Socio-economic analysis in chemicals risk management

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REACH*

Registration
Evaluation
Authorisation
(and Restriction)
of **Ch**emicals

* Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending …….

Aims of REACH

- Ensure a high level of protection of human health and the environment
- Promote alternatives to animal testing
- Ensure the free circulation of substances on the internal market
- Enhance competitiveness and innovation

How to achieve the health and environment objective?

- Better knowledge on properties and uses
- Better safety and control measures
- Reducing exposure and hence negative impacts
- Replacing (gradually) hazardous substances with less hazardous ones

Key legislative drivers: Registration; supply chain communication; authorisation; restriction

Shifting burden of proof

- REACH is based on the principle that industry:
  - ✓ Should manufacture, import or use substances with responsibility and care;
  - ✓ to ensure that human health and the environment is not adversely affected.
- Companies should take necessary risk management measures
  - ✓ In accordance with the assessment of the risks of substances;
  - ✓ and pass on relevant risk management recommendations down the supply chain.

Additional risk management instruments

- Authorisation
  - ✓ after a given date uses of a substance are banned unless specifically authorised
- Restriction
  - ✓ full ban of a substance or
  - ✓ ban of specified uses and/or
  - ✓ condition on the specified uses

Risk management based on hazard or risk?

- In practice it is both:
  - Any type of risk management of chemicals needs to begin with a hazard assessment (first step)
  - The most basic risk management measure is to communicate hazard information to those concerned
  - Classification and labelling was a cornerstone in the regulation of dangerous chemicals already in the 19th century
- In REACH, substances identified as SVHC may be included in the candidate list for authorisation

Substances of Very High Concern (SVHCs)

- CMRs (substances that are carcinogenic, mutagenic or toxic for reproduction),
- PBTs (substances that are Persistent, Bioaccumulative or Toxic for the Environment),
- vPvBs (substances that are very Persistent and very Bioaccumulative),
- substances of equivalent concern (such as endocrine disruptors or sensitisers).

Substitution

- Replacement or reduction:
  - ✓ of hazardous substances in products or processes
  - ✓ by less hazardous or non-hazardous substances
  - ✓ or by achieving an equivalent functionality via technological or organizational measures.
- Important objective in EU chemicals policy
- Key element in the REACH regulation

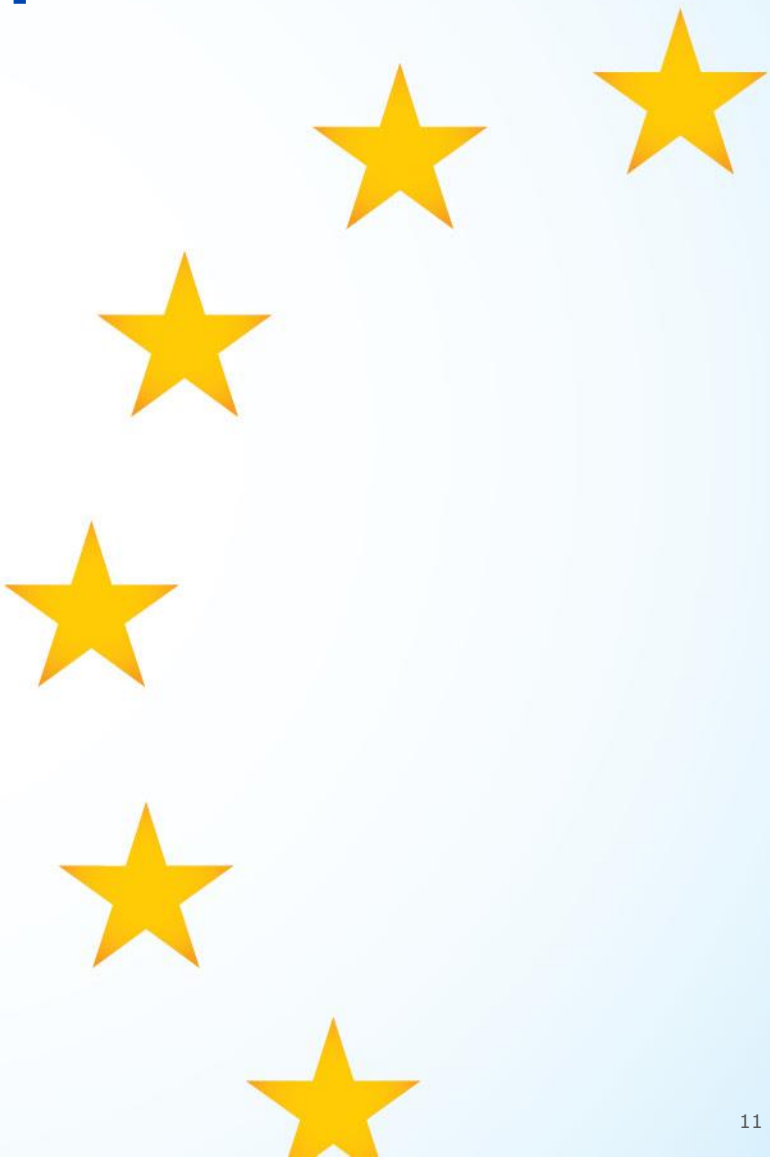
Authorisation

To ensure that:

- the risks from SVHCs are properly addressed, and
- that these substances are progressively substituted by alternative substances or technologies;
- where these are economically and technically viable, whilst
- ensuring the good functioning of the internal market.

