

# REACH rules & OSH rules: conflicts or synergies ?

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Paris, 13 Feb 2015

- Background info on chemicals in the EU
- Main EU legislations relevant for hazardous substances
  - Classification & Labelling – CLP regulation
  - Marketing & use of chemicals : REACH regulation
  - Occupational Safety & Health (OSH) legislation
    - a. Chemical Agents Directive
    - b. Carcinogens & Mutagens Directive
- Conflicts or Synergies ?
  - Risk Assessment in REACH and OSH legislation
  - Limit values: IOELs vs DNELs
  - Substitution principle
- Conclusions

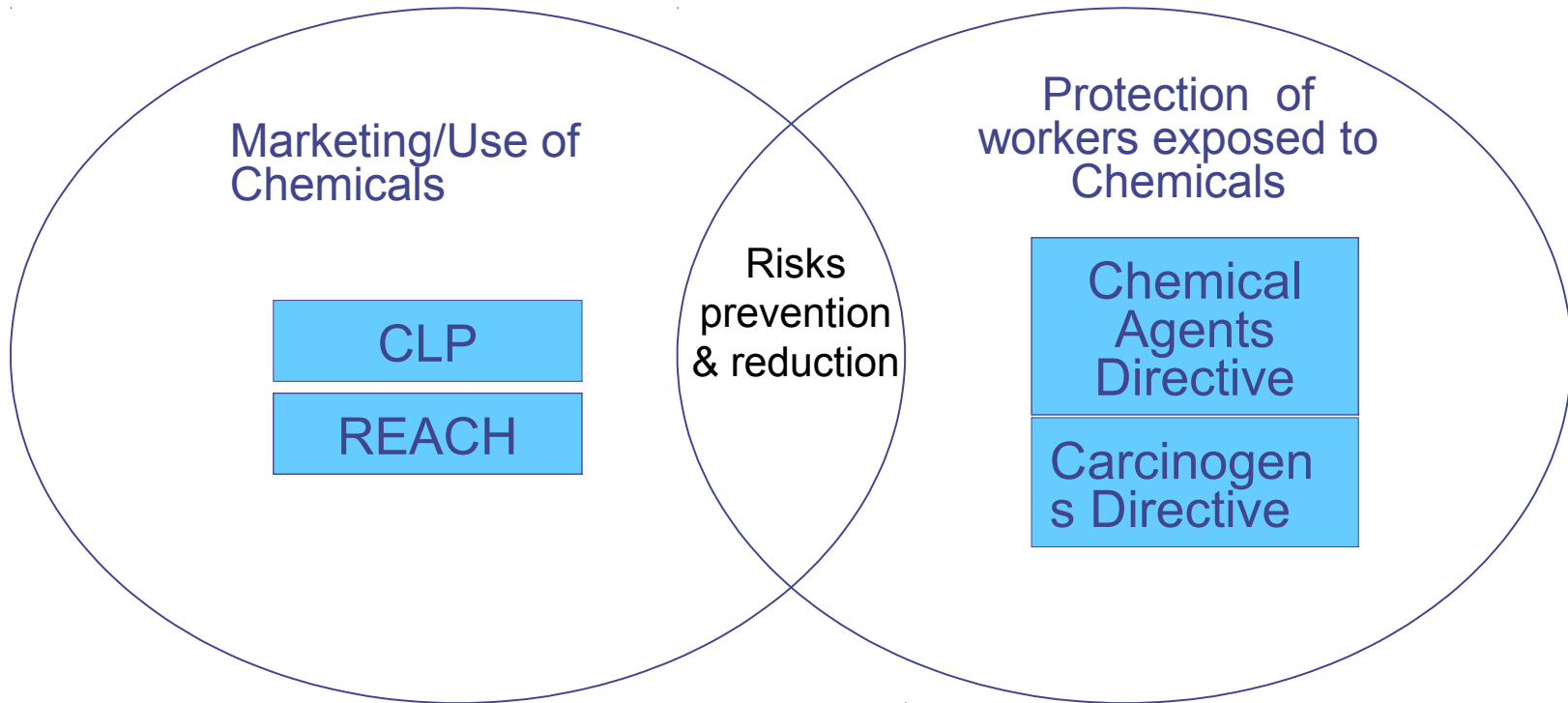
# Why chemicals are key for workers and their representatives ?

