Scientific basis of conclusions on socio-economic analyses [1]

1. Introduction

On 30 November 2020, the Commission requested ECHA to modify the opinion format used by SEAC to provide its scientific advice, so as to include an explicit conclusion on whether or not *the applicant has shown* that the socio-economic benefits outweigh the risks to human health or the environment arising from the use of the substance. The language used in the format and the opinions should explicitly clarify the scientific nature, purpose and scope of the advice given. The Commission also requests that—in addition to the assessment and conclusions on the availability and feasibility of alternatives for the applicant—an assessment and conclusion be provided in the opinions on whether safer alternatives are feasible and available in the EU.

Both aspects are addressed in this note, which is intended as background information for the Management Board. The note starts with a short discussion of the 'science of analysis'[2] to give a background for a meaningful interpretation of the Commission's request to "clarify the scientific nature, purpose and scope of the advice given". It then sets out the methods currently used to compare the socio-economic benefits and remaining risks of continued use of substances of concern. Based on these established methods for socio-economic analysis (SEA) certain conclusions can be drawn with regard to both the benefit-risk comparison and the availability of safer alternatives. These are explained in the penultimate sections. All of these reflections will ultimately inform how the SEAC opinion format could/should be revised to satisfy the Commission's request while at the same time preserving the scientific integrity of the Agency and its scientific committees.

2. What is the science of analysis?

While analysis is not a science in the sense of formulating and testing hypotheses, it does rely on scientific results to guide judgements about the plausibility of consequences, calculating their likelihood and assessing the robustness of these estimates. For example, when evaluating the use of a substance of concern, analysts' conclusions on the risks of continued use are informed by research into the consequences of exposure to the substance. Similarly, scientific judgments about the socio-economic benefits of continued use are informed by research into how markets react to the premature retirement of existing production capital. Fischhoff[1] concludes that "exercising scientific judgment when gathering and interpreting evidence is a task faced by both analysts and scientists". There is however an important difference in that analysts apply, but do not produce science. This is particularly relevant for the use of values that were derived through scientific methods (e.g. DNEL or WTP values) but that do incorporate value judgments. Such values are often set in guidance documents or Committee papers. When applying them in the evaluation of applications for authorisation, RAC and SEAC have to presume that these values reflect accepted views and preferences of the decision maker. This should, however, not be interpreted as an endorsement of a specific value, but as a pursuit of regulatory science.

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[1] This background paper was provided for information by the ECHA Secretariat to the 61st meeting of ECHA's Management Board on 25 March 2021, in relation to the discussion about REACH Authorisation opinions. It is reproduced here for transparency and to outline the scientific underpinning of ECHA's opinions on socio-economic aspects of applications for authorisation.

[2] The discussion draws on Fischhoff, *Science* **350**, aaa6516 (2015).

3. What are established methods for comparing benefits and risks?

This section provides a comprehensive overview of established SEA methods. It should be stressed that there is official Guidance on the preparation of socio-economic analysis, which follows established impact assessment methodology as provided by the Better regulation guidelines of the European Commission. Before turning to the actual methods, it seems useful to remind the reader about the manifold impacts that regulating SVHC has. These impacts include in no order of hierarchy and without intending to be exhaustive the following:

- Impacts on human health
- Impacts on the environment
- Impacts on producers (including suppliers, customers and competitors)
- Impacts on consumers
- Wider socio-economic impacts (incl. unemployment, taxes, outsourcing of risks, etc.)
- Distributional impacts

Some of these impacts are relatively straightforward to quantify or even express in money equivalents. Others are more difficult to compare against each other. Often, these differences are substance and use specific. E.g., it is not possible to quantify—let alone monetise—the risks of a substance to which people are exposed close above the DNEL. This is because the concept of DNEL does not reveal anything about excess risk. Nevertheless, there are some methods in the "SEA toolbox" that under certain conditions may guide the analyst still to a conclusion on whether the benefits can plausibly outweigh the risks. In the following these methods will be summarised, emphasising the situations in which they are most useful.

