

# **REACH&CLP: CURRENT STATUS AND NEXT STEPS OF THE DIFFERENT PROCEDURES**

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**Chamber of Commerce, 3 December 2015**

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# CONTENT

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## REACH

- Registration
- Evaluation
- Authorisation
- Restriction

## CLP

- Adaptation to technical and scientific progress
- Classification of mixtures
- Poison centre

## Enforcement

# REGISTRATION

## REACH 2018

### Data requirements:

- Regulation (EU) 2015/282: **Extended One-Generation Reproductive Toxicity Study (EOGRTS)** added to Annex VIII-X REACH (**update testing proposals!**)
- Regulation (adopted April 2015): Update **Test Method Regulation**: 20 new OECD test guidelines
- Draft Regulation (submitted Nov 2015) on Annex VII-VIII REACH: ***In vitro* studies** (skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation); option to waive the dermal testing for acute toxicity

### Data sharing:

- Commission Implementing Regulation (adopted by REACH Committee in October 2015): Specific duties and obligations for parties to agreements where the **sharing of information and associated costs** are required under REACH



# REGISTRATION

## Statistics

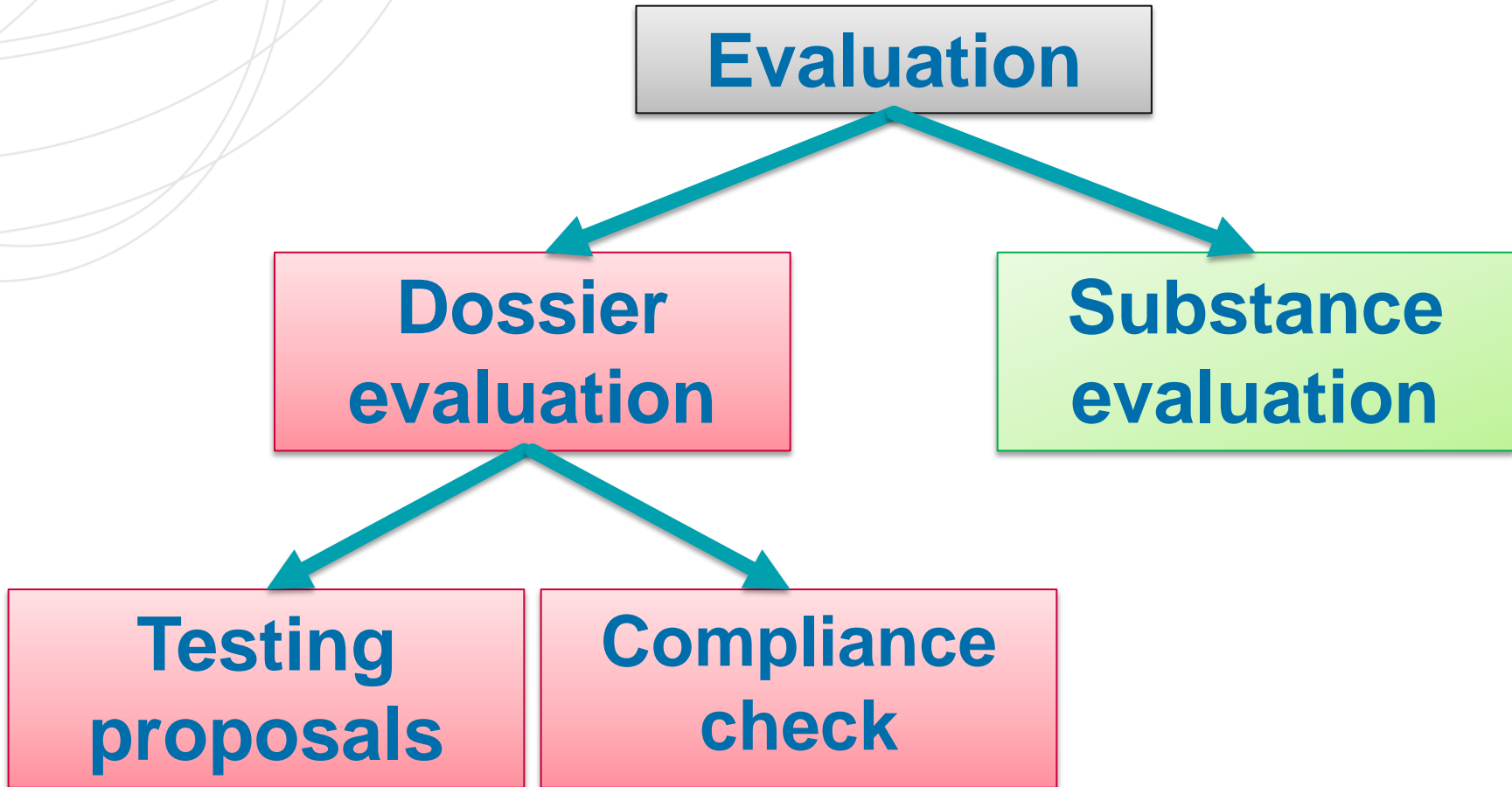
EU (Aug 2015)	Registrations	Unique substances
TOTAL	42,507 (+2,278)	8,613 (+621)
Phase-in	39,388	7,245
Non phase-in	3,119	1,368