- 1.3 million workers in the EU chemical industry
- Millions of jobs in downstream sectors (building, textile, automotive, electronic, etc...)
- Chemicals contribute to the EU economic prosperity in terms of trade and jobs

*But on the other side:*

- 16 % of workers in Europe declare to handle hazardous products and 22 % to breath in toxic vapours (Dublin Fd, 2008)
- Around 30% of all occupational diseases recognised each year in EU are related to exposure to chemicals (ETUI, 2006) & up to 50% according to EU-OSHA (EU-OSHA, 2012)
- Over 100 000 work-related deaths per year in EU-28 due to exposure to hazardous substances (ETUI, 2014)

# Main EU legislations on chemicals ?



# Classification, Labelling & Packagind (CLP) Regulation

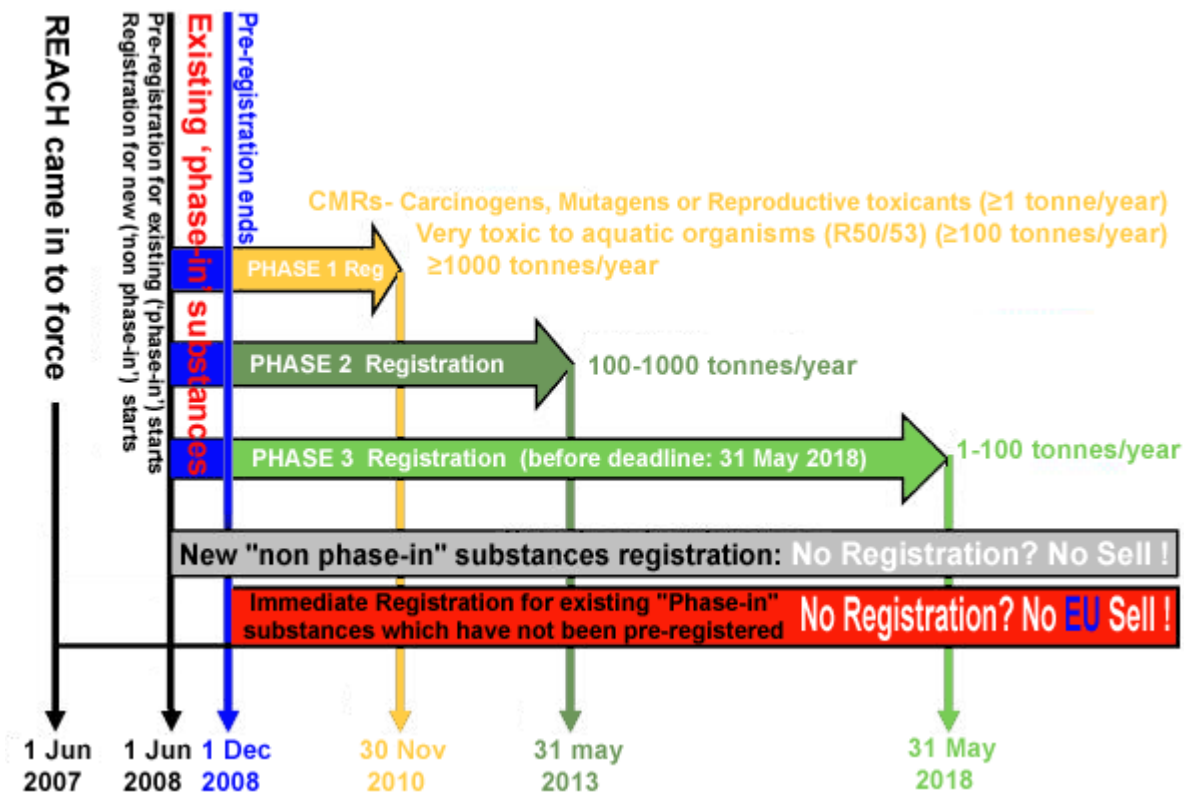
- For all substances & mixture marketed in the EU
- Criteria for C&L laid down in CLP Regulation (EC 1272/2008) to implement Globally Harmonised System.
- Industry to self-classify all substances or mixtures placed on market
- some substances with EU harmonised classification (Annex VI of CLP Regulation) managed by European Chemicals Agency (ECHA)



