REACH

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Issues

1. As a source of information on chemicals, particularly post 2018

2. Advantages and disadvantages of REACH safety data

Outline

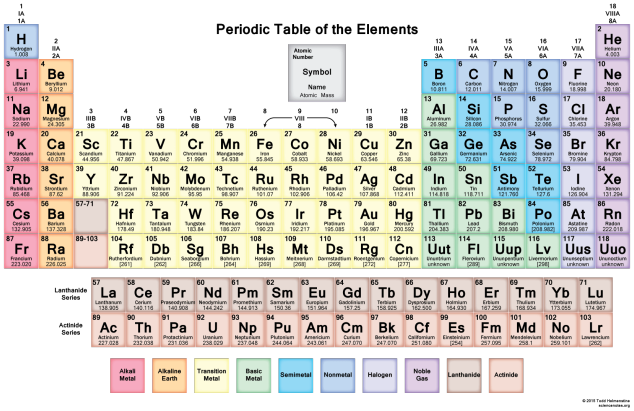
1. What is a substance
2. How does safe use work
3. Post 2018
4. Advantages and disadvantages
5. Conclusions

1. What is a substance?

REACH and CLP approach:

Starting point: everything is a substance. Then, we build the exemptions from specific provisions.

1. What is a substance?



Natural state OR through any production process

Substance

1. What is a substance?

Only things not in the REACH and CLP world:

- whole living organisms
- unprocessed dead organisms
- parts of unprocessed dead organisms
- waste

1. What is a substance?

Examples of registered substances

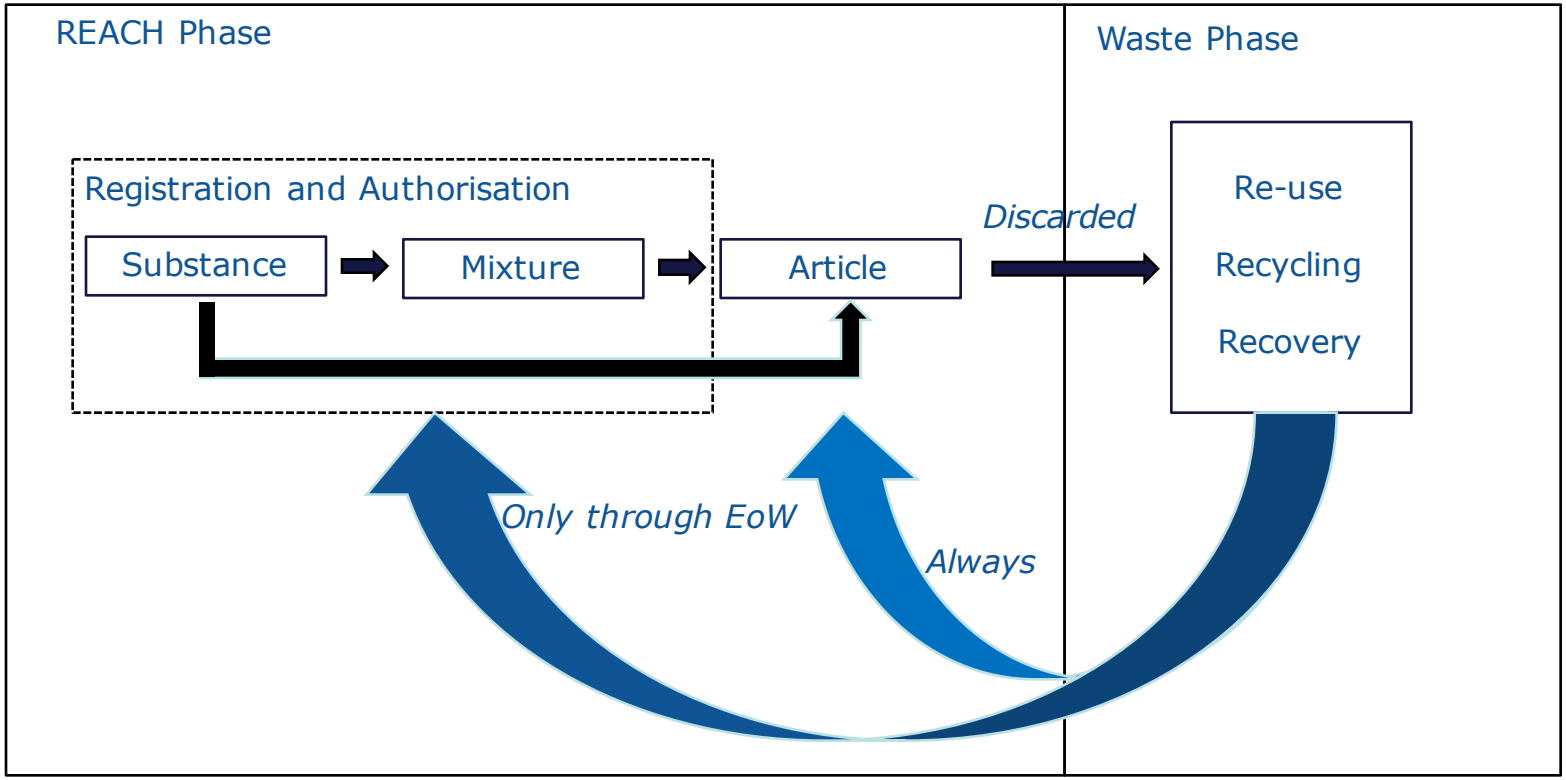
273-721-3	69012-21-1	Wastewater, cadmium sulfate electrolytic, acid	Intermediate	Joint Submission	Intermediate Use Only
273-723-4	69012-24-4	Wastewater, zinc sulfate electrolytic, acid	Intermediate	Joint Submission	Intermediate Use Only
297-648-1	93685-99-5	Oil shale, thermal processing waste	Full	Joint Submission	100,000 - 1,000,000 tonnes per annum
