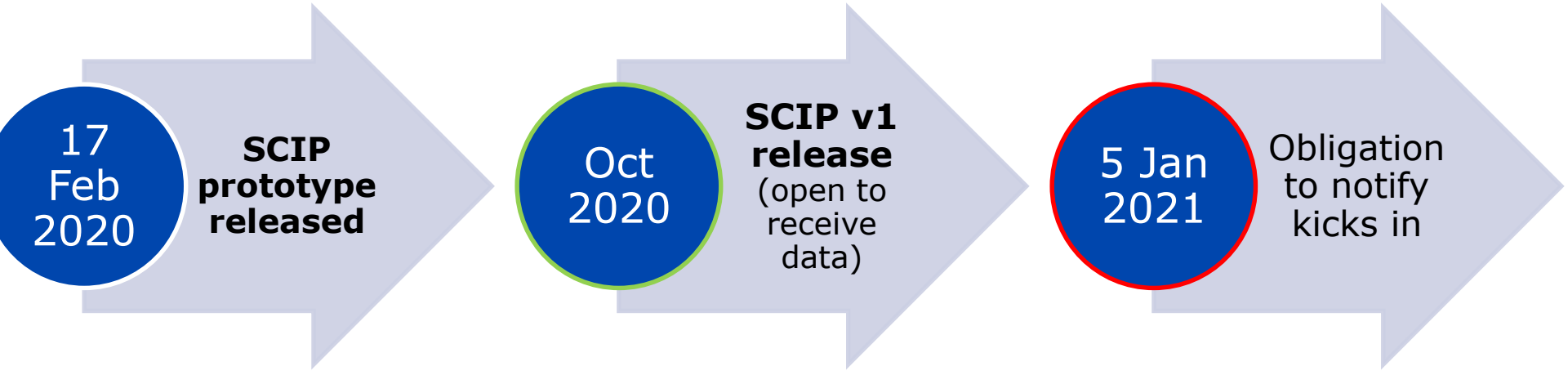
ECHA
EUROPEAN CHEMICALS AGENCY

SCIP

Release of SCIP v1

(planned for end of **October 2020**)

Open to received data to fulfil legal obligation



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jukka.malm@echa.europa.eu

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