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# Guidance Fact Sheet

## SOCIO-ECONOMIC ANALYSIS – RESTRICTIONS

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# Guidance on socio-economic analysis – restrictions

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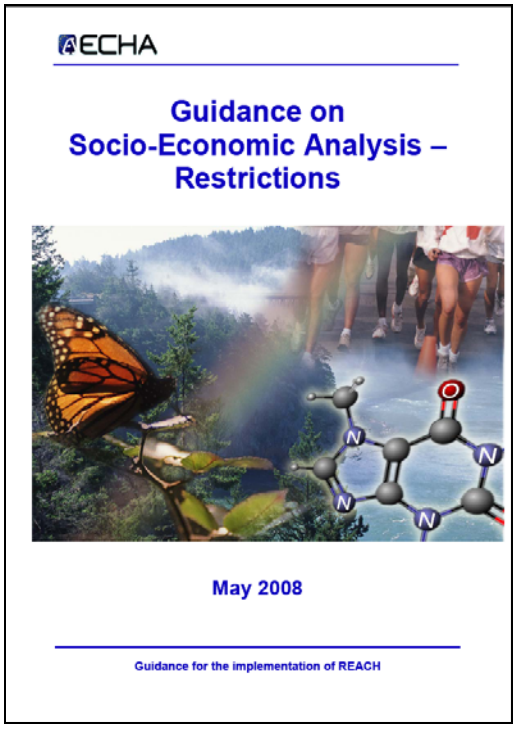

## WHO SHOULD READ THE GUIDANCE DOCUMENT?

The Guidance on socio-economic analysis – restrictions is aimed at those intending to undertake a socio-economic analysis (SEA) as part of a restriction proposal or at those giving comments on the restriction proposal at a later stage. Therefore, it is specifically addressed to:

- Member State Competent Authorities;
- The European Chemicals Agency;
- Interested parties – who are either submitting a SEA or information which can contribute to one.

The guidance is also a reference document for the Agency's Committees for Socio-Economic Analysis (SEAC) and Risk Assessment (RAC), as the guidance aims to describe good practice.

The guidance may also assist the Commission when it prepares a proposal for a decision on the inclusion of a substance on Annex XVII (Restrictions) of the REACH Regulation.

## WHAT IS THIS GUIDANCE ABOUT?

This guidance provides technical advise on how to undertake socio-economic analysis as part of a proposal to restrict the manufacturing, placing on the market and/or use of a substance in accordance with Article 69 of the REACH Regulation. Those using this guidance should be familiar with the restriction process, including the "Guidance on Annex XV for restrictions".

Socio-economic analysis is used:

- to describe and analyse socio-economic impacts of imposing a restriction compared to continued use, referred often to a "baseline" where no new risk management options (RMO) or restrictions are introduced;
- to assess whether the proposed Community-wide restriction is the most appropriate action as compared to other RMOs;
- to provide supporting information on several sections of a restriction proposal;
- in decision making.

Within the restriction process (decribed in Title VIII of the REACH Regulation) socio-economic impacts of the proposed restriction may be analysed according to Annex XVI (Socio-economic analysis). However, a significant amount of socio-economic information is also required in other parts of the restriction proposal. This includes e.g. health and/or environmental impacts as well as the costs of a restriction.

The Agency will make proposals for restrictions available on its website. It will invite interested parties to submit comments on dossiers and the suggested restrictions and/or the SEA or information which can contribute to a SEA within 6 months. These comments will be taken into account in the adoption of an opinion on the suggested restrictions by SEAC and RAC.

The SEA facilitates a systematic and comprehensive comparison of the different risk management options and/or of the relevant costs/benefits of the conditions of the proposed restriction compared to the baseline. Therefore, it is advisable to make the SEA as an integral part of a restriction proposal.

The guidance covers the use of the SEA approach and information for four purposes:

1. Justification that Community-wide action is required;
2. Assessing whether the proposed restriction is the most appropriate Community-wide action compared to other risk management options;
3. Refining the scope, timeline and conditions of the proposed restriction;
4. Assessing the proposed restriction in terms of net benefits to human health and/or the environment and the net costs to the actors affected and society as a whole.

The guidance focuses on purposes 2, 3 and 4. It also addresses how SEA can be

used to compare one or more RMOs/restriction proposals against the baseline.

