ECHA
EUROPEAN CHEMICALS AGENCY

REACH 2018
webinars

Assess hazards and risks – What does it mean?

20 July 2016

Catherine Cornu
European Chemicals Agency

Phase 4: Assess hazard and risk

Activities:

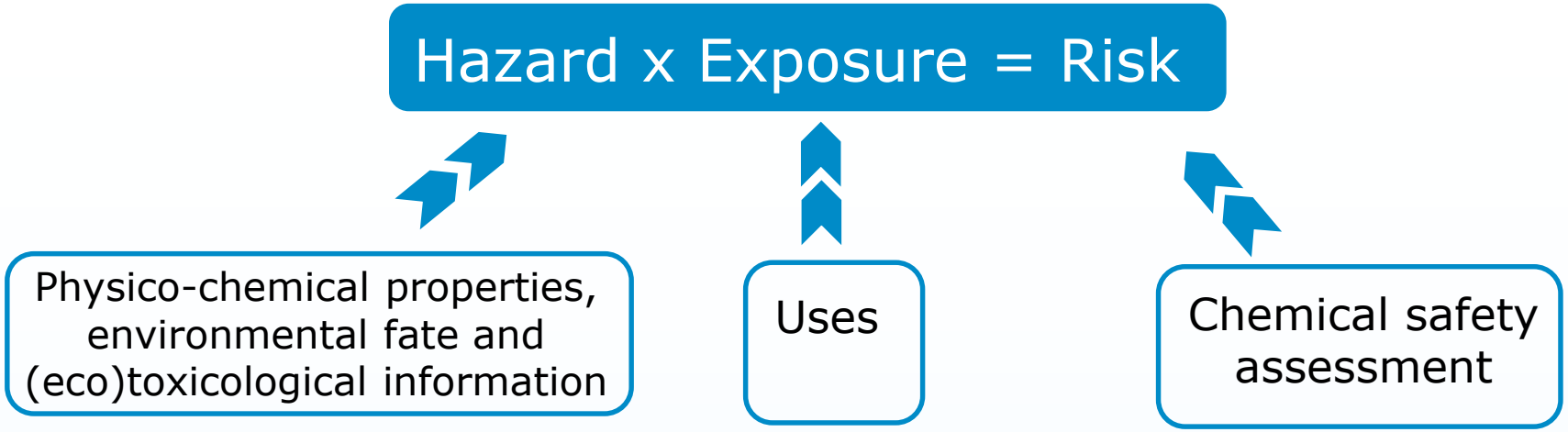
1. Understand your information requirements
2. Gather hazard data and fill data gaps
3. Agree classification and labelling in the Substance Information Exchange Forum (SIEF)
4. Gather information on uses
5. Assess risks and risk management measures

Understand your information requirements

REACH registration

Why? To ensure that the risks posed by your substance are controlled

How? Assessing hazard and risk



Hazard: any source of potential damage, harm or adverse effects

Exposure: chemical agent in contact with an organism or the environment

Risk: likelihood that a hazard will cause its adverse effects

Information requirements

When? information requirements depend on your type of registration

- intermediate under strictly controlled conditions
  → all available data

- standard registration
  → depends on your tonnage band

Understand your information requirements

Information requirements

The information requirements depend on your tonnage band

- 1-10 tonnes per year
  → Annex VII

Information required for standard registration of 1-10 tonnes a year (Annex VII of REACH)	
Non-vertebrate animal endpoints	**Vertebrate animal endpoints**
Description of the state of the substance at 20°C / 101.3 kPa	
Melting/freezing point	Acute toxicity: oral
Boiling point (if applicable)	
Relative density	
Vapour pressure (if applicable)	
Surface tension (if applicable)	
Water solubility	
Partition coefficient	
Flash-point	
Flammability	
Explosive properties	
Self-ignition temperature	
Oxidising properties	
Granulometry (if applicable)	
In vitro skin irritation/corrosion	
In vitro eye irritation	
Skin sensitisation*	
In vitro gene mutation in bacteria	
Short-term toxicity on invertebrates	
Growth inhibition study aquatic plants	
Ready biodegradability (if applicable)	

Low risk substances

Low risk substances in the 1-10 tonnage band can benefit from reduced information requirements, i.e. only physico-chemical properties in Annex VII

- **Annex III** of REACH sets the criteria for deciding on **low risk**

- Inventory of substances on ECHA's website
  - Substances likely to need the full dataset

