ECRAN Regional Workshop
on Compliance with REACH/CLP Regulations
TAIEX/ECRAN

REACH specific
Registration, Evaluation, Authorisation and Restrictions

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Elements of REACH

- Registration By industry
  - Document that human health & environmental risks are adequately controlled in all identified uses
- Evaluation By ECHA or CA
  - Review of registration dossiers for compliance and animal testing proposals
- Authorisation By ECHA/EC or CA
  - For substances of very high concern (CMR class 1 and 2, PBT, vPvB, others, e.g. endocrine disrupters)
- Restriction By ECHA or CA
  - for substances where risks are unacceptable

ECHA= European Chemicals Agency, Helsinki
CA= National Competent Authority

2

REACH & CLP Implementation – Challenging for Industry as well as for Authorities

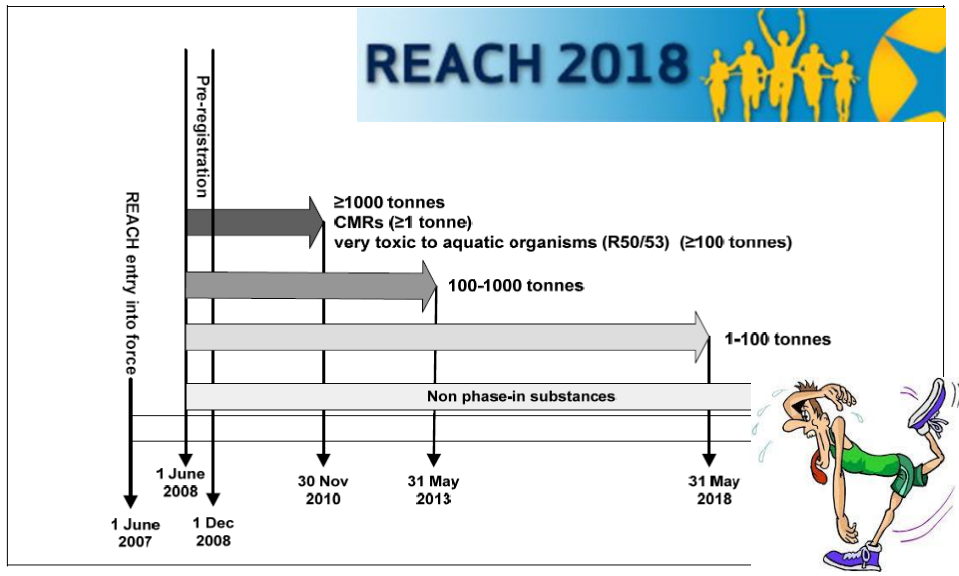
- Pre-registration - Late Pre-registration
- Registration – SIEFs – CSR –
- ESs – Dossier submission – up-dates
- **Restrictions**

- Authorisation – CL 161 / AL 31
- **CLP – 2015**…2017

- SDS – eSDS (ESs) = DNELs / PNECs
- **Downstream Users – consequent duties**
- Compliance – Enforcement

- **Market & Consumers**

Registration deadlines



(Pre)registration...??

- **Pre-registration/Registration** – duty to act - limiting the production and import
- ??Missed?? ??or not in compliance??

!out of the market!

- **Late pre-registration**
  - ?by other entity?
- New production? / import?:
  - late pre-registration
  - or ELINCS registration
  - or direct **REGISTRATION**

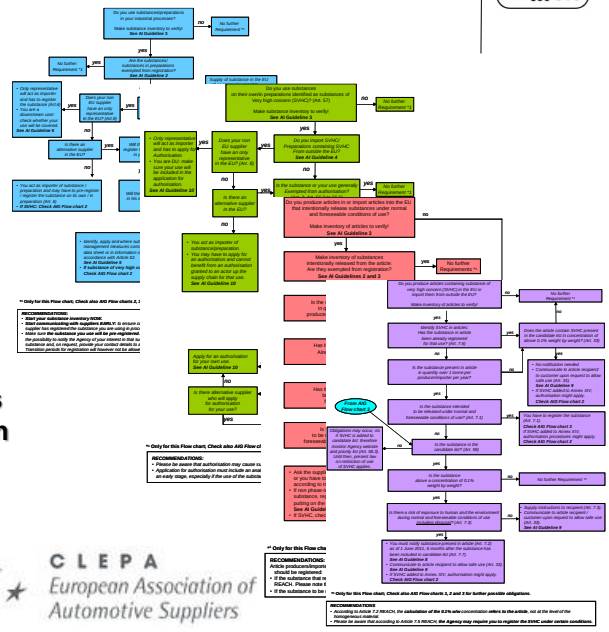
Registration timetable

All substances (approx 30,000) manufactured/imported over 1 t/year (= existing substances, unless new registration pending)