### Luxembourg (as of May 2015):

- **267 (+13) registrations** for 156 (+3) substances
- 0.64% of all registrations
- Still few **SMEs**:
  - 228 registrations by large companies
  - 39 by SMEs
- Rather unique distribution of **roles**:
  - 150 by Only Representatives (56%)
  - 100 by importer (37%)
  - 17 by manufacturer (and partly also importer, 6%)

# EVALUATION

## Procedures



# EVALUATION

## Dossier evaluation (ECHA)

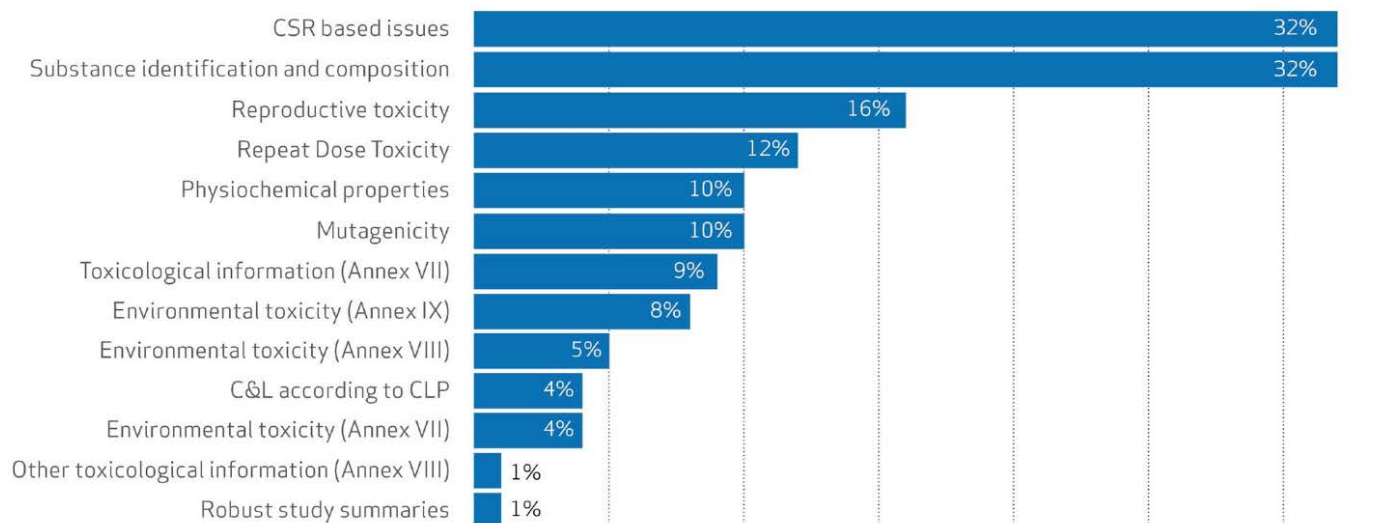
### Testing proposals

- 2013 registration deadline: 770 endpoints included in 376 unique dossiers
- **Regular public consultations** for vertebrate tests (three running, overall 956)
- So far **476 ECHA decisions** published

### Compliance checks

- So far **561 ECHA decisions** published (full and targeted compliance checks)
- Updated guide; **Evaluation Report 2014** with recommendations (Feb 2015):  
[http://echa.europa.eu/documents/10162/13628/evaluation\\_report\\_2014\\_en.pdf](http://echa.europa.eu/documents/10162/13628/evaluation_report_2014_en.pdf)

Figure 5: Types of information requested as a percentage of the 273 CCh decisions taken in 2014.



