ECHA and Control of Endocrine Disruptors

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ECHA

ECHA overview

Chemicals legislations managed by ECHA

REACH
Registration
Evaluation
Authorisation

All chemicals
>1 tonne
per annum

CLP
Classification
Labelling
Packaging

All chemicals
and mixtures

UN-wide standards

BPR
Biocides

Active substances
and biocidal
products

PIC
Prior Informed
Consent

Import/export of
certain hazardous
chemicals

Rotterdam
Convention

Wealth of information unique in the world

Companies are required to collect or generate information on properties and uses of their chemicals, assess the risks and recommend safety measures. All this information is submitted to ECHA

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)

REACH and CLP – main processes and actors

Registration
Self-classification

Facilitated by ECHA, industry gathers information and ensures management of risks

ECHA
EUROPEAN CHEMICALS AGENCY

Member States

Evaluation

- Dossier evaluation
- Substance evaluation

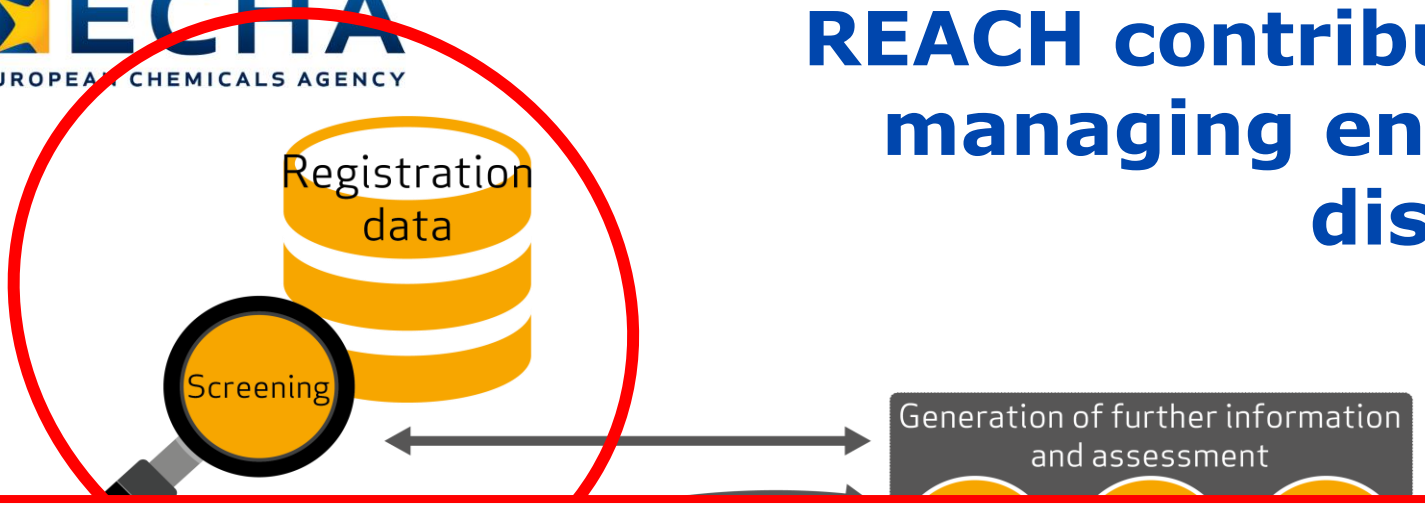
ECHA and MSCAs control and request further info

Authorisation
Restriction
Harmonised C&L

Commission, with support of ECHA and MSCAs, applies community wide risk management measures

How are endocrine disrupting chemicals regulated?

