

# ECHA contribution to OSH regulation

Roadmap on Carcinogens Conference  
“Working together to eliminate  
occupational cancer”

27-28 November 2019  
Helsinki

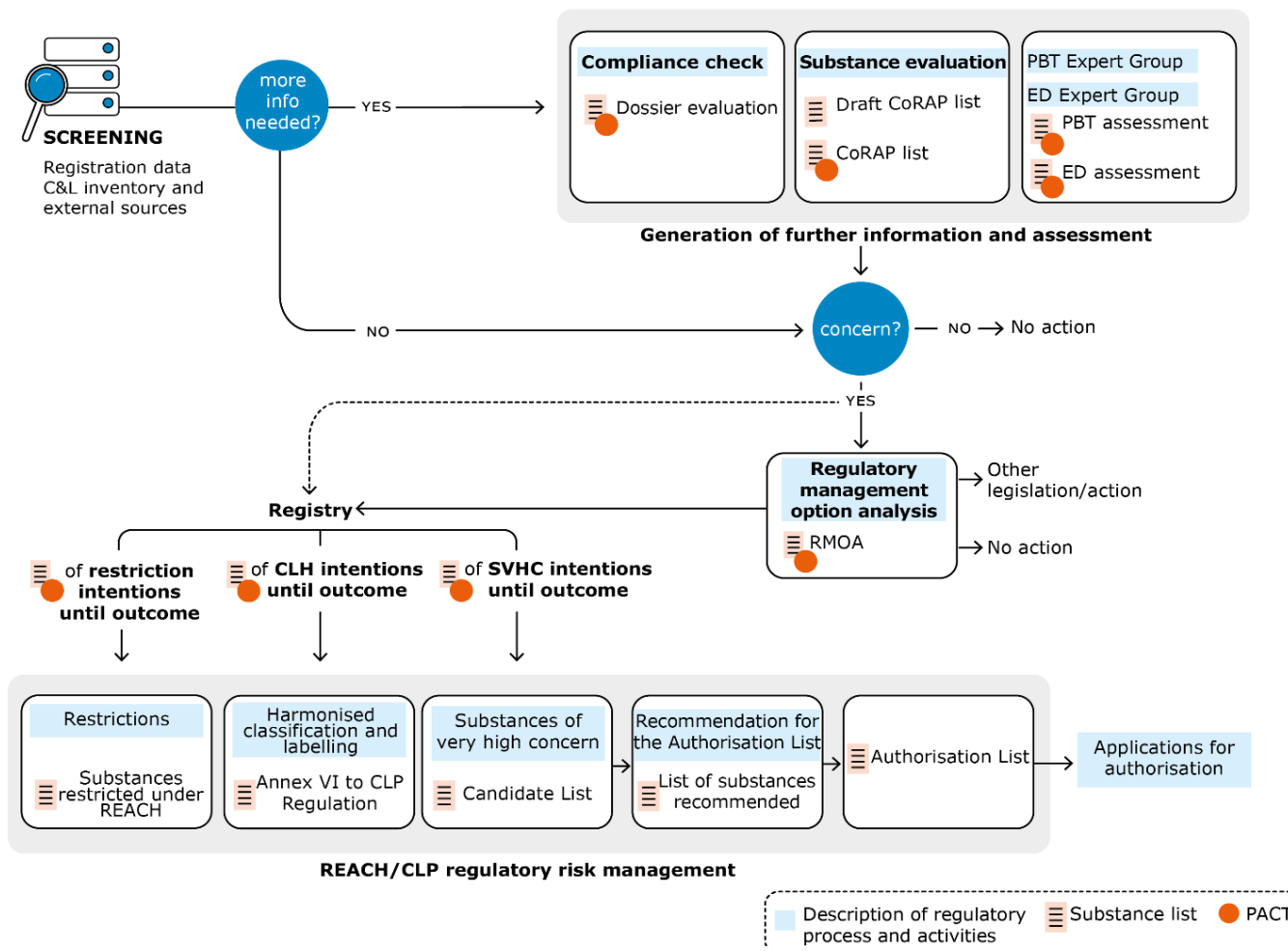
Bjorn Hansen  
Executive Director  
European Chemicals Agency

