What to consider in risk reduction

Workshop on Risk reduction
Brasilia 18-19 October 2018

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Prioritisation of substances for risk reduction

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First priority

Implementing obligations in ratified global conventions and agreements

- Need to be adopted legally, by the legislator body, such as the Parliament or Congress
- Necessary to allow for future amendments to be implemented
- Coherent with the aim of the agreement and the country's constitution and legal framework
- Time limits for implementation often included in the agreement

Stockholm, Minamata contains bans and cessation of use.

Rotterdam, prior informed consent for export and import Basel is dealing with trade in hazardous waste between countries

but these need to be legally implemented as well.

Starting point for prioritisation

- Apply the precautionary approach and try to identify potential problematic substances before they have caused any damage.
  - A systematic approach would build on the prioritisation of substances that due to their assumed hazards or use patterns are likely to give rise to risks that need to be eliminated or at least reduced to an acceptable level.
  - A National Chemicals policy could help
    - Contributes to transparency, clarity and certainty for industry
  - However, if cases of pollution or poisoning occur, such risks need to be dealt with a high priority

Prioritisation based solely on hazard

- Substances with inherent properties giving risk to very severe or irreversible effects
  - PBTs
  - vPvBs
  - CMRs (1A and 1B) especially those with a non-threshold effect
  - Giving rise to other severe and irreversible effects
- In line with SAICM objectives for risk reduction
- Example EU SVHC - Candidate list

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Prioritisation based on potential risk – risk assessment needed

- Risk assessment need both information on hazard and use of the substance as a basis
- Authorities need to consider prioritise risk reduction if there is a great number of producers/importers/users which gives rise to many different sources or if
- If a group of substances has a similar structure and mode of action and the end – point for effect are the same

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What to take into account for prioritisation

- Degree of severe inherent properties
- Exposure
  - volume of the substance produced and/or used, including import as a proxy for potential exposure and/or
  - Use pattern
    - The Substance/product is likely to be used by a vulnerable group of people
  - Wide-spread and or well-known exposure from, monitoring or surveillance
    - Includes a large number of producers/users or
    - the chemical is available to the general public
- Need to be based on available data, simplest method is volume of the substance on the market
- Not having detailed exposure data should not prevent authorities making an estimate of the likelihood that the use of this substance entail a risk

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Sources of information for prioritisation

- Known adverse effects of a substance in the country
- Work done or ongoing in other countries
  - Restrictions
  - Proposals for restrictions or authorisations (Candidate lists)
- Rotterdam Convention Annex III and the corresponding DGDs
- Look into notified substances to the RC
- GHS classification
- Use hazard assessments available
- Assess the exposure in the country
  - Register, surveys, questionnaires
- Compare the exposures to see if the risk assessment is relevant for using in your country

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Prioritisation

Weigh all information together before final decision of prioritisation!

Precaution should be applied if there are threats of serious or irreversible damage!

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Choice of instruments

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Risk reduction is deemed necessary

- **What** risk reduction is to be achieved?
- **Who** needs to take measures
- **How** might the risk be managed
- **When** should a specific instrument be used in relation to use of another instruments etc

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Which instrument to choose?

- If a **high hazard**, measures might be taken without a full risk assessment – **a total Ban** might be most relevant
  - CMRs, PBTs, vPvBs especially in products available to the general public
- Where is the exposure the highest?
- What is giving rise to the exposure?
  - Emissions?
    - Point source or many different sources?
      - Use BAT and BEP
  - General use?
  - Waste stage?

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Which instrument to choose?

Factors to take into account when considering the most appropriate instrument:

- Degree of hazard and risk
- Efficiency
- Sustainability over time
- Cost and benefits for different actors – socioeconomic consequences
- Administrative burden including enforceability

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Which instrument to choose?

Final considerations:

- Important to assess of the chosen/proposed instrument is reducing the risk to an acceptable level.
- Can a combination of instruments reduce the risk more efficiently or speed up the reduction of the risk?

Remember transparency and dialogues improves the effectiveness of the risk reduction!