# REACH regulation (EU 1907/2006)

- **Registration**: Manufacturers and importers of chemicals > 1 tpa are required to register their substances to demonstrate they can be used safely (no data = no market)
- **Evaluation** of some substances by Member States / European Chemicals Agency
- **Authorisation** only for substances of very high concern
- **Restrictions** when risks are unacceptable

# Timeline for REACH registration



# Chemical Agents Directive (98/24/EC)

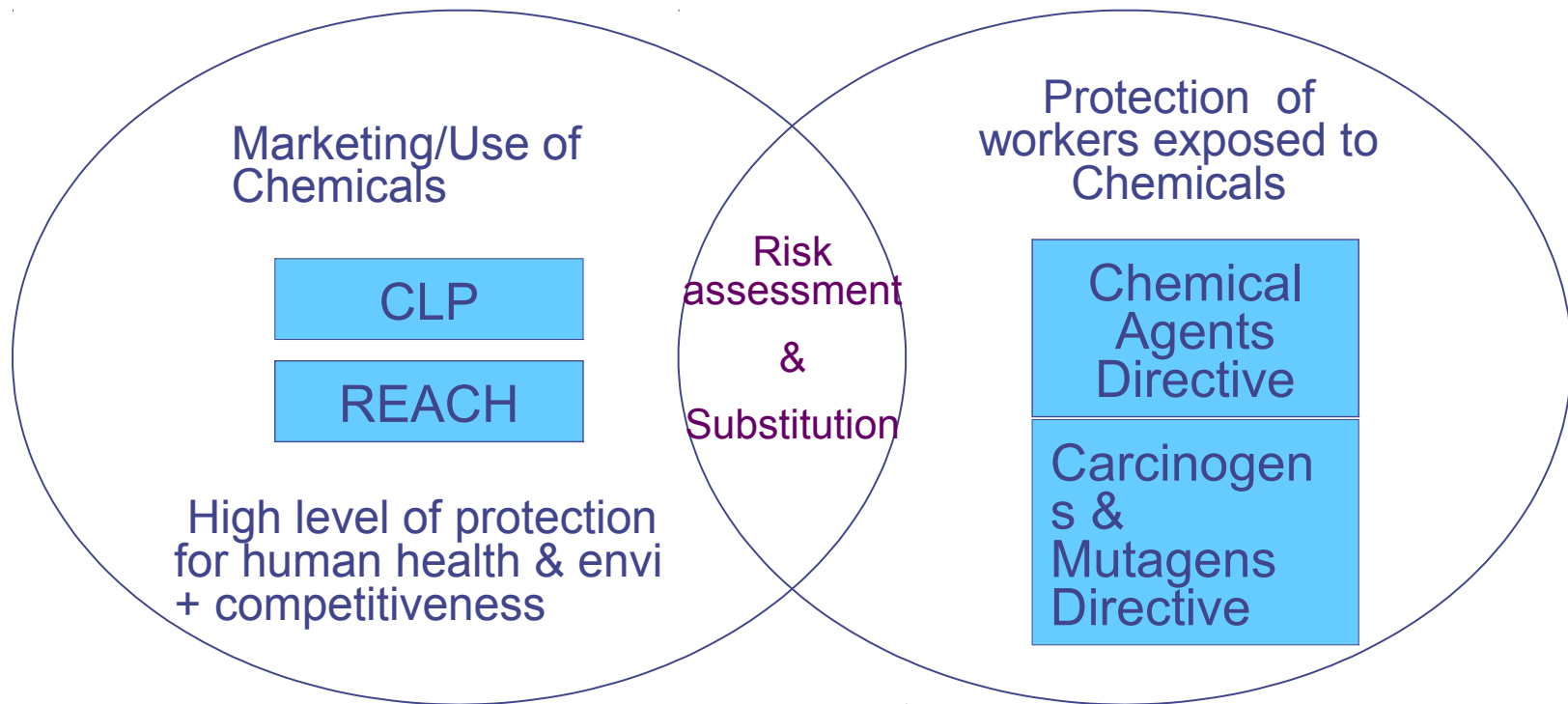
- Aim: protection of workers from risks related to chemicals at work
- Scope: all chemicals used at the workplace (regardless of volume)
- Obligations for employers:
  - Determine whether any hazardous chemical agents are present in the workplace
  - Assess any risk to the H&S of workers arising from their use
  - If risks do exist, mandatory hierarchy of prevention and protection measures (substitution > exposure reduction > protective equipmt)
  - Monitor the workers'health
  - Comply with existing Occupational Exposure Limit Values (OELVs); up to now 121 substances with indicative OELVs at EU level
  - Keep risk reduction measures up to date
  - Provide information and training to workers



