

Impact of regulatory actions on substance registrations under REACH

HWC Summit 2019 Bilbao

12 November 2019

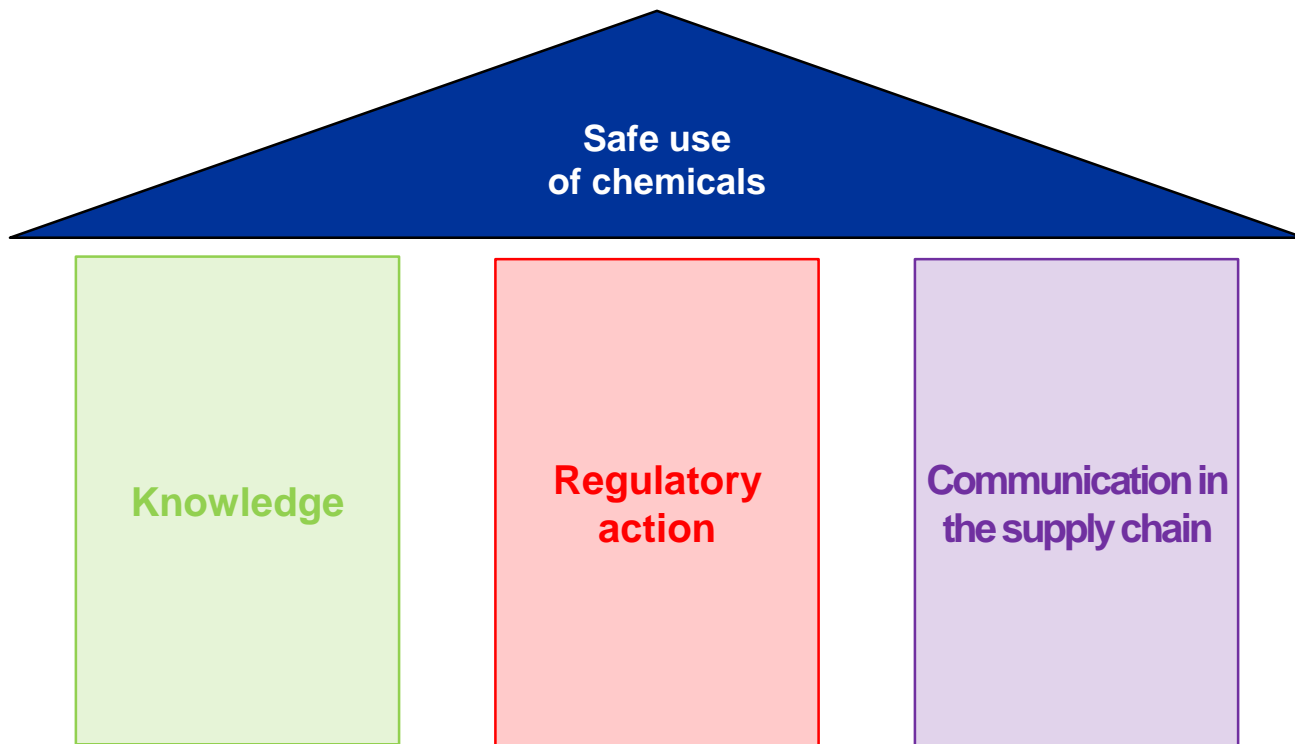
Fesil Mushtaq

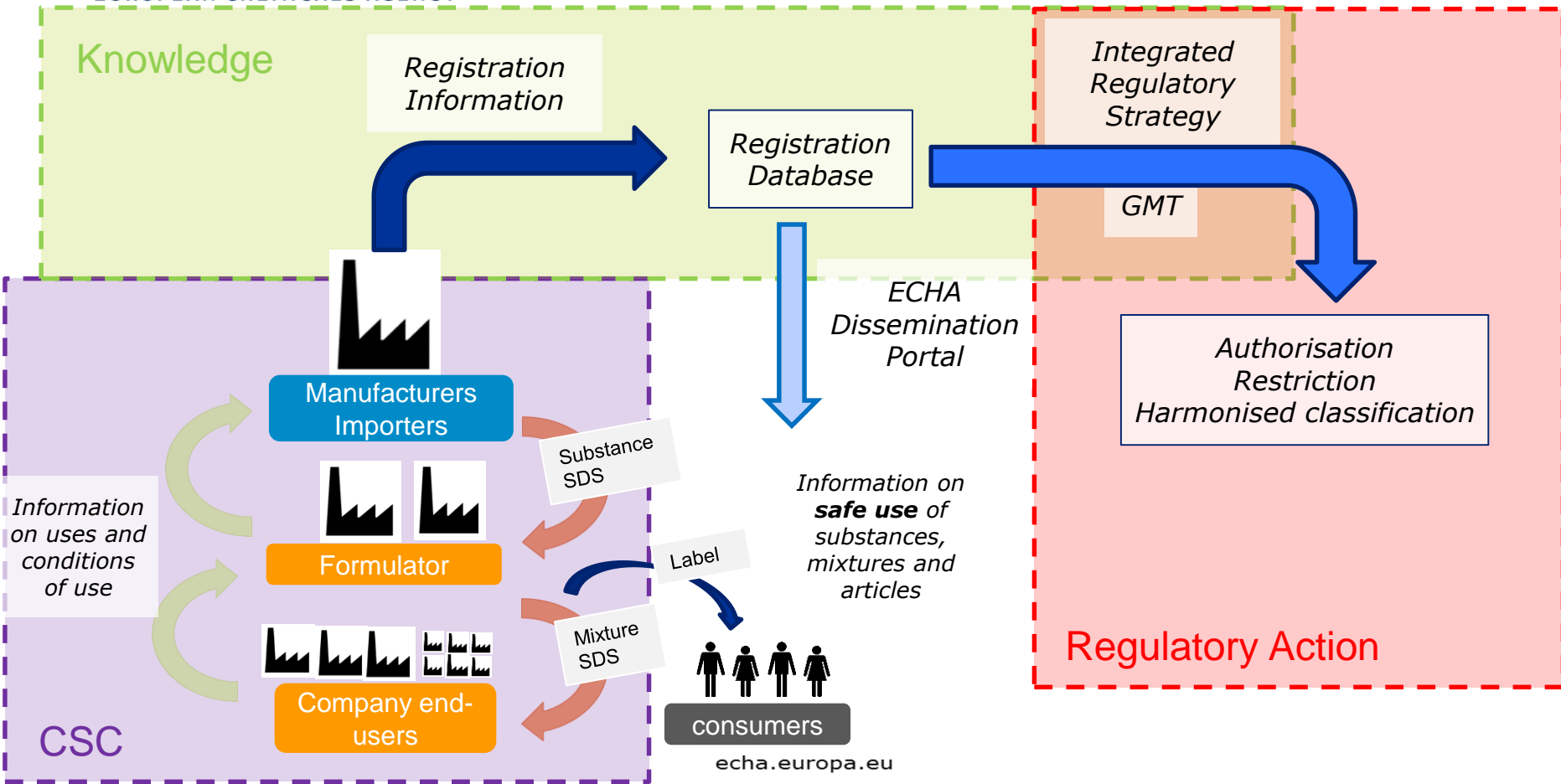
ECHA

Unit B4 Exposure and Supply Chain