# Carcinogens under REACH and CLP

- REACH generates data on chemicals, e.g., mutagenicity, reproductive toxicity and carcinogenicity
- CLP classifies substances which have data as mutagens, reproductive toxins and carcinogens
- OSH uses the data and classification to protect workers

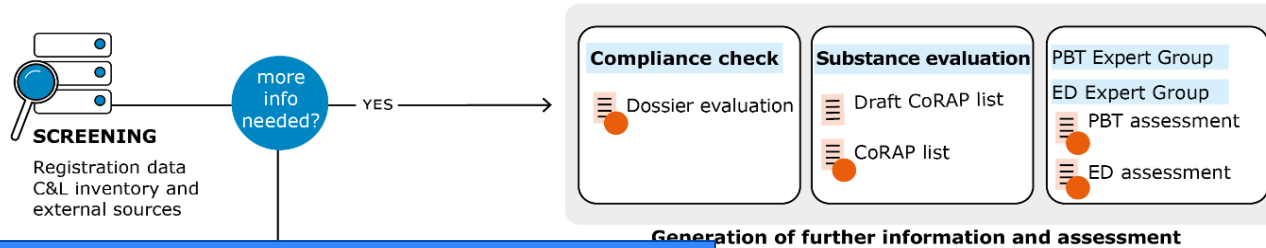


# Integrated regulatory strategy



# Carcinogens with harmonised classification (cat. 1A/B and 2)

## Integrated regulatory strategy

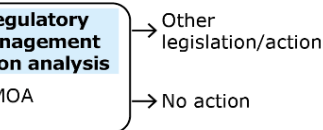


~400 registered; all scrutinised, further action taken or ongoing

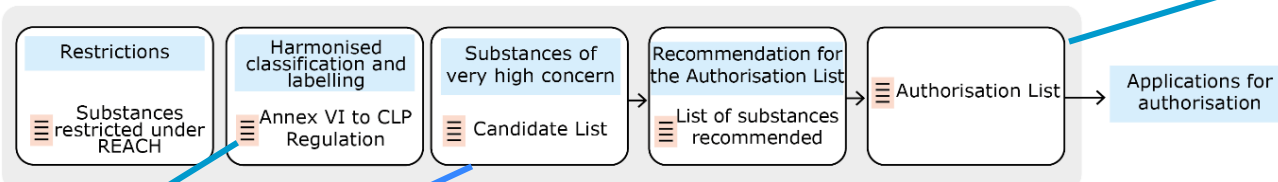
Also covered:

- Substances containing carcinogenic impurities.
- Structurally similar substances.