Authorisation is not a ban

- Allows companies to apply for an authorisation for a continued (or new) use of an SVHC
  - ✓ Requires analysis of alternatives
  - ✓ Public consultation on alternatives
  - ✓ Subject to time-limited review, providing pressure to continue the search for long-term alternative solutions



Authorisation application requires assessment of risks and impacts

- Applications for authorisation are evaluated by ECHAs
  - Committee for Risk Assessment (RAC)
  - Committee for Socio-Economic Analysis (SEAC)
- Authorisation can be granted if
  1. risks are adequately controlled
  2. or if the socio-economic benefits outweigh the risks and if there are no suitable alternatives
- Hazard identification is only the starting point for the process

Restrictions

- To tackle use(s) that pose unacceptable risks
  - ✓ In case of ban, substitution is a must
  - ✓ Time needed for implementation significantly reduced
  - ✓ After sunset date, restricting the use of SVHCs in (imported) articles must be considered
- Proposal from a Member State or ECHA (asked by the Commission)

Scientific basis for decision

The decision to restrict a substance or/and use shall take into account:

- Whether there is an unacceptable risk to human health and/or the environment
- Appropriateness of the proposal to reduce the risk
- The socio-economic impact of the proposed restriction

Socio-economic analysis (SEA)

- Aims and scope
- Types of impact
  - ✓ Human health and environmental impacts
  - ✓ Economic impacts
  - ✓ Social impacts
  - ✓ Wider economic impacts
- Evaluation
  - ✓ Compare qualitative, quantitative or monetised impacts
  - ✓ Compare distribution of impacts
  - ✓ Uncertainty analysis

SEA <—> Impact assessment

- Environmental impact assessment since 1970s
- Regulatory impact analysis since 1980s
- European Commission impact assessment system 2003
- OECD Socio-economic analysis in chemicals risk management
  - ✓ Workshop 1998
  - ✓ Guidance 2000
- REACH regulation, since 2007
  - ✓ General waiver from other IA requirements

Aspects of implementation

- SEA in REACH aims at a demonstrating or providing arguments for a case rather than 'proof'.
- Who makes the SEA and how and how is it evaluated?
  - ✓ In AfA, industry prepares and RAC and SEAC evaluate
  - ✓ Information –asymmetries exist, mechanisms to deal with
- A SEA needs to be specific to the case
  - ✓ Holistic approaches are nice but do not make the SEA practical
- The interface between natural sciences and social sciences takes places through RAC-SEAC dialogues
  - ✓ Essential in making the information from both RAC and SEAC fit for the purpose of decision making

The scientific committees of ECHA

- ECHA has four Committees (3 on REACH & 1 on Biocides):
  - ✓ Member State Committee (MSC)
  - ✓ Committee for Risk Assessment (RAC)
  - ✓ Committee for Socio-economic Analysis (SEAC)
  - ✓ Biocidal Products Committee (BPC)
- The 4 Committees form an integral part of ECHA and allow it to deliver its objectives
- Responsible for Agency opinions and solving divergences of views between Member States authorities

RAC - responsibilities

Articles REACH 76(1)(c) & CLP 37(4)

- Responsible for preparing the opinion of the Agency on:
  - ✓ Proposals for harmonised classification and labelling (CLH)
  - ✓ Proposals for restrictions
  - ✓ Applications for authorisation
  - ✓ Any other questions that arise from the operation of REACH relating to **risks to human health or the environment**

SEAC - responsibilities

Article 76(1)(d)

- Responsible for preparing the opinion of the Agency on:
  - ✓ Proposals for restrictions
  - ✓ Applications for authorisation
  - ✓ Any other questions that arise from the operation of REACH relating to the **socio-economic impact of possible legislative action on substances**

Example: chromium in leather articles

- Health impact:
  - ✓ chromium allergy cases reduced by ~10,000/y (now 1.58m cases/y in EU)
- Benefits (as assessed by SEAC) from:
  - ✓ alleviate existing cases: ~€66m/y
  - ✓ avoiding new cases: ~€38m/y
- Costs to industry:
  - ✓ €83-100m/y (DS) composed of higher import prices, production costs, monitoring costs.
- Voluntary shift by producers signals moderate industry costs

Example: lead and its compounds – I.