Cost-benefit analysis (CBA)

CBA is the preferred method of impact assessment as it seeks to compile all relevant impacts and compare them in the same unit. Money typically serves as unit of comparison.[3] CBA is well established and documented in many textbooks and official guidance (incl. in the ECHA Guidance on SEA and the Better regulation toolbox). To facilitate the application of CBA in chemicals risk management, various valuation metrics for many relevant impacts are readily available and documented either in the aforementioned guidance or in specific SEAC position papers[4]. Notably, CBA can be modified to account for distributional concerns about income, risk, life expectancy etc. In fact, one can demonstrate that with the correct weights CBA can mimic any social welfare function, be it utilitarian or prioritarian or egalitarian.[5] That means that in theory CBA can be refined to address all the points of criticism typically raised against it by non-economists.

Cost-effectiveness analysis (CEA)

CEA is a method widely used in health economics to evaluate policies/programs that result in benefits to human health. It relates quantified impacts to compliance costs but does not convert these impacts into money equivalents. Instead it relies on benchmark values (in health economics often referred to as "**I**ncremental **C**ost-**E**ffectiveness **R**atio" or ICER) to conclude on whether desirable impacts are large enough compared to costs these impacts would incur. CEA is ECHA's standard approach for PBT/vPvB substances and other substances for which it is currently not possible to quantify the risks and thus determine the benefits of stopping the use of a specific substance. While this method avoids putting a value on risk it still requires an explicit value judgment as to what cost per unit of benefit is acceptable/unacceptable. Again, there is

[3] The widespread repugnance against using money metrics in the evaluation of risks to human health and the environment is based on a common misunderstanding. What makes SEA useful is the possibility to convert changes in multiple dimensions of well-being into changes in a single dimension (the so-called numeraire). However, there is no law in economics dictating that money ought to be this numeraire. Changes in wellbeing could just as well be measured in life-years lost, or consumption equivalents gained, or another metric. The reason why money is typically used relates to the availability of market prices that express how people value different dimensions of life.

[4] See https://echa.europa.eu/fi/applying-for-authorisation/evaluating-applications.

[5] For an overview, see Nurmi & Ahtiainen, *Ecological Economics* **150**, 217 (2018).

no "scientific" answer to that question, but one may use previous regulatory actions as a benchmark.[6]

Break-even analysis (BEA)

BEA is another truncated version of CBA which focuses on the switching point at which results of a CBA are reversed. Based on that one may back-calculate the harm that would have to materialize in order to pass the switching point. The plausibility that the concurrent exposure or emission would lead to the level of harm identified may then be determined by expert judgment. As such this can be a useful method in situations in which risk cannot be quantified (e.g. in case that a DNEL is exceeded) but endpoints are known, and cases can be monetised using WTP values. If the outcome of the BEA suggests that more cases would be needed than people exposed or emissions measured, one may logically conclude that the benefits of the activity outweigh the risks B>R. However, the reverse inference is incorrect because the finding that less cases are needed does not say anything about the likelihood of cases. In the end, the use of BEA requires similar value judgments as CBA.

Compliance-cost analysis (CCA)

According to ECHA SEA Guidance, the CCA consists of the assessment of i) investment and operating costs, ii) changes in production costs, iii) changes in product/service characteristics, and iv) the aggregation of costs as a proxy of producer surplus changes. The obtained compliance cost estimate may then be compared in a qualitative weight of evidence (WoE) analysis against the risks resulting from the use of a substance. This approach is used mainly when risks can only be described in a qualitative way and endpoints are either not known or cannot be monetised. Obviously, the WoE analysis requires expert judgment about etiology—how likely is it that exposure at level A results in B cases of impact X? This likelihood can then be discussed against the compliance costs assessed and it can be qualitatively judged whether the benefits outweigh the risk. However, the scientific basis of such a conclusion rests more on the expertise of the analyst than on other pieces of evidence.

Weight-of-evidence (WoE) analysis

WoE analysis may be used even in the absence of compliance costs. Both the ECHA WoE Guidance and the EFSA WoE Guidance explain that such an analysis combines and weighs information from several sources. The weight given should reflect available evidence such as the quality of data, consistency of results, nature and severity of effects, relevance of information. Clearly, WoE analysis requires scientific judgment and—of utmost importance for the interpretation of its results—an adequate documentation. Specifically, explanations should be given of how the conclusions reached depend on judgment and how they would alter if other judgment was made. This approach is the most subjective one and is applied when neither the risk nor the cost can be quantified with any degree of reliability. In such cases analysts must revert to a fully qualitative analysis of all impacts, requiring expert judgment about etiology as well as about cost implications. Necessarily, the conclusions of such an analysis will not be value free even if a scientific approach has been followed to arrive at them.