305-445-7	94551-99-2	Wastes, lead battery reprocessing	Full	Joint Submission	100,000 - 1,000,000 tonnes per annum
305-449-9	94552-05-3	Waste solids, lead silver anode	Intermediate	Joint Submission	Intermediate Use Only
308-526-5	98072-70-9	Waste solids, precious metal refining	Full	Joint Submission	1,000 - 10,000 tonnes per annum
700-549-2		Reclaimed >C5 aromatic compounds from tar oils manufacturing wastewater treatment	Intermediate	Individual Submission	Intermediate Use Only
700-550-8		Reclaimed >C5 aromatic compounds from waste tars and tar oils and tar pitches	Intermediate	Individual Submission	Intermediate Use Only
700-588-5		Sodium phenolates and benzoate from tar oils and phenol resins manufacturing wastewater treatment	Intermediate	Individual Submission	Intermediate Use Only
700-869-2		Solid Recovered Fuel (Municipal Solid Waste and similar wastes, processed)	Full	Joint Submission	10,000 - 100,000 tonnes per annum
918-168-7		anode, copper	Full	Joint Submission	100,000 - 1,000,000 tonnes per annum
922-670-1		Sulfuric [illegible] gas washing, copper smelting	Intermediate	Joint Submission	Intermediate Use Only
[illegible]		[illegible] oxide,	Full	Individual	[illegible]