# Carcinogens Directive (2004/37/EC)

- Aim: protection of workers from risks related to carcinogens and mutagens at work
- Scope: all carcinogens and mutagens (category 1A or 1B)
- Main obligations for employers:
  - Eliminate/Replace with a substance which is not or less dangerous (mandatory if the alternative is available & regardless of cost)
  - If substitution is not technically feasible, use a closed system
  - Reduce workers' level of exposure as low as is technically possible
  - Comply with Binding Occupational Exposure Limit Values (BOELVs) (benzene, vinyl chloride monomer and hardwood dust + soon ~20 additional substances ?)
  - Consultation and participation of workers on the measures to minimize exposure

# Conflicts or synergies between REACH and EU OSH ?



Some employers say OSH directives not needed anymore, to avoid duplications we only need REACH regulation but.....

REACH, Art 4 (2) : This Regulation shall apply without prejudice to Dir 89/391, Dir 98/24, Dir 2004/37, [.....]

# Risk Assessment under CAD/REACH are complementary tool

Chemical Agents Directive	CSA under REACH
All hazardous chemicals present in the workplace (= irrespective of volume)	Chemical Safety Assessment only for chemicals > 10t/y
Including process generated substances	Process generated substances outside scope
Workplace specific (holistic: including multi-exposure, non-chemical hazards,...)	Substance specific
Obligation on Employers	Obligation on the Manufacturer/Importer/ DUs
Provide information & training to workers	Information & training of workers outside scope

# Risk Assessment under CAD/REACH are complementary tool

Chemical Agents Directive	CSA under REACH
Obligation to review the effectiveness of control measures	Obligation to communicate up the supply chain inappropriate RMM (information can only be obtained under OSH !)
Binding hierarchy of control measures	Non-binding hierarchy of RMM (in guidance only)
Health surveillance in line with national laws	Health surveillance outside scope
Indicative Occupational Exposure Limit Values (IOELs)	Derived No Effect Levels-DNELs
Obligation to comply with OEL	Obligation to comply with Risk Management Measures -RMM

# Limit Values under CAD/REACH still under discussion....

Indicative Occupational Exposure Limit Values (IOELs) under CAD	Derived No Effect Levels (DNELs) under REACH
Health-based	Health-based
Developed by a Scientific Committee (SCOEL)	Developed by companies for their own substances > 10 tpa
Adopted by a formal legislative procedures at EU level and transposed into national legislation	Adopted by companies as part of their registration dossiers
Used by employers at workplaces to assess and control workers' exposure	Used by companies to implement the Risk Management Measure to ensure risks are adequately controlled
Obligation for employers to comply with the OEL	Obligation for companies to comply with the RMMs
Available for 121 substances ( ~600 substances with national OELs) and mentioned in SDS	Available for more than 10 000 registered substances and mentioned in SDS

# Comparison of EU IOELVs with long-term worker DNELs (1)

Table adapted from Tynkkynen et al, Ann. Occup. Hyg., 2015, 1-15

Substances	CAS number	IOELVs (TWA 8h) mg/m <sup>3</sup>	DNEL (workers, long-term exposure) mg/m <sup>3</sup>
Chloroform	67-66-3	10	2,5
1,2-Dichlorobenzene	95-50-1	122	10
2-Ethoxyethanol	110-80-5	8	0,083
Toluene	108-88-3	192	192
Cyclohexane	110-82-7	700	700
Ethylacrylate	140-88-5	21	21
Chlorobenzene	108-90-7	23	23/42,3*
Heptan-2-one	110-43-0	238	394
Oxalic acid	144-62-7	1	4,03

