ECHA update

10th BfR User Conference
on Product Notifications
18 November 2019

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Deputy Executive Director
European Chemicals Agency

The European Chemicals Agency

- EU Agency operating in Helsinki since 2007
- Implementing 4 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**

Working with EU chemicals legislation

REACH
Registration, evaluation, authorisation and restriction of chemicals (2007)

All chemicals ≥ 1 tonne per year

CLP
Classification Labelling Packaging (2009)

All chemicals and mixtures

United Nations standards

BPR
Biocides

(2013)

Active substances and biocidal products

PIC
Prior Informed Consent

(2014)

Import/export of certain hazardous chemicals

Rotterdam Convention

Several new work areas, e.g.

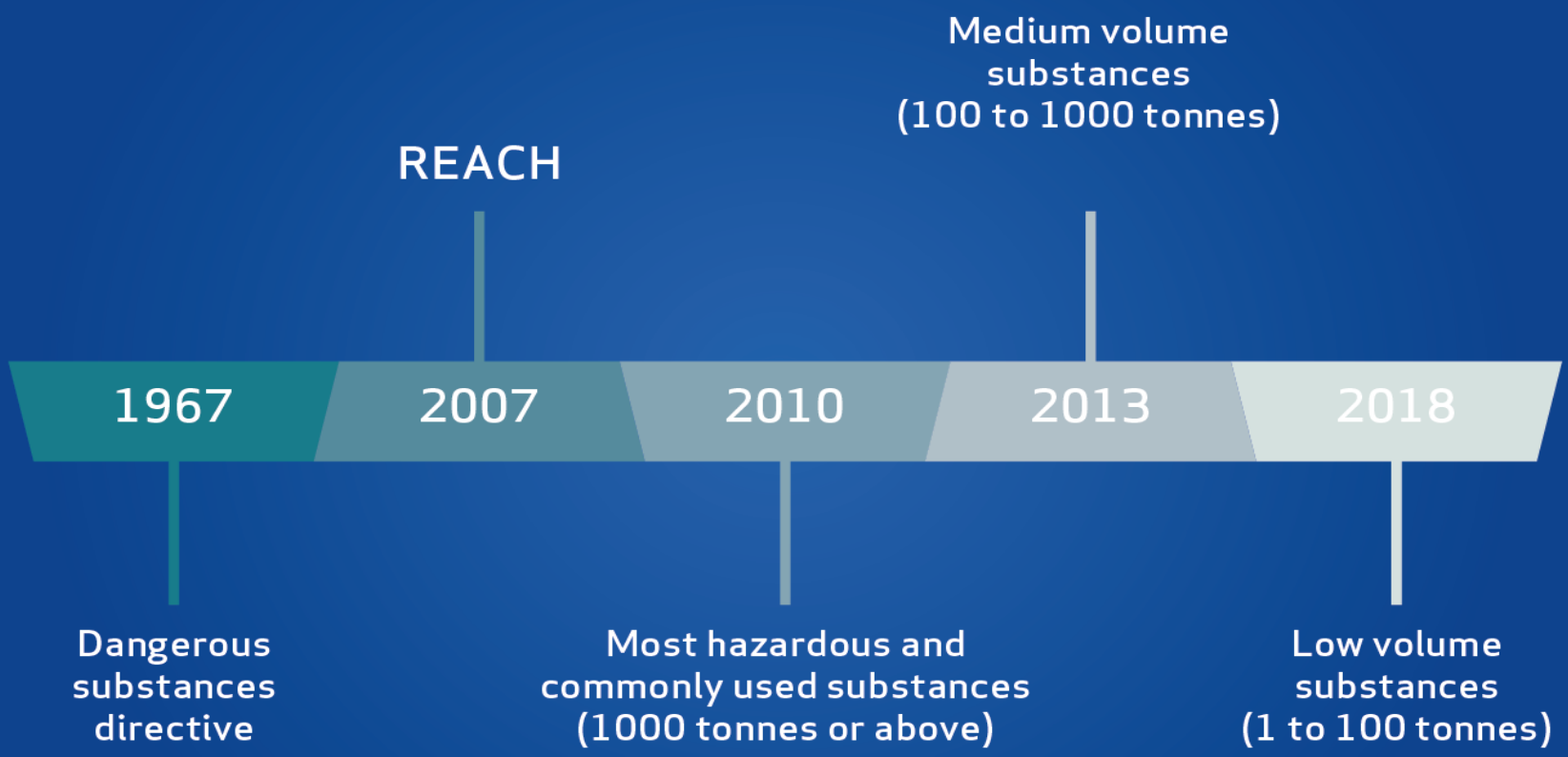
- Portal for notifications of hazardous mixtures to the national poison centres
- EU Nano Observatory
- EU Chemicals Legislation Finder
- Occupational Exposure Limits (OELs)
- Persistent organic pollutants (POPs) Regulation
- Database to track chemicals (Waste Framework Directive)

