

SEAC's evaluation of qualitative assessments in restriction reports

1. Introduction

This paper gives guidance to SEAC rapporteurs on how to evaluate qualitative assessments of socio-economic impacts (i.e. costs, benefits, and proportionality) in restriction reports. The content is also of relevance for Dossier Submitters, insofar as it establishes what content and level of detail is expected for qualitative impact assessments.

The focus of this paper is on the qualitative assessment of impacts, i.e. situations in which it is not possible or meaningful to monetise impacts expected from a specific regulatory action, but they can still be characterised in words or even compared ordinally. This includes situations where (at least some) quantified information is available, but it is not possible to monetise the impacts. The guidance given in the present paper therefore also applies to methods such as break-even and cost-effectiveness analysis.¹ This is in line with SEAC's approach for PBT/vPvB substances (ECHA, 2016), which requests contextual information to describe the relevance of quantified release estimates. As such, the present paper and SEAC's approach for PBT/vPvB substances are complementary to each other.

Approaches to assess or describe impacts qualitatively can be based on syntheses of evidence, descriptions of meta-analysis, defaults, assumptions, or logical arguments. These approaches draw on available literature or expert judgement/knowledge and feed into methods for carrying out possible options appraisal that collate various types of evidence, such as Weight of Evidence or Multi-Criteria (Decision) Analysis.

SEAC recognises that some level of expert judgement is always required in evaluating impacts qualitatively, either by directly drawing conclusions, or in defining frameworks by which restriction proposals and options are assessed (e.g. scoring criteria and aggregation rules to use).

¹ It also applies to other supporting argumentation that has been used in restriction reports, such as affordability.

2. When does SEAC consider qualitative assessments of impacts justified?

SEAC acknowledges that several types of scientific evidence and knowledge are used by Dossier Submitters in the assessment of impacts to arrive at main conclusions in a restriction report. At the same time, SEAC recognises that Dossier Submitters, when carrying out their assessment, may be constrained regarding the availability of evidence or knowledge about impacts on a Union-wide basis.

SEAC prefers robust quantitative and monetised assessments of costs, benefits, and proportionality, as these elements contribute to coherence and consistency of the assessments and allow for meaningful comparisons across restriction options and cases. In general, cost-benefit analysis is the preferred method because it seeks to compile the most relevant impacts and compare them in the same units and relies on measured preferences (ECHA, 2021). However, if data is not available to quantify or monetise costs or benefits, or is too costly to obtain, a semi-quantitative or qualitative assessment and comparison of impacts can be performed.

SEAC recognises all restriction reports in practice include some combination of qualitative, quantitative, or semi-quantitative assessments, which presents a challenge in drawing conclusions on costs, benefits, and proportionality when integrating different types of assessments.

SEAC expects relevant impacts to be assessed quantitatively or monetarily where this is feasible and proportionate. Where a quantitative assessment is not considered feasible or proportionate by the Dossier Submitter, SEAC considers a qualitative assessment justified. In these cases, SEAC expects Dossier Submitters to clearly document the systematic efforts made towards a quantitative assessment and the reasons why a quantification was ultimately not possible or proportionate. However, the outcome of SEAC's evaluation may be affected by the robustness and conclusiveness of the qualitative assessment.

3. What will SEAC evaluate if presented with restriction reports that include qualitative assessments of impacts?

SEAC evaluates all the information provided in the restriction report. Consequently, the evaluation is always case-specific. In general, SEAC will provide a critical evaluation of the Dossier Submitter's assessments. When Dossier Submitters report qualitatively assessed impacts, SEAC will evaluate the completeness and appropriateness of the assessment focusing on three aspects: A) whether there is **enough and sufficiently transparent information**; B) whether the **qualitative assessment is consistent and transparent**; and C) whether SEAC considers that the **conclusions reached by the Dossier Submitter are justified**.

This evaluation will be based on the following non-exhaustive list of guiding questions:

A) Is there enough and sufficiently transparent information for SEAC to understand how the Dossier Submitter has critically appraised and arrived at a particular conclusion (e.g. about the (non-)relevance or the magnitude of an impact, or about proportionality)?

