Socio-economic analysis and REACH

Introduction

Socio-economic analysis (SEA), in the context of REACH, is an approach or tool used in a decision making process to describe and analyse all relevant impacts (both positive and negative) of:

- granting an authorisation as compared to refusing the applicant such permission;
- imposing a restriction as compared to continued use.

The overall aim is to analyse and document whether the socio-economic benefits of continued use of a substance outweigh the risks of continued use for human health and the environment. In the case of restriction, SEA can also facilitate an assessment of whether the proposed Community-wide restriction is the most appropriate action as compared to other risk management options (RMOs).

Obligations under REACH

In accordance with Article 62 (5)(a), Applications for authorisations and Article 69 (6)(b) Preparation of a proposal for restriction, a SEA can be conducted.

Applications for authorisations

An application for Authorisation for specific uses of a substance included in Annex XIV takes one of two approaches: 'socio-economic route' or the 'adequate control route'.

1. Socio-economic route

Under the socio-economic route, the socio-economic benefits of using the substance need to outweigh the risks and there are no suitable alternative substances or technologies. If suitable alternatives are available in the EU but these are not feasible for the applicant, an authorisation might still be granted providing the applicant submits a credible substitution plan (further information here).

This route requires the completion and submission of a SEA and will apply to applications for authorisations for Annex XIV substances that are:

- PBT, vPvB, non-threshold CMRs or non-threshold substances of equivalent concern, or
- CMRs and substances of equivalent concern that do have an effect threshold, but where it is not possible to reduce exposure below these threshold levels.

REACH defines that such substances cannot be 'adequately controlled' in accordance with Annex I (Section 6.4).

2. Adequate control route

Under this approach an authorisation will only be granted if the applicant can demonstrate that there are no alternatives to the Annex XIV substance or there are suitable alternatives to the Annex XIV substance for which a substitution plan is provided ensuring adequate control of associated risks.

This route requires the applicant to update their registration dossier (where applicable) and SDS under Article 31 (9), and to prepare (or update) a CSR and submit it as part of the application for authorisation. It is relevant for authorisation applications for Annex XIV substances that are CMRs for which a threshold can be established (DNEL) and substances of equivalent level of concern for which a threshold can be established such as DNEL or PNEC and where the implemented and recommended Exposure Scenarios can be demonstrated to control risks below these levels.

If the analysis shows that there are suitable alternatives available, then the applicant must prepare and submit a substitution plan which details how and in what timetable the applicant will conduct the transferral to the substitute. An SEA is not mandatory for applications that follow the adequate control route, but is strongly recommended to support the authorisation application.

