

Lost at SEA*

**The information policymakers actually need
from applicants and SEAC opinions**

***Socioeconomic analysis**

Content

Executive summary	3
What is the value of human health and of the environment?	4
Why are SEAs not useful in their current form?	5
Recommendations for better SEAs	9
ECHA's opinions need to change – Here are the reasons why	10
Recommendations for better opinions	11
Conclusions	12

Executive summary

In the EU, companies need authorisation from the EU Commission to use Substances of Very High Concern (SVHCs) that are included on the Authorisation list (Annex XIV). Even though this procedure is only applied to the most hazardous industrial chemicals – all with severe health and/or environmental effects – continued use may be allowed if applicants can show the substance is used safely, or when it can be argued that the pros outweigh the cons and there are no available alternatives. Each application includes a Socio-Economic Analysis (SEA), in which applicants need to demonstrate that the societal benefits of continued use are greater than the risks. The SEA is evaluated by the European Chemicals Agency's (ECHA's) scientific committee (SEAC), whose opinion arguably plays a large role in the Commission's final ruling.

THIS PAPER ANALYSES the SEA that forms part of the REACH Authorisation process and argues that the current practices in preparing SEAs and the way that SEAC's opinions are presented do not yield satisfying results. In some cases, the procedure even threatens the aim of REACH, which is to encourage substitution of SVHCs with safer technologies.

ONE OF THE CORE PROBLEMS is that the socio-economic analysis actually only makes good on the last half of its name – the economic part – but fails to capture the first half, which relates to other societal issues – in a satisfactory way. Benefits that cannot be quantified in monetary values, such as human life and the environment, are mostly ignored or, at best, are given much less weight than other aspects that can be quantified and monetised. As long as a product can be sold it is considered a benefit to society. This results in an SEA that is very one-dimensional.

Furthermore, even the part of the SEA that lends itself well to economic calculations has many flaws, the most glaring being that it only looks at the benefits of the applicant. Market competitors who have invested heavily in innovation and safe technology, and therefore may be selling their products at a higher price point, are not taken sufficiently into account. What's even worse is that the SEA builds heavily on applicants' economic calculations, even though ECHA's own review shows that applicants grossly overstate the benefits of continued use.

Lastly, there is an issue with transparency around how SEAC has come to its conclusions. Not even the Commission are given all the bits and pieces in the opinions it is supposed to rule on; what has been omitted, what are the levels of uncertainty for different factors, to what extent have market competitors been taken into account, and so on.

THIS PAPER AIMS TO HIGHLIGHT THE CURRENT CHALLENGES and recommend appropriate solutions for both the SEA prepared by the applying companies and the opinions from SEAC. Based on our analysis and recommendations, ChemSec calls for a political discussion on how SEA is used in the regulation of chemicals, and how SEAC's opinions can be further developed to become more transparent, give a better understanding and provide true information on the societal pros and cons of granting or not granting an authorisation.

What is the value of human health and of the environment?

In order to carry out an SEA, various techniques can be used. The most popular and most widely used in the authorisation procedure is the Cost-Benefit Analysis (CBA)*. CBAs are a tool for comparing the cost of regulation (in this case, phasing out an SVHC) with its benefits (avoided deaths, avoided health impacts, avoided environmental harm). This technique requires the placing of a monetary value on human life, on the environment and on the willingness of individuals and society to pay to avoid diseases. Cost-benefit analyses are a widely used tool in regulation that has been extensively criticised. One of the main problems of this technique, aside from the ethically questionable monetisation of human life and of the environment, is the fact that many benefits that cannot be quantified are mostly ignored or, at best, given much less weight than those that can be quantified and monetised.

Benefits are defined as increases in human wellbeing (utility) and costs are defined as reductions in human wellbeing. As such benefits are nothing else but monetary values. The major limitation of cost-benefit analyses is that they present a picture that has only one dimension: money. As a tool, it doesn't sufficiently inform the decision makers and it is even unclear if the decision makers are aware of how cost-benefit analysis works. The consequence of this limitation is that SEAs may conclude huge benefits for uses of SVHCs that are extremely questionable.