concern? → NO → No action



28 require authorisation



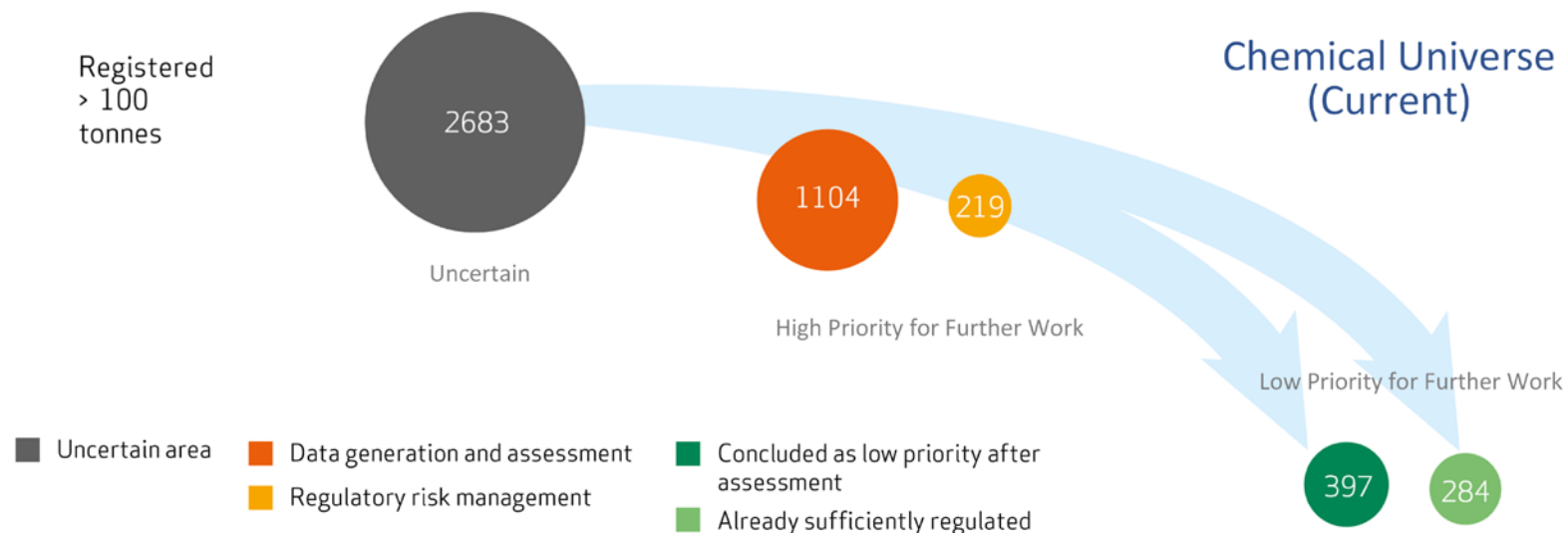
1245 harmonised classification

83 in Candidate List of substances of very high concern

PACT

# The chemical universe

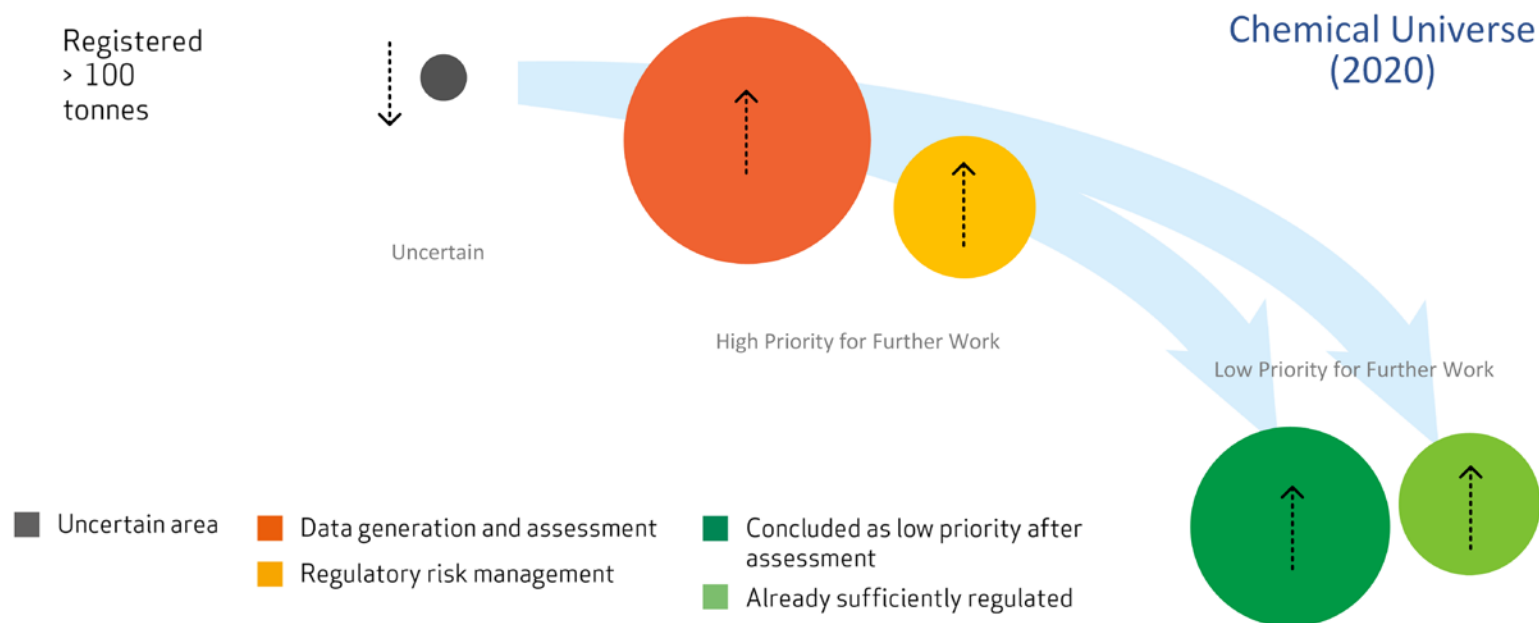
- mapping the REACH chemical space



- A mapping tool to support the Integrated Regulatory Strategy (snapshot from May 2018)

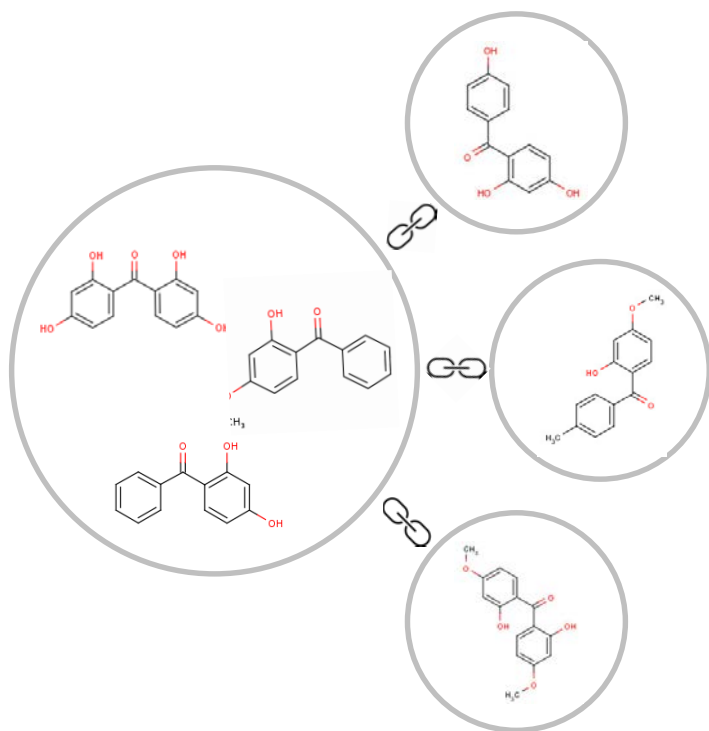
# The chemical universe

- mapping the REACH chemical space



➤ *Where we want to be in 2020!*

# Grouping of substances



- Objectives
  - *Accelerate* data generation and *intensify* identification of substances of concern and
  - *Accelerate* regulatory action of substances of concern.
    - The time from identification of concern to (final) regulatory risk management as short as possible.

# ECHA's contribution to OEL

- DG EMPL decides on substances, consulting WPC, other services and ECHA
- ECHA secretariat develops scientific base for OEL
- ECHA RAC develops opinion
- Package handed to DG EMPL for WPC discussion





# Processing OELs (Commission)

Setting of OELs for carcinogens at EU level follows the ordinary legislative procedure

(For Indicative OELs a lighter legislative procedure applies)

1

## Selection of chemicals for Scientific Evaluation

DG EMPL establishes lists of priorities for scientific evaluation based on inputs from various sources and application of priority criteria.

2

## Scientific Recommendation

DG EMPL issues mandates to scientific committee, who will deliver as a rule the exposure-risk-relationships (ERR) for non-threshold carcinogens, or a practical threshold when possible. Scientific Recs are subject to external consultation before adoption.

3\*

## WPC - ACSH

The Working Party on Chemicals (WPC) discusses the scientific Recommendation and various feasibility issues and comes up with a consensus based suggestion for the OEL value. This is integrated in a draft opinion for adoption by the Plenary of ACSH.

4

## Impact Assessment (IA)

DG EMPL drafts IA containing policy options and associated impacts. IA is discussed within an Interservice Steering Group and submitted to the Regulatory Scrutiny Board (RSB). A positive reply is required.

