

Restriction under REACH

History, structure of REACH Annex XVII
Overlap by other legislation
Challenges in enforcement
Example: Consumer product for repairing bicycles

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History

- **Originally:**
 - Directive 76/769: “Marketing & Use Directive on Dangerous Substances and Preparations”
- **Integrated in REACH (Regulation 1907/2006):**
 - Title VIII: Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles
 - Annex XVII: [same title]



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Structure of Annex XVII (1/3)

- **Part 1: List of banned and severely restricted substances and mixture including conditions of restrictions**
 - Since 2006, already 11 amendments of part 1 of Annex XVII
 - At this moment 64 entries
- **Part 2: entries 28, 29 and 30: list of identified CMRs**
 - Entry 28, Appendices 1 and 2: list of carcinogens cat. 1A (new 1) and 1B (new 2)
 - Entry 29, Appendices 3 and 4: list of mutagens cat. 1A(new 1: none identified) and 1B (new 2)
 - Entry 30, Appendices 5 and 6: list of reprotoxic substances cat. 1A (new 1) and 1B (new 2)



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Structure of Annex XVII (2/2)

- **Part 3: labelling of articles containing asbestos (appendix 7)**
- **Part 4: entry 43 azocolorants**
 - Appendix 8, list of aromatic amines
 - Appendix 9, list of azodyes
 - Appendix 10, list of testing methods for determining azocolorants
- **Part 5: entries 28 to 30, Derogations for specific substances**



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General conditions of restriction

- **Part 1 regards specified conditions of restriction in manufacture and or use of specified substances/mixtures**
- **Part 2 regards CMRs with the general restriction not to be placed on the market for consumer use. For mixture max. conc. $\leq 0,01\%$ or otherwise specified.**

In his presentation focus on part 1 restrictions



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Well-known substances subjected to restrictions (list not complete)

- **Benzene, toluene**, trichlorobenzene, dichlorobenzene
- **Asbestos**
- PBBs, PCTs
- 2-Naphthylamine, benzidine, 4-nitrobiphenyl, 4-aminobiphenyl, xenylamine
- **Lead carbonates, sulphates**
- **Lead and its compounds**
- **Mercury and its compounds**
- **Cadmium and its compounds**
- **Nickel and its compounds**
- **Chromium-VI compounds**
- Arsenic compounds
- Organostannic compounds
- Pentachlorophenol
- Creosotes, coal tar, anthracene oil, etc.
- Azocolourants and azodyes
- Nonylphenol and nonylphenol ethoxylates
- PAHs
- **Phalates (DEHP, DBP, BBP, DINP, DIDP, DNOP)**
- DEGBE and DEGME
- MDI and its isomers
- Cyclohexane
- Ammonium nitrate
- Chloroform, tri-, tetra-, penta- and hexachloroethane, dichloroethene
- Dichloromethane
- Acrylamide
- Dimethylfumarate



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Legal issues regarding enforcement of REACH restrictions

- Misunderstanding scope of legislation on cosmetics, medical devices, human and veterinary drugs, pesticides and biocides
 - Within the scope of REACH:
 - Ingredients of cosmetics
 - Precursors of end-use substances in medical devices, human and veterinary drugs
 - Precursors of active ingredients for pesticides and biocides
- Overlap with ROHS (Restrictions of use of certain hazardous substances in electrical and electronic equipment (EEE))



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Overlap by other legislation (1/2)

- **Overlap with ROHS (Restriction of Hazardous Substances in electric and electronic equipment)**
 - Regulation 2002/95, last amended 2011/65
 - Substances showing overlap:
 - Mercury in lamps for lighting, etc.
 - Lead in glass of tubes (cathode ray, fluorescent), as alloying element, in solders, in ceramics, etc.
 - Cadmium in electrical contacts, Cd-alloys in solder joints, etc.
 - Cr-VI in absorption refrigerators



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Overlap by other legislation (2/3)

- Scope of REACH partially overlaps scope of ROHS
- COM proposed in 2014 a working procedure for preventing conflicts between ROHS and REACH, but not the case for already defined restrictions and exemptions in ROHS and REACH
- ROHS considers electric & electronic equipment including waste management, but no exemption/exclusion of electronic equipment in REACH

Conclusion:

Possibility for conflicts in restrictions between REACH and ROHS regarding control of electric & electronic equipment on the market