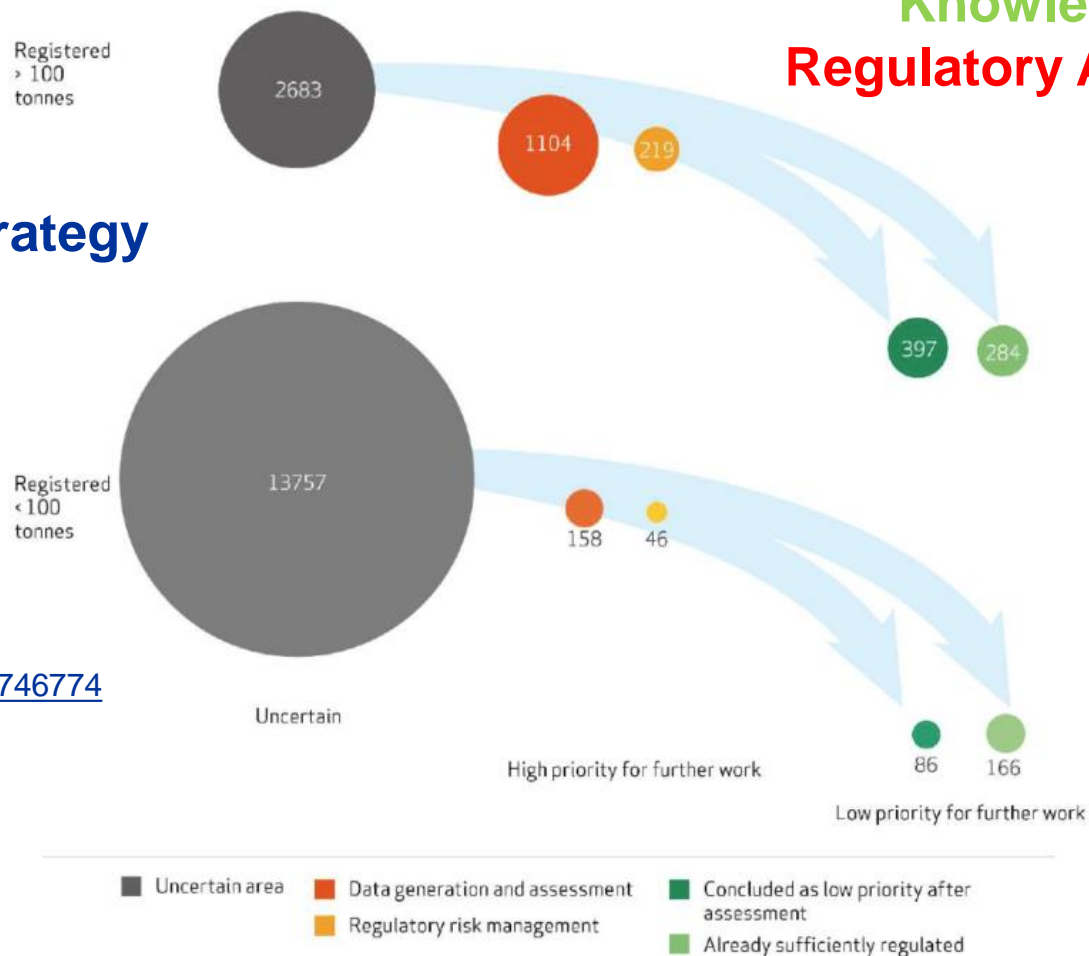


Basic pillars of REACH and CLP legislation





Integrated Regulatory Strategy (IRS)



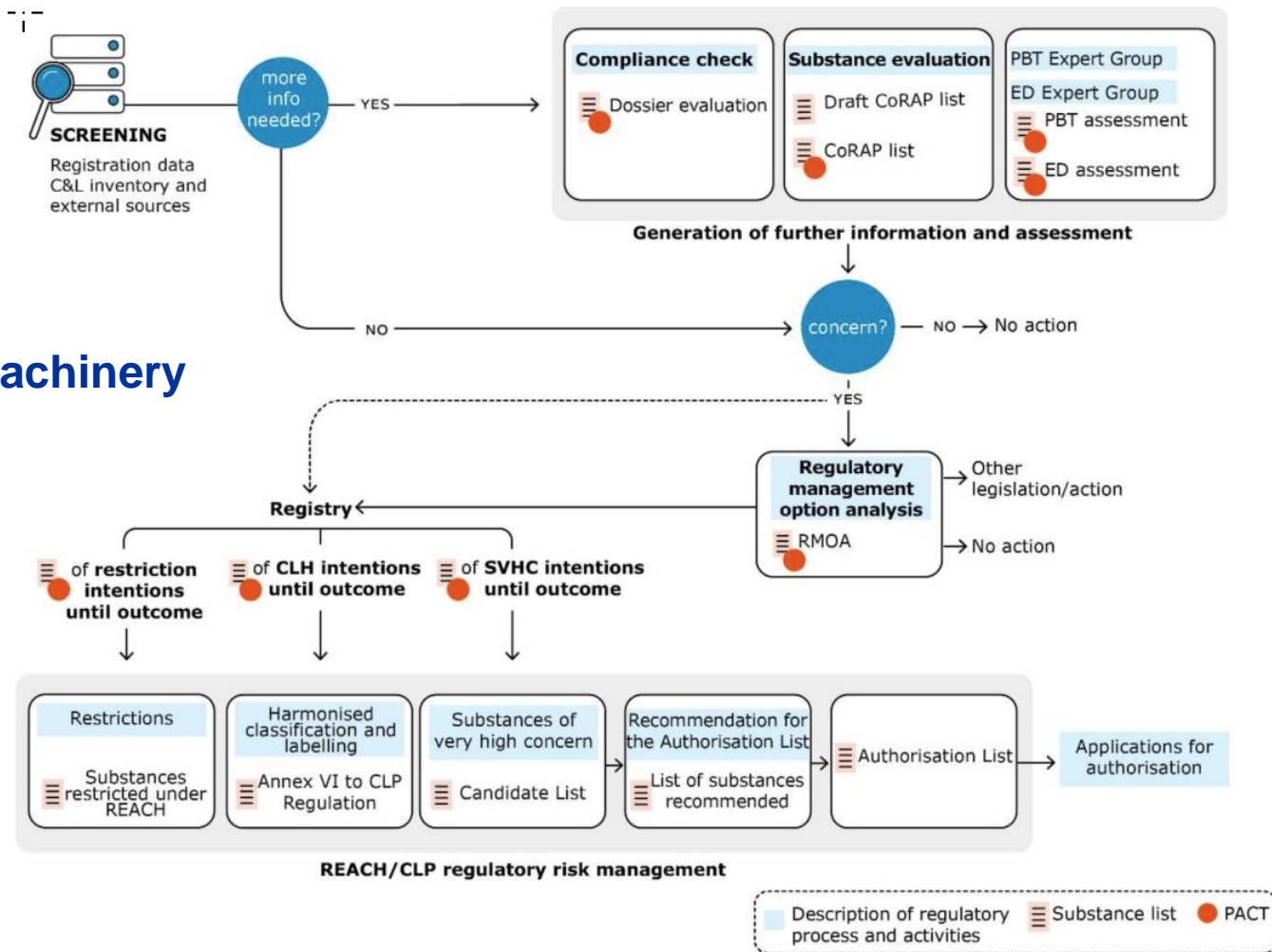
https://echa.europa.eu/documents/10162/2746774/8/irs_annual_report_2018_en.pdf

IRS: Objectives and timelines

- To have concluded which substances are:
 - (i) of high priority for regulatory risk management,
 - (ii) need more data for a judgement to be made
 - (iii) are currently of low priority for further work.