- For **new** substances, registration is essential before manufacture
- For **existing** substances on EINECS and ELINCS, phase-in period over 11 years (to 2018)
- Notify intention by 1/12/2008 (**pre-registration**)
- Phase 1: **>1000 tonnes/year + CMR, PBT** (by 1/12/2010)
- Phase 2: **100 – 1000 tonnes/year** (by 1/6/2013)
- Phase 3: **10 – 100 and 1 – 10 tonnes/year** (by 1/6/2018)

CLEPA: How to comply with REACH - a step-by-step process

- Flow chart 1: **Registration of substances**/substances in preparations used in industrial (including engineering) processes
- Flow chart 2: **REACH authorisation** procedures
- Flow chart 3: **Registration of substances** intended to be released from **articles**
- Flow chart 4: **Notification of substances in articles** and obligation to communicate information



CLEPA
European Association of Automotive Suppliers

REGISTRATION-SIEFs

- **Participation – active? / dormant?**
  - Consortia? / Licence?
  - Lead? Take part? Wait?
- Dossiers – joint and individual
- Classification
- Safety Assessment – Exposure scenarios
- Downstream users – communication
  - Identified uses
  - Registration numbers
  - Exposure Scenarios

Chemical Safety Assessment hazard assessment

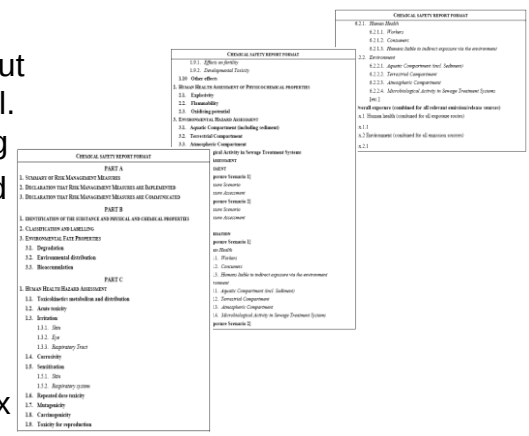
- Human health
  - Evaluate data (animal data, epidemiology)
  - Decide on classification and labelling
  - Establish Derived No-Effect Level (**DNEL**)
- Safety (physico-chemical)
  - Explosivity, flammability, oxidising potential
- Environmental
  - Evaluate data, including PBT and vPvB assessment
  - Decide on classification and labelling
  - Establish Predicted No-Effect Concentration (**PNEC**)

9

Chemical Safety Assessment exposure assessment

Exposure scenarios

- Cover manufacture and intended uses throughout substance life cycle, incl. waste disposal/recycling
- Describe processes and tasks
- Operational conditions
- Risk management measures required
- Included as an appendix to enhanced SDS



10

SDS-eSDS

- **Communication in supply chain**
  - **Basic and binding document**
  - Limit values – DN(M)ELs, PNECs
  - National laguages
  - National specifics...
- Who is really responsible?
  - Producer or importer from EU / outside
  - Importer / distributor / market company
- When to up-date?
- What will happen once I get e-SDS???
  - Nothing / PANIC ?
  - Partners understand ???

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Risk characterisation

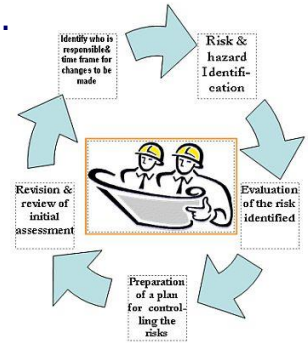
- For each exposure scenario; and
- for each human population exposed (as workers, consumers, indirectly via the environment, or a combination)

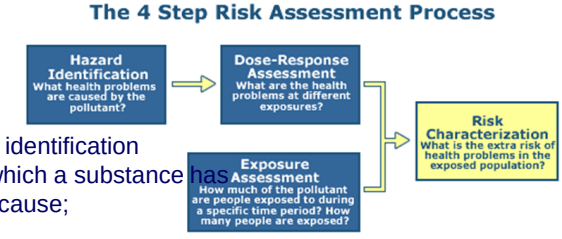
- Residual risk (after RMM implemented); and
- comparison of exposure with relevant DNEL / PNEC

12

RA within REACH context

- For chemicals manufactured/imported ≥ **10 tonnes per year**, Chemical Safety Assessment (CSA) (**human health AND environment**) must be performed.