1. What is a substance?

The REACH and CLP world is made of:

- Substances
- Mixtures (intentional mixtures of substances)
- Articles (shape more important than substance composition)

1. What is a substance?



2. How does safe use work

Step 1: M/I must generate information on the hazards of a substance (uses often animals)

Step 2: M/I must classify, label and package

Step 3: M/I must determine uses and resulting exposures

Step 4: M/I must conclude that risks are adequately controlled

2. How does safe use work

M/Is must:

- consider the full life cycle of a substance, as such, in a mixture or article including its waste stage

- consider workers, consumers and the environment, including possible vulnerable populations (pregnant workers, babies, the elderly)

= La totale

2. How does safe use work

M/Is must:

- consider/include obligations arising from (any) other legislation, e.g.,

- Worker protection (substance Agents Directive, Pregnant workers directive, young workers directive, ….
- Consumer protection (General Product Safety Directive, …)
- Environmental protection (IED, Water Framework Directive, ….)

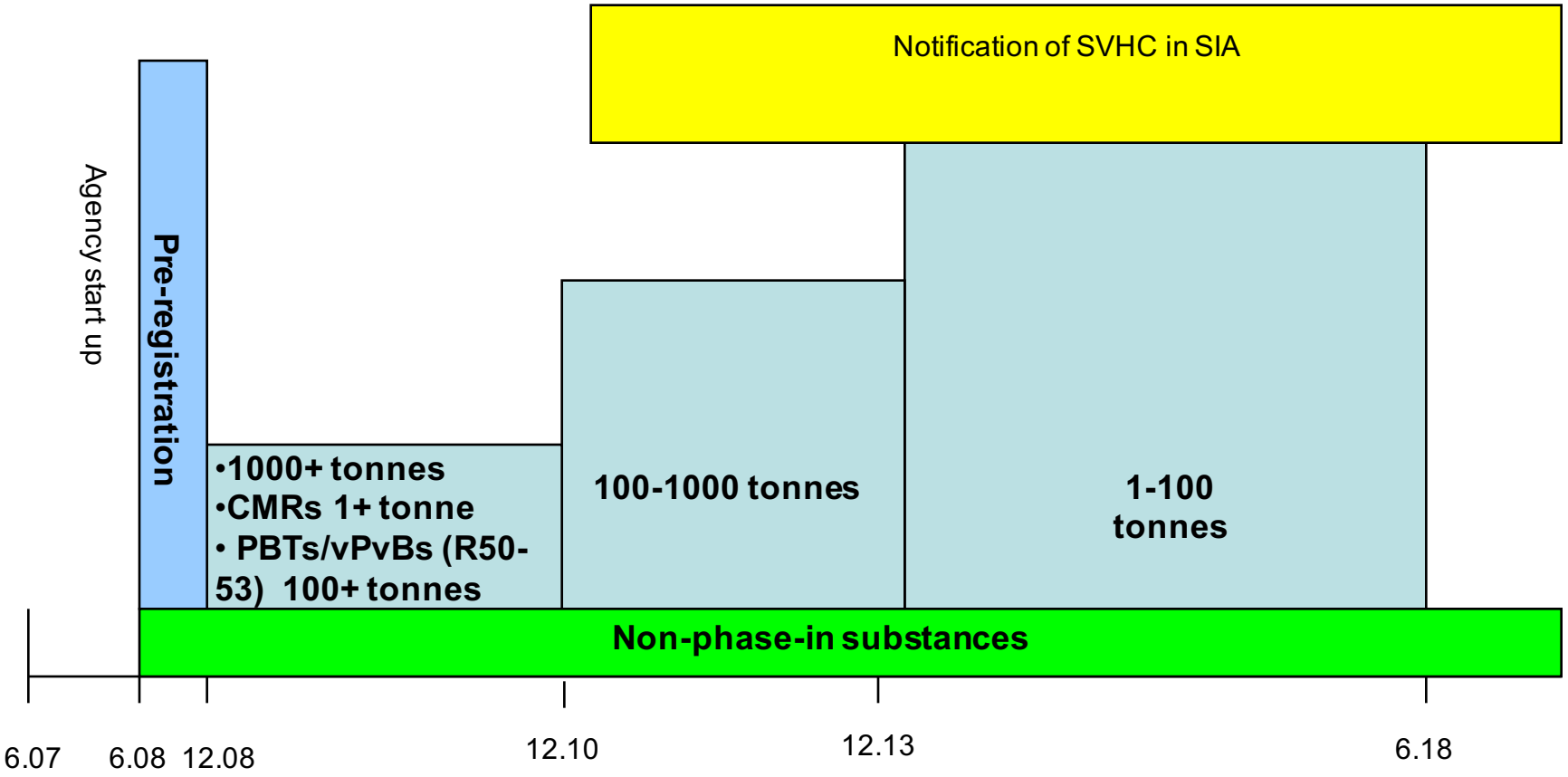
= La totale

2. How does safe use work

And then REACH has:

- Evaluation
- Restrictions
- Authorisation

3. Post 2016


Notification of SVHC in SIA
Agency start up
Pre-registration
•1000+ tonnes
•CMRs 1+ tonne
• PBTs/vPvBs (R50-53) 100+ tonnes
100-1000 tonnes
1-100 tonnes
Non-phase-in substances
6.07
6.08
12.08
12.10
12.13
6.18

	Health	Environment
1-10t prioritised	❑ *In vitro* skin and eye irritation ❑ Skin sensitiation ❑ *In vitro* mutagenicity ❑ Acute toxicity (one route)	❑ Acute aquatic toxicity – Daphnia ❑ Biodegradation – biodegradability and hydrolysis ❑ Acute aquatic toxicity – Algae
10-100t	❑ *In vivo* skin and eye irritation ❑ Further *in vitro* mutagenicity ❑ Sub acute toxicity (28 days) ❑ Reproductive toxicity screen	❑ Acute aquatic toxicity – Fish ❑ Activated sludge ❑ Adsorption/desorption screening
100-1000t	❑ Further mutagenicity tests ❑ Sub-chronic toxicity (90-days) ❑ Further reproductive toxicity tests	❑ Long term aquatic toxicity daphnia and fish ❑ Further degradation and fate/behaviour studies ❑ Short term effects on terrestrial organisms
>1000t	❑ Further mutagenicity tests ❑ Carcinogenicity ❑ Chronic toxicity ❑ Further reproductive toxicity tests	❑ Further degradation and fate/behaviour studies ❑ Long term effects on terrestrial organisms

4. Advantages and disadvantages

Advantages:

REACH safety data provides:

- the hazard data
- the classification and labelling
- the risk assessment of identified uses
- the risk management measures

For safe use of chemicals

Disadvantages:

If it is compliant to the REACH requirements.

Thank you for your attention

Chemicals Unit, DG Environment, European Commission, Brussels

http://ec.europa.eu/environment/substances