Socio-economic assessment and REACH authorisation

The mismatch between law and practice

Executive summary

Socio-economic assessment (SEA) is a tool that serves to identify the impacts on society of a particular policy option.

The societal context plays an important part in chemicals' risk decision-making in the EU. Notably, REACH requires authorities to take into account socio-economic impacts when deciding whether or not to restrict or authorise chemicals of concern.[1] Although broadly defined in the legal text,[2] the scope and methods for this assessment have been specified by ECHA through a variety of guidance documents.

The intention behind this report is not to dwell on the well-known issues regarding the application of the tool, but rather to describe how it was conceptualised in the dedicated ECHA guidance and other decision-making documents compared with REACH provisions.

One of the main issues is that the normative network supporting the use of SEA creates a context where a narrow interpretation of scope of the social factors to take into account is favoured. This was in particular promoted by the preferred valuation method: quantitative cost-benefit analysis (CBA). Such a narrow focus directly results in favouring business-as-usual (the continued use of dangerous substances) over innovation and substitution. This therefore threatens the effectiveness of the objective of REACH and specifically of its authorisation title.

The approach has also failed to facilitate the decision-making process because a positive conclusion from SEAC on the socio-economic assessment has not been sufficient to secure support across the board.

Our in-depth analysis of the guidance and decision-making documents demonstrates that the specific framing of SEA as a quantitative impact assessment mechanism has shaped the implementation of authorisation against the requirements and main objective of REACH, i.e. the protection of health and the environment. While we agree that making space for societal considerations in the assessment of applications for authorisations is of utmost importance, we believe SEA has not served this objective so far.

Our main conclusion, considering both the resources needed to do a SEA and the fact that it has not proven to be a highly useful tool, is that the REACH reform should maintain the authorisation process but stop relying on the SEA as currently described by the ECHA guidance. Among our recommendations, we suggest to look at societal impacts as part of a broader analysis of alternatives. That would mean:

→ analysing the economic impact of authorisation on the applicant company through the analysis of the economic feasibility of alternatives and of the substitution plan,

→ assessing the technical feasibility of alternatives with a focus on the criticality of the function to the end-use, but also its criticality to health, safety or the functioning of society,

→ once a substance is put on the Candidate List, starting to consult with the companies using the substance, the alternative providers, competitors and other interested parties in order to gather data as early as possible on the broader societal impact of a potential authorisation.

[1] For restriction, see Article 68(1) REACH and for authorisation, see Article 60(4) REACH
[2] See Annex XVI 'Socio-economic analysis' of REACH

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Introduction

When a substance is highly hazardous, authorising companies to use it without adequately controlling its risks is politically sensitive. The EU legislator decided that under REACH the Commission may make such a decision only when there is no suitable alternative and when the socio-economic benefits of using the substance outweigh its risks.[3]

For the great majority of applications for authorisation, the companies may not demonstrate that the risk is adequately controlled, which is why they often have to apply for authorisation using the 'socio-economic' route. Because of this, the analysis of alternatives and the socio-economic analysis, and therefore the Socio-economic Assessment Committee (SEAC), have become the central pieces of the authorisation system. **The current issues with the authorisation system result from how these decision-making tools have been developed and used**.

ClientEarth, in collaboration with ChemSec, has already sent the European Commission and the European Chemicals Agency (ECHA) detailed recommendations on how to find and assess alternatives,[4] and will keep working on the topic to ensure that the practice is brought back into compliance with REACH.[5] But not all current issues with the authorisation system result from the analysis of alternatives; the socio-economic assessment contributes a fair share.

To figure out how and what to do about it, our report analyses the guidance and decision-making documents developed by ECHA, the requests the Commission has sent to SEAC, and SEAC debates and opinions, in the light of REACH (1).

From these materials, we highlight that SEAC members appear constrained by a mandate and by tools that are unfit to ensure the effectiveness of REACH (2).

As a result, we give concrete recommendations on how to proceed until the REACH reform happens, as well as during the REACH reform. While we eventually advise to abandon SEA as it is currently applied, we suggest ways to better incorporate socio-economic components as part of the analysis of alternatives (3).

[3] Article 60(4) Regulation (EC) No 1907/2006 of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), OJ L 396 30.12.2006, p. 1
[4] See ChemSec and ClientEarth Reports, "How to find and analyse alternatives in the authorisation process" (2019) and "A fresh coat of paint on the Analysis of Alternatives" (2019)
[5] As required by the European Court of Justice in its Lead Chromate Judgment - Case C-389/19, Judgment of the Court (First Chamber) of 25 February 2021. *European Commission v Kingdom of Sweden*

1 The inconsistency between REACH and SEA as framed by ECHA

1.1 REACH: the necessity of a SEA with a broad scope

REACH charges the Commission with deciding what social factors to take into account when deciding whether the socio-economic benefits of business-as-usual outweigh its risk. Before this final stage, the ECHA secretariat has influence on what social factors will be covered by the applicants and how. The stakes of this process, as explained below, are high.