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

All substances > 1 tpa now registered

- 23 000 substances - 97 000 registration dossiers
- Can be searched via ECHA website



More data on chemicals than ever before

201
substances of very high concern

580
risk management proposals

2 700
high production volume chemicals 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

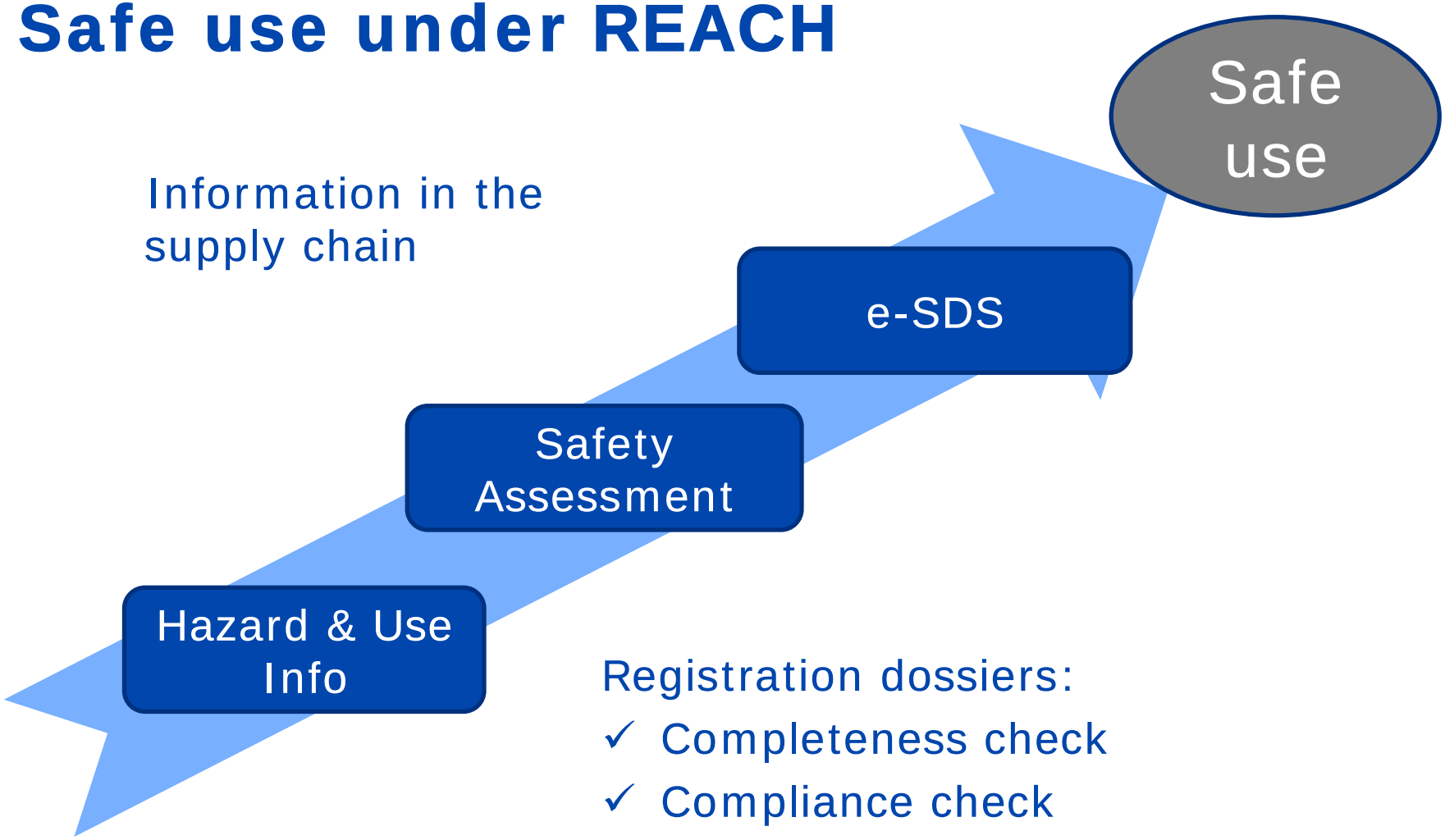
- Information on hazards and safe use of **140 000** chemicals
- 24 000 daily users

