

Benefit-Cost Analysis in Chemicals Regulation in the EU

The role of BCA in regulatory decisions

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- Legal basis for socio-economic analysis (SEA)
 - CBA, CEA, compliance cost, Multi-criteria, impact assessment
 - linked to the technical and economic feasibility of alternatives
- Guidance
- Practice
- State of play
- Contributions from Academics
- Key points



- REACH Regulation refers to "socio-economic analysis" in two cases SVHC
 1. Applications for Authorising the use of a substance that is on Annex XIV
 2. Restricting manufacturing, placing on the market or use of a substance
- Socio-economic analysis is defined in Annex XVI – Guidance documents on SEA in Restrictions and Applications for authorisation bring (process) clarity
- ECHA's Committees for Socio-economic Analysis (and Risk Assessment) give opinions
- The Commission decides (in comitology) with Member States on restrictions or if authorisation should be granted.
- Commission's Impact Assessment system applies (REACH SEA complements)
- Article 191 (3) of Treaty on the Functioning of the EU: *"In preparing its policy on the environment, the Union shall take account of... the potential benefits and costs of action or lack of action"*

Legal reasons for conducting SEA in restrictions

1. Member States **may** prepare an SEA

- *“The socio-economic impacts of the proposed restriction may be analysed with reference to Annex XVI. To this end, the net benefits to human health and the environment of the proposed restriction may be compared to its net costs to manufacturers, importers, downstream users, distributors, consumers and society as a whole. (Annex XV)*

2. ECHA **shall** formulate an opinion

- *“Any [...] decision [of restriction proposal] shall take into account the socio-economic impact of the restriction, including the availability of alternatives.” (Article 68(1))*
- Without SEA difficult for the Committee for Socio-economic Analysis (SEAC) to give an opinion whether restriction is justified
 - “SEAC shall formulate an opinion on the suggested restrictions, based on its consideration of the relevant parts of the dossier and the socio-economic impact”. (Article 71(1))
 - “SEAC [...] shall be responsible for preparing the opinion of the Agency on ... proposals for restrictions... relating to the socio-economic impact of possible legislative action on substances” (Article 76(1)d)

Legal reasons to conduct SEA in Authorisation applications (Article 60(4))

- European Commission **needs** this information
"... authorisation may only be granted if it is shown that socio-economic benefits outweigh the risk"
- ECHA Committees **shall** formulate their draft opinions within 10 months (Art 64(1))
" The draft opinions shall include... "an assessment of the socio-economic factors and the availability, suitability and technical feasibility of alternatives..." (Art 64(4)(b))
- Note: it is possible to apply without SEA if the risks are considered "adequately controlled" (i.e. below a given threshold)

What can be included in SEA

(Annex XVI)

1. Impact on business

- eg. investment and operating costs, R&D

2. Impacts on consumers

- eg. product prices and quality

3. Social implications

- eg. employment

4. (Economic) analysis of alternative substances and/or technologies

5. Trade, competition and economic development implications

- ECHA shall prepare guidance for preparing SEA, including the format
- Effectiveness and costs of alternative risk management measures

1. Environmental benefits

2. Health benefits

3. Social benefits

4. Economic benefits

Guidance

- Guidance on SEA for Restrictions and AfA
 - http://echa.europa.eu/documents/10162/13641/sea_restrictions_en.pdf
 - http://echa.europa.eu/documents/10162/13576/appendix1-calculation_compliance_costs_case_restrictions_en.pdf
 - http://echa.europa.eu/documents/10162/13643/sea_authorisation_en.pdf
- Values of human health endpoints (very recent!)
 - Skin and respiratory sensitisation and dose toxicity
 - Fertility and developmental toxicity
 - Carcinogens
- "If nothing helps, read the manual" syndrome
- ECHA and its committees have established how they will evaluate applications for authorisation
 - Dose-response functions for Annex XIV substances ---> **CBA easy**
 - Economic feasibility
 - Proportionality

- Companies & regulators, have very few economists who know regulatory impact assessment/SEA/BCA
- (Over?) reliance on consultants
Who do not know the specifics of the clients' needs
- Different regulatory traditions in Member States (eg. UK and Sweden have often made Impact Assessments), many others less so.
- SEAC members have various experience in economics
- Not established what is a "fit-for-purpose", good assessment.

Examples

- The use of phthalate DEHP requires an authorisation
 - FAZ, Deza and Arkema have applied to be granted an authorisation for “Industrial use of DEHP in polymer processing by calendaring, spread coating, extrusion, injection moulding to produce PVC articles”
- Restriction of dichlorobenzene
 - Based on the request of the European Commission, ECHA prepared proposal to restrict the placing on the market and use of dichlorobenzene in air fresheners and toilet blocks.

- Since 2008, 17 restriction proposals made
1 had no cost estimates, 3 compliance costs, 7 CEA and 6 CBA
- Since 2013, 20 applications received for 55 uses
1 had no cost estimates, 10 compliance costs, 0 CEA and 44 CBA
- All published on ECHA's website
 - Restrictions <http://echa.europa.eu/web/guest/previous-consultations-on-restriction-proposals>
 - Applications <http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations>
- Quality varies naturally
- In 2015-16 (perhaps 100 chromate applications)

Contributions from academics in chemicals

- CBA framework works in the context of impact assessment
 - Sometimes "full" CBA, sometimes CEA, sometimes Compliance cost analysis , sometimes purely qualitative assessment
- But externalities/Coase Theorem does not work for chemicals
 - Often the negative externality is actually the reason why you want to use the substance – tradeoffs become harder to analyse
 - E.g. i) persistency (in PFOS) is what you want (Teflon) ii) a pesticide has to be toxic (enough)
- Calculating costs is neglected (apart from discount rates)
 - Not academically interesting ?
 - In practice often the reason why you can or cannot take action

Key points

- Legal and regulatory requirements
 - Legal requirement (of the Treaty) for environmental regulation
 - Impact assessment (of the European Commission)
 - Specific requirements (in restrictions and applications for authorisation) in the REACH Regulation
- Cost-benefit and -effectiveness and compliance cost analysis made
 - Varying quality -- A lot of applied work on ECHA's website
 - **Someone(s) could review this extensive**
 - Is the problem in ignorance (not having guidance) or in skills (not having enough people having practical knowledge)?
 - Network of REACH Socio-economic Analysis and Analysis of Alternatives Practitioners (NeRSAP) created to apply CBA better, see <http://echa.europa.eu/support/socio-economic-analysis-in-reach/network-of-reach-sea-and-analysis-of-alternatives-practitioners>
- Academics uninterested in costs. Why? No research challenge?
- CBA is used more extensively in the US vs the EU
 - Is environmental and health regulation better or more optimal in the US?
 - Or is there analysis paralysis?

Thank You.

Link to Socio-economic Analysis web-site

<http://echa.europa.eu/web/guest/support/socio-economic-analysis-in-reach>