Summary

To summarise, the SEA toolbox consists of several methods that may be applied in different circumstances. Each of these methods has its peculiarities. In general, CBA is the preferrable method as it most conclusive and least based on explicit value judgments, i.e. relies most on measured preferences. However, it is also the most demanding method in terms of information requirements. If data is not available to either quantify the risks or the benefits, one may still conclude based on a semi-quantitative or even qualitative comparison of the impacts. However, such comparisons are by their very nature less conclusive, see Figure 1 which shows the trade-off between conclusiveness and explicit value judgement that the analyst faces when deciding whether the socio-economic benefits of continued use of a substance outweigh the corresponding risks.

[6] See Oosterhuis et al., *Integrated Environmental Assessment and Management* **13**, 1100 (2017).

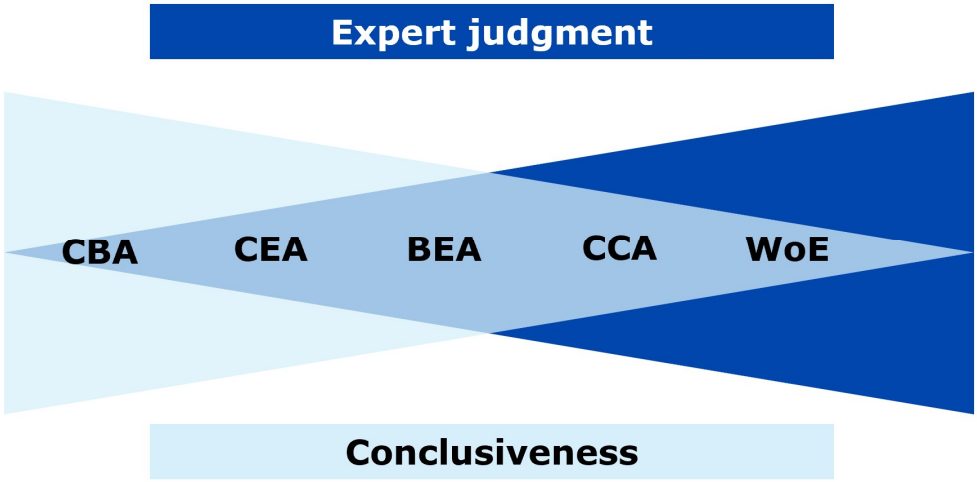

Fig. 1. Trade-off between conclusiveness and explicit value judgment.

4. What conclusions can be drawn based on established SEA methods?

To illustrate the type of conclusions that one can draw based on the SEA methods discussed in Section 3, it seems useful to turn to some stylised examples. Table 1 illustrates the extent to which it is possible to conclude based on each of the discussed SEA methods whether the socio-economic benefits outweigh the risks in the context of an application for authorisation. It should be stressed that these illustrations are exemplary and non-exhaustive.

Table 1. Summary of the scientific basis for making a comparison of benefits and risks.

Type of analysis	Sub-type	Benefit of continued use	Remaining risk of continued use	Scientific basis for comparison
Weight of Evidence		Some positive benefits	Some exposure may remain	Based on expert judgment
Compliance cost analysis		€10 million	Some exposure may remain	Based on expert judgment
Break-even analysis		€10 million	10 workers are exposed to a substance, but risk cannot be established	Possible if a WTP value exists for the endpoint of interest, and one can thus deduce that >10 workers would have to develop in order to outweigh the benefit of €10m
Cost-effectiveness analysis	A	€10 million	5 quality-adjusted life years	Possible if either a monetary value per quality-adjusted life year is used or a €/QALY benchmark is established
	B	€10 million	1 tonne of emissions of substance	Possible if a €/kg benchmark is established
Cost-benefit analysis	A	€10 million	€1 million	Possible if both a dose-response function and a WTP value exist for the reduced risk
	B	€10 million	None (the exposure is under DNEL/PNEC)	Possible if one assumes that no risk occurs below the DNEL/PNEC