# EVALUATION

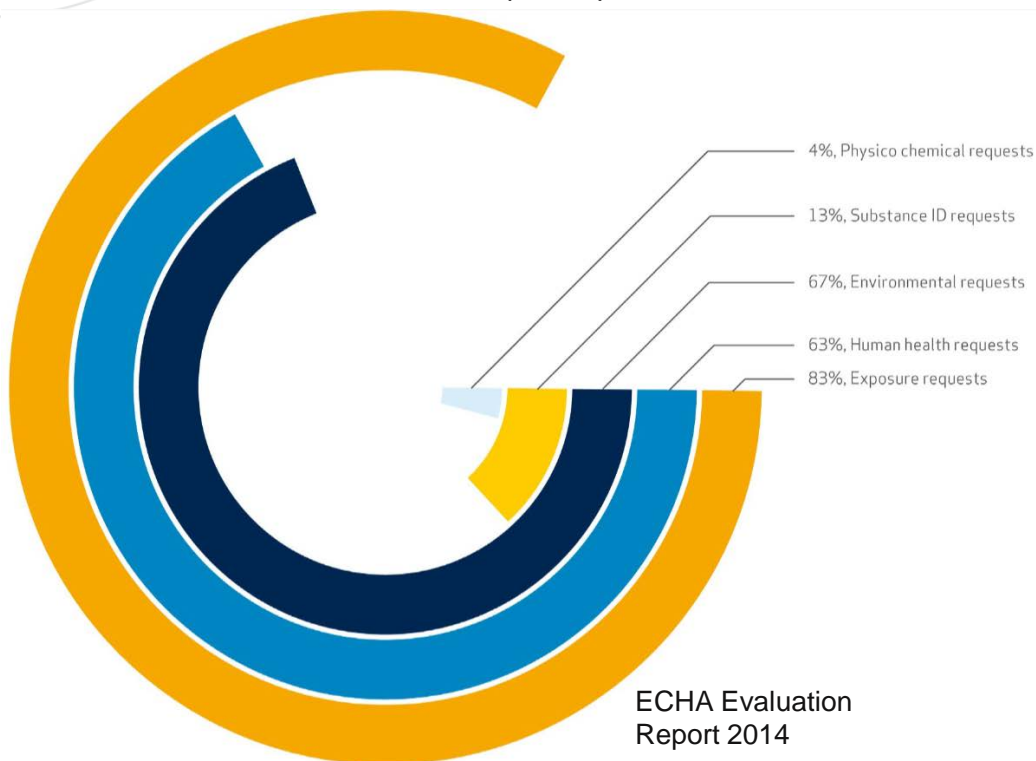
## Substance evaluation (Member States)

### Community Rolling Action (CoRAP) (<http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table>)

- Last annual update **2015-2017** (March): 134 substances (66 newly selected)
- Draft update **2016-2018** (October): 138 substances (53 newly selected)

### Substance evaluation:

- **Interaction with registrations** during evaluation (formal and informal)
- 2012/13: 13 of 83 (**15%**) concluded **without draft decision** (= data request)



Conclusions (15 SEv, Nov 15)	#
Need for harmonised classification and labelling	4
Need for identification as SVHC (authorisation)	1
Need for restrictions	1
Need for other community-wide measures	3
No need for regulatory follow-up action	8

# AUTHORISATION

## Identification of substances of very high concern (SVHC)

- **Candidate List: 163 substances**
- **Last updates:**
  - **December 2014 (7): ED:** DEHP (update); **PBT/vPvB:** UV-328, UV-330; **CMR:** cadmium fluoride, cadmium sulphate, DOTE, reaction mass of DOTE and MOTE
  - **June 2015 (2): CMR:** Benzenedicarboxylic acid/esters  $\geq 0.3\%$  of dihexyl phthalate, **vPvB:** 5-sec-butyl-2-(2,4(or 4,6)-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane
- **Submitted proposals (six, August 2015):**
  - **PBT:** UV-327, UV-350, Perfluorononan-1-oic acid
  - **CMR:** 1,3-propanesultone, Nitrobenzene
  - **Sensitiser:** hexamethylene diacrylate
- **Withdrawn submissions:** Dicyclohexyl phthalate (SE, Nov 2015 to be submitted later again), update of DBP, DiBP and BBP as environmental ED
- **Registry of intentions (six added 2015 for submission in February 2016):**
  - **ED:** 4-Methylbenzylidenecamphor, 3-Benzylidenecamphor, 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol, 4,4'-methylenediphenol, Dicyclohexyl phthalate
  - **PBT/CMR:** Benzo[a]pyrene