Why does the interpretation of the scope of a SEA matter?

The scope defines what factors matter and who matters when determining what constitutes a socially beneficial risk. The factors included are de facto prioritised; that is, they are treated as more socially and politically relevant than the factors excluded. Setting the scope of a SEA is therefore a political decision. The narrower the scope, the less ambitious/protective the process is.

Environmental and health risks of substances:

Narrow scope	**Broad scope**
Focuses only on the properties of the substance of very high concern ('SVHC') for which it was listed in Annex XIV and on the emissions caused by the applicant.	Considers all the potential health and environmental impacts of the substance, an approach that Advocate General Kokott confirmed as necessary under REACH.[6]

The scope of a SEA can encompass the following perspectives:

Private or micro-economic perspective	Focuses on the impacts on the applicant companies.
Market or macro-socioeconomic perspective	Considers actors other than the applicant: competitors, alternative providers, customers, consumers, suppliers, workers, investors, etc. This perspective is as broad as its geographical limits (national, EU, international).
Societal perspective	Focuses on the social nature of the risk as well as on the social importance of the service provided to society by the activity while taking into account the market impact.

[6] Opinion delivered on 25 February 2021 on Case C-458/19 P, *ClientEarth v European Commission*

REACH gives several indications as to the scope and role of the SEA and those involved.

REACH element	*Related to*	*Scope*
Article 60	Commission	Assess whether the evidence is sufficient to prove that the socio-economic benefits of using the substance outweigh the risks to human health or the environment (Article 60.4 REACH); "Take into consideration", while doing so, the socio-economic benefits arising from the use and the socio-economic implications of a refusal to authorise, as demonstrated by the applicant or other interested parties (Article 60.4b); Take into account elements or considerations other than those raised by the applicant or by any third parties. Recital 83, for example, states that the Commission and a committee of Member States are in charge of final decisions in order to "allow for an examination of their wider implications within the Member States".
Annex XVI	Applicant	A non-exhaustive, broad and indicative list of the elements that may be included in the SEA, stating that the level of detail and scope is ultimately the applicant's responsibility. While it covers diverse factors, its focus is particular – on competitors, market, sectors, alternative providers, consumers and workforce. Essentially, it endorses a macro-economic perspective, although it is clear that other elements may be considered, including the distribution of impacts as well as "any other issue".
Article 64.4b	SEAC	An assessment "of the socio-economic factors".

REACH therefore sets no limits on the scope of the socio-economic factors that must be considered by the Commission, or even by SEAC. The text is a bit more precise for the applicants, but barely, considering the flexibility provided by Annex XVI. In any case, the information submitted by the applicant must not be the only material on which the Commission relies to make its assessment. REACH obligates the Commission to consider information other than that submitted by the applicant.[7]

All this points to a SEA with a broad scope. Contrary to the analysis of the feasibility of an alternative, the SEA is not only about the impact on the applicant. It must make it possible to compare the societal impacts of not using the substance with the impacts of using it.

This is confirmed by the interpretative rules of EU law. When vague, EU law provisions must be given the interpretation that best fits their context and objective to ensure their effectiveness[8] and respect for the Treaties and principles of EU law.[9] When applied to the authorisation context, this rule points to an

[7] Judgment of 25 February 2021, *Commission v Sweden*, C-389/19 P, para. 35
[8] Judgment of 28 September 2016, *United Kingdom v Commission,* T-437/14 (cf. points 59, 60)
[9] Judgment of 21 March 1991*, Rauh / Hauptzollamt Nürnberg-Fürth,* C-314/89 *(Rec._p._I-1647) (cf. al. 17)*

obligation for the Commission to give a broad scope to its SEA and an obligation for ECHA to guide applicants in that direction. Indeed, the EU Court has stated several times that the main objective of REACH is the protection of health and the environment.[10] Any interpretation that would undermine the effectiveness of REACH in that regard should therefore be set aside in favour of an interpretation that actively facilitates the realisation of REACH's aims. The authorisation title was specifically designed to encourage and ensure substitution.[11]

In addition, if authorisation "shall be granted" where sufficient evidence proves that the risk is adequately controlled, no such obligation exists for the socio-economic route. It is only exceptionally and if "it is shown" that the conditions are fulfilled that the Commission "may" authorise use when the risk is not adequately controlled.[12] This is because SVHCs must "be subject to careful attention […] to ensure a sufficiently high level of protection for human health, including having regard to relevant human population groups and possibly to certain vulnerable sub-populations, and the environment", in accordance with the precautionary principle.[13]

All this confirms that the "socio-economic reasons"[14] that may justify the authorisation of a use with known risks must be broad enough to "reflect the needs of society",[15] which REACH intended for the authorisation system to do.