An SEA values everything that can be sold as important to society and as providing a benefit. An SEA does not make any distinction as to whether the product sold is important for society as such. If it gives economic value it's regarded as a benefit. This means that even products that are irrelevant for the functioning of society, such as shiny lipstick cases, are valued as important to society simply because consumers buy these products.

On the one hand, it is positive that SEAs let us understand what the trade-offs are for using extremely dangerous chemicals that make objects shiny; but on the other, there is something completely inhuman in a society that accepts that people will get fatal cancer and die to provide society with these goods, and label something beneficial only because someone is buying it. There is also a question of fairness, since the beneficiary of the alleged benefit – in this case the consumer buying a lipstick – is not the one at risk.

EXAMPLE

In an opinion on plating for decorative purposes using chromium trioxide, ECHA's scientific committees (RAC and SEAC) estimate around 11 fatal cancer deaths per year due to exposure to this substance. In this same opinion, ECHA concludes that the operational conditions and risk management measures described in the application for authorisation (AfA) are not appropriate and effective in limiting the risk. Nevertheless, ECHA went on to recommend that this use of chromium trioxide is continued so that society can continue to have shiny brand labels or shower heads, lipstick caps, and other trivial benefits.

* Another technique that is widely used in public policy is cost-effectiveness analysis, which aims to calculate the unit cost of reduction of pollution. The advantage of this technique is that it doesn't need to monetise the benefits but only to seek for the best option to phase out a polluting activity. ECHA foresees using this technique when assessing authorisation requests for PBTs and vPvBs due to the difficulty of valuing the benefits of ending the use of these substances.


1. Ackerman, Frank & Heinzerling, Lisa (2001–2002) "Pricing the Priceless: Cost-Benefit Analysis of Environmental Protection". *University of Pennsylvania Law Review*, 150: 1553–1584.

Why are SEAs not useful in their current form?

Industry overestimates cost

One of the main problems encountered in SEAs is the overestimation of the cost for companies to comply with legislation. Since the outcome of the SEA has a large impact on the actual decision there are no incentives for the company performing the SEA to resist overestimating the costs and underestimating the benefit of a regulatory decision that phases out the substances in question.


According to ECHA's review of the first 100 opinions on AfA, the applicants had overestimated the benefits to society in 75 percent of the cases (mainly avoidance of job losses and profit losses) from their use of SVHCs, while at the same time underestimating the negative impacts on workers and the general public.² ECHA observed how AfAs typically highlight aspects of the SVHC use that are in favour of granting an authorisation, but ignore or misrepresent aspects that would reduce or limit the benefit of granting an authorisation.

- 
SEA needs to provide a balanced analysis in order to work as a tool for decision-making; companies need incentives to provide relevant and accurate information.

Economic impacts on competitors and alternative providers are not taken into account

One particular aspect that SEA often ignores or misrepresents is the socio-economic impact of granting authorisation on a company that supplies alternative substances and technologies, or on competitors that have already substituted the chemical and thus already incurred the cost for doing so. Alternative providers, competitors, and innovators might be positively impacted if authorisation is not granted. This aspect needs to be taken into account in the SEA as well as the loss in revenue from allowing the continued use of the SVHC. The cost that innovators have put into investing in safer technologies should also be included.

The economic impacts on alternative providers and competitors are often assessed in a qualitative manner, even where it should be possible to estimate the actual impacts. This basically means the current assessment has little or no impact as non-monetised impacts are almost ignored in an SEA.³



- 
SEA needs to include the impact on alternative providers and competitors of the outcome of the authorisation decision.

The ability for the market to adapt to changes and to innovate is not included

The market is not static and unable to adapt to regulation. A well-functioning market will innovate and adapt to regulation without major problems. There is also growing evidence that environmental regulation stimulates innovations.⁴

Initially, innovations are normally more expensive than standard, well-established systems or chemicals. This doesn't mean the new alternatives will always be more expensive. Normally prices fall when demand and supply is rising. However, there is no analytical model used to take into account this probable decrease in price in the SEA.