1. Are all relevant impacts² covered and clearly described, including the type(s) of evidence (data/information/knowledge)³ underpinning the assessment?
2. Has the Dossier Submitter clearly described the reasons for not further assessing impacts – i.e. impacts that are considered to be minor, as they are unlikely to affect the outcome of the socio-economic analysis – and clearly explained the assumptions, available evidence that this conclusion is based on?
3. Are the relevant criteria (e.g. potency of intrinsic properties, severity of effects, exposure characteristics, geographical scale or duration of impacts, reduced service life, reduced functionality) used to characterise the impacts clearly described, including the type(s) of evidence and corresponding sources underpinning the assessment?

² Checklists for potential human health, environmental, economic, social and wider economic impacts are available in Appendix G of ECHA's guidance on socio-economic analysis in restrictions (ECHA, 2008).

³ Available evidence (data/information/knowledge) could emanate from several different sources, e.g. scientific literature, stakeholder interviews and consultations, precedence, principles, consistency arguments, defaults, or expert judgement.

4. If the Dossier Submitter has used arguments such as precedence⁴, principles⁵, consistency⁶, or defaults⁷ to assess impacts, are they clearly described, including the type(s) of evidence and corresponding sources underpinning the assessment?
5. Has the Dossier Submitter screened the impacts for magnitude /significance/importance to the outcome of the socio-economic analysis (e.g. using ordinal scales, such as minor, medium, major impacts)?

B) Is the qualitative assessment transparent and consistent, i.e. is it structured, documented, and traceable, with a clear explanation of the logic used by the Dossier Submitter?

1. Is it clear how the Dossier Submitter performed their expert judgement⁸ and has the expert judgement been used in an appropriate manner, using best practices and accounting for typical biases (e.g. cherry picking⁹, acknowledge dissent/rival framings¹⁰, use of devil's advocate¹¹, over-confidence bias¹², etc.)?¹³
2. Has the Dossier Submitter documented the theoretical or conceptual foundations and assumptions underlying the approach chosen for integrating different impacts (including qualitatively assessed but also any quantitatively assessed or monetised impacts) to arrive at their conclusions (e.g. clearly explaining (causal) criteria,

⁴ Precedence relates to the generalisation of previous decisions or cases. For example: "Due to the targets under the Landfill Directive to reduce landfilling, it is expected that the relative tonnage landfilled instead of incinerated or recycled will decrease over time."

⁵ Principles relate to economic principles and theories. For example: "The Dossier Submitter considers the industry goods to be price elastic/inelastic and that companies can/cannot pass on the possible substitution costs to consumers, thus impacting on consumer surplus in X manner."

⁶ Such as consistency with other regulations or guidance documents. For example: "The proposed 6-month transition period is consistent with the Commission Implementing Regulation EU 2020/1435."

⁷ Defaults reflect typicality arguments and can be regarded as a form of reasoning where plausible conclusions are inferred based on general rules (which may have exceptions). For example: "Currently only two countries in the EU have national measures in place to reduce releases of X substance. The Dossier Submitter concludes that these two national measures are not sufficient to address the risks at the EU level" or "A default X% discount rate is used."

⁸ For examples of processes related to Expert Knowledge Elicitation, see EFSA (2017) or EFSA (2014).

⁹ Confirmation bias (also referred to as cherry picking): where experts/scientists select evidence to support a particular outcome, while ignoring other relevant evidence or disregarding refuting information.

¹⁰ The analysis of rival framings by the Dossier Submitter expert team could contribute to discovering unintended consequences resulting from inherent biases of alternative problem formulations.

¹¹ To play devil's advocate is a process of constructive debate around key decision points. This could be linked to the level of agreement between experts when expressing a level of confidence.

¹² For example, where experts are overconfident that certainty in one aspect of the problem applies to all other aspects as well, or where experts draw inferences from an insufficient data base.

¹³ For further information on important heuristics and biases, see EFSA (2014).

design of a scoring or indexing system, allocation of scores or weights used, or the conceptual model used)?¹⁴

3. Has the Dossier Submitter expressed their level of confidence when estimating the magnitude/significance/importance of the impact or the likelihood of the impact occurring? Confidence could be described, for example, by assessing the quality of available evidence and the level of agreement by the Dossier Submitter expert team, for example, related to the importance of the impact or the likelihood of the impact occurring. Confidence levels could also be expressed using ordinal scales or with subjective probability ranges.¹⁵

C) Does SEAC consider the conclusions reached by the Dossier Submitter to be justified and well-reasoned?