5

## Draft legislative proposal

DG EMPL prepares the draft legislative proposal and submits it to inter-service consultation. Thereafter, a final draft legislative proposal is prepared.

6

## College of Commissioners

The College of Commissioners adopts the proposal and sends it to Council and Parliament for negotiation and subsequent adoption. As a Directive.

7

## Adopted Directive published in EU Official Journal

MSs will transpose the legal text into national legislation by the date set in the Directive.

\*2 stages of social partners' consultation have to be carried out in accordance with Article 154 of TFEU

## ECHA process for OELs

Steps in ECHA's process:

- a. Request from the EU Commission
- b. Call for evidence
- c. ECHA Scientific Report
- d. Public consultation
- e. Risk Assessment Committee opinion

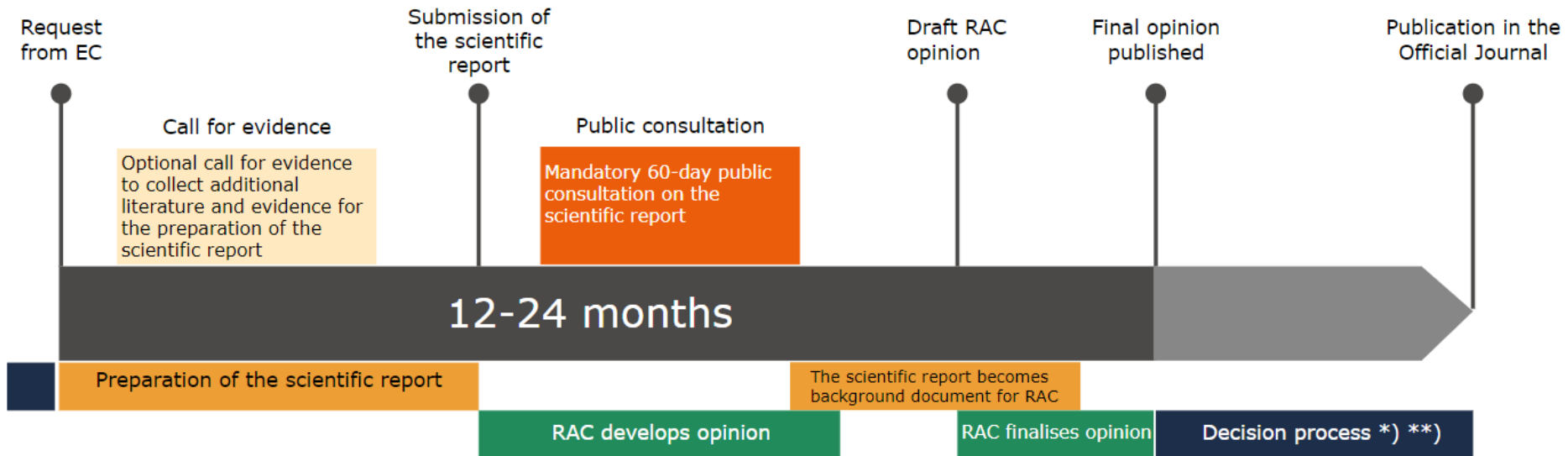


**This process is equivalent to steps 1 and 2 in the EU Commission process**

Next step:

⇒ Commission Decision process

# ECHA process - timeline



\* When a substance is evaluated under the Chemical Agents Directive (CAD) and the occupational exposure limit is indicative, the decision is made by the European Commission

\*\* When a substance is evaluated under the Carcinogens and Mutagens Directive (CMD), the decision is made in agreement between the Council and the European Parliament based on a proposal put forward by the European Commission



## Pilot Project - 5 substances in 2018

- Arsenic acid and its salts
- 4,4'-methylene-bis(2-chloroaniline) – MOCA

OELs adopted & published June 2019: Dir 2019/983

- Nickel and its salts
- Benzene
- Acrylonitrile

OELs adopted by ACSH June 2019; Draft legislation proposed to Council and Parliament

## Under Service Level Agreement (SLA) between Commission and ECHA

- The requests/substances are decided by Commission/DG EMPL.
- 2 substances in 2019:
  - Lead and its compounds
  - Diisocyanates
- Proposed 2 substances for 2020:
  - Cadmium and its inorganic compounds
  - Asbestos
- SLA to be reviewed/renewed in 2021/2022.