1. **Assessment of effects:**
   - **hazard identification:** identification of the adverse effects which a substance has an inherent capacity to cause;
   - **dose (concentration) - response (effects) assessment**: estimation of the relationship between dose, or level of exposure to a substance, and the incidence and severity of an effect.
2. **Exposure assessment -** estimation of the concentrations/doses to which human populations (i.e. workers, consumers and man exposed indirectly via the environment) or environmental compartments (aquatic environment, terrestrial environment and air) are or may be exposed
3. **Risk characterisation -** estimation of the incidence and severity of the adverse effects likely to occur in a human population or environmental compartment due to actual or predicted exposure to a substance, and may include “risk estimation”, i.e. the quantification of that likelihood

PNEC(s) / DNEL(s) / DMEL(s)

- ***PNEC*** = Predicted no effect concentration
  - the concentration of a chemical in any compartment below which unacceptable effects on the aquatic ecosystem and its organisms will most likely not occur during long term or short term exposure.
- ***DNEL*** = Derived no effect level
  - DNEL defined in REACH: the level of exposure above which humans should not be exposed.
  - The risk to humans can be considered to be controlled if the exposure levels estimated do not exceed the appropriate DNEL.
- ***DMEL*** = Derived minimal effect level
  - reference risk level considered to be of very low concern and should be seen as a tolerable level of effects

DNEL(s) & DMEL(s) derivation

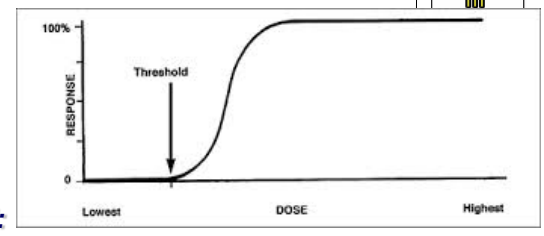
Consider:

- Data requirements - derivation of DNEL/DMEL is required for the CSA of substances manufactured/imported/used in quantities from 10 t/y onwards (REACH Annexes VII-X, in conjunction to Annex XI).
- Uncertainty/variability – within and between species
- Populations - workers, general population (consumers and men exposed via environment)
- Routes – dermal, oral and inhalation routes
- Duration of exposure – long-term and acute DNEL/DMEL
- Systemic and local effects
- Units – expressed in the external exposure values:
  - Relevant external dose units for DNEL: mg/person/day, (or mg/cm2 body area/day), mg/kg bw/day, and mg/m³ for dermal, oral, and inhalation exposure.

Steps in DNEL/DMEL derivation

1. Decision on mode of action of a substanc
2. Selection of a relevant dose descriptor for the endpoint of interest
3. Modification of the dose descriptor to the correct starting point
4. Application of assessment factors to the correct starting point to obtain DNEL
5. Selection of **the main/leading DNEL** per health effect

General principles



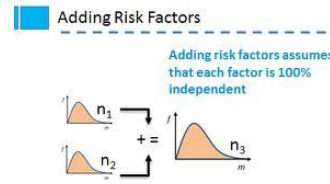
- 2 types of the effect:
  - ***Effects with a threshold:***
    - The dose of a chemical must reach a certain level in order to elicit any adverse effect = a chemical is thought to be harmless at sufficiently low concentrations.
      - Type of chemicals: non-carcinogens and non-genotoxic carcinogens
  - ***Effects without a threshold:***
    - No safe dose of a chemical exists = an adverse effect may be elicited at any level
      - exposure level regarded as “acceptable”
      - Type of chemicals: genotoxic carcinogens and germ cell mutagens

Dose descriptor

= a value obtained from a toxicity test, or an epidemiological study on human population