If an SEA assumes the market is static it will reward companies that fail to adapt in society and give a competitive advantage to companies that are unable or unwilling to innovate.

- 
SEA needs to include the ability of the market to adapt to changes and innovation.
- 
New alternatives are likely to cost less with time and increased demand. The SEA needs to take this into account.

2. ECHA (2017) *Socio-economic impacts of REACH authorisations – A meta-analysis of the first 100 applications for authorisation*. Helsinki: European Chemicals Agency, p. 24.

3. *Ibid*, p. 15.

4. Porter, Michael E. and van der Linde, Claas (1995) "Toward a New Conception of the Environment-Competitiveness Relationship". *Journal of Economic Perspectives*, 9 (4): 97-118; Ambec, Stefan, Cohen, Mark A., Elgie, Stewart, and Lanoie, Paul (2013) "The Porter Hypothesis at 20 – Can Environmental Regulation Enhance Innovation and Competitiveness?". *Review of Environmental Economics and Policy*, 7(1): 2–22.

EXAMPLE

In its opinion on DEHP in PVC⁵, SEAC states “since the alternatives are in general more expensive, a significant increase of the soft PVC production costs in the EU would result from using alternative plasticizers.” The opinion later adds that “in the future, increasing production capacities and offer for alternative plasticizers on the market could also decrease the price of some if not a majority of alternatives.” However, no analytical model is used to take into account this probable decrease in price.

Similarly, in the case of lead chromate pigments⁶, the economic argument against substitution rests on the higher costs of alternatives. The opinion states that the assessment of the economic feasibility of alternatives submitted by the applicant is based on the direct cost of alternatives. Indeed, the applicant based most of its SEA on compliance costs for the non-use scenario that mainly consisted of substitution costs. The impact of the authorisation on the economic operators that have invested resources to develop safer alternatives is ignored.

Discounting – giving too little weight to future generations

Since the costs of phasing out a substance arise in the present but the benefits might happen in the future, applicants use discounting as a technique to bring future monetary values to present ones.

The use of discounting is like saying that the future is less valuable than the present, that the future lives that chemicals legislation intends to protect are valued less or much less depending on how far the benefits will happen in the future.⁷ Although this may be economically sound, it is ethically unjustifiable.

The higher the discounting rate that is chosen, the lower the future is valued. For example, at a 4 percent constant discount rate, any value of a benefit gained in 100 years would be worth one-fiftieth (1/50). Discounting implies, that the monetary value is interest-bearing, meaning that you save money now and get interest on it until the benefit starts. It disregards the fact, that the money is used differently and doesn't bring interest.

Decreasing discounting rates would be more accurate to use in some cases in order to give higher values to impacts on the future generation that would be negligible with a constant rate.⁸ Particularly useful for PBT and vPvB chemicals since, being stock pollutants, the benefits from interrupting their use may happen in several decades from now.

The choice of the discount rate in SEA largely impacts on the result of the comparison between present costs and future benefits. Besides, discounting is only relevant for benefits that have been monetised.⁹ It doesn't take into account non-monetised benefits. Therefore, to make sure this calculation exercise brings value to the SEA it needs to be very clear why a certain discount rate has been chosen and what non-monetised benefits are not included in this calculation.



Give accurate weight to future benefits for human health and the environment.



If this technique is used in the SEA, the applicant must be clear on how the discount rate has been set and why the specific rate is chosen.

5. RAC/SEAC (2015) *Opinion on an Application for Authorisation for Bis(2-ethylhexyl) phthalate (DEHP) for industrial use in polymer processing by calendaring, spread coating, extrusion, injection moulding to produce PVC articles*. Helsinki: European Chemicals Agency.

6. RAC/SEAC (2014) *Opinion on an Application for Authorisation for Lead chromate molybdate sulphate red (C.I. Pigment Red 104)*. AFA-O-0000004723-74-15/D.