The guidance makes some suggestions on how to undertake the SEA:

- It recommends undertaking an SEA as an iterative process: to start with a qualitative assessment based on readily available data and then – in additional iterations – to provide more detail. Where applicable, a more quantitative assessment should be undertaken until all key impacts are covered in a sufficiently robust way to draw a conclusion.
- It suggests that the SEA be undertaken in 5 stages:
  - **Stage 1** is the setting of the aims of the SEA. This is to answer the question: Why is the SEA or input to one being developed?
  - **Stage 2** is the scoping phase, to define what economic and other responses and changes will occur as a result of the proposed restriction. A key question to answer is: How will actors in the relevant supply chain react if they are subjected to the proposed restriction?
  - **Stage 3** involves the identification and assessment of impacts. The aim is to answer the question: What are the impacts of the "proposed restriction" compared to the "baseline" scenario?
  - **Stage 4** focuses on interpreting the impacts identified and assessed in stages 2 and 3. It is about bringing the information on different impacts together and undertaking an uncertainty analysis to test the robustness of the SEA. Based on the assessment and the uncertainty analysis, it can be decided to either conclude the SEA or undertake more analysis by reverting back to stage 2 or 3.
  - **Stage 5** is the final stage. In this stage the main findings and results of the analysis are summarised. It is important to present all data in a systematic and transparent way in order to aid the decision-making process. The outputs of this stage are the SEA related sections in the overall restriction proposal. The Agency has issued a separate reporting format for this.
- Uncertainties can arise during the SEA process and they need to be:
  - considered throughout the process;
  - minimised where possible;
  - assessed for their importance with respect to the outcome of the SEA;
  - documented.

## HOW TO READ THIS GUIDANCE?

Chapter 1 is an introduction to the guidance and also describes stage 1 of the SEA, setting the aims of the SEA.

Chapter 2 describes stage 2 of the SEA process which is the scoping phase.

Chapter 3 describes stage 3 of the SEA process on identifying and assessing impacts.

Chapter 4 describes stage 4 of the SEA process on interpretation and conclusion drawing.

Chapter 5 describes stage 5 of the SEA process on presenting the results.

There are several appendices attached to the guidance with practical examples:

- Appendix A describes the consultation process during the preparation of the restriction proposal;
- Appendix B on estimating impacts (economic, social);
- Appendix C on valuation techniques;
- Appendix D on discounting;
- Appendix E describes uncertainty analysis techniques;
- Appendix F describes socio-economic assessment tools;
- Appendix G provides initial checklists on identification of impacts.

## KEY ASPECTS

**Socio-Economic Analysis (SEA)**
An approach to analysing all relevant impacts in socio-economic terms (i.e. both negative and positive changes) of imposing a restriction compared to the continued use (i.e. the baseline). Relevant impacts include human health, environment, economic and social.

**Restriction**
Restriction is "any condition for or prohibition of the manufacture, use or placing on the market of a substance". The substances restricted under REACH and the conditions of their restrictions are included in Annex XVII of the REACH Regulation. The restriction procedure is a safety net to address unacceptable risks to human health and/or the environment, arising from the manufacture, use or placing on the market of substances, which need to be addressed on a Community-wide basis.

**Risk Management Option (RMO)**
RMOs include any possible changes to legislation or other requirements on industry (e.g. permits) to control identified risks. RMOs may also cover the use of economic instruments and industry's voluntary commitments. A restriction is one type of RMO.

**Baseline scenario**
This means the continued use without the introduction of any new RMO or restriction.

**Proposed restriction scenario**
The likely responses and outcomes of a proposed restriction. It should be noted that there are RMOs that are not restrictions. (See RMOs)

**Interested party**
Any organisation, individual, authority or company – other than the Member State Competent Authority that prepared the Annex XV dossier – with a potential interest in submitting SEA information on the proposed restriction.

## LINKS TO RELATED MATERIAL

REACH Regulation EC No 1907/2006
REACH Guidance website is a single point of access to general and detailed technical guidance on REACH.
Guidance on Annex XV for restrictions, which should be read in parallel to this guidance.
Formats for the Authorities is a website including the most up-to-date reporting format for Annex XV restriction proposal.
REACH Guidance Fact Sheets and Frequently Asked Questions (FAQs) can be found in the REACH section of the ECHA website.

## BIBLIOGRAPHIC INFORMATION OF THE GUIDANCE DOCUMENT

**Guidance on socio-economic analysis – restrictions** can be downloaded from the ECHA website.

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