echa.europa.eu

Strategic aims 2019-2023

- Identification and risk management of substances of concern
- Safe and sustainable use of chemicals by industry
- Sustainable management of chemicals through the implementation of EU legislation

Safe use under REACH



Registration dossiers:

- ✓ Completeness check
- ✓ Compliance check

REACH compliance – a priority

- Direct impact on ensuring that REACH delivers its objectives
- **Commitment to take action**:
  joint ECHA-Commission action plan
  - Adopted by Management Board in June 2019
  - Concrete actions to improve compliance, engaging all stakeholders

https://echa.europa.eu/documents/10162/21877836/final_echa_com_reach_evaluation_action_plan_en

REACH Evaluation Joint Action Plan

1. Address all substances
   - 16500 substances registered in full in 66000 dossiers (2018)
   - By end 2020: put all substances >100T in ‘regulatory pools’
     i) of priority for regulatory risk management,
     ii) currently of low priority for further regulatory action, or
     iii) need more data for a judgement to be made → candidates for CCH
   - By 2023: info requested for registrations >100T needing CCH
   - By 2027: info requested for registrations 1-100T needing CCH

2. Improve clarity of legal provisions
3. Accelerate decision making
4. Improve follow-up and enforcement of decisions
5. Industry takes on the compliance challenge

e-Government by design

- **No-paper Agency:** Electronic submission of information is required in all legislations
- ECHA must **develop data formats and provide IT tools** free of charge to industry and authorities
- Registration dossiers are in IUCLID format**,** developed by law in cooperation with OECD to ensure **interoperability of systems worldwide** and facilitate electronic data exchange
- **All data in digital format** for ready access by humans and computers, automation and efficient data processing
- Member States have secure access to **ECHA's central databases**

ECHA work on Poison Centres

Why emergency health response?

- Consumers and workers come into daily contact with hazardous chemicals
- Chemicals expected to be used according to *safe use instructions*
- But unintentional exposure happens:
  - Ingestion, Skin contact, Inhalation

- Rapid product identification
- Chemicals contained
- Hazardous properties

- Identification of correct treatment
- Avoid further damage

History of EU level emergency response

1988 - Dangerous Preparations Directive

Article 12

Member States shall appoint the body or bodies responsible for receiving information on dangerous preparations, including their chemical composition, placed on the

preparations placed on the market

Article 17

Bodies responsible for receiving information relating to health

including chemical composition,

Member States shall appoint the body or bodies responsible for rec
to
dar
their physico-chemical effects.

dangerous on the basis of their health effects or on the basis of their physico-chemical effects.