# AUTHORISATION

## Annex XIV REACH (SVHC with authorisation obligation)

- **No Annex XIV inclusions in 2015** (currently 31 substances)
- **Submitted recommendations** (still to be decided by Commission):
  - 5<sup>th</sup> ECHA recommendation (Feb 2014): five substances, e.g. DMF, ADCA
  - 6<sup>th</sup> ECHA recommendation (July 2015): 15 substances, e.g. anthracene oil, several boron compounds
- **Draft Proposal for ECHA Recommendation** (Nov 2015): 11 substances, **public consultation** until February 2016, e.g. several lead compounds
- **Sunset dates in 2015** (no use without authorisation):
  - Several **phthalate** (BBP, DEHP, DBP, DIBP) (plasticisers)
  - Diarsenic pentaoxide and trioxide
  - Lead chromate and C.I. Pigments Red 104 and Yellow 34
  - 2,4 – Dinitrotoluene (2,4-DNT)
  - HBCDD (flame retardant)
  - Tris(2-chloroethyl)phosphate (TCEP)
- Sunset date in 2016: **Trichloroethylene** (process solvent, e.g. for degreasing)

# AUTHORISATION

## Applications for authorisation

- So far: 34 applications covering 63 applicants, most applications so far for **Trichloroethylene**
- Current **public consultation** on authorisation applications (3): Chromium trioxide in (electro)plating
- 10 **pending Commission decisions**
- **Granted authorisations** for 10 uses/applicants (DEHP (1), DBP (4), diarsenic trioxide (5); <http://ec.europa.eu/DocsRoom/documents/9827>)
- No **latest application dates** in 2015, but 12 in 2016:
  - Seven **chromium substances** (e.g. (electro)plating, surface treatment)
  - Arsenic acid, Diglyme, Technical MDA, 1,2-Dichloroethane (EDC), 2,2'-dichloro-4,4'-methylenedianiline (MOCA)

**Downstream users: Notification of uses covered by a REACH authorisation (Article 66) via Webform within three months** (<http://echa.europa.eu/support/dossier-submission-tools/reach-it/downstream-user-authorised-use>)

Under preparation: **Simplified authorisation procedure for low volumes, spare parts**

# RESTRICTION

## New/updated restrictions and proposals in comitology

### New/updated restrictions:

- Regulation (EU) 2015/628: **Lead and its compounds** (in articles that are supplied to the general public, and which can be placed in the mouth by children)
- Regulation (EU) 2015/1494: **Benzene** (exemption for natural gas containing benzene)
- Regulation (EU) 2015/326: **Polycyclic aromatic hydrocarbons** (new test method) and phthalates (editorial changes)

### Restriction process terminated:

- **Cadmium** and its compounds in **artist paints** (limited risk)

### In comitology:

- **Nonylphenol** + Nonylphenol ethoxylates in textiles (adopted in July 2015)
- **Cadmium** + its compounds in paints (adopted in September 2015)
- **Chrysotile** (asbestos) in diaphragms (Draft regulation to REACH Committee in Oct.)
- **Ammonium salts** in cellulose insulation materials used in buildings (Draft regulation to REACH Committee in November 2015)
- 1-methyl-2-pyrrolidone (**NMP**): Manufacturing, and all industrial and professional uses with certain worker exposure (submitted to Commission in November 2014)
- **DecaBDE**: Manufacture, use and placing on the market of DecaBDE and of mixtures and articles containing it (submitted to Commission in June 2015)

# RESTRICTION

## Proposals under preparation

### Submitted proposals in ECHA Committees:

- **Methanol** in windshield washer fluids
- Octa- + Decamethylcyclopentasiloxane (**D4, D5**) in wash-off personal care products
- **Bisphenol A** in thermal paper
- Perfluorooctanoic acid (**PFOA**), its salts and similar substances: Manufacture, use and placing on the market
- Certain **perfluorinated silanes** and its derivatives: Use in combination with organic solvents in sprays used for the general public