1. Has the Dossier Submitter provided a concise and systematic overview of the key elements feeding into their conclusions (e.g. in the form of a table) and are the conclusions justified given the key elements identified and the logic used?
2. Has the Dossier Submitter attempted to compare (the relative contribution of) all impacts (including qualitatively assessed but also any quantitatively assessed or monetised impacts) in their conclusions of the socio-economic analysis?
3. Has the Dossier Submitter clearly explained and consistently applied the criteria/reasoning used for ranking/deciding between different restriction options, in a manner that is scientifically relevant and robust and that represents the relevant state of the art?¹⁶
4. Is it clear how uncertainty was dealt with and how results and conclusions regarding impacts would be affected by different assumptions (e.g. for impacts taken forward for further assessment, did the Dossier Submitter use scenarios, such as high/low, worst/best case, etc., to reflect higher levels of uncertainty)?¹⁷

¹⁴ See, for example, Linkov et al. (2009) for further details.

¹⁵ For details on confidence levels and use of probability ranges, see ECHA (undated) and EFSA (2017). For example, confidence levels can be expressed as: high (strong); medium (moderate); low (weak) (ECHA, undated) or with subjective probability ranges (see Table 7 of EFSA, 2017). See also IPCC (2014) for a summary related to the use of ordinal scales and subjective probabilities.

¹⁶ Various methods exist for carrying out options appraisal using qualitative or semi-quantitative data, such as a Weight of Evidence approach or Multi-Criteria (Decision) Analysis. SEAC does not prescribe or recommend any particular method of options appraisal; what matters is how well reasoned and documented the assessment is.

¹⁷ Guidance on carrying out uncertainty analysis in restriction reports is available in ECHA (2023).

4. Conclusions

This paper sets out a series of guiding questions which form the basis of SEAC's evaluation of the completeness and appropriateness of qualitative assessments of impacts in restriction reports. As such, the paper also serves to inform Dossier Submitters of SEAC's expectations concerning qualitative assessments of impacts.

To enable SEAC to evaluate the Dossier Submitter's conclusions on the assessment of a restriction option or comparison of restriction options, SEAC expects that the Dossier Submitter has taken into consideration the guiding questions outlined in section 3 and that a restriction report contains at a minimum:

- a description of the assessed impacts;
- an explicit rationale for including the impacts in the assessment;
- an indication of the level of confidence in the assessed impacts, based on the available evidence;
- a description of the approach to integrating the different impacts (including impacts assessed qualitatively, quantitatively, or monetarily), including a transparent description of its conceptual or methodological foundations;
- a discussion that makes apparent the relative importance of the different impacts and their contribution to the overall conclusion of the socio-economic analysis; and
- an indication of the assessment's robustness with respect to plausible changes in the overall structure, parameters and assumptions used, and considering the quality of the underlying information.

References

- ECHA (2023). [Guiding principles for uncertainty analysis in Annex XV Restriction Reports – a proposal based on EFSA's guidance material.](#)
- ECHA (2021). [Scientific basis of conclusions on socio-economic analyses.](#)
- ECHA (2016). [Evaluation of restriction reports and applications for authorisation for PBT and vPvB substances in SEAC.](#)
- ECHA (2008). [Guidance on Socio-Economic Analysis – Restriction.](#)
- ECHA (undated). [Weight of Evidence/Uncertainty in Hazard Assessment – Background Document & Examples.](#)
- EFSA (2017). The principles and methods behind EFSA's Guidance on Uncertainty Analysis in Scientific Assessment. EFSA Journal 2018;16(1):5122, <https://doi.org/10.2903/j.efsa.2018.5122>.
- EFSA (2014). Guidance on Expert Knowledge Elicitation in Food and Feed Safety Risk Assessment. EFSA Journal 2014;12(6):3734, <https://doi.org/10.2903/j.efsa.2014.3734>.
- IPCC (2014). [Climate Change 2014: Synthesis Report. Contribution of Working Groups I, II and III to the Fifth Assessment Report of the Intergovernmental Panel on Climate Change.](#)
- Linkov I, Loney D, Cormier S, Satterstrom FK and Bridges T (2009). Weight-of-evidence evaluation in environmental assessment: Review of qualitative and quantitative approaches. Science of the Total Environment, Volume 407, Issue 19, 5199–5205, <https://doi.org/10.1016/j.scitotenv.2009.05.004>.