# REACH Authorisation and Restrictions in promoting substitution of carcinogens

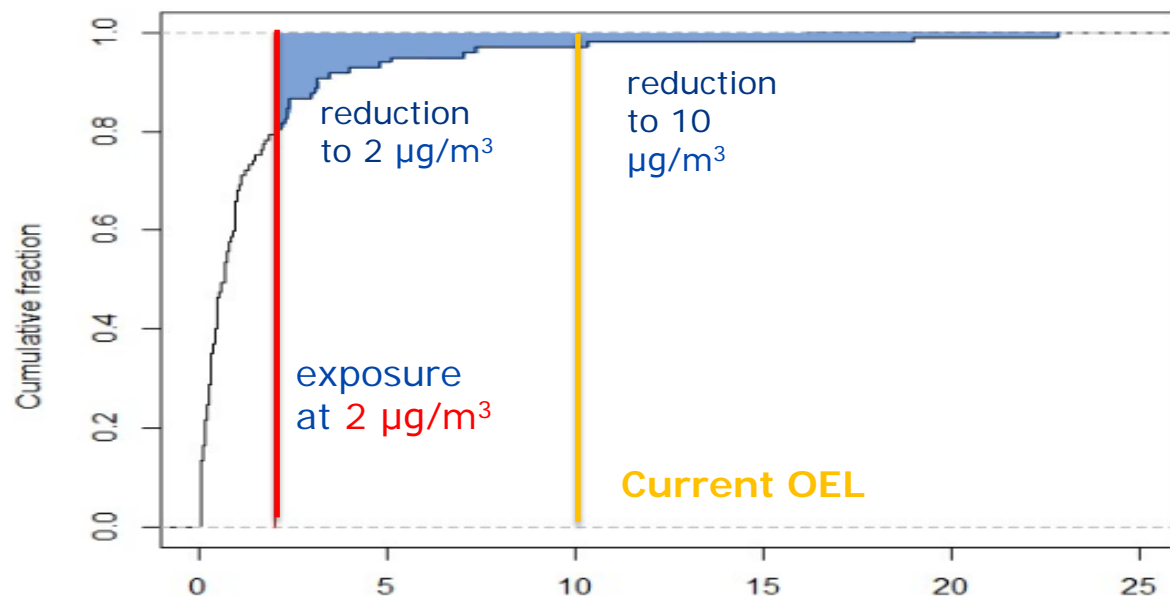
- REACH Authorisation implements OSH substitution of mutagens, reproductive toxins and carcinogens by mandatory analysis of alternatives and proper control of risks
- REACH Restrictions sets timelines for substitution where workers are at risk



# REACH Authorisation and Restriction

- REACH Authorisation and Restriction processes are powerful tools to promote substitution of substances of concern, including carcinogens
  - E.g. **Applications for Authorisation: Cr(VI)**  
Innovative alternative developed: [RotoHybrid](#): a Diamond-Like Carbon coating process for press gravure printing cylinders
  - E.g. **Restrictions: 1,4-dichlorobenzene** in air fresheners and toilet blocks  
Safer alternatives: existing safer consumer products , technical alternatives such as more frequent cleaning, automatic flush toilets, greater ventilation

## Hexavalent 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

# Safe use in the supply chain

- REACH requires a chemical safety assessment, incl. maximum exposure levels for workers: What risk management is needed beyond C&L?
- REACH requires this info be communicated to employers in a Safety Data Sheet
- OSH uses the info for employer risk management