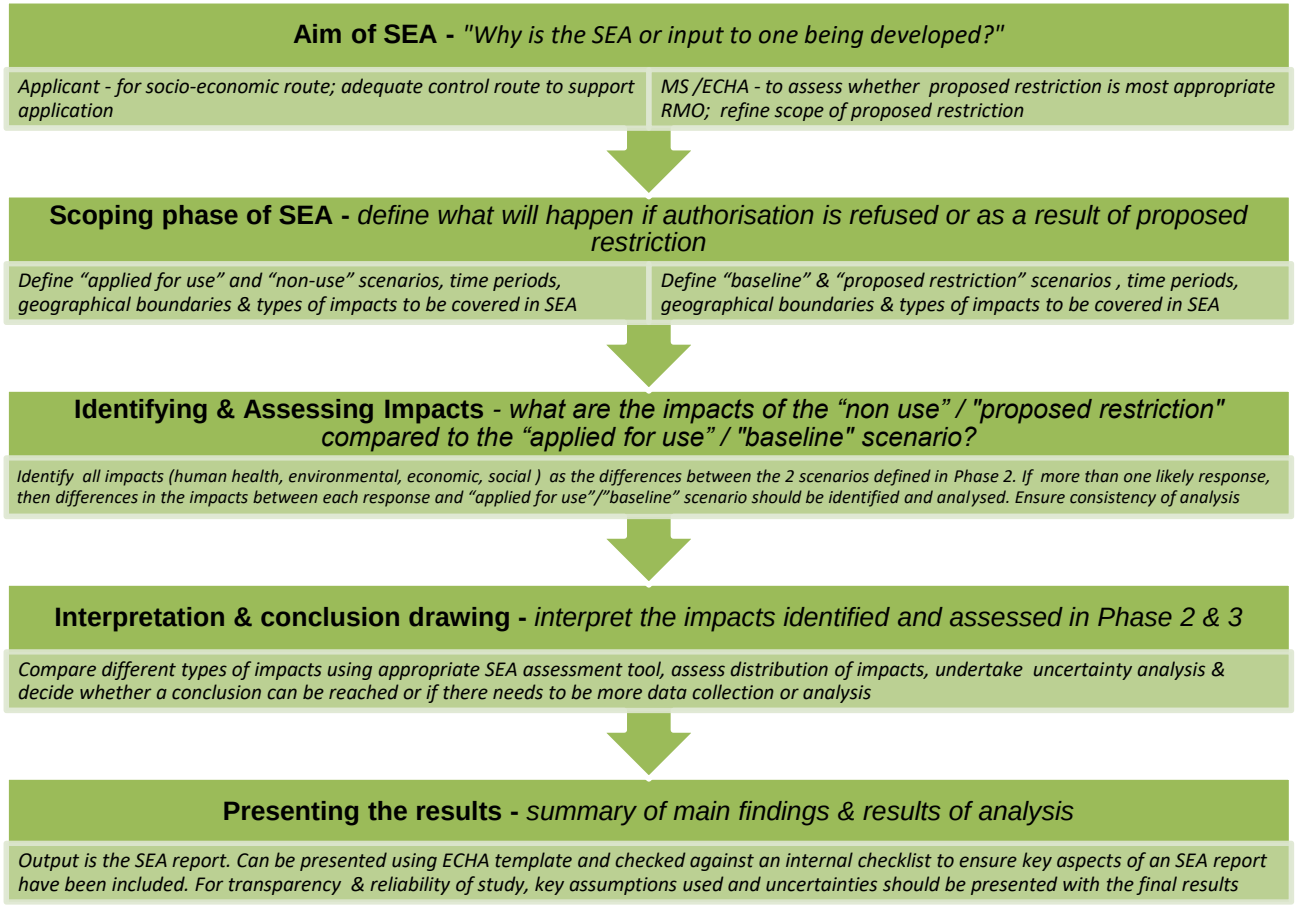
Preparation of a proposal for restriction

Under the restriction process according to Title VIII, an SEA report may form part of an Annex XV dossier proposing restriction of a substance. This dossier is submitted by a Member State or ECHA, the latter following a request from the European Commission and is performed when an opinion needs to be given on a proposal to restrict the use of a chemical substance.

ECHA will invite interested parties to submit comments on a SEA within six months of the date of publication of the restriction proposal on their website. The information gathered will be considered in the adoption of an opinion on the suggested restrictions by the Agency's Committees for Socio-economic Analysis (SEAC) and Risk Assessment (RAC).

SEA Process

The SEA process can be simplified into a five phased approach, shown on the following page.



Data requirement for an SEA

This section summarises some of the questions that needs to be answered to produce a robust, scientifically sound SEA. Further information and methodologies are detailed on ECHA's website (for links please see the SEA Report section on page 4).

Phase		Data requirement
Scoping phase		Most, if not all, of the information required should already have been collected during the development of the Annex XV dossier
Identifying and assessing Impacts	human health impacts	Are there any changes in risks to workers and consumers health associated with using the substance or known substitute? Are there any changes to public health and safety risks? If there are any changes in the process used, would these changes have an impact on worker and consumer health and safety? Are there any significant changes in emissions to air, water, land and/or any significant changes in raw material usage, which could have potential implications for human health? Are there any other risks/impacts that need to be considered?
	environmental impacts	Are there any changes in risks in water, air and soil quality, biodiversity, and land use which may affect the environment? Are there any changes in risks to the emission of ozone depleting substances and greenhouse gases into the atmosphere? Are there any changes in demand/usage of renewable resources or changes to rate of demand/usage of non-renewable resources? Are there any changes to waste production or how waste is treated, disposed of or recycled? Are there any changes in the risks to the likelihood of the prevention of fire, explosives, breakdowns, accidents and accidental emissions? Any changes risks to the likelihood of natural disasters? Are there any changes to mobility (transport modes) and the use of energy?