- By 2020, to have all substances registered above 100 tonnes/year allocated to these pools.

- By 2027, to have all substances registered above one tonne/year allocated to these pools.

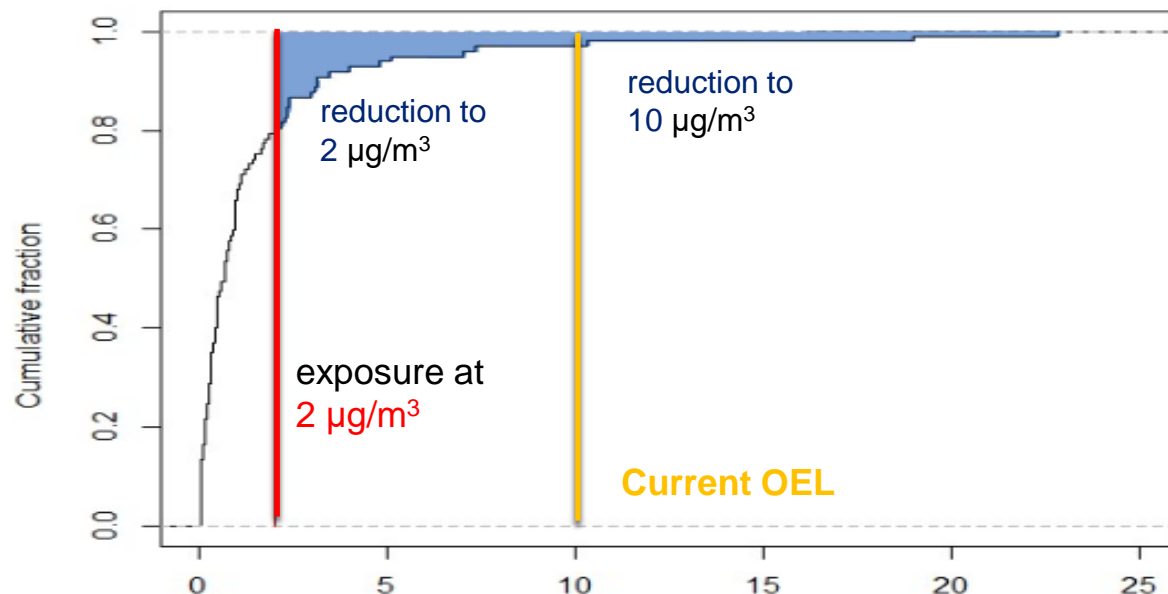


The REACH and CLP machinery for EU Regulatory Action

Authorisation example: Exposure reduction of Hexavalent Chromium (Carc 1A - No safe threshold)

- Used in surface treatment of metals and plastics amongst others
- Increased attention to occupational safety
- Some companies leave the market
- Increased R&D in alternatives:
 - Trivalent chromium
 - Physical Vapor Deposition technologies
 - “Diamond-like-carbon” for coating of cylinders for printing and packaging
- Authorisation reduces exposure (supports the attainment of OELs)

Hexavelant chromium (Cr(VI)): Exposure reduction in surface treatment supporting the attainment of OEL



Based on CrVI compounds in 97 samples in 11 sites in France 2010-13 (Vincent et al. 2015)

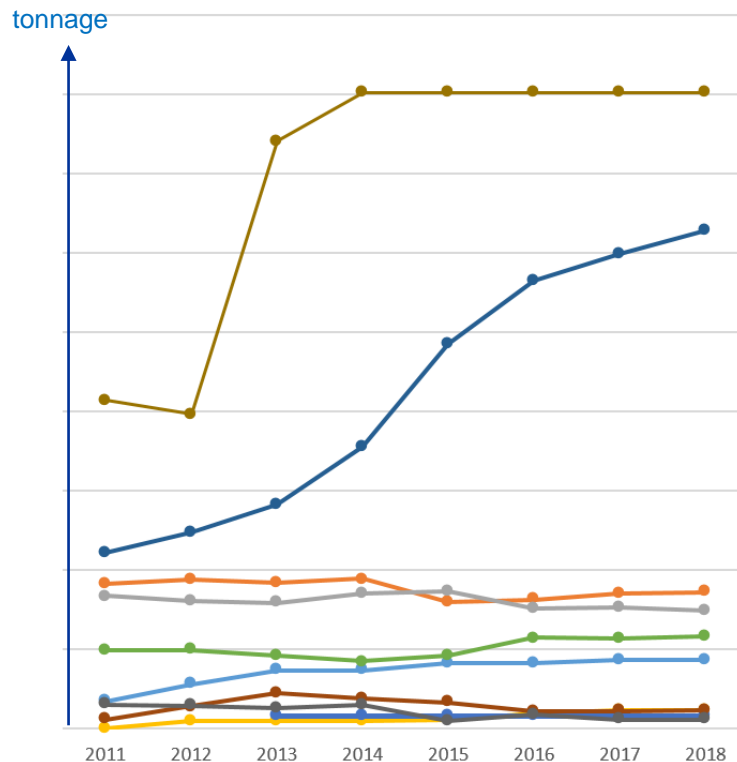
- Applicants committed to reduce exposure to 2 $\mu\text{g}/\text{m}^3$ or even lower (current OEL is 10 $\mu\text{g}/\text{m}^3$ going to 5 $\mu\text{g}/\text{m}^3$)
- Authorisation requirement clearly supports the attainment of the OEL