- You need to fill in a justification to benefit from reduced requirements

ECHA
EUROPEAN CHEMICALS AGENCY

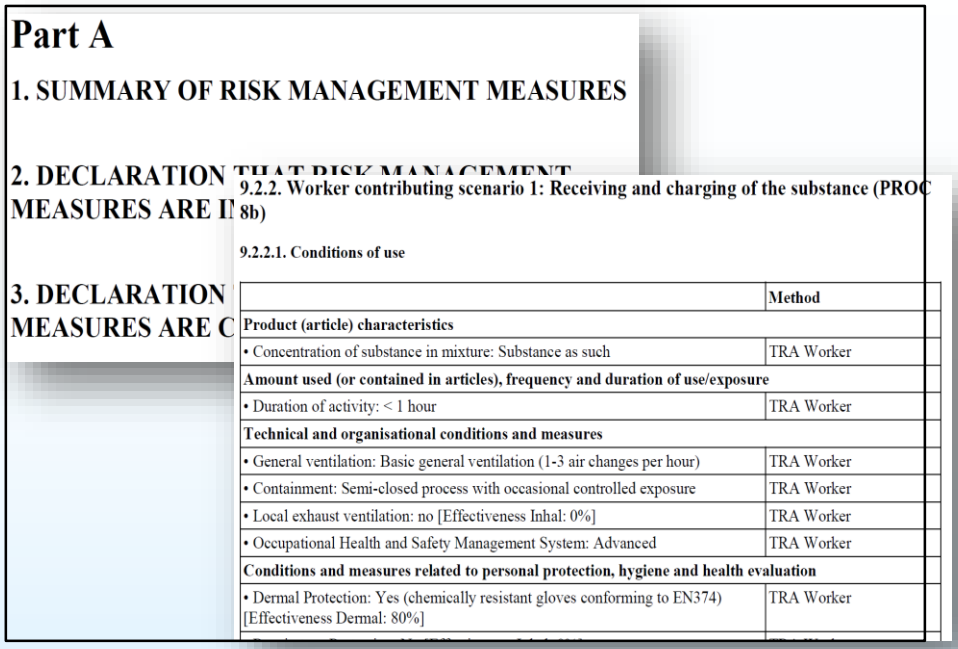
REACH 2018

Understand your information requirements

Information requirements

The information requirements depend on your tonnage band

- 10-100 tonnes per year → Annexes VII + VIII + chemical safety report



Part A

1. SUMMARY OF RISK MANAGEMENT MEASURES

2. DECLARATION THAT RISK MANAGEMENT MEASURES ARE I

3. DECLARATION MEASURES ARE C

9.2.2. Worker contributing scenario 1: Receiving and charging of the substance (PROC 8b)

9.2.2.1. Conditions of use

	Method
Product (article) characteristics	
• Concentration of substance in mixture: Substance as such	TRA Worker
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 1 hour	TRA Worker
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker
• Containment: Semi-closed process with occasional controlled exposure	TRA Worker
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker
• Occupational Health and Safety Management System: Advanced	TRA Worker
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374) [Effectiveness Dermal: 80%]	TRA Worker

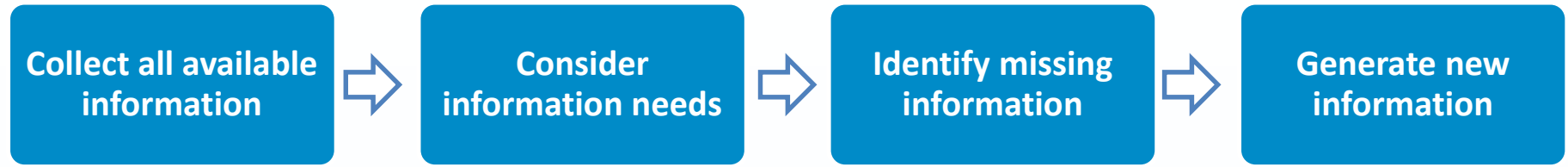
Information required for standard registration of 1-10 tonnes a year (Annex VII of REACH)

Information required for standard registration of 10-100 tonnes a year (Annex VIII of REACH)
Note: this is to be provided in addition to the information which is listed above

Non-vertebrate animal endpoints	Vertebrate animal endpoints
In vitro mutagenicity study in mammalian cells or *In vitro* micronucleus study	*In vivo* skin irritation*
In vitro gene mutation in mammalian cells	*In vivo* eye irritation*
Activated sludge respiration inhibition test	Testing proposal for *in vivo* genotoxicity (if applicable)
Degradation	Acute toxicity: inhalation
Hydrolysis	Short-term repeated dose toxicity (28-day)
Adsorption/desorption screening	Screening for reproductive/developmental toxicity
	Short-term toxicity on fish or testing proposal for long-term toxicity on fish (if applicable)