- Usually the dose needed to induce a specified adverse effect (e.g. 50% lethality), or the highest dose not causing adverse effects (e.g. NOAEL).
- Typically used dose descriptors are LD50, LC50, T25, NOAEL, BMDL10, RR, OR, and SMR.
  - **LD50** = dose of a substance that kills 50% of animals in a specified time exposed by oral or dermal route.
  - **LC50** = concentration of a substance that kills 50% of animals in a specified time exposed by inhalation route.
  - **T25 =** the chronic dose that will give 25% of the animals' tumours at a specific tissue site after correction for spontaneous incidence.
  - **NOAEL** = the *highest dose leve*l or concentration of the substance used in test at which no significant adverse effects were observed.
  - **BMD10 =** the dose that produces a 10% excess risk in the experimental dose range, if compared to background level.
  - **RR** = relative risk = the probability of an event (developing a disease) occurring in exposed people compared to the probability of the event in nonexposed people
  - **OR** = odds ratio = the ratio of the odds that the cases were exposed to the odds that the controls were exposed.
  - **SMR** = standardized mortality ratio = the ratio of deaths observed to deaths expected per year in the population of interest, if the age specific death rates were the same as a standard population.

Modification of the dose descriptor



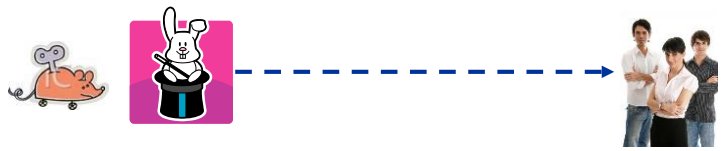
Why?

- Difference in bioavailability between animals and humans;
- The animal dose descriptor is for another exposure route than the human exposure (requiring route-to-route extrapolation);
- Differences in human and experimental exposure conditions (e.g. 6 hours of inhalatory exposure in rat vs. 8 hours in worker);
- Inhalation exposures - differences in respiratory volumes between experimental animals and humans

- Important way of circumventing modifications – biomonitoring!

Assessment factors (DNELs)

= numerical values addressing differences between experimental data and the human situation taking into account the uncertainties in the extrapolation process and the available data set.



Assessment factors

- **Interspecies differences** - variation in the sensitivity of species due to differences in toxicokinetics and toxicodynamics;
  - correct for differences in metabolic rate (allometric scaling - AS)
  - Additional factor of 2,5 for remaining differences
- Main assumption: People are more sensitive than animals
  - Allometric scaling – metabolic rate dependent on body weight
  - Different AS factors for different animal species with respect to humans

Species	Body weight (kg)	AS factor[b]
Rat	0.250	4
Mouse	0.03	7
Hamster	0.11	5
Guinea pig	0.8	3
Rabbit	2	2.4
Monkey	4	2
Dog	18	1.4

a) assuming the human body weight is 70 kg

Not applicable if the effects are not dependent on metabolic rate or systemic absorption (e.g. local effects); or if animal inhalation study.

The risk assessment process, in relation to both human health and the environment, entails a sequence of actions:

1. Assessment of effects:
   (a) hazard identification: identification of the adverse effects which a substance has an inherent capacity to cause; and
   (b) dose (concentration) - response (effects) assessment: estimation of the relationship between dose, or level of exposure to a substance, and the incidence and severity of an effect, where appropriate
2. Exposure assessment: estimation of the concentrations/doses to which human populations (i.e. workers, consumers and man exposed indirectly via the environment) or environmental compartments (aquatic environment, terrestrial environment and air) are or may be exposed.
3. Risk characterisation: estimation of the incidence and severity of the adverse effects likely to occur in a human population or environmental compartment due to actual or predicted exposure to a substance, and may include "risk estimation", i.e. the quantification of that likelihood.

23

Dose (concentration) - response (effects) assessment

- At this step the predicted no effect concentration (PNEC), shall, where possible, be determined
- For derivation of PNECs, all available hazard information needs to be evaluated.
- For the characterization of the PNEC it is of high importance to evaluate the data with regard to their adequacy and completeness.
- The evaluation of adequacy shall address the reliability and relevance of data.