Illustrative example: cadmium



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Example Cadmium

REACH

- Not to be used in mixtures and articles produced from specific synthetic organic polymers,
- not be placed on the market if conc. $\geq 0,01\%$
- Not to be used in paints
- Painted articles not be placed on the market if conc. $\geq 0,1\%$ in paint; exemption if for safety reasons
- Jewels, etc. max conc. $0,01\%$
- Many other articles specified and exemptions.
- Recovered PVC max. conc. $0,1\%$ used for specified applications
- Cd-plating not allowed in specified applications, but with exemptions, a.o. electrical contacts if necessary

ROHS

Cd max $0,01\%$ in homogeneous material, but exempted if

- In electrical contacts
- In filter glasses and relextants
- In printing inkt for enamels on glasses
- Cd-alloys as solder joints in specific high-power loadspeakers
- In film pastes used on Aluminium-bonded beryllium oxide

Observation:

Glass, inkt for enamels, solder and alloys as specified in ROHS are not specifically defined as exemption in REACH



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Case study: Consumer product for repairing bicycles

During inspection in retail store found in sport department



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10 ml glue; marked with
Label contains
model number, bar code
and name importer
No label on blister package



Sample taken and analysed:
Benzene (14,7% and
toluene (1,1%)



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Observation on composition:

Sample taken and analysed, mixture flash point 28 °C, boiling point 58 °C

Composition	Conc. (%)	Classif. CLP	Classif. DSD
Benzene	14,7	Flam. Liq. 2, H225 Carc. 1A , H350 Muta. 1B , H340 STOT RE 1, H372 Asp. Tox. 1. H304 Eye Irrit. 2, H319 Skin Irrit. 2, H315	F; R11 Carc. Cat. 1;R45 Muta. Cat. 2;R46 T; R48/23/24/25 Xn; R65 Xi; R36/38
Toluene	1,1	Flam. Liq. 2, H225 Repr. 2, H361d Asp. Tox. 1, H304 STOT RE 2* H373 Skin Irrit. 2 H315 STOT SE 3 H336	F; R11 Repr. Cat. 3;R63 Xn; R48/20-65 Xi; R38 R67



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Observation on labelling

- Classification of mixture shall be
 - Carc 1A, H350 May cause cancer
 - Muta 1B, H340 May cause genetic defects
 - STOT RE 1; H372 Causes damage to organs through prolonged exposure
 - Asp Tox 1; H304 May be fatal if swallowed and enters airways

And in addition

- Eye Irr 2 ; H319 Causes serious eye irritation
- Skin Irr 2, H315 Causes skin irritation
- Flam Liq 2 H225 Highly flammable liquid and vapour.



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Observation on labelling

- Labelling shall contain
 - Name, address and telephone number of the supplier;
 - The nominal quantity of mixture in the package where this is being made available to the general public, unless this quantity is specified elsewhere on the package;
 - Product identifiers;
 - Hazard pictograms, where applicable;
 - The relevant signal word, where applicable;
 - Hazard statements, where applicable;
 - Appropriate precautionary statements where applicable;
 - A section for supplemental information, where applicable.
- Blister package also need to carry a CLP label (or DPD until 2015)



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Annex XVII: Benzene and toluene

5. Benzene CAS No 71-43-2 EC No 200-753-7	1. Shall not be used in toys or parts of toys where the concentration of benzene in the free state is greater than 5 mg/kg (0,0005 %) of the weight of the toy or part of toy. 2. Toys and parts of toys not complying with paragraph 1 shall not be placed on the market. 3. Shall not be placed on the market, or used, — as a substance, — as a constituent of other substances, or in mixtures, in concentrations equal to, or greater than 0,1 % by weight. 4. However, paragraph 3 shall not apply to: (a) motor fuels which are covered by Directive 98/70/EC; (b) substances and mixtures for use in industrial processes not allowing for the emission of benzene in quantities in excess of those laid down in existing legislation.
48. Toluene CAS No 108-88-3 EC No 203-625-9	Shall not be placed on the market, or used, as a substance or in mixtures in a concentration equal to or greater than 0,1 % by weight where the substance or mixture is used in adhesives or spray paints intended for supply to the general public.



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Observation regarding presence on the market

- According to Annex XVII, entry 5 (benzene) mixture not allowed on the market for consumer use in conc. $\geq 0,1\%$
- According to Annex XVII, entry 48 (toluene) mixture not allowed on the market for consumer use in conc. $\geq 0,1\%$

Conclusion:

- Product shall be taken from the market
- If solely for professional use: C&L shall be modified



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