Regulatory impact assessment using socio-economic analysis

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Impact assessment

- Regulatory impact analysis since 1980s (EC impact assessment system 2003)
- Socio-economic analysis (SEA) is a tool to assess impacts:
  - ✓ What are the benefits of a regulatory action?
  - ✓ What are the corresponding costs?
  - ✓ How do benefits and costs compare?

REACH*

- REACH = Regulatory framework for the safe management of chemicals
- Objectives of REACH:
  - ✓ Protect human health and the environment
  - ✓ Promote alternatives to animal testing
  - ✓ Ensure functioning of the internal market
  - ✓ Enhance competitiveness and innovation

* Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the **R**egistration, **E**valuation, Authorisation and Restriction of **Ch**emicals (REACH)

Two REACH processes where socio-economic analysis is instrumental

- 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

Basis for regulatory decisions

- Decision to restrict/authorise the use of substances shall consider:

- ✓ Whether risk to human health and/or environment is adequately controlled
- ✓ Appropriateness of the proposal to reduce/control the risk
- ✓ Socio-economic impact of the proposed restriction/authorisation and availability of alternatives
- ✓ In authorisations: a driver for substitution of SVHC

Socio-economic analysis (SEA) – I.

- Principles of SEA:
  - ✓ input for regulatory decision making
  - ✓ always case-specific
  - ✓ relates to the risk assessment
- Actors (in REACH):
  - ✓ Dossier submitters and applicants prepare the SEA
  - ✓ The Committee for Socio-economic Analysis (SEAC) reviews the SEA
- Where does SEA feed in?
  - ✓ Restriction proposals
  - ✓ Applications for authorisation

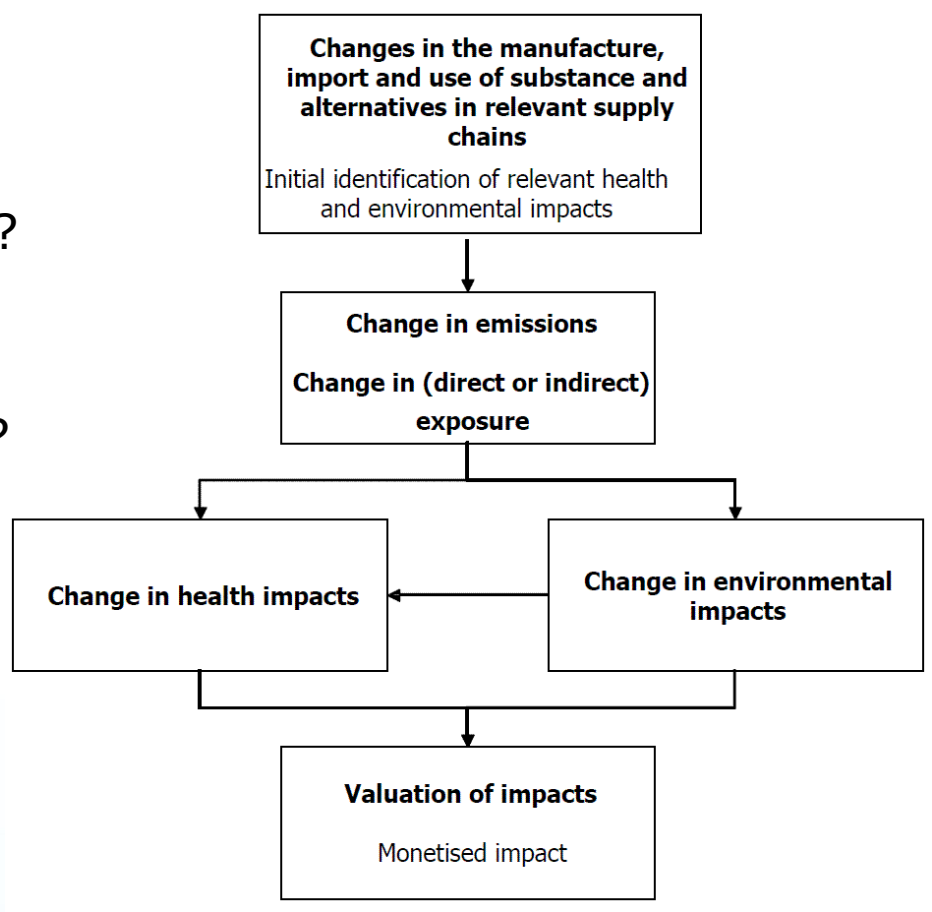
Socio-economic analysis (SEA) – II.

- Aims and scope:
  - ✓ Compare different impacts qualitatively or quantitatively (in money terms)
  - ✓ Compare distribution of impacts
  - ✓ Conduct uncertainty analysis
- Types of impact:
  - ✓ Human health and environmental impacts
  - ✓ Economic impacts
  - ✓ Social impacts
  - ✓ Trade, competition and economic development impacts

From hazard to risk to impact to value

- Four basic steps:

1. Hazard assessment: is there a potential for an adverse health and or environmental outcome?
2. Risk assessment: who/what would be negatively affected from the use of this substance?
3. Impact assessment: what are the expected impacts on health, environment & society?
4. Valuation: what values does society attach to the different impacts?