# Basic pillars of chemicals legislation

## Safe use of chemicals

**Knowledge**

**Regulatory  
action**

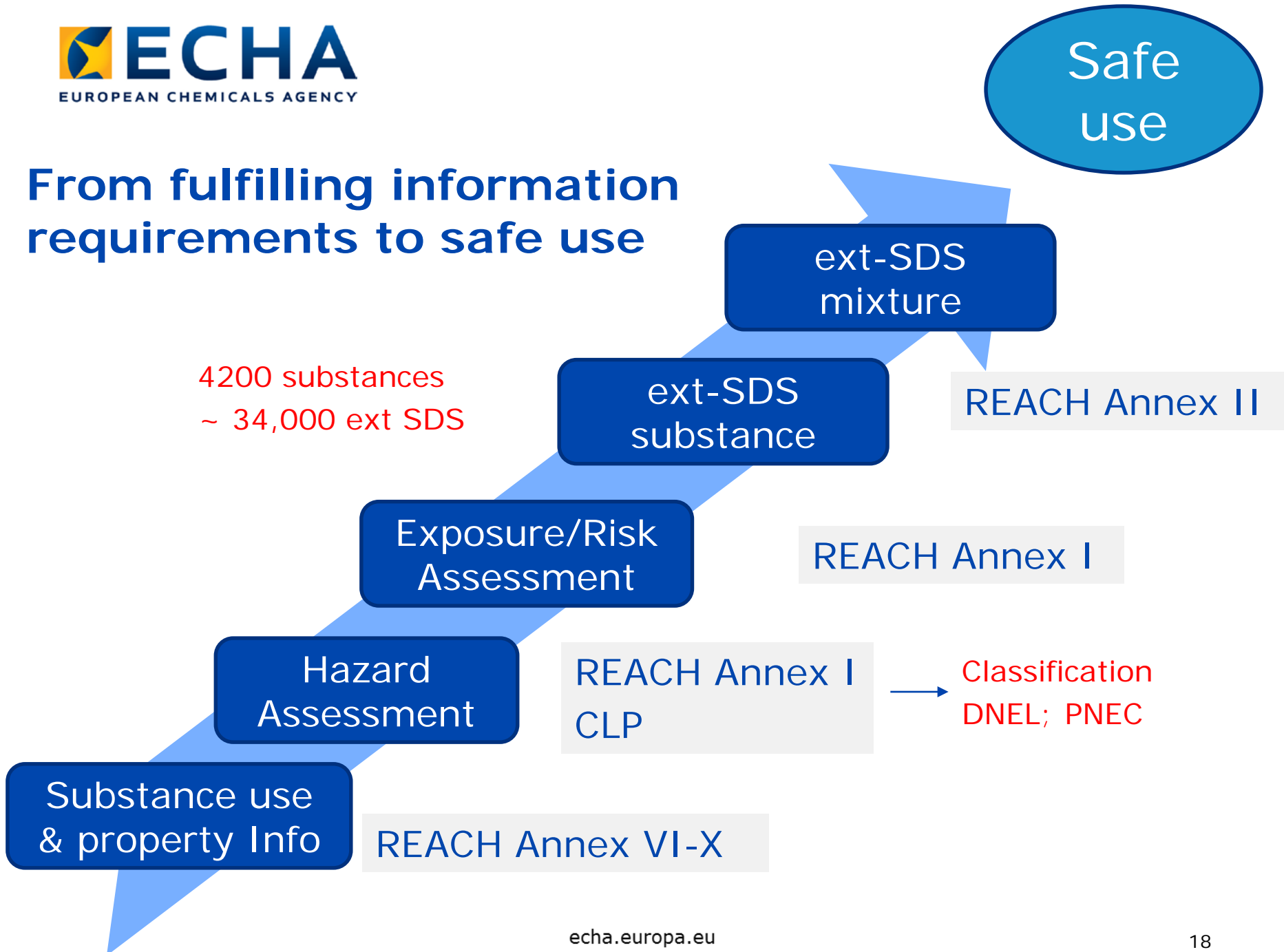
*"10%" of  
substances*

**Communication  
in supply chain**

*Information on uses  
Hazards  
Use restrictions  
Safe use advice*

# From fulfilling information requirements to safe use

4200 substances  
~ 34,000 ext SDS



## What to do?

- Demonstrate concretely how REACH can satisfy **OSH employer information needs** => Make system effective.
- Develop **minimum requirements for exposure scenarios**
  - Commission open to make them binding.
  - Supports one holistic [coherent] system for generation and communication by all actors in the supply chain => Synchronise the system.
- Prepare the ground for **digitalisation** of safety data => Make system efficient.

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