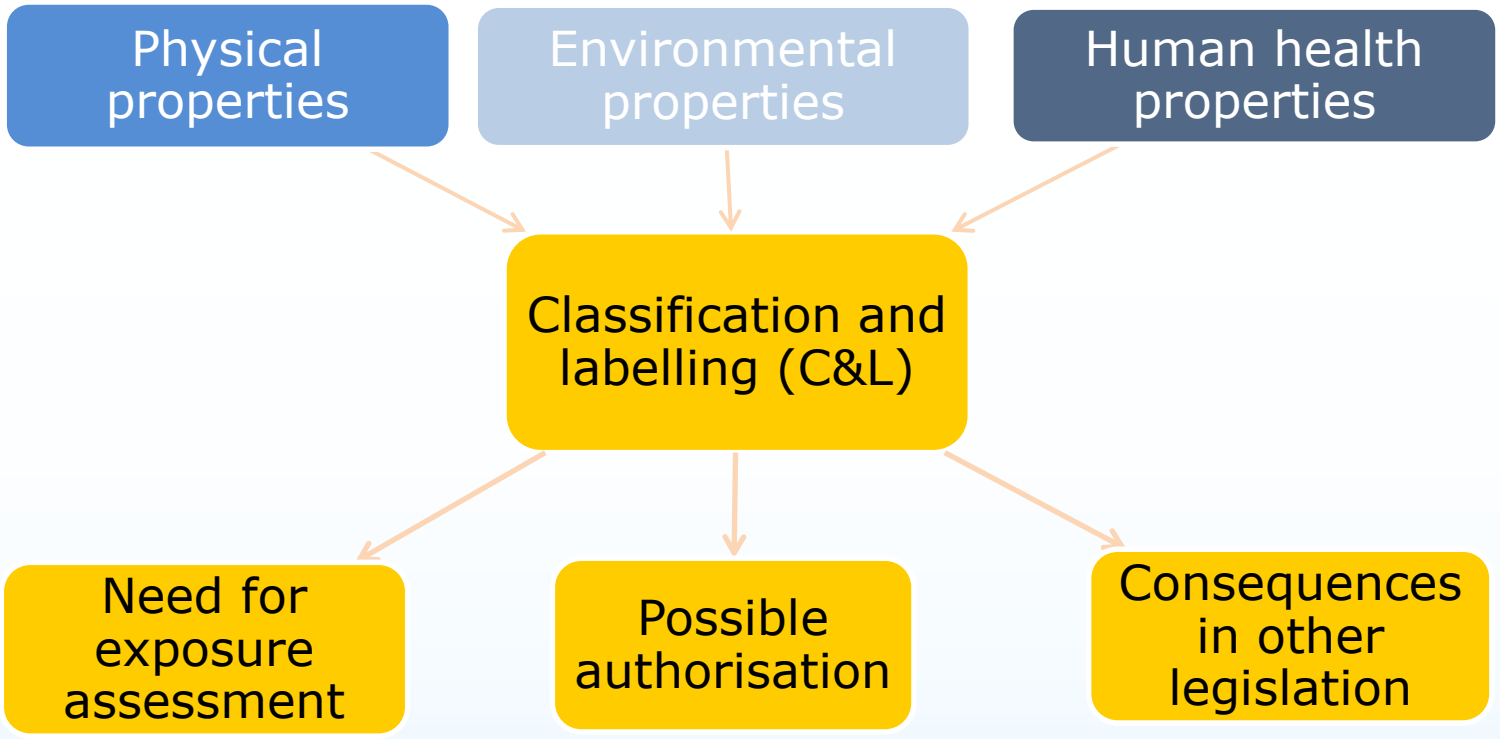
* You are allowed to do an *in vivo* study only if you are not able to classify your substance based on the *in vitro* results.