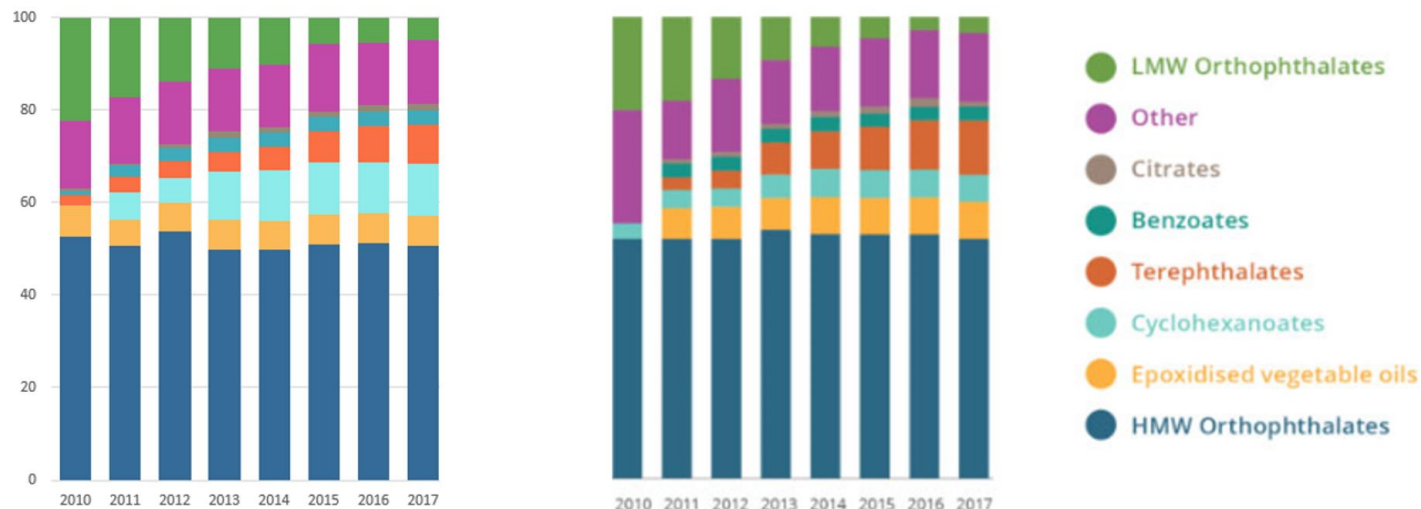
Authorisation example 2: Substitution of arsenic trioxide in Murano Glass, Italy (Carc 1A - No safe threshold)

- No application: substitute found (cerium oxide + ground granulated blast furnace slag)
- Arsenic concentrations in the air of Murano islands dropped by 98 % (from 200 ng/m³ in 2014 to 4 ng/m³ in 2016)! (EU air quality target value is 6 ng/m³)
- Workers exposed to arsenic dropped significantly: companies would comply with OEL of 0.01 mg/m³ (i.e. 10 ng/m³) inhalable fraction, 8 hrs
http://www.europarl.europa.eu/doceo/document/TA-8-2019-0307_EN.html
- Authorisation requirement supports the attainment of the OEL in Murano.

Restriction example: plasticiser substitution

- 4 phthalates restricted (R, ED)
- 10 alternatives monitored for the study
- 2 main alternatives identified (a terephthalate, a cyclohexanoate)
 - Not classified





(a)

(b)

Normalised plasticiser tonnage market trend:

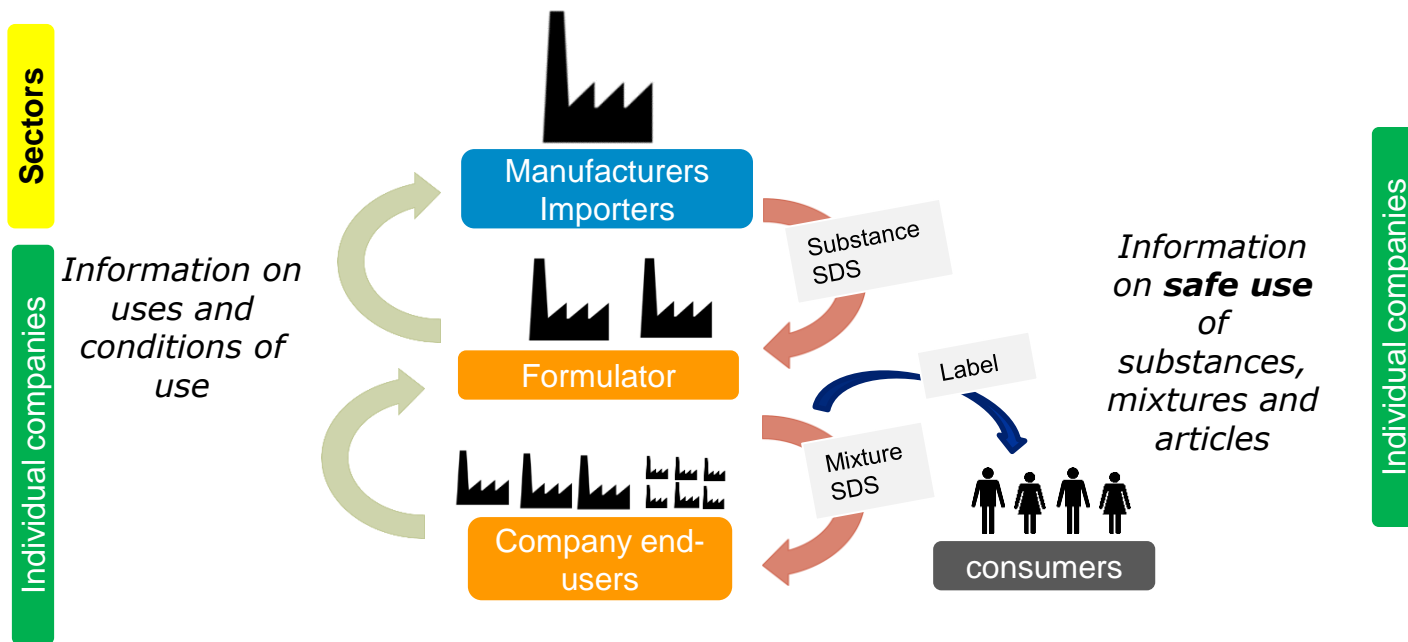
(a) as derived from the registration data based on technical function information

(b) as published in 2018 by the “European Plasticisers” sector group

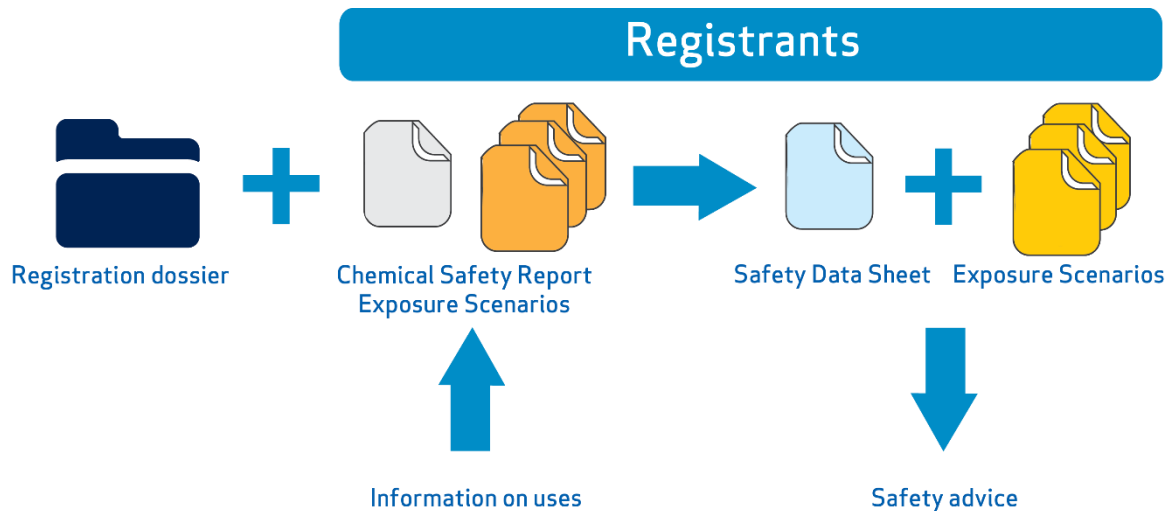
Restriction example 2: Bisphenol A (BPA)

- **Dec 2016 restriction of BPA in thermal paper to take effect in 2020 giving time to phase out**
- **Bisphenol S (BPS) as possible substitute, which may have similar health issues (under Evaluation at ECHA)**
- **While market share of BPA reduces market share of BPS increases**
 - Market share of other alternatives also increases (some have potential health issues)
- **Group Management Team approach, to avoid regrettable substitution**
- **https://echa.europa.eu/documents/10162/22863068/use_of_bisphenol_and_alternatives_in_thermal_paper_en.pdf/**