20,7%  
n = 87

73,6%  
n = 87

5,75%  
n = 87

\* Two registrations giving different DNELs

# Trade union views on substance with both an OEL\* and a DNEL

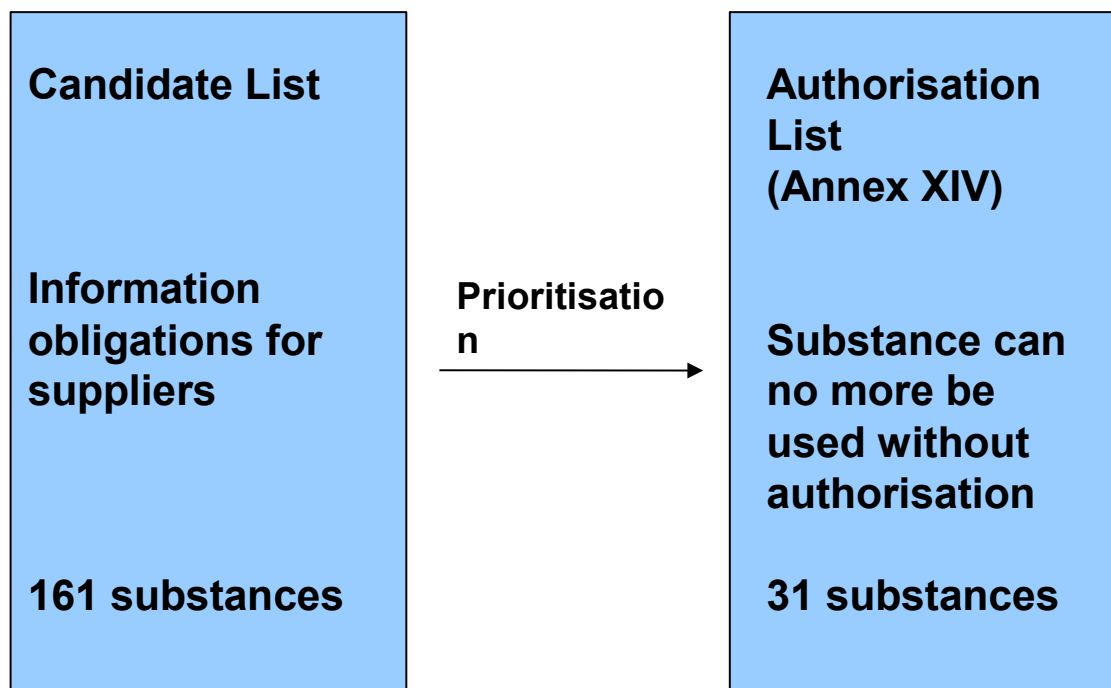
- ❑ Case 1: DNEL is lower than OEL:
  - ❑ If based on the same data, a difference is not surprising due to different methodologies (AF or expert judgment). Either the DNEL or the OEL can be used.
  - ❑ If based on different data (new data), the DNEL has to be used and the OEL has to be revised
- ❑ Case 2: DNEL is higher than OEL
  - ❑ DNEL derivation should be checked for compliance by ECHA and the OEL might need to be revised
  - ❑ If the OEL is binding at national level it has to be complied with