- Targeting at lead-containing consumer products that children could place in their mouth
- Restriction considered most appropriate EU-wide measure conditional on:

✓ Concentration of lead > 0.05% of weight

✓ Derogation on crystal glass, (semi-) precious stones, enamels, keys & locks,…

✓ Transition period.

Example: lead and its compounds – II.

- ❑ Total costs: €25M/y
- ✓ Substitution cost (~€12M/y),
- ✓ Product redesign & related costs (€4.5M/y)
- ✓ Testing costs (€8.5M/y)
- ❑ Benefits
- ✓ Cognitive abilities tested with IQ tests
- ✓ SEAC proposed 'break even' approach (accounts only for IQ losses)
- ✓ Costs & benefits balanced if each child in Europe mouthed lead-containing articles (1%) for 4.2 seconds per day

→ Proportional

Example: authorisation cases

- Industry has burden of proof
  - ✓Direct costs of non-use generally known
  - ✓Indirect costs to society (unemployment, price increases,…) much less known
  - ✓Costs of alternative(s) sometimes known
- Difficult cases:
  - ✓benefits of authorisation outweigh the monetised health impacts,
  - ✓but also involve large health risks
- Might lead to:
  - ✓additional risk management measures and monitoring requirements
  - ✓authorisation with a short review period

Substance EC No	Substance name
215-481-4	Diarsenic trioxide
204-118-5	Tris(2-chloroethyl) phosphate (TCEP)
202-974-4	4,4'-diaminodiphenylmethane
204-211-0	Bis(2-ethylhexyl) phthalate
201-557-4	Dibutyl phthalate (DBP)
201-553-2	Diisobutyl phthalate (DIBP)
204-450-0	2,4-Dinitrotoluene (2,4-DNT)
201-329-4	5-tert-butyl-2,4,6-trinitro-m-xylene (Mysk xylene)
201-622-7	Benzyl butyl phthalate (BBN)
215-116-9	Diarsenic pentaoxide
231-846-0	Lead chromate
235-759-9	Lead chromate molybdate sulfate red
215-693-7	Lead sulfochromate yellow
247-148-4, 221-695-9	Hexabromocyclododecane (HBCDD) and major diastereoisomers
215-607-8	Chromium trioxide
231-906-6	Potassium dichromate
232-143-1	Ammonium dichromate
231-801-5,236-881-5	Acids generated from chromium trioxide and their oligomers
231-589-4	Cobalt dichloride
208-169-4	Cobalt(II) carbonate
200-755-8	Cobalt(II) diacetate
233-402-1	Cobalt(II) dinitrate
233-334-2	Cobalt(II) sulphate
232-140-5	Potassium chromate
231-889-5	Sodium chromate
234-190-3	Sodium dichromate
201-167-4	Trichloroethylene
204-826-4	N,N-Dimethylacetamide (DCAM)
203-924-4	Bis(2-methoxyethyl) ether (Diglyme)
203-458-1	1,2-dichloroethane (EDL)
500-036-1	Formaldehyde, oligomeric reaction products with aniline (technical MDA)
232-142-6	Strontium chromate
202-918-9	2,2,'-dichloro-4,4'-methylenedianiline (MOCA)
231-901-9	Arsenic acid
234-329-8	Potassium hydroxyoctaoxodizincatedichromate
246-356-2	Dichromium tris(chromate)
256-418-0	Pentazinc chromate octahydroxide

Included in Annex XIV
Recommended for Annex XIV inclusion 3rd round, Dec 20th 2011
Recommended for Annex XIV inclusion 4th round, Jun 20th 2012

PBTs/vPvBs – a particular challenge

- Benefits (damages) are not possible to estimate
- SEAC has agreed on a preliminary framework using a cost-effectiveness approach
- Costs are be scrutinized, while emissions are used as proxy for benefits
- Hazard/damage properties and monitoring data is expected to be included in the dossiers
- Substances currently ”on the table”: HBCDD (auth), deca-BDE (restr), PFOS/PFAS (restr), D4/D5 (restr)

Conclusions

- Hazard assessment is the starting point for any type of risk management of chemicals, but it is not enough.
- The potential for human and environmental exposure is considered in setting priorities for authorisation.
- Authorisation applications always require a full risk assessment, and also often an impact assessment
- Restriction proposals likewise come with both risk and impact assessments (socio-economic analyses) included
- ECHA's scientific committees evaluates these applications and proposals and give their recommendations

Outlook

- Challenges for the socio-economic analysis are often related to the assessment of benefits
- This in particular applies to substances identified as PBT compounds
- SEA methodology needs to be developed in close collaboration with the scientific community!

Thank you

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The author is Chairman of the Committee for Socio-economic Analysis at the European Chemicals Agency. The views expressed are solely his own and do not represent a position of the Agency.

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