24

Overview of toxicity test endpoints and guidance on derivation of L(E)C_{50} and NOEC values

Short-term studies:

- If a test report does not indicate the L(E)C50 values but the raw data are presented, **the L(E)C50 should be calculated**, for example by regression analysis. If only one toxicity value lies between the L(E)C0 and the L(E)C100, the L(E)C50 cannot be calculated e.g. by Probit analysis. Instead, the L(E)C50 may be estimated by, e.g., linear regression.
- If results are presented as >L(E)C10 and <L(E)C50, they can be rated as L(E)C50 while results clearly above a L(E)C50 can only be used as an indication of the short-term toxicity of the chemical considered.

25

General principles of derivation of PNEC values

- **Aim** - to derive a Predicted No-Effect-Concentration for long and/or short term exposure of a given environmental compartment (PNECcomp).
- **Environmetal compartments**:
  - Water
  - Sediment
  - Soil
  - Air
  - Microorganisms in sewage treatment plants (STP)
  - Assessment of secondary poisoning
- The **PNEC** is the concentration of a chemical in any compartment below which unacceptable effects on the aquatic ecosystem and its organisms will most likely not occur during long term or short term exposure.

26

Assessment factor methods

- The general principle of these methods is that the result from a laboratory test is divided by an appropriate assessment factor (AF).
- PNECs are estimated by division of the lowest value for the toxicity with the relevant assessment factor.
- Results of long-term tests (expressed as EC10/NOEC for a sublethal parameter) are preferred to those of short-term tests (EC/LC50), because such results give a more realistic picture of effects on the organisms during their entire lifecycle.
- In establishing the size of these assessment factors, a number of aspects have been addressed to extrapolate from single-species laboratory data to a multi-species ecosystem. These areas comprise:
  - intra- and inter-laboratory variation of toxicity data;
  - intra- and inter-species variations (biological variance);
  - short-term to long-term toxicity extrapolation;
  - laboratory data to field impact extrapolation.

27

Assessment factor methods

Calculation for the determination of the PNEC: $\mathrm{PNEC}_{comp} = \frac{\mathrm{Min}\{\mathrm{EC}_{comp}\}}{AF}$

Input

Parameter	Description
$\mathrm{Min}\{\mathrm{EC}_{comp}\}$	The lowest valid effect concentration for organisms from the compartment, i.e. EC50 or LC50 for short-term toxicity or EC10/NOEC for long-term toxicity, typically given in [mg/L] or [mg/kg]
AF	Assessment factor, the size of which depends on the type and amount of toxicity information available

Output

Parameter	Description
PNEC_{comp}	Predicted No-Effect-Concentration for the compartment in question, typically given in [mg/L] or [mg/kg]

Assessment factors to derive a $PNEC_{freshwater}$

Available data	Assessment factor
At least one short-term L(E)C50 from each of three trophic levels (fish, invertebrates (preferred Daphnia) and algae)	1000 [a)]
One long-term EC10 or NOEC (either fish or Daphnia)	100 [b)]
Two long-term results (e.g. EC10 or NOECs) from species representing two trophic levels (fish and/or Daphnia and/or algae)	50 [c)]
Long-term results (e.g. EC10 or NOECs) from at least three species (normally fish, Daphnia and algae) representing three trophic levels	10 [d)]
Species sensitivity distribution (SSD) method	5-1 (to be fully justified case by case) [e)]
Field data or model ecosystems	Reviewed on a case by case basis [f)]

29

Example

Method	Results 96h LC50 (mg/L)	Remarks	Reference
EEC 92/69 C1	**2.2** (1.3-2.5)	– *Brachydanio rerio* – semi static	IUCLID, 1999
EEC 92/69 C1	**0.9** (0.7-1.2)	– *Brachydanio rerio* – flow through	IUCLID, 1999

Method	Results (mg/L)	Remarks	Reference
EE92/69	**3.4** (48 h EC50)	– *Daphnia magna*	IUCLID, 1999
Other	**5.2** (4.7-5.6) - (48 h EC50)	– *Daphnia magna*	IUCLID, 1997

Method	Results (mg/L)	Remarks	Reference
Other	**1** (21 d NOEC)	– *Daphnia magna*	IUCLID, 1999
OECD202	**0.56** (21 d NOEC)	– *Daphnia magna*	IUCLID, 1998

$PNEC_{aquatic}$ = 0.56/100= 0.0056 mg/L

30

CLP obligations

- supplier of chemicals or mixtures must classify, label and package in accordance with the CLP Regulation.
- **obligations for mixtures:**

  Safety Data Sheets for mixtures must be classified, labelled and packed only in accordance with CLP Regulation from **June 1, 2015**.