Communication in the supply chain



Exposure scenario information



Downstream users: Formulators or End users

Manufacturer



Knows the properties of the substance

Downstream user



Knows how the substance is used:

- **Products, processes**
- **Concentrations, amounts**
- **Operational conditions/Risk management measures**

- **Capacity to carry out the assessment**
- **Efficiency by avoiding multiple repetition of similar assessments**
- **Allocation of assessment responsibilities**
- **Exchange of information (via supply chain or other means)**

Assessment capacity in the supply chain

Few Manufacturers

Knows how to carry out chemical safety assessment



More Formulators

Some know, some don't



Many large downstream end user



Knows how/Capacity to ensure safe use, based on supplier's data on hazard and substance behaviour
NEED: Straightforward documentation of conformity

Many SME downstream end user



No own risk assessment capacity

NEED: Reliable instructions to follow

- **An assessor at the top of the supply chain is expected to:**
 - **Differentiate** the safe use advice per substance according to:
 - The identified uses in the life cycle of the substance.
 - The variety of the operational conditions existing for a use.
 - The risk management measures appropriate to the use and the sector of use.
 - **Demonstrate** control of risk based on exposure quantification (where thresholds exist) or qualitative considerations.
 - **Communicate** relevant and targeted advice in a terminology understandable to recipients.
- All this, based on information to be obtained from a complex, diversified and competitive market (for initially extending the SDS) and an absence of rules/system for feedback

- **Action 3: Improving the workability and quality of extended Safety Data Sheets**

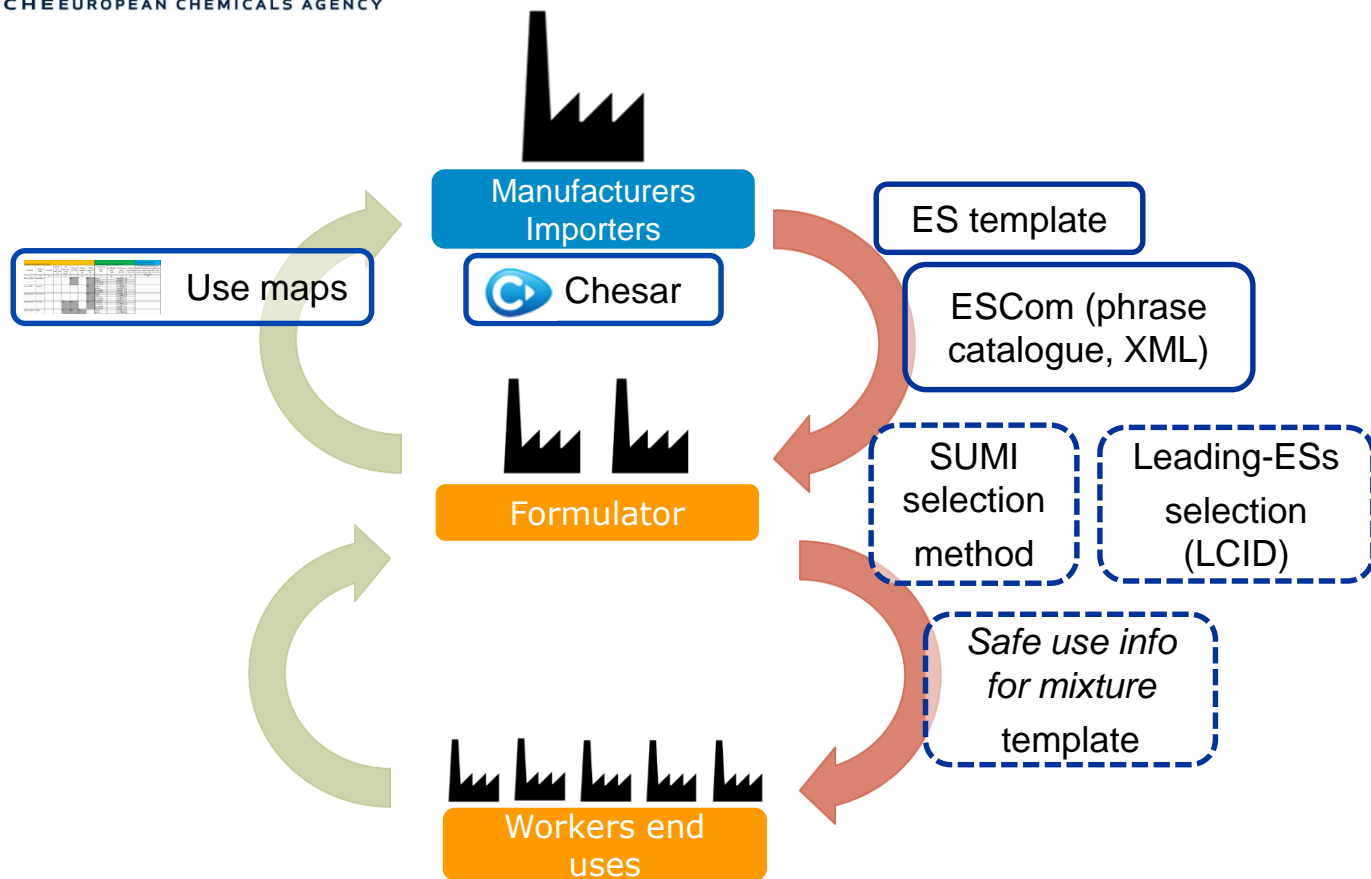
3(1): The Commission encourages more industry sectors to develop and use harmonised formats and IT tools that would provide more **user-targeted information** and **simplify the preparation and use of extended Safety Data Sheets as well as facilitate their electronic distribution**;