In other words, the SEA should not be done by adopting a micro-economic perspective, focusing on the direct or indirect impact of the applicant. The analysis of alternatives, which considers technical and economic feasibility for the applicant, already does that. The Commission must adopt a societal perspective, informed by the analysis submitted by the applicants and by third parties offering data on macro-socioeconomic changes. The fact that the use contributes to the economy alone is not enough; it must bring a concrete and significant benefit to society at large for its risk to be tolerable. But this is not how the authorisation provisions have been applied so far.

The choices impacting the scope of SEA	
Baseline	The impacts considered against business-as-usual market conditions where REACH has not transformed the playing field or against the conditions of the market as it should exist after REACH – where use is exceptional.
Level of analysis	Micro-economic – focused on company Macro-economic – societal
Type of impacts considered	Positive and negative, financial, and others such as liability
Method of valuation	Plays a significant role in the extent to which these choices will lead to a narrower or wider scope

[10] See the judgments of 7 July 2009 in *S.P.C.M. and Others*, C-558/07, ECR, EU:C:2009:430, paragraph 45, and *Bilbaína de Alquitranes and Others* v *ECHA*, T-93/10, EU:T:2013:106, para. 116
[11] REACH Article 55 and Recitals 70, 72, 73, 74
[12] REACH Recital 68 and Article 60(4)
[13] Recital 69, REACH
[14] Recital 22, REACH
[15] "As well as scientific knowledge and developments" (Recital 78, REACH)

Geographical coverage	The impacts considered taking place inside or outside the EU
Time period	Determines when impacts are *triggered* and when they actually *occur*; some impacts, in particular health/environmental effects, may materialise long after they were triggered

1.2 ECHA's decision-making documents: inconsistent but encouraging a narrow scope

The inconsistency on the breadth of the scope

Who decides on the scope?

REACH gives four main actors a role in the interpretation of the scope of the SEA.

The Commission	Has a central role as it is tasked by REACH with making the final assessment on whether the socio-economic benefits of using an SVHC outweigh its risks.[16]
ECHA	Influences the scope when it provides guidance for applicants as required by Annex XVI.
Applicants	Benefit from ample discretion in the choice of the scope of the SEA they submit, in line with Annex XVI and the ECHA guidance.
SEAC members	Bring their own stone to the edifice. Indeed, the interpretation of their role and the definition of the methods they use to assess the "socio-economic factors" described in the applicants' and third parties' submissions also impact the final interpretation.

In practice, **interpretative power over the scope of the SEA is mostly exercised by the Commission and the ECHA secretariat**, the latter often complying with requests from the former with little to no contribution from Committee members. Sandwiched between administrative and political power, SEAC members have seen their own power and independence restricted.

The interpretation of the scope is determined by the vast collection of documents aimed at guiding applicants or committee members through the authorisation process. One might think that the SEA guidance is the most influential, but its length and age make it a repertoire of methods and ideas rather than a practical guide, and limit the extent to which it is actually used. This is why the most impactful documents are the application and opinion templates, the documents guiding the work of SEAC, such as the "SEA checklist",[17] and especially the documents setting out SEAC's evaluation approach on specific aspects, such as the economic feasibility approach paper.[18]

[16] Article 60(1) REACH
[17] Checklist for evaluating socio-economic analysis in applications for authorisation (2016): https://echa.europa.eu/documents/10162/13580/sea_evaluation_checklist_en.pdf
[18] "How the Committee for Socio-Economic Analysis will evaluate economic feasibility in applications for authorisation", SEAC/18/2013/03 (2013)

As a result, the interpretation of the scope is highly fragmented, making it hard to access and understand. Some documents are hosted on ECHA's public website, others on S-Circabc. The older documents have not always been updated or have been deleted, resulting in incoherence.

There is a high level of ambiguity in how the ECHA guidance defines what the scope of a SEA should be.

On the face of it, the main guidance supports an inclusive understanding, whereby the applicant is asked to assess **all** relevant impacts. Those include:

- costs and benefits for the applicant, including the workforce;
- effects on the wider market economy (such as alternative providers, investors, consumers);
- impacts on health and the environment; and
- more general "societal" impacts (e.g. the distribution of impacts across social and income groups).[19]

Furthermore, SEAC considers in its *Approach to economic feasibility of alternatives* that a SEA aims to provide a "social" perspective on the impact of authorisation, whereas the assessment of economic feasibility looks at the "private" costs and benefits that impact the applicant, either directly or indirectly.[20] This broad understanding of the scope of SEA is, however, contradicted when examining further the content of ECHA's decision-making documents.