5. What can SEAC assess and conclude regarding alternatives?

One aspect that has become increasingly important in the assessment of applications for authorisation is the availability and feasibility of safer alternatives in the EU.[7] It seems helpful to set up a logical hierarchy of alternatives to better understand and embrace the meaning of 'safety', 'availability', 'technical feasibility', 'economic feasibility' and 'economic viability' of alternatives. As can be seen from the Venn diagram in Figure 2, one can generically differentiate different layers in the analysis of alternatives and the question to be addressed now is what can SEAC conclude with regard to each of these layers.[8]

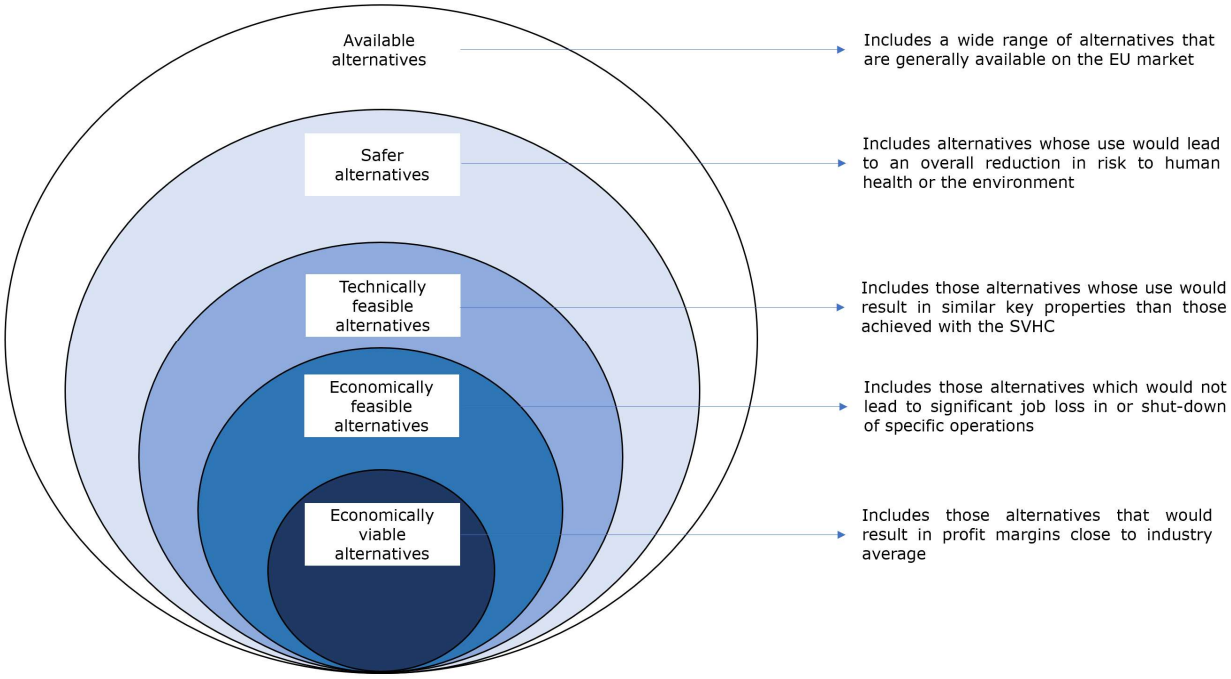

Fig. 2. Venn diagram presenting a logical hierarchy of alternatives.