  Time remaining: June 2017

CLP obligations II

- If you place a hazardous substance on the market, you must notify ECHA of its classification and labeling within one month of placing the substance on the market for the first time.
- For importers, the one month is counted from the day when a substance, on its own or contained in a mixture, is physically introduced in the customs territory of the EU.

Restriction

- the alternative method in REACH of controlling hazardous substances that do not fully meet the criteria for authorisation.
- harmonised controls on the uses of such substances across the EU, up to and including a complete ban as appropriate. Current restrictions are listed in REACH Annex XVII.

https://www.gov.uk/eu-rules-on-the-use-of-chemicals

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List of Restrictions

http://echa.europa.eu/eu/addressing-chemicals-of-concern/restrictions/list-of-restrictions

Showing 1 - 50 of 105 results. Items per Page 50

Entry no	Substance / group of substances / mixture	EC Number	CAS Number	Consolidated text	Appendix
1	Polychlorinated terphenyls (PCTs)	-	-	Page 217	
2	Chloroethylene (Vinyl chloride)	200-831-0	75-01-4	Page 217	
3	Liquid substances or mixtures, which are regarded as dangerous in accordance with Directive 1999/45/EC or are fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: (a) hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F,(b) hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10,(c) hazard class 4.1,(d) hazard class 5.1.	-	-	Page 217	
4	Tris (2,3 dibromopropyl) phosphate	-	126-72-7	Page 218	
5	Benzene	200-753-7	71-43-2	Page 219	
6a	Asbestos fibres: Crocidolite		12001-28-	Page 219	Appendix 7

The Commissioners' commitments

- 2010: Vice-President Tajani and Commissioner Potočnik publicly committed to
  - **"have a candidate list of 136 Substances of Very High Concern by the end of 2012 "**
    - Currently :144 (7 more substances in the pipeline for December '13)
  - "**have all relevant currently known SVHCs included in the candidate list by 2020"**
    - a the roadmap "should build on the Risk Management Option (RMO) framework, setting out clear milestones, deliverables and division of work between the Commission, Member States and the European Chemicals Agency"

What is not a "relevant" SVHC by 2020?

- Indications in the Roadmap:
  - A SVHC that is not registered is not a priority (some exceptions possible in the Roadmap, e.g. category approach)
  - A SVHC that has been registered as intermediate only is not a priority (but enforcement actions *(cf. intermediate)* if appropriate and some exceptions possible in the Roadmap, e.g. category approach)
  - A SVHC that fulfils the conditions of art. 69(1) : if its use(s) pose(s) a risk to human health and environment that is not adequately controlled, a restriction process should be started (second step: SVHC for remaining uses)
  - A SVHC with (all) uses already regulated by specific EU legislation that provides a pressure for substitution or (all) uses exempted from the authorisation (see article 5, 56 or 60)

What is not a "relevant" SVHC by 2020?

Exception from the two last criteria:

A PBT, vPvB or SVHC fulfilling art. 57(f) for a hazard property without harmonised criteria in Annex I of CLP (*e.g.*, EDs)

In this case, COM believes that an official identification by the Member States Committee via an Annex XV dossier for SVHC identification could be foreseen. If a restriction is considered necessary, this will avoid the need to discuss the hazard properties in the restriction process.

Authorisation

- Authorisation required for all uses of substances of very high concern (eg CMR, PBT vPvB substances)
- Authorisation granted if risks are under "adequate control"
- adequate control allows authorities to prioritise action to haz subst that cannot be so controlled
- If adequate control not possible, authorisation may still be granted on socio-economic grounds (i.e. no suitable safer alternative)
- Companies required to make efforts to find safer alternative as part of their application for authorisation
- Any substitute must be "feasible" and deliver lower overall risks

38

CL / AL - Authorization

June 2008:
ECHA received its first 17 Annex XV dossiers (all from MSs)
➔ 16 passed the accordance check
30.06-14.08.08: public consultation
07-08.10.08:

MSC agreed on 14 substances (+ 1 automatically selected because of no comment received)

28.10.08:
1st **Candidate List** officially adopted and published (15 substances)

…**today 161 substances in 2015…**
??? 2016…2017…2018…2019…???
2020 = all SVHCs???...2600???