First, the guidance tends to focus on *economic* impacts, whether at micro or macro level, rather than broader societal considerations. The main SEA Guidance explicitly asks the applicant to determine "how the supply chain would react" to the non-use of the SVHC.[21] The practical guidance to applicants similarly explains that "applicants should not only consider the impacts on them but also explain the *anticipated reaction of the market* to the changes in the product/service".[22] Although not explicitly, the ECHA guidance steers the SEA in a specific direction: what must be captured as a priority are the impacts on the affected industry, that is, the applicant and its workforce as well as the broader supply chain, alternative producers, competitors and consumers. Other societal impacts take a back seat in the applicant's assessment[23] and SEAC evaluation. Besides, they are aggregated with other impacts.[24] There is not even a precise description of what those "additional qualitatively assessed impacts" could be[25]. "Social" impacts are narrowly described in terms of effects on employment, e.g. with regard to working conditions or social security.[26] Broader societal considerations, such as the criticality of the service

[19] ECHA Guidance on the preparation of socio-economic analysis as part of an application for authorisation (2011), p. 16. See Guidance at: https://echa.europa.eu/documents/10162/23036412/sea_authorisation_en.pdf/aadf96ec-fbfa-4bc7-9740-a3f6ceb68e6e
[20] "How the Committee for Socio-Economic Analysis will evaluate economic feasibility in applications for authorisation", SEAC/18/2013/03 (2013)
[21] ECHA Guidance on the preparation of socio-economic analysis as part of an application for authorisation, pp. 17-19
[22] "How to apply for Authorisation" (Feb. 2021), p. 53
[23] The AfA template for applicant (Version 3.0 , Sept 2021) refers to "additional qualitatively assessed impacts" (p.9): https://echa.europa.eu/documents/10162/17229/aoa_sea_format_with_instructions_v3_en.doc.docx/c32a68c1-200b-6b6d-ca01-55bf36787ea7?t=1631601292433
[24] See SEAC Checklist; and Format for RAC and SEAC Opinion (Version 4.0 – Sept 2021) Table 13, p. 32: https://echa.europa.eu/documents/10162/17086/format_rac_seac_opinions_en.pdf/bd186fd3-2ee2-4557-8fa0-64dd559e1006?t=1631687421742
[25] AfA template for applicant (Version 3.0, Sept 2021), pp. 9-10
[26] Chapters 3.1, 3.2, 3.5 of the Guidance on SEA in Authorisation

provided by the end-use or the intergenerational distribution of benefits and risks, tend to be either pushed into the background[27] or not considered systematically relevant.[28]

The selected baseline exacerbates the focus on market consequences. The baseline is the situation against which the impact of the regulatory action is assessed. In the context of REACH authorisation, it can be the continued use of the SVHC or its non-use. When the SEA guidance was discussed, several Member States were keen on making non-use the baseline – which the term "authorisation" logically implies. But strict opposition from the Commission led to the opposite result, and the baseline became the business-as-usual scenario in which companies are allowed to use the SVHC. Because of the focus on what is rather than on what REACH was designed to bring about, this approach mostly focuses on the loss borne by the polluters rather than on the broader societal changes that a market oriented by regulation towards alternative solutions could bring.

Furthermore, contrary to the initial ambition, the guidance narrows the scope of the SEA to the positive economic impacts of use, so that the negative impacts are left out. The SEA guidance rightly identifies the goal of the SEA to be the facilitation of "a systematic and comprehensive comparison of the relevant costs/benefits of continuing to use an Annex XIV substance with the costs/benefits of no longer being able to use the substance".[29] However, there is often a lack of consistency between the decision-making documents. The templates leave aside negative impacts of continued use for the applicants.[30] Only potential liability and reputational impacts[31] are mentioned in the application template, but they are not re-listed in the opinion template.[32] For example, the costs involved in reducing and monitoring SVHC risks, or the foregone benefits that could come with an activity that could be cleaner and/or more innovative, are not considered. Similarly, the SEAC Checklist does not make space for the negative economic and social impact of continued use.[33] This might be due to the baseline selected, as explained above, or to the often-repeated assumption that companies apply only if there are no overriding benefits to phasing out the SVHC.[34] The latter belief, based on the assumption that the applicant is a rational economic actor, has been repeatedly debunked by behavioural economics.[35]

In turn, **the positive impacts of alternatives (non-use) are also left aside**. This is highly visible from the SEAC Checklist[36] and practical guide for applicants,[37] which simply ignore the importance of reporting the benefits of switching to the alternative, whether for the applicant or for other market actors who would invest in substitute technologies.

[27] Distributional impacts of continued use were mentioned in Table 13 of the previous SEAC Opinion template (p 33). They have been removed from the most recent version of the opinion template (version 4.0 from Sept 2021).
[28] The guidance mentions that impacts on certain social groups "may" need to be considered - Guidance on SEA in Application for authorisation, p. 23
[29] ECHA Guidance on the preparation of socio-economic analysis as part of an application for authorisation, p.5
[30] RAC and SEAC Opinion template, pp. 30-32.
[31] Format for SEA, version 4.0, February 2019, p.14
[32] Version 4.0 September 2021.
[33] Checklist for evaluating socio-economic analysis in applications for authorisation (2016): https://echa.europa.eu/documents/10162/13580/sea_evaluation_checklist_en.pdf
[34] This assumption is made explicit in SEAC paper "How the Committee for Socio-Economic Analysis will evaluate economic feasibility in applications for authorisation" (2013), p. 2: "as long as any increase in costs from substituting for an alternative is less than the expected costs of applying for authorisation, the firm will switch to the alternative and not apply for authorisation".
[35] Rieskamp, J., Busemeyer, J. and Mellers, B. 2006. Extending the bounds of rationality: evidence and theories of preferential choice. Journal of Economic Literature XLIV, 631- 661; Miller, G. 2006. The Emotional brain weighs its options. Science 313, 600-601; Arkes, H., and Ayton, P. 1999. The sunk cost and Concorde effects: Are humans less rational than lower animals? Psychological Bulletin 125:591-600.
[36] SEAC Checklist for evaluating socio-economic analysis in applications for authorisation (2016)
[37] "How to apply for Authorisation" (Feb. 2021), pp. 55-57