1999 - Directive 1999/45/EC

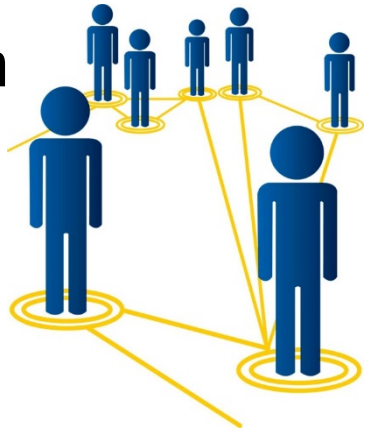
Article 45(1) of CLP Regulation (EC) 1272/2008

"Member States shall appoint a body … responsible for receiving information relevant … for ***formulating preventative and curative measures*** *… in the event of emergency health response,* ***from importers and downstream users*** *placing* ***mixtures on the market****. This information shall include the* ***chemical composition*** *of mixtures placed on the market and* ***classified as hazardous on the basis of their health or physical effects****…"*

Who ✓ What ✓ Why ✓ ***How*** ?

Why EU level action?

- Differences between national submission systems, formats, information requirements
- Difficulties for industries in complying with the obligations from one Member State (MS) to another
- Information available to medical personnel/Poison centres inconsistent between MSs
- Problems in the identification of poisoning agent and its chemical composition



It's about harmonisation…


21.3.2017 EN Official Journal of the European Union L 78/1

II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) 2017/542

of 22 March 2017

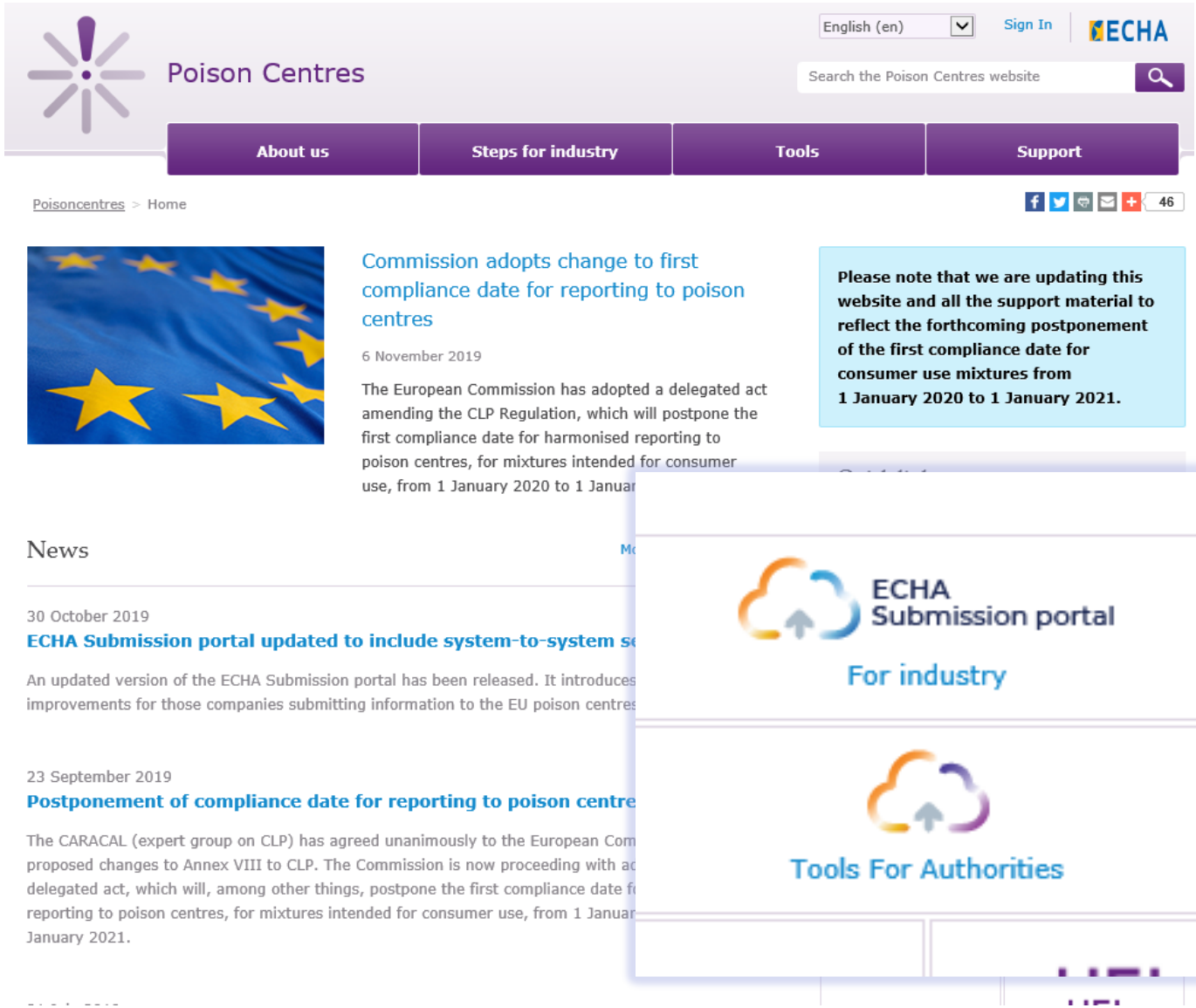
amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures by adding an Annex on harmonised information relating to emergency health response