3(2): The Commission will consider including **minimum requirements for the exposure scenarios** for substances and mixtures in Safety Data Sheets and request ECHA to **develop a methodology for Safety Data Sheets for mixtures**

- <https://echa.europa.eu/reach-review-action-3>

- **Action 12: Interface REACH and OSH legislation**

1. Use of REACH tools (e.g. extended SDS) to enhance the effectiveness of OSH legislation.



Schema with system building blocks

https://echa.europa.eu/documents/10162/28268216/rra3_potential_building_block_en.pdf/6f62553c-4943-aced-a80a-e27a0fabd252

Tools

Green:

Available

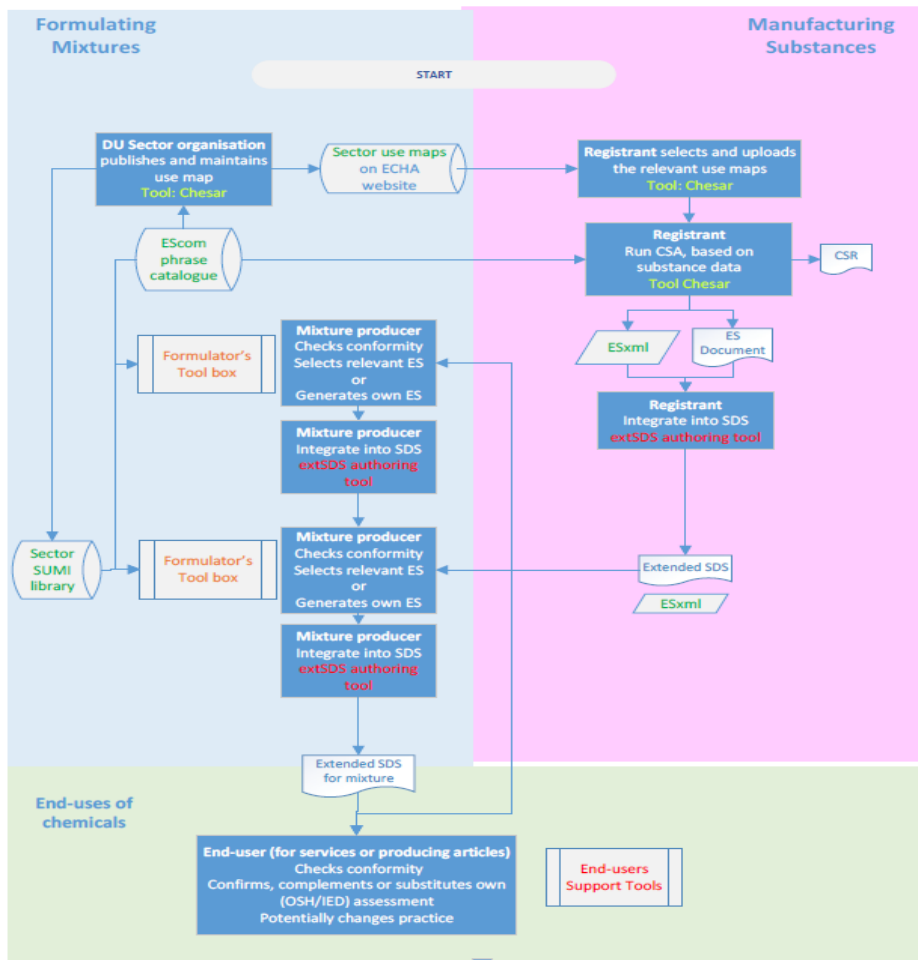
Orange:

Under development

Red:

Not yet in place

Broad consensus on system



- REACH & CLP contribute towards exposure reduction in the workplace
- Knowledge/data: needs to be improved (both authorities + industry rely on it)
- The most hazardous substances will be subject to regulatory risk management reducing exposure (in the workplace)
 - Targets have been set, grouping will be a feature of the processing
 - Authorisation reduces worker exposure and supports the attainment of OELs
 - Authorisation/restriction have been shown to encourage substitution
- For the rest: communicating clear, understandable information via the supply chain should ensure safe use (including the mixtures)

Thank you!

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