The narrow scope locked in by the dominance of quantitative valuation methods

The many ways to compare the impact of change

There are several methods that may be used to collect and analyse data on socio-economic impacts. They offer different approaches to what should be taken into account and how.

Cost-Benefit Analysis (CBA)	Values the expected costs and benefits of a measure in a common unit, generally money.
Cost-Effectiveness Analysis (CEA)	Identifies the least cost-intensive way to achieve a particular objective. Both this and CBA favour quantitative data, in particular monetary valuation.
Multi-Criteria Analysis (MCA)	Ranks preferences between options by reference to an explicit set of objectives for which measurable criteria have been determined, to assess the extent to which the objectives have been achieved. Because it does not assign monetary values to non-monetary consequences, this method allows for a comparison of the positive and negative impacts of change in their natural units (death and disease, rather than monetised quality-adjusted life years), which also makes it impossible to hide distributional inequities in an aggregated net benefit figure. Nicholas Ashford described this difference of approach by saying "decisions would be based on accountability rather than accounting".[38]

At first glance, ECHA's guidance on SEA embraces this diversity of methodologies by cataloguing several of them in Annex F. But a more detailed analysis of the guidance and, more importantly, an analysis of the decision-making documents that have a greater weight on the system lead to a different conclusion. ECHA has a clear preference for CBA or, more generally, for quantitative monetised data:

Emphasis on quantitative data	ECHA informs the applicant that quantification must be used *as much as possible*.[39] The agency has made clear in various seminars and presentations that a full CBA would make it much easier for SEAC to compare the costs of non-authorisation with possible remaining risks in the case of authorisation.[40]

[38] N.A Ashford, *Implementing the precautionary principle: incorporating science, technology, fairness and accountability in environmental health and safety decision* IJOMEH 2004; 17(1). Nicholas Ashford is Professor of Technology and Policy and Director of the Technology & Law Program at the Massachusetts Institute of Technology (MIT).

[39] See Reader's Guide for preparing an application for Authorisation (2018); How to Apply for Authorisation (2021); and "Examples of assessment reports in applications for authorisation" at : https://echa.europa.eu/fr/applying-for-authorisation/start-preparing-your-application

[40] See for example Workshop on SEA in authorisation and restriction (2016): Workshop on Socio-economic analysis in applications for authorisation and restrictions under REACH - All Events - ECHA (europa.eu)

The practical guide to applicants further encourages reliance on quantification and particularly monetisation. Using real applications for authorisation as best-practice examples, [41] ECHA explicitly states that a "good SEA" must demonstrate that *monetised* costs are greater than benefits.[42] For instance, *Eli Lilly's* socio-economic analysis related to the use of endocrine-disrupting chemicals (EDC) is presented as a good example of "how human health impacts can be estimated and monetised".[43]

Unequal guidance on methods

Although ECHA indicates that equal weight should be given to quantitative and qualitative data, it does not set a method to account fairly for qualitative information. Even when it does, for example to assess the impacts of PBT/vPvB substances, the applicant has the discretion to choose whether to apply it. [44] The applicant is even encouraged to ignore impacts that cannot fit into a CBA. For example, applicants are free to choose whether to include the non-quantifiable impacts of unemployment, such as effects on wellbeing, as part of the SEA.[45]

In contrast, methods for estimating the monetary value of impacts are provided in painstaking detail in the ECHA guidance,[46] or with reference to Commission documents.[47] In particular, dedicated guidance is provided on valuation models for health impacts, such as "Willingness to Pay" values[48] and weights based on disability or quality adjusted life years (DALY or QALY).[49]

Why has ECHA favoured CBA?