### Registry of intention:

- **Diisocyanates**: Industrial and professional uses with some exemptions (Call for comments and evidence ended this week)
- **Bisphenol A**: 2-component epoxy based on bisphenol A in relining of tap water pipes
- N,N-Dimethylformamide (**DMF**): Manufacturing and industrial use
- **DEHP, BBP, DBP and DIBP** in articles

### Under consideration:

- Commission consultation: Possible restriction of **CMR substances** (Cat. 1A/B) in **textile articles + clothing** for consumer use (until January 2016)

### Withdrawn intentions

- Grill lighters fluids and fuels (no need to amend current restriction)

# VARIOUS

- Regulation (EU) 2015/830: New version of **Annex II REACH on Safety Data Sheet**: Adaptation to the fifth revision of the GHS rules for safety data sheets (transitional period until 2017)
- Regulation (EU) 2015/864: **Fee Regulation** (EC) 340/2008 adjusted for inflation
- European Court of Justice: Substances in articles: **Once an article, always an article**, 0.1% threshold for notifying SVHCs in articles
- New working group to address **petroleum and coal stream substances** (65 priority substances)

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# ADAPTATION TO TECHNICAL AND SCIENTIFIC PROGRESS (ATP)

- Regulation (EU) 2015/491 (**March 2015**): **Prolongation of transitional period** for the application of the 6<sup>th</sup> ATP (Regulation (EU) 605/2014, adopted June 2014)
- Regulation (EU) 2015/1221 (**July 2015**): Annex VI CLP: **New and updated harmonised** classification and labelling (**CLH**)

## ATP under preparation:

- **Draft Regulation** sent to REACH Committee in **October 2015**: Adaptation to **5<sup>th</sup> revised edition** of Globally Harmonised System (**GHS**), e.g. **classification** of oxidising solids, skin corrosion/irritation, serious eye damage/eye irritation, aerosols + changes to several **precautionary statements**
- **Draft Regulation** sent to REACH Committee in **Nov 2015**: **Annex VI CLP: Removal Table 3.2** (“old” CLH acc. to Directive 67/548/EEC) + new, updated or deleted **CLH**

## Further CLH under preparation:

- **Opinion** by ECHA’s Risk Assessment Committee: 17 substances
- **Public consultations**: 43 in 2015, four still on-going
- Submitted CLH **proposals**: 42 in 2015
- **Registry of intention**: 52 substances
- **Withdrawn** from Registry of intention: 34 substances

# CLASSIFICATION & LABELLING

## Mixture classification since June 2015

- New “product groups” under CLP, e.g. plant protection products, biocidal products



- But: Some areas stay **outside CLP**, e.g. transport of dangerous goods





# POISON CENTRE

## Cooperation Agreement Luxembourg – Belgium June 2015

- **Company declaration of hazardous mixtures:** Body responsible for receiving information relating to emergency health response according to **Article 45 CLP** for all hazardous mixtures placed on the market in Luxembourg
- **Emergency telephone number** in the Safety Data Sheet (section 1.4): **8002 5500**



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# Enforcement of REACH & CLP in Luxembourg

Administration de l'environnement

Service produits chimiques et substances dangereuses

- Example of inspections carried out in 2015:
  - Follow up of the REACH EN FORCE-3 (REF-3) project, focusing on the duties of **Only Representatives (ORs)**
- On-going activities:
  - Participation in a ECHA Pilot Project to check that the packaging of chemical products available to the general public have appropriate **child resistant fastenings** where needed.
  - Compliance of **safety data sheets** with CLP requirements.

# Enforcement of REACH & CLP in Luxembourg

Administration de l'environnement


Service produits chimiques et substances dangereuses

- Foreseen enforcement activities:
  - Participation in the REF-4 project, to check compliance with REACH Annex XVII **restrictions** on the manufacturing, placing on the market and use **of certain hazardous substances, mixtures and articles**, through sampling and analysis.
  - Participation in a pilot project aiming at monitoring **internet trade of chemicals**.

# CONCLUSION

**REACH and CLP have reached their top speed...**

**... be prepared and follow your substances!**




**Overview of information sources on the ECHA website**

Implementation of REACH and CLP and future challenges

3 December 2015  
Luxembourg

Laura Walin  
Directorate of Registration  
European Chemicals Agency



# Thank you for your attention!



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**REACH & CLP**

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et le Ministère de l'Économie



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