REACH contribution to managing endocrine disrupters



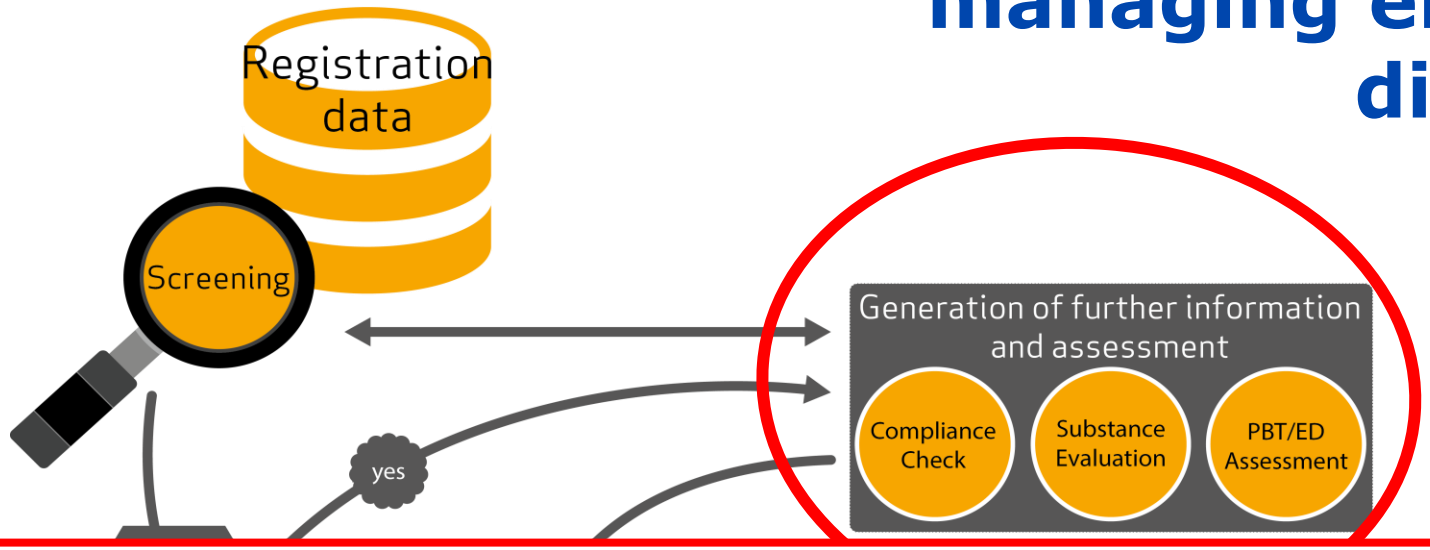
Registration and screening

- The registration data together with other available information allows identification of potential EDs
- ECHA screens the data regularly and identifies candidates for further work by MSCAs and itself;
- Focus on fully registered substances **and** structurally similar substances

No action

legislation/ action

REACH contribution to managing endocrine disrupters



Further information generation

- Further information on ED properties can be requested from industry: 82 substances on ECHA's Community Rolling Action Plan for evaluation due to potential ED properties
- Assessments are not straightforward: ED expert group supports the Member States
- Information obliges industry to ensure safe use

ED Assessment

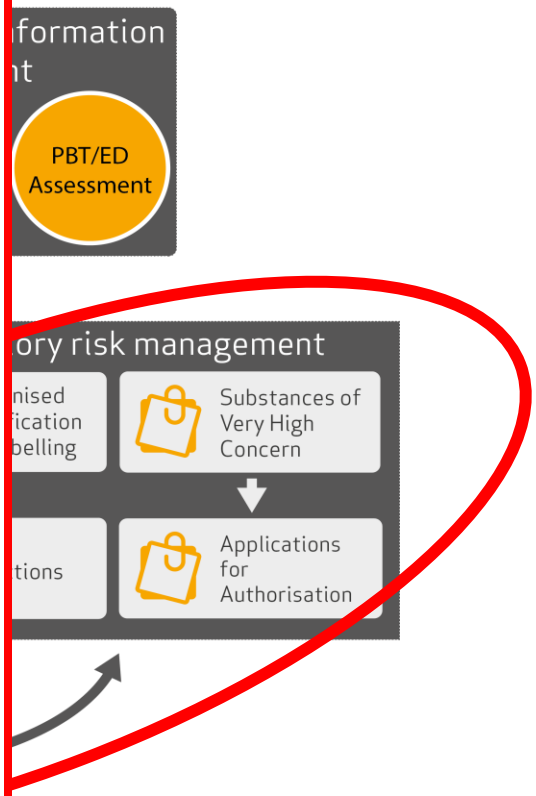
Discussions informed by e.g.:

- Widely accepted ED definition (WHO/IPCS, 2002) *"exogenous substances that alter function(s) of the endocrine system and consequently cause adverse health effects in an intact organism or its progeny, or (sub)populations*"
- Joint Research Centre ED Expert Advisory Group report and European Food Safety Authority (EFSA) opinion on identification of EDs
- OECD conceptual framework for testing and assessment of EDs and guidance documents

REACH contribution to ing endocrine disrupters

Regulatory risk management under REACH

- Aim: promote substitution and ensure high level of protection until the move to alternatives takes place
- 12 substances included in the Candidate List due to ED properties - mainly phthalates and phenols including BPA
- Substances with ED properties are already subject to authorisation requirement and restrictions
- REACH data and identification of the ED properties can be used as a basis to take action under other legislation
- Several EU legislation refer to and require action based on the ED properties



Biocidal Product (and Plant Protection Product) Regulations

- ED criteria for biocidal products in force and currently under scrutiny for plant protection products
- ED criteria for biocides and PPP are based on the WHO definition

- ECHA is developing together with EFSA and JRC guidance for hazard based identification of EDs
  - MSCAs and stakeholders have been consulted during the drafting, public consultation
  - Current timetable: publication June 2018

Concluding remarks

- REACH provides
  - Information and tools for the identification of EDs – but potential room for improvement in data quality / quantity and speed of identification process
  - Obligations on industry to ensure safe use, support for substitution
  - Possibilities for authorities to introduce regulatory risk management

- Under REACH, ECHA has identified, and imposed more severe controls on, ED substances

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