The focus on CBA in the ECHA guidance did not happen in isolation but results from a broader political context. Encouraged by the industry, international organisations, such as the Organisation for Economic Co-operation and Development (OECD), and the political success of the narrative

[41] "Examples of assessment reports in applications for authorisation" (ECHA website)
[42] One SEA submitted by Grohe AG in an application for authorisation for uses of Chromium (VI) trioxide is taken as an example: the risk of cancer for Use 1 has been monetised (7,099eur) and compared with cost for company due to closing the plant and relocating (183m of eur). See at: 008a678a-1034-4f32-9b57-3497cf175aa4 (europa.eu)
[43] See application at : https://echa.europa.eu/documents/10162/1964ae5d-5c14-446f-ac42-eadbd5ff9130
[44] Evaluation of authorisations for application for PBT and vPvB substances (2016), SEAC/31/2016/05 Rev.1
[45] "The social cost of unemployment" (2016), SEAC/32/2016/04; to be read in conjunction with Dubourg, Richard (2016). "Valuing the social costs of job losses in applications for authorisation". Report prepared for the European Chemicals Agency. Version 3, September 2016
[46] Annexes B and C of ECHA Guidance on the preparation of socio-economic analysis as part of an application for authorisation
[47] The Commission has specifically detailed the approach to valuating ecological damages in the context of REACH. See for example: Report to DG Environment, "The impact of REACH on the environment and human health", 2005, see at: REACH-WP2 (europa.eu)
[48] See "Willingness-to-pay values for various health endpoints associated with chemicals exposure" (2016), SEAC/32/2016/05.2 Rev.1
[49] Report on the "Quantification and valuation of the human health impacts of chemicals based on quality and disability-adjusted life-years" (2015), ECHA/2011/01

denouncing excessive regulation, CBA rose as a popular tool for governments. It is, for example, the method favoured by the Commission in the application of its Better Regulation Agenda.[50]

In the context of chemical regulation, the OECD has supported the use of CBA as best practice for conducting the socio-economic analysis since 1990.[51] By allowing like-for-like comparison using money as a common unit of measurement, CBA has been painted as an objective and rigorous approach to assessing the advantages and disadvantages of a policy option.[52]

The discretion left by Annex XVI, as well as the inconsistency of ECHA's guidance, leave space for the applicant to set the scope that will best support its case. Even if the applicant was tempted to choose a broader scope, the dominance of CBA would likely lead to a narrow scope when it came to preparing the application.

This is because the easiest impacts to quantify are the **financial or economic** consequences of ending business-as-usual. It leads to foreseeable results: applicants report what is easily quantifiable for them (e.g. losses in profit) but neglect other types of impacts, in particular those which are not easily quantifiable or for which data is unavailable.[53] The application by *Salzgitter Flachstahl* for uses of chromium trioxide in chrome plating shows how detailed an assessment of the costs for the company and the wider market can be, but also how broader societal considerations can be neglected.[54] The company perceives societal impacts for "the public at large" solely in terms of "*economic losses* resulting from increased investment costs and variable production costs".[55] The narrow focus on what is immediately measurable necessarily impairs the quality and credibility of the analysis, which should have aimed to capture all impacts, whether quantifiable or not.

This narrow focus is exacerbated by the fact that the very tools used to conduct the CBA are not fit for purpose. The impact of job loss is consistently evaluated in terms of costs (e.g. value of wages lost during the unemployment period), which does not make it possible to capture the societal acceptability of that loss.[56] The application of generic "willingness-to-pay" indicators (i.e. how much members of the public would be willing to pay to avoid an outcome such as a disease),[57] for example, to monetise the risks to workers of developing cancer in the *Gruppo Colle* case, is also highly problematic. It fails to consider how the actual workers from the company in question would react to the probability of getting cancer, and how much they and society as a whole would be willing to pay to avoid it.[58] The use of willingness-to-pay indicators upholds the contentious assumption that everything has a price and that individual monetary preferences reflect society's *willingness to accept* a particular risk.

[50] European Commission, Better regulation guidelines, Commission staff working document. SWD (2017) 350
[51] See: The costs and benefits of regulating chemicals - OECD
[52] See Mandelkern Group on Better Regulation, Final Report (2001)
[53] ECHA Report, Socio-economic impacts of REACH authorisations, A meta-analysis of the state of play of applications for authorisation (January 2021), p. 12
[54] Salzgitter Flachstahl application for authorisation (Feb 2020), Analysis of Alternatives and SEA, from page 89 to 100, at: https://echa.europa.eu/documents/10162/e02a6c91-ba16-ed9d-4f1a-4a90edb65b0c
[55] Salzgitter Flachstahl application for authorisation, p. 102
[56] For example see the details on unemployment costs in LARS Chemie's application for authorisation of use of CRVI (2019): https://echa.europa.eu/documents/10162/fb017bdc-bd82-fdea-c807-a6865cddf3e4
[57] "Valuing selected health impacts of chemicals", Summary of the results and a critical review of the ECHA study (ECHA, February 2016): https://echa.europa.eu/documents/10162/13630/echa_review_wtp_en.pdf/dfc3f035-7aa8-4c7b-90ad-4f7d01b6e0bc
[58] See for example: Final RAC and SEAC Opinion on Gruppo Colle application for authorisation for sodium dichromate use as mordant in wool dyeing (07/07/2017)

It might make economic sense to compare the economic benefits of SVHC use with the cost of protecting health or the environment, but the underlying value judgment is hardly uncontroversial.[59]