Comparison with EFSA's risk-benefit assessment paradigm

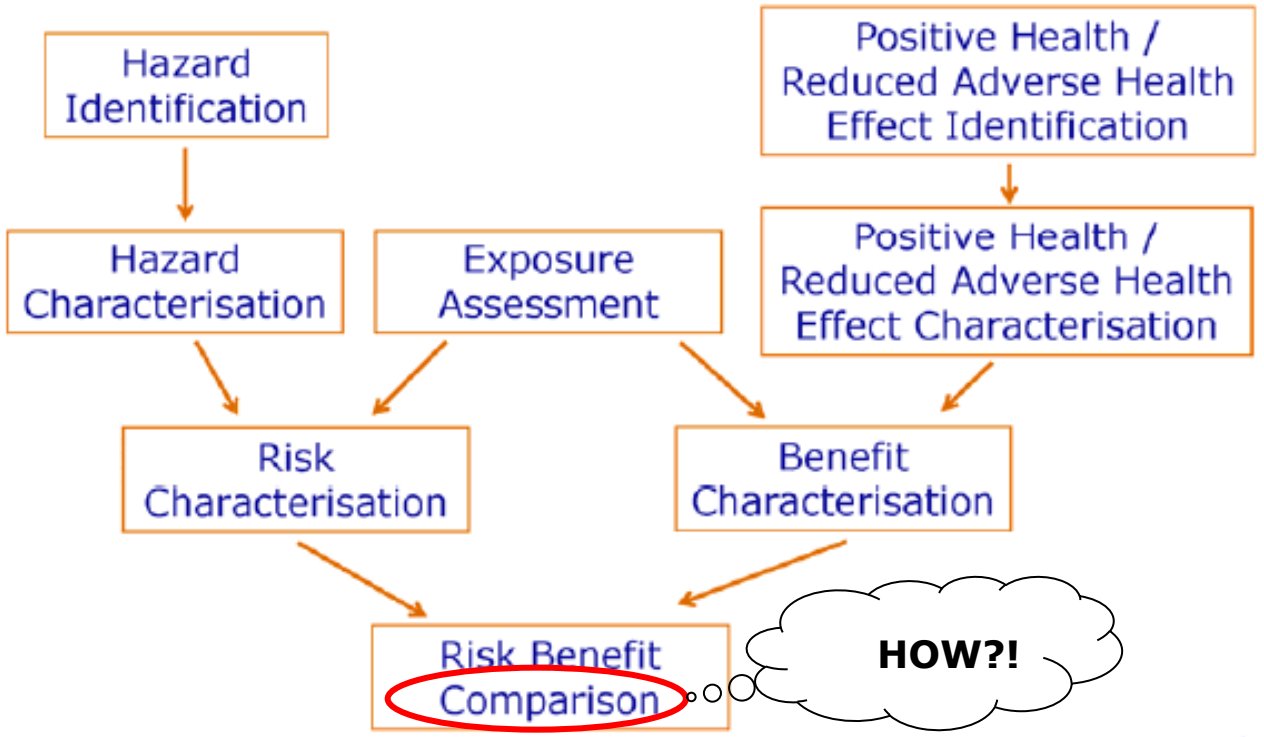


Figure 1: The risk-benefit assessment paradigm, as recommended by the EFSA Scientific Committee and based on the discussions of the EFSA scientific colloquium on risk-benefit analysis of foods[4].

Key difference: valuing impacts

- SEA under REACH seeks to value impacts whenever possible
- Tangible impacts monetised based on market prices
- Intangible impacts monetised based on the concept of WTP: how much is society willing to spend on reducing/avoiding a specific impact?
- Impacts that occur in the future are discounted to reflect preferences of both current and future generations

Using money as common denominator

- Pro's:
  - ✓ yields common denominator for balancing different impacts
  - ✓ facilitates transparency: figures can be challenged
  - ✓ helps spotting inequity in the distribution of risk
- Con's:
  - ✓ adds another layer of uncertainty
  - ✓ might trigger resistance based on moral grounds
  - ✓ reduces "flexibility" for the policymaker

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

Specific considerations

- Industry usually have relevant information about costs and feasibility of alternatives
- Asymmetric information: when preparing (assessing) restriction dossiers MS/ECHA rely on industry information
- Benefits generally difficult to quantify due to externalities and public good characteristics
- Acceptability of discounting is often an issue
- Risks of alternatives are less well-known

General conclusions

- Knowing the risk is not enough
- Potential harms need to be quantified AND
- …compared to all the benefits society gets from using the substance
- Balancing regulatory impacts requires that they be measured in one common unit
- Money lends itself as that unit, but other metrics are conceivable as well…

Outlook

- Socio-economic analysis is challenging.
- There is room for improvement: SEA methodology to be refined in close collaboration with the scientific community.
- But overall, SEA under REACH works and gives a balanced view on the various impacts of regulatory actions.
- Would other regulatory areas in the EU also benefit from a scientific view on the impacts?

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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