7. Kyser, Douglas A. (2007) "Discounting ... on Stilts". *University of Chicago Law Review*, 74 (1): 119-138.

8. Gabbert, Silke; Scheringer, Martin; Ng, Carla A. & Stolzenberg, Hans-Christian (2014) "Socio-economic analysis for the authorisation of chemicals under REACH: A case of very high concern?" *Regulatory Toxicology and Pharmacology* 70 (2014) 564-571

9. ECHA (2011) *Guidance on the preparation of socio-economic analysis as part of an application for authorisation*. Helsinki: European Chemicals Agency, p. 89.

Willingness to pay implies there is a market for health and environmental services

In an effort to include non-financial benefits in the SEA like human and environmental costs economists have developed methods to estimate the monetary value of preserving environmental goods as well as human wellbeing. These methods try to measure the societal willingness to pay for remaining healthy and for environmental services, even if a market for these amenities doesn't exist.

Economists generally use two classes of methods¹⁰ to assess the economic value of the environment, human life, and health when a specific market is absent:


1. Revealed preference methods in which the values are determined by observing consumer choices and implying the value that consumers give to the environment or their own life. For example, the value of statistical life may be calculated by determining how much workers are willing to be paid to accept an increase in risk from their profession.
2. Stated preference methods ask consumers how much they value the environment through carefully structured surveys. These surveys can be used to value anything, from whales to remote arctic areas; they put a price tag on environmental amenities.

Stated preference studies are used more often for environmental decision-making. They are controversial, however, because in order to estimate the value of goods it is necessary that the respondents understand the attributes they are going to value, which is not always the case.

EXAMPLE

A stated preference study was used to support the proposal for the restriction of the PBT substance (D4) and the vPvB substance (D5) used in cosmetics. The result from the study estimated willingness to pay (WTP) per person per year to be €46 to reduce the risk associated with D4, and €40 to reduce the risk associated with D5. However, one of the problems with PBT and vPvB substances is that the risks of future effects are unknown, and often even the potential effects are unknown (even to experts).¹¹ So, while these studies show that people care for the environment and for their own health the values they express cannot be considered reliable.

Economically it's logical to compare the economic benefits of using SVHCs with the cost of saving human lives. Ethically, such trade-offs are nonsense. Moreover, when using these kinds of methods, the same value may be obtained for extremely high or very low individual risks depending on the number of people exposed. Meaning, even severe health risks can result in SEA concluding that there are large economic benefits. It is therefore important that SEA also makes clear that the economic values obtained from willingness-to-pay studies are intended to represent priceless amenities such as health, human life, and the environment, which cannot simply be represented by such values but need to be understood in qualitative terms.

 **SEA needs to clearly define the limitations of used willingness-to-pay studies (i.e. priceless amenities such as health, human life, and the environment).**



10. Mendelsohn, Robert and Olmstead, Sheila (2009) "The economic valuation of environmental amenities and disamenities: methods and applications". *Annual Review of Environment and Resources*, 34: 325-347.

11. RAC/SEAC (2016) *Opinion on an Annex XV dossier proposing restrictions on octamethylcyclotetrasiloxane, decamethylcyclopentasiloxane*. Helsinki: European Chemicals Agency, p. 38-40.

All relevant endpoints are not taken into account

In order to monetise the benefits of avoided health impacts, economists need clear dose-response curves. A dose-response curve illustrates the cause and effect relationship between chemical exposure and an adverse effect. However, there are many hazardous endpoints for which a dose-response relationship is uncertain, difficult to calculate or even impossible to calculate. This means that the benefits of preventing exposure to, for example, chemicals linked to adverse health outcomes such as neurodevelopmental effects and cardiovascular problems, will not be monetised and therefore have less or no weight in the assessment of socio-economic factors. The same holds true for persistent, bio accumulative and toxic substances (PBTs) and very persistent and very bio accumulative substances (vPvBs) that have no dose-response curve. Moreover it's extremely difficult to estimate the benefits (not only economic) of phasing PBTs and vPvBs out.¹² In addition, there is a growing body of evidence that links adverse effects to exposure to chemicals at low doses or of chemicals with non-monotonic dose response, meaning that the adverse effect is not proportional to the exposure (e.g. the dose-response curve may be U-shaped or inverted U-shaped when plotted on a graph).¹³ These uncertainties need to be reflected in the SEA .