1.3 The practice: REACH undermined by an overly narrow scope

Applicants favour a narrow scope

The practice up until 2018 was effectively summarised by former SEAC members and two ECHA staff in charge of authorisation in a paper entitled "Benefit-Cost Analysis in EU Chemicals Legislation: Experiences from over 100 REACH Applications for Authorisation".[60] The authors explain that applicants have favoured a private, micro-economic perspective, most of the time ignoring the macro-economic perspective and systematically ignoring a broader societal perspective.[61]

Since 2018, this practice has not stopped: in a recent application for authorisation of chromium trioxide use in etching plastics, the company *Viega* provided a detailed account of the impacts of non-authorisation on the company itself, the workforce, as well as the supply chain and the wider market. However, the "other societal impacts" part of the application template was left empty.[62] In *Oras*'s application for authorisation to use the same substance, the company explicitly mentioned that it did not account for distributional impacts on socio-economic groups "since the magnitude of these impacts cannot be quantified at the moment".[63] Similar results can be observed in other recent applications, including review reports.[64]

SEAC's analysis is constrained by the applicants' biased analysis

Despite the initial request of SEAC members to the contrary, it was decided that they must not consider information other than that submitted by the applicant or in the public consultation.[65] It is true that this approach is grounded in the law and that it recognises that not all SEAC members have the same resources. It comes at the cost, however, of an over-reliance on the applicants' submissions, which, considering the information asymmetry, are necessarily partial. REACH relies on the hope that third parties will provide a counterweight to the influence of the applicant, but this hope has not materialised. Competitors and alternative providers in particular face significant barriers to participation that we detailed in another publication.[66] This will not be solved without ECHA directly reaching out to them.

[59] For more details, see: "Lost at SEA" report, Chemsec (2019)
[60] Christoph M. Rheinberger and Matti Vainio, *Benefit-Cost Analysis in EU Chemicals Legislation: Experiences from over 100 REACH Applications for Authorisation*, 2018, Journal of Benefit Cost Analysis, 9(1):1-24
[61] See also the examples listed in the ChemSec report "Lost at Sea" (2019)
[62] Viega Supply Chain GmbH & Co. KG Application for authorisation for use of Chromium trioxide (etching of plastic), Analysis of Alternatives and SEA, see at: https://echa.europa.eu/documents/10162/3bf969bb-e83c-7c05-e59e-8d7ba0c07d91
[63] Oras Oy Application for authorisation of Chromium trioxide (electroplating of metal and plastic substrates), Analysis of Alternatives and SEA, p. 122: https://echa.europa.eu/documents/10162/75d72160-61c0-04e5-a9bc-65584aa3448d (2020)
[64] See for example Roquette Frères review report application for use of trichloroethylene as a processing aid in the biotransformation of starch to obtain betacyclodextrin (2020): https://echa.europa.eu/documents/10162/f9fc592d-db6a-497d-c255-fc089de60652
[65] Minutes of the 13th meeting of the Committee for Socio-economic Analysis, 14-15 December 2011
[66] ChemSec and ClientEarth "How to find and assess alternatives" report (2019). See at: how-to-find-and-analyse-alternatives-in-the-authorisation-process-coll-en.pdf (clientearth.org)

The Commission does not comply with its obligation to look beyond the dossier

The work of SEAC is about scrutinising the evidence brought by the applicant against the criteria set by REACH, not about making a call on the acceptability of a given risk. It is up to the Commission to determine whether the criteria are met and the consequences justified.

The Commission and the Member States have the obligation to consider the bigger picture when assessing whether the socio-economic benefits outweigh the risks, which includes taking into account available information not submitted by applicants and third parties. The Court has confirmed this for the analysis of alternatives[67] and the Advocate General for SEA.[68] This obligation is not surprising; the Court has consistently found that "it is for the institutions that are responsible for making political choices to determine the level of risk considered acceptable to society, that level of risk being determined not only on the basis of strictly scientific considerations but also taking account of social factors".[69]

However, the Commission does everything in its power to avoid fulfilling this obligation, including by asking ECHA's secretariat to make the SEAC's opinion a "pre-decision" (see below). This wrong-headed approach is obvious from the following:

- The application format wrongly asks the applicant to determine whether the societal costs of non-use outweigh the risks of continued use[70], whereas REACH requires only a description of the socio-economic benefits of using the SVHC and the socio-economic implications of a refusal.
- The Commission has pushed – and recently secured[71] – the inclusion of a finding on the "proportionality" in the final opinion. This flies in the face of explicit opposition by the European Parliament[72] and some SEAC members.
- The Commission's decisions, which must be reasoned under EU law, tend to refer abstractly to the Committees' opinion without further detail.[73]