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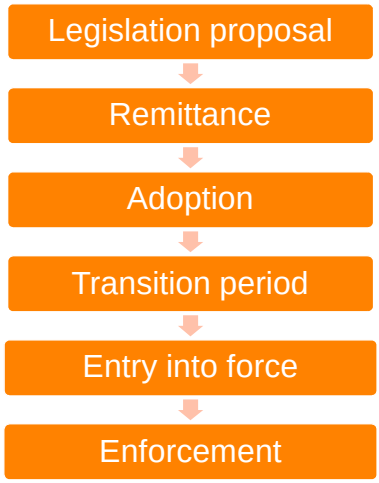
Regulatory decision-making



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Decision making

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Legal clarity

To introduce risk reduction measures there is a need that

- The basic legislation is clear, explicit and consistent in terms of at what level and by whom a decision can be taken – clear mandates for all levels of decisions:
  - Decision on the general policy
  - Decision on basic legislation, roles, responsibilities, GHS requirements
  - Decision on choice of chemicals for hazard/risk assessments based on
  - Decision on whether to continue with development of proposals
  - Decision on risk reduction measures

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Socio-economic assessment and Regulatory Impact Assessments

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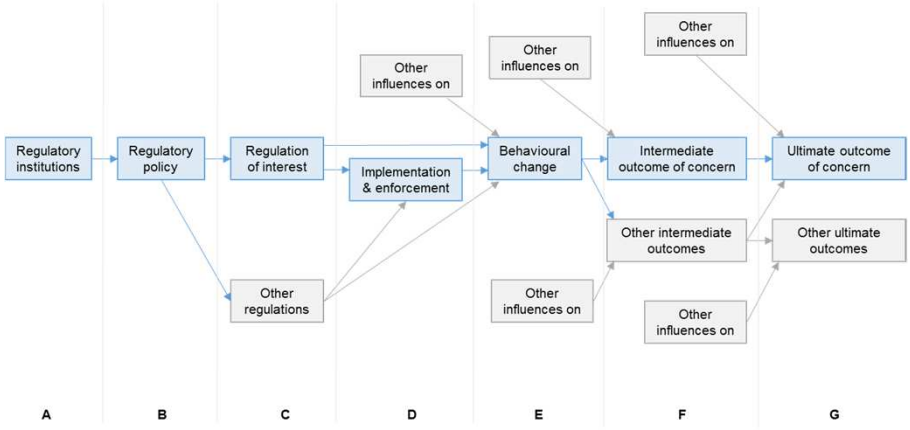
A causal map of regulation and its effects



Adapted from Coglianese, 2012. *Measuring Regulatory Performance - Evaluating the impact of regulation and regulatory policy,* OECD.

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What is environmental cost-benefit analysis

Environmental cost-benefit analysis

Costs
Reductions in human well-being

+

Benefits
Increases in human well-being

Aggregate environmental and social impacts
Across different people within a given geographical boundary

Taking into account

Monetisation + Different points in time

After: www.oecd.org/environment/cost-benefit-analysis-and-the-environment

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EU better regulation agenda and impact assessments

- Key part of the Commission's better regulation agenda
  - Design/evaluate EU policies and laws so that they achieve their objectives in the most efficient and effective way
- IA report must include a description of:
  - the environmental, social and economic impacts
  - who will be affected by the initiative and how
  - the consultation strategy and the results obtained from it
- IA reports are
  - published
  - sent to the EU law-makers, to consider as they decide on whether to adopt the proposed law
- INFORM decision-making, does not replace it

All aspects

Transparent

Questions an impact assessment should answer (EU)

1. What is the problem and why is it a problem?
2. Why should the EU act?
3. What should be achieved?
4. What are the various options to achieve the objectives?
5. What are their economic, social and environmental impacts and who will be affected?
6. How do the different options compare (effectiveness, efficiency, and coherence)?
7. How will monitoring and subsequent retrospective evalaution be organised?

Iterative process

Regulatory impact assessment

- Scale varies!
  - Impact assessment of REACH-regulation estimated costs to chemical industry and downstream users
    - Several BILLIONS of EUR
  - Cost for producers and sellers of a restriction – Cadmium in jewellery
    - Some millions of EUR over 20 years

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Socio-economic analysis in REACH

- Authorisation
  - Granting an authorisation if no safe levle (e.g. PBT/vPvB, some Carc)
  - *'an authorisation may only be granted if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies*'
- Restriction
  - Member states proposing a restriction have to show that it will reduce the risks to an acceptable level at a cost which is proportionate to the avoided risk

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Concluding remarks on impact assessments

- Socio-economic impact assessments make the trade-offs inherent in risk management policy explicit
- Not possible to get a complete description of the impacts
- The aspects judged to be the most important ones should be prioritized
- The assessment has to be ”tailor-made” to specific aspects of a certain risk management problem
- Lack of data is often a constraint