(Text with EEA relevance)

- same information requirements in all EU Member States
- preparation of data in a harmonised format
- (optional) submission of data possible via central system (ECHA portal)

…and harmonisation brings synergies and efficiencies.

ECHA Submission portal



Our tasks in Art 45 and Annex VIII

(…) The submissions should be made electronically in a **harmonised XML format** maintained by the European Chemicals Agency and made available free of charge.

1.1 The submission of information to appointed bodies in accordance with Article 45 shall be in a format to be provided by the Agency.

3.1 (…) The submission shall (…)be submitted by electronic means in an XML format provided by the Agency and made available free of charge.

(…) a **European product categorisation system** should be developed by the European Chemicals Agency and used in the submission of information

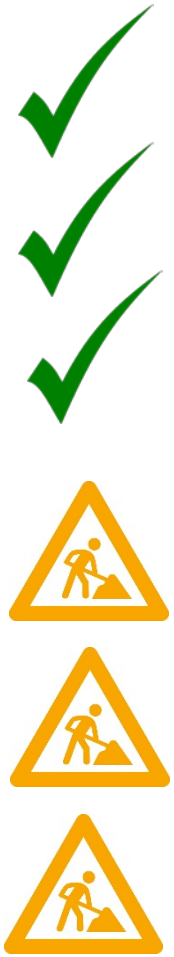
3.4 The intended use of the mixture shall be described in accordance with a harmonised product categorisation system provided by the Agency.

6.1. The Agency shall specify, maintain and update the **UFI generator**, the XML formats for submissions and a harmonised product categorisation system and make them available free of charge on its website.

6.2. The Agency shall provide technical and scientific **guidance**, **technical support** and **tools** facilitating the submission of information.

Our mandate for the database

- Possibility for AB and PC to search, retrieve and view the submissions in the **PCN portal online**;
- Support of the **automatic verification** of completeness of the incoming submissions;
- Support of **additional quality checks** of submissions performed by appointed bodies;
- Possibility to **provide comments** and to flag potential issues found during the completeness and quality checks of submissions as well as to **record the status of the review**;
- **Support of communication** between appointed bodies and submitting entities/importers and downstream users placing mixtures on the market;
- **Reporting** of the submissions received.



Thank you!

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