Although only certain hazardous endpoints are included in Annex XIV of REACH for each substance covered, these substances may have other hazardous properties. Even if a hazardous endpoint was not considered for inclusion in Annex XIV its socio-economic impacts should be considered in the SEA. If not, clear benefits to society would be ignored while any costs can be taken into account. The purpose of an SEA is to analyse the cost of phasing out a use and the benefits of avoided health and environmental impacts, which means that all costs and all benefits should be taken into account.

- 
Provide clear information about which benefits to human health and the environment have been monetised and which have not i.e. priceless amenities provided in qualitative terms.
- 
Include all hazardous properties for the specific substance, including endpoints that are not included in Annex XIV of REACH.

EXAMPLE










Chromium trioxide was included in Annex XIV of REACH for its carcinogenic and mutagenic effects. However, chromium trioxide is also a skin and respiratory sensitizer. Sensitizers can, if deemed of the equivalent level of concern to other endpoints, be included in Annex XIV, but this is not the case (at present) for chromium trioxide. Nevertheless, these properties can have huge economic impacts as they may lead to allergic reactions, need for medical expenses and loss of productivity due to sick leave. However, these costs are not included. Further, chromium trioxide is toxic to the aquatic environment, so avoiding its use may have positive environmental impacts that should also be taken into account.

12. Gabbert, Silke; Scheringer, Martin; Ng, Carla A. & Stolzenberg, Hans-Christian (2014) "Socio-economic analysis for the authorisation of chemicals under REACH: A case of very high concern?" *Regulatory Toxicology and Pharmacology* 70 (2014) 564–571.

13. Vandenberg, Laura N, Colborn, Theo, Hayes, Tyrone B, Heindel, Jerrold J., Jacobs, David R., Lee, Duk-Hee, Shioda, Toshi, Soto, Ana M., vom Saal, Frederick S., Welshons, Wade V., Zoeller, R. Thomas, Peterson Myer, John (2012) "Hormones and Endocrine-Disrupting Chemicals: Low-Dose Effects and Nonmonotonic Dose Responses". *Endocrine Reviews*, 33(3): 378-455.

Recommendations for better SEAs

There is a need to improve SEAs to make them useful in chemical regulation, and easy to understand for citizens and decision makers. Therefore, SEAs should:

-  Include the impact on alternative providers and competitors of the outcome of the authorisation decision.
 -  Include the ability of the market to adapt to changes and innovation.
 -  Provide a balanced cost analysis for the continued use of the SVHC in question.
 -  Take into account that the prices of new alternatives are likely to fall with time and increased demand.
 -  Give accurate weight to future benefits for human health and the environment.
 -  If used, be clear on how the discount rate is set and why the specific rate is chosen.
 -  Clearly define the limitations of used willingness-to-pay studies (i.e. how priceless amenities such as health, human life, and the environment have been taken into account).
 -  Provide clear information about which benefits to human health and the environment have been monetised and which have not i.e. priceless amenities provided in qualitative terms.
 -  Include all hazardous properties for the specific substance, including endpoints that are not included in Annex XIV of REACH.
-

ECHA's opinions need to change – Here are the reasons why

The way the ECHA opinions are formed today do not provide policymakers with accurate information regarding uncertainties in the assessment of the application for authorisation, and hence do not give policymakers all relevant information. So far, SEAC has concluded for almost all applications for authorisation received that the benefits outweigh the risks and that no alternatives were available – even when an alternative was available¹⁴, when the benefits are questionable, and when the risks are clear.

ChemSec together with ClientEarth published a paper¹⁵ last year (2018) focusing on the alternative assessment part in the authorisation (“How to find and analyse alternatives in the authorisation process”). The report suggests a number of improvements for ECHA and SEAC to consider to make sure SEAC opinions do not state alternatives do not exist when in fact they do or when SEAC do not know if they do or not.