		Are there any changes in the environmental consequences of firms' activities? Are there any changes in risks to animal and plant health, food and/or feed safety? Are there any changes in environmental risks associated with substitutes? Are there any changes in the process used that may have an impact on the environment? Are there any significant changes in emissions to air, water, and land or in raw material usage, which could have potential implications for the environment Are there any other risks/impacts that need to be considered?
	economic impacts	Are there any changes to operating and investment costs, profitability, sales and turnover, administration costs, innovation and research, market price, quality of the final product, employment, monitoring, compliance and enforcement, trend in sales and production, cost associated with substitutes, and performance and product quality associated with substitutes? Are there likely to be any changes in the process used that may have an impact on economic costs and emissions to air, water, land and/or any changes in raw material usage, which could have potential economic costs? Are there any other risks/impacts that need to be considered?
	social impacts	Are there any likely to be changes in employment at an EU level, MS level or outside the EU? Are there any likely to be changes in the type of job occupations, working environment? Are there any likely to be changes to employment to other sectors within the community? Are there any other risks/impacts that need to be considered?
	wider economic impacts	Are there any likely to be changes to competition within the EU and outside the EU? Are there any likely to be changes to international trade and investment flows? Are there any likely to be changes on EU and MS finances? Are there any likely to be changes to the labour market? Are there any other risks/impacts that need to be considered?
Interpretation and conclusion		All data collected from the above can be analysed using SEA assessment tools. Software for these are readily available

SEA Report

The following guidance documents on ECHA website give technical support for undertaking an SEA. It includes information of the overall SEA process, scoping phase, identifying and assessing the impacts of the proposed authorisation or restriction and, interpreting, presenting and documenting the findings.

http://echa.europa.eu/documents/10162/17235/sea_authorisation_en.pdf

http://echa.europa.eu/documents/10162/17233/sea_restrictions_en.pdf

Additional supplemental information is also given on the calculation of costs resulting from restriction of substance under REACH. This focuses of the compliance costs.

http://echa.europa.eu/documents/10162/17087/appendix1calculation__compliance_costs_case_restrictions_en.pdf

It is also very important to consider as well as minimise uncertainties throughout the entire SEA process. These uncertainties should be documented together with any assumptions used during the SEA. The importance of the uncertainties on the outcome of the SEA should be assessed to decide what further collection of information can best reduce these uncertainties.

There is no set level of detail or page requirement for the final SEA report but the summary of the SEA should in general be restricted to no more than 10 pages.

SEA Tools

ECHA's information and data portal for SEA presents a number of sources of data that may be used to prepare a SEA. This is available at https://echa.europa.eu/socio-economic-analysis-in-reach/sea-web-portal

The following tools may be useful for completing the SEA assessment:

- Cost benefit Analysis (CBA) - compares the costs and benefits of each RMO. The analysis may range from one which is mainly qualitative to one which is fully quantitative (and monetised);
- Multi Criteria Analysis (MCA) - structured approach used to determine overall preferences among alternative options, where the options have several types of impacts and/or accomplish several objectives. This method utilizes both quantitative and qualitative data;
- Cost Effectiveness Analysis (CEA) - determines the least cost means of achieving pre-set targets or goals, with these targets defined by government guidelines or legislation. CEA is often defined in terms of finding the minimum cost of meeting a specified physical outcome;
- Compliance cost assessment - focuses on the direct costs associated with the adoption of a particular measure, although it should also identify any savings in costs due to changes in processes;
- Macro-economic modelling - mathematical models that aim to describe the interactions in the economy. They allow for all economic effects including all feedback responses on different markets to be covered in a consistent way.

Examples of SEA can be found on the ECHA website.

Complexities of SEA

Some of the major challenges when developing an SEA include:

- being able to use the information available to identify (and where possible quantify) the impacts that could occur under the "non-use" or "proposed restriction" in a proportionate and robust way;
- determining the different use scenarios or RMOs as these are dependent on the response of relevant actors such as the manufacturers, importers downstream users, consumers as well as suppliers of alternatives. The scenarios should be made up of the likely response for each actor in relevant supply chains;
- Availability and ability to find and use appropriate data for estimating potential impacts. For example, the quantification of damage to populations or ecosystems based on observed effects are not supported scientifically, hence difficulties in assessing ecosystem impacts;
- Project coordination: the team leader should have a thorough understanding of the restriction process, the development of a restriction dossier and the expertise fields covered by the SEA.

It is therefore very important not to underestimate the amount of work required to conduct a SEA, to produce a scientifically accredited report. The SEA assessment requires high levels of expertise.

Do you need help with your SEA?

Through our Matchmaker programme we can help you find trusted suppliers to meet your REACH needs. Our network of approved service providers includes organisations with expertise in socio-economic analysis and experience of authorisation applications.

Contact our Helpdesk on enquirires@reachready.co.uk or +44 (0) 207 901 1444 for more information.