(\*): valid for OELs derived either at EU or national level by Scientific Cttees

# REACH authorisation : main aim is substitution of SVHC

**Substances of very high concern:**

**PBTs, vPvBs, CMRs (1&2), equivalent concerns**

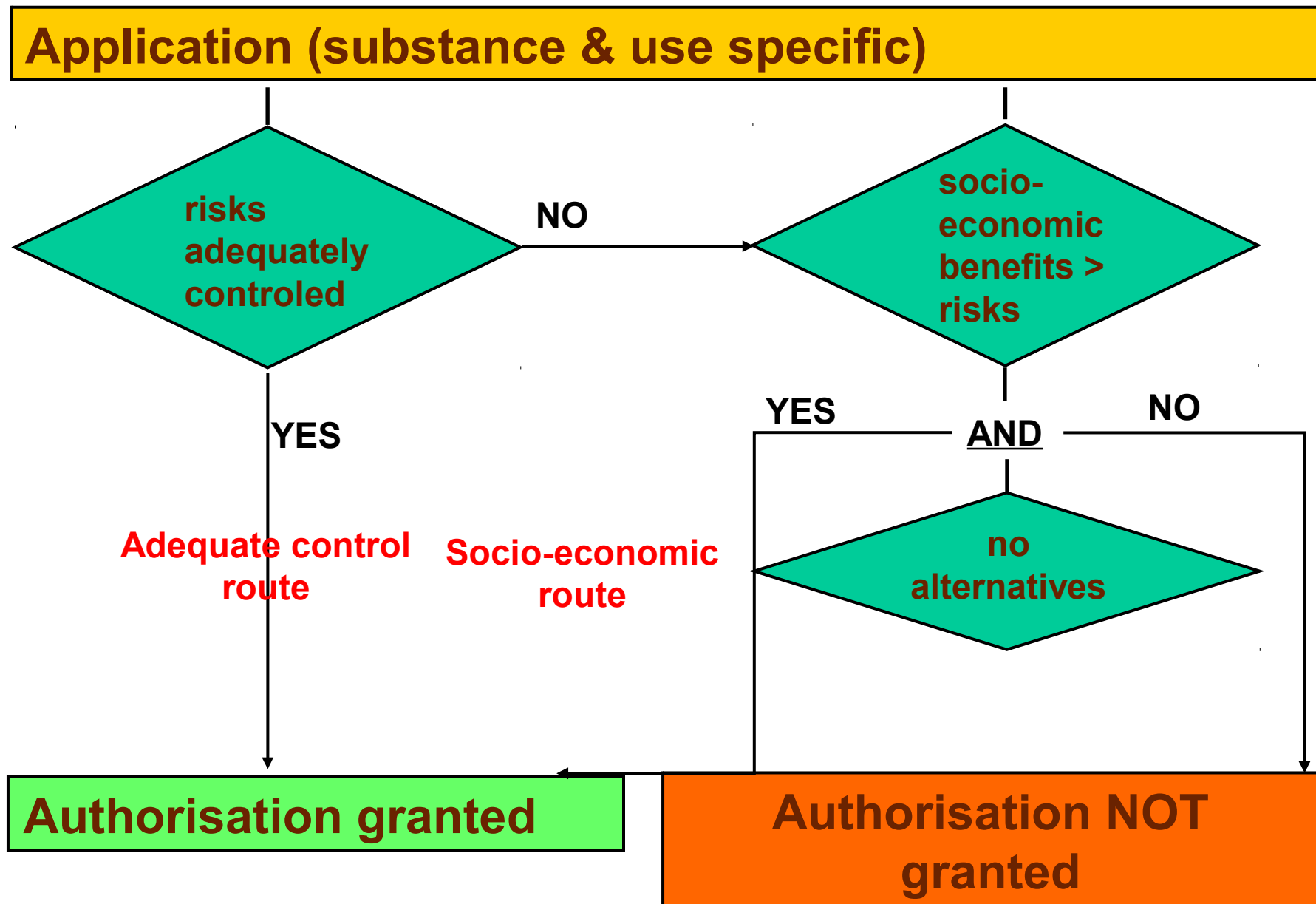


<http://www.echa.europa.eu/web/guest/candidate-list-table>

<http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list>



## Granting authorisations – The 2 routes



## Possible conflict between REACH & OSH on substitution

- Under REACH, authorisations for continued use of carcinogens & mutagens can be granted despite the availability of safer alternatives (under the adequate control route or under socio-economic route when alternatives are technically feasible but economically infeasible)
- Under the Carcinogens & Mutagens Directive, there is an obligation to substitute when safer alternatives are available & technically feasible (no cost consideration)

# Applications for authorisations so far (Feb 2015) ?

ECHA opinions in favor of granting the autorisations:

<b>SVHC</b>	<b>Classification</b>	<b>Route</b>
DEHP	Repr 1B	Socio-economic
DBP	Repr 1B	Socio-economic
Diarsenic trioxide	Carc 1A	Socio-economic
Lead (sulfo)chromate	Carc 1A & Repr 1B	Socio-economic
HBCDD	PBT	Socio-economic
Trichloroethylene	Carc 1B	Socio-economic

# Conclusions

- REACH/CLP and OSH legislations share the objective of protecting workers exposed to chemicals
- Synergies between REACH/CLP and OSH are more likely than conflicts
- REACH/CLP will enhance the effectiveness of OSH legislation
- The data generated by REACH will foster a better knowledge of the properties of chemicals, their effects on human health and ways of reducing risk during their use (better quality labelling and Safety Data Sheets)
- Authorisation and Restriction procedures in REACH will progressively promote the substitution of the most harmful substances by safer alternatives
- Training of workers and employers is key for effective use of the data generated by REACH/CLP and working out synergies with OSH legislation

# Thank you, further info on:

<http://www.etuc.org> > Our activities > REACH

<http://www.etui.org/Topics/Health-Safety/Chemicals-and-REACH>