Uncertainties in the application may arise at any stage of the socio-economic analysis and of the analysis of alternatives due to lack of data, information or a lack of a full scientific certainty. As REACH places the burden of proof on the applicant we argue it is important to have the maximum transparency about the level of uncertainty and the factors determining the uncertainty. Clear and transparent scientific opinions, with all uncertainties well defined, are therefore a prerequisite for the member states in the REACH Committee as well as the European Commission to take well-founded policy decisions based on the precautionary principle.

An SEA aims to give a relevant picture of the socioeconomic implications that arise from a decision to grant or refuse an authorisation. It builds on monetising all parameters possible. Of course, this methodology has its limitations and will have certain boundaries. One of the consequences of the limitation is that SEAs may conclude huge benefits for uses of SVHCs that are extremely questionable. It is important to be very clear about what has been included in the analysis and what has been left out. For example, an SEA uses economic values to represent priceless amenities such as health, human life, and the environment, which we argue cannot only be represented by such values, but need to be understood in qualitative terms, and presented and taken into account in the SEA and in the opinion as such.

Moreover, since an SEA does not make any distinction about whether the product sold is important to society as such but just takes into account if it delivers economic value the consequences are that even products without clear benefits to our society may be given a positive opinion by the SEAC committee. Policymakers need to see the full picture of the continued use of a SVHC, not just a summary of economic benefits. Would policymakers really support the continued use of a substance just because someone is buying it, regardless of where it's used and the risk it pose to humans and the environment?






The result of SEAC putting great emphasis and focus on methods of monetising non-monetised aspects such as human health and the environment in their analyses is that the final opinion focuses on monetary cost-benefit and disregards the risks. This has also lead to that economic benefits have become the dominant factor in the decision-making process, while the risk to individuals has become almost irrelevant. This was not the intention of REACH. We therefore strongly urge that SEAC's approach of putting economic interests before reducing risk for very hazardous substances needs to be discussed at the political level.

14. ChemSec & ClientEarth (2018) *How to find and analyse alternatives in the authorisation process*. Available: <https://chemsec.org/publication/authorisation-process,reach/how-to-find-and-analyse-alternatives-in-the-authorisation-process/>.

15. Ibid.

Recommendations for better opinions

The opinions of SEAC need to be easy to understand for citizens and decision makers. They need to provide a summary that actually informs on the societal benefits of a granted or refused authorisation. SEAC opinions therefore need to include:

-  All omissions, together with the level of uncertainty and factors that determine the uncertainty in the analysis of alternatives (AoA) and SEA.
 -  Information on what costs and benefits have and have not been included, or are uncertain, in the SEA.
 -  What priceless amenities such as health, human life, and the environment, which cannot be represented by economic values, have and have not been described in qualitative terms in the SEA.
 -  How the market has been defined in the AoA and in the SEA, for example:
 - to what extent have the economic effects of rejection for alternative providers, innovators and competitors been taken into account;
 - to what extent have the market's ability to shift to other chemicals been taken into account.
 -  If a discounting rate is used in the SEA, there should be clarification of why and how the discounting rate is set and why this level is chosen, as well as the implications of this level on the overall result.
-

Conclusions

THIS PAPER HIGHLIGHTS some of the issues that we encountered following the REACH authorisation from its inception. The authorisation chapter has, without doubt, been a driver for substituting hazardous chemicals and for better control of the risk of SVHCs. However, to be meaningful the authorisation process cannot become a process where it is enough to apply to get an authorisation. The socio-economic analysis is a tool (like many others) for understanding the trade-offs between environmental and health protection and the use of extremely harmful chemicals. In order to become a tool that helps deliver better results and that actually helps to inform people about the impacts of granting or refusing authorisation, SEAC's opinions need to be easy to understand for citizens and decision makers.

THIS REPORT AIMS TO ASSIST ECHA AND THE COMMISSION to improve SEAC's working procedure for developing opinions on applications for authorisation, to ensure that they provide a summary that gives decision makers the information they actually need on the societal benefit of granting or refusing authorisation, so that they can make the final political decision on the continuing use of extremely hazardous chemicals.