Gather hazard data and fill gaps

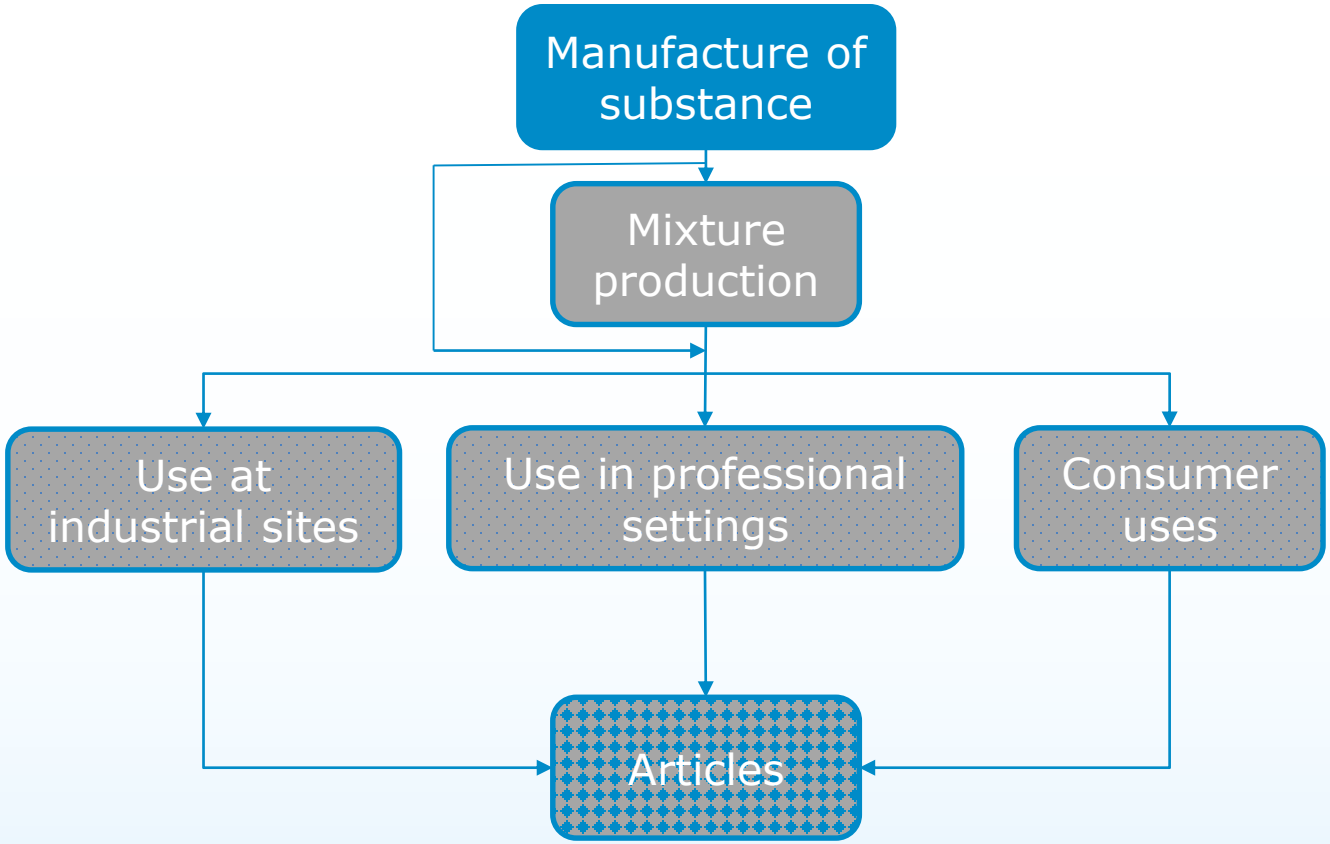


Agree Classification and labelling in the SIEF

Classification and labelling



Description of uses



Downstream users: make sure that your uses are covered

Make sure that your critical substances are registered and uses are covered

- Are sector organisations preparing use maps?
- Do they cover your use?

"I advise DUs to join forces and start creating sector use maps. We will get better exposure scenarios and avoid lots of correspondence with our suppliers if we receive everything in a good condition from the beginning."

Reetta Puska (Yara Finland)

Assess risks and risk management measures

Assess risk and ensure safe use

	1-10 tonnes/year Chemical Safety Report not needed	**10-100 tonnes/year** Chemical Safety Report needed
Substance not classified, not PBT/vPvB	• Information on use and exposure • Guidance on safe use	• Hazard assessment • PBT/vPvB assessment
Substance classified, or PBT/vPvB	• Information on use and exposure • Guidance on safe use	• Hazard assessment • PBT/vPvB assessment • Exposure assessment • Exposure scenarios • Risk characterisation

PBT= persistent, bioaccumulative and toxic
vPvB= very persistent and very bioaccumulative

Joint submission of data

- Joint part (only in the dossier of the lead registrant, with the support of co-registrants)
  - Substance Identity Profile (SIP)
  - Physico-chemical properties
  - Toxicological properties
  - Ecotoxicological properties
  - Classification and labelling information

- You can opt-out if justified

- Individual part (every co-registrant)
  - Substance identification
  - Uses and conditions of use of the substance through its life cycle

- Joint or individual part
  - CSR, upon agreement

Key messages

- ✓ Understand your requirements
- ✓ Generating information is a joint effort in the SIEF
- ✓ Both **hazard** and **exposure** information need to be carefully considered for proper **risk** assessment and management
- ✓ Take advantage of ECHA's support http://echa.europa.eu/reach-2018

ECHA
EUROPEAN CHEMICALS AGENCY

Thank you

echa.europa.eu/en/contact

Subscribe to our news at
echa.europa.eu/subscribe

Follow us on Twitter
@EU_ECHA

Follow us on Facebook
Facebook.com/EUECHA