Auhorisation process e.g.

- *DEHP*

- RAC established reference DNELs for the reproductive toxicity of DEHP. The reference DNELs for workers are: Inhalation:

  - DNEL of 0.88 mg/m³ (8h-TWA)
  - Dermal: DNEL of 1.882 mg/kg/d (external values)

Tasks of the MS CA

- Provide a Helpdesk for (national) duty holders and other stakeholders under REACH

- Enforce compliance

- Evaluate substances and suggest to relevant EU REACH committees appropriate regulatory consequences (eg C&L, restrictions on use)
- Nominate candidates to sit on the various EU REACH decision-making committees

-Liaise as appropriate with relevant enforcing organisations in relation to "downstream" responsibilities under REACH

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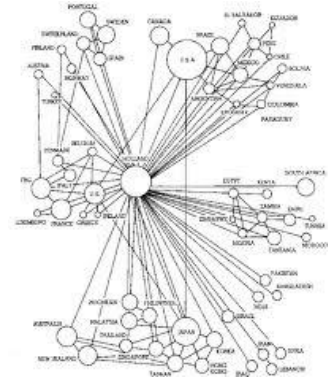
REACH vs other EU legislation

- Workers protection legislation
- Environment – Surface water, ground water, soil…
- General population – drinking water
- PIC / Stockholm Convention
- Products
  - General products
  - Construction products
  - Toys
  - PPE
  - …



Articles on EU market

- **Rapid Alert System for dangerous non-food products**
  - 31 participating countries (EU countries, Norway, Iceland and Liechtenstein) and the European Commission
  - to **exchange information** on products posing a risk to health and safety of consumers and on the measures taken by these countries to do away with that risk.

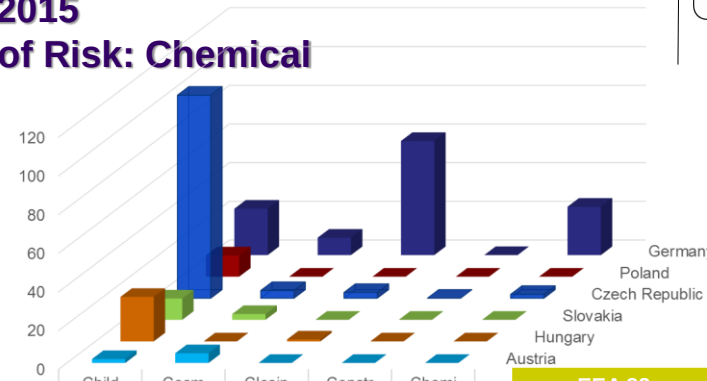
Chemicals Risks – Consumer Products 2014-2015

- **Czech Republic**
  - Toys
    - 105 entries - 11 Plastic doll (CofO 100% China)
      - 11x DEHP 12,5 – 32,6%
      - 1x DBP 0,32%
  - Cosmetics
    - 8 entries

Chemicals Risks – Consumer Products 2014-2015

- **Slovakia**
  - Toys
    - 11 entries - 11 Plastic doll (CofO 100% China)
      - 11x DEHP 12,5 – 32,6%
      - 1x DBP 0,32%
  - Cosmetics
    - 3 entries (CofO 100% Germany)
      - 1x Eyelash and eyebrow dye - 2-Methylresorcinol 1758 mg/kg
      - 2x Make-up set - Chromium VI 33,2 mg/kg

RAPEX Hazardous Articles Entries 2014-2015 Type of Risk: Chemical



	Child care & Toys	Cosmetics	Closing & Textiles	Construction materials	Chemical Products
Austria	2	5	0	0	0
Hungary	23	0	1	0	0
Slovakia	11	3	0	0	0
Czech Republic	105	4	3	0	2
Poland	11	0	0	0	0
Germany	24	9	59	0	25

EEA 32	
Child care	343
Cosmetics	70
Textiles	102
Construction	0
Chemical P	65

Safety on the market

RAPEX – SR – 2014 - 2015

Content of DEHP – up to 32,6%!!!

RAPEX – ČR, PL – 2014 - 2015

Content of DEHP – up to 37,4%!!!

…because of REACH

- Will “EU origin” means SAFE(r)?
- Will we better protect EU citizens /environment ?
- Will be consumer products on EU market safer?