To answer this question, it is paramount to stress that SEAC has limited capacities for undertaking own research into alternatives (indeed, this is the job of the applicant and SEAC has previously been criticised by the EU Parliament for bolstering applications) and therefore relies on two information sources: the application itself (and any complementary information provided by the applicants or their downstream users in response to questions from the Rapporteurs or comments in the consultation) and the information obtained through the consultation. In most cases, applicants do provide information on alternatives including on their availability and technical feasibility and, in some cases, on their economic feasibility/viability. However, they typically cannot provide information on the safety, i.e. the risks associated with the use of these alternatives, as these depend on operating conditions not (yet) known to the applicants. More generally, applicants seem to have difficulties to carry out comparative hazard assessments and have hence not used them as a formal argument to support their application. One may consider that, as the REACH authorisation process deals with the substitution of SVHC, it is unlikely that many alternatives would be more hazardous.[9]

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[7] In reaction to the ECJ ruling in Case T-837/16, the Commission clarified under which circumstances applicants need to submit a substitution plan if there are alternatives generally available in the EU, see the Commission's note on 'Suitable alternative available in general & Requirement for a substitution plan'.

[8] The Venn diagram is based on the definition of economic feasibility and viability provided by the Commission in a recent draft implementing decision: Comitology Register (europa.eu).

[9] It is important to note though that the use of a substance which is less hazardous but used in a less safe way may result in higher risk (e.g. the use of PERC in outdated equipment may entail larger risks to workers than the use of TCE in state-of-the-art equipment). From this discussion it should also be clear that even if an alternative is resulting in less risk, it may still entail some risk.

For these reasons, it is unlikely that applicants will formally conclude on the safety of alternatives and RAC or SEAC would normally not have to assess such conclusions. Unless the committees are meant to shoulder work for the applicant, it would not seem appropriate to ask RAC to conduct proper comparative hazard assessments and SEAC assess the socio-economic impacts of switching to a safer albeit not entirely safe substance. This would go clearly beyond the evaluation of applications for authorisation. Instead, it seems advisable to continue the case-by-case approach in which applicants discard specific alternatives based on their hazard properties.

As regards technical feasibility, SEAC is often able to conclude whether certain key functionalities are met by an alternative. However, setting acceptable thresholds that need to be attained by an alternative is challenging in cases where no official quality standards (such as CEN or ISO) are available, and applicants simply compare alternatives against the functionalities achieved with the SVHC. In such cases, it is often difficult for SEAC to be conclusive. This problem is more pronounced in broad-use upstream applications, where the applicant or their downstream users supply various sectors, each with their own quality standards. Where these key functionalities are based on matters of taste or aesthetics (e.g. colour tones, feel and touch) SEAC cannot conclude on the societal importance of such SVHC uses as exercising such judgment cannot be science-based.

As for economic feasibility and viability, SEAC is often able to conclude based on the foreseeable investment cost whether an applicant could switch to a particular alternative. However, it is more difficult to conclude on the viability of, i.e. the business case for, switching to that alternative. This can be judged in cases where the applicant provides a substitution plan that details out how they are going to transition to an alternative. However, in cases where applicants claim that it is currently not economically feasible to switch to an alternative, such evidence is either not provided or of hypothetical nature. In general, it can only be concluded that entering an existing market is often challenging. Indeed, compared to incumbents (current users of the alternative), entrants have to 1) invest into the adoption of the alternative, 2) build up knowledge that incumbents already have, 3) secure a customer base as their own customers may not be interested in the use of the alternative (otherwise they could already buy it from the alternative producers).

In sum, SEAC can assess and conclude on the safety and feasibility of available alternatives in certain cases. In other cases, these conclusions will necessarily remain vague as they rely on factors that are not science-based.

6. Conclusions

As the above discussion has shown, based on established and accepted guidelines for impact assessment SEAC can, in many cases, conclude on the comparison of benefits and risks of continued SVHC use. Likewise, where applicants provide detailed information about alternatives available in general SEAC can conclude on several aspects of the suitability of these alternatives for the use applied for. Dependent on the substance use applied for, these conclusions may be more or less firm, and they are relative to guidance values related to exposure which themselves may not be endorsed by every stakeholder of the REACH authorisation system. This said, the reader should remember that 1) the Better regulation guidelines are the fundament of impact assessment in the European Union, 2) the Guidance on Socio-economic Analysis in applications for authorisation is based on the Better regulation guidelines and has been endorsed by Member States[10] in CARACAL, and 3) as outlined by Article 60(4) of REACH a recommendation made on the basis of these guidelines does not prevent the Commission to take into account other elements in its decisions.

[10] Some Member States have similar impact assessment guidance for policy analysts.