[67] Judgment of the Court (First Chamber) of 25 February 2021. *European Commission v Kingdom of Sweden,* Case C-389/19
[68] Opinion delivered on 25 February 2021 on Case C-458/19 P, *ClientEarth v European Commission*
[69] Case C-499/18 P, *Bayer et al. v Commission*, ECLI:EU:C:2021:367, Para 155 that confirmed Case T-429/13 and T-451/13 ECLI:EU:T:2018:280 which also stated that "The level of risk deemed unacceptable for society will depend on the assessment made by the competent public authority of the particular circumstances of each individual case. In that regard, the authority may take account, inter alia, of the severity of the impact on public health, safety and the environment were the risk to occur, including the extent of possible adverse effects, the persistency or reversibility of those effects and the possibility of delayed effects as well as of the more or less concrete perception of the risk based on available scientific knowledge" para 124.
[70] AfA format, Table X, p. 9
[71] The Commission asked again the Management Board that SEAC concludes on proportionality. The opinion template is currently being updated to include this conclusion.
[72] European Parliament resolution of 25 November 2015 on draft Commission Implementing Decision XXX granting an authorisation for uses of bis(2-ethylhexhyl) phthalate (DEHP) under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (D041427 — 2015/2962(RSP))
[73] Commission implementing decision of 15.4.2020 partially granting an authorisation for certain uses of potassium hydroxyoctaoxodizincatedichromate (PPG Industries UK Ltd. and others) reads: "(9) In its opinions on both uses covered by the application, SEAC concluded that the overall socio-economic benefits outweigh the risk to human health arising from those uses. Although SEAC identified uncertainties in the applicants' assessment, it considered the information provided by the applicants sufficient to reach a conclusion. (10) Despite the uncertainties identified by RAC and SEAC and on the basis of their opinions, the Commission concludes that socio-economic benefits from uses 1 and 2 outweigh the risk to human health" (p.3). See also as examples: Commission implementing decision of 14.4.2020 partially granting an authorisation for certain uses of sodium dichromate (Gentrochema BV); and Commission implementing decision of 18.12.2020 partially granting an authorisation for certain uses of chromium trioxide (Chemservice GmbH and others)

The result is that decisions are taken on the basis of a very narrow understanding of what amounts to a socially acceptable uncontrolled risk.

When we talk about a SEA with a narrow or broad scope, we are talking about something bigger: two incompatible visions of the role of REACH authorisation.

A narrow scope turns the authorisation process into a mechanism whose mission is to protect the applicant from the impact of an early phase-out. This is needless duplication: the applicant is already protected by virtue of asking if suitable alternatives are economically feasible for them.

A broader scope, in particular a societal perspective, prioritises the protection of society at large. Even the worst-case scenario of the disappearance of some products or activities might be acceptable if innovators benefit and essential human needs are not impacted.

Both perspectives are meant to identify when taking uncontrolled or uncontrollable risks benefits society. However, the first puts a premium on the preservation of existing activities only because they contribute to the economy, while the second puts a premium on activities that contribute to a safer society. The latter approach is what is needed to promote the full effectiveness of REACH's main objective.

1.4 Recommendations

Commission

→ Take full responsibility for the decisions, taking into account SEAC opinion but also other available information and relevant social factors, as required by law. Do not force SEAC members to reach conclusions on proportionality and stop similar interference.

ECHA secretariat

→ Clarify, shorten and simplify the guidance by reviewing the existing documents.

→ Create a map of existing guidance and decision-making documents with a clear explanation of respective roles.

→ Transition towards a better balance of quantitative and qualitative approaches by developing a clear and simple methodology for the latter.

SEAC members

→ More systematically ask for additional information from applicants and third parties to get a broad picture.

→ Exercise your power to shape your role by pushing back against the ECHA secretariat and Commission demands that undermine the effectiveness of REACH – whenever that is needed.

→ Systematically require a detailed explanation of the costs of use from applicants (liability, reputation, costs of risk management measures).

→ Pay particular attention to the impacts that are not quantifiable.

→ Include in the opinion a summary of the work done outside the plenary – notably by the rapporteurs – that would allow SEAC to reach a certain conclusion.

Adjust your practice towards a macro-socioeconomic and societal perspective, including by considering the impacts on the applicant in the analysis of economic feasibility only.

2 The failure to identify tolerable risk

A decision-making tool is effective when:

1. it secures political buy-in on how trade-offs between competing priorities must be settled; and
2. it is not too resource intensive in light of its contribution to the decision-making process.

SEA as practiced in REACH authorisation does not meet either of these objectives.

2.1 Failure to secure political buy-in

Critics of the inherent limitations of CBA in REACH authorisation

In the context of REACH and beyond, CBA, and more generally the over-reliance on quantitative analysis, have been heavily criticised.[74] ECHA has defended its preference for CBA by claiming that it is "the most conclusive and least based on explicit value judgments".[75] It is true that CBA gives the appearance of a straightforward conclusion by aggregating impacts of a different nature (impact on investment, impact on life) and type (positive and negative) into a final monetised net cost (or benefit). But how to deliver a meaningful analysis of this nature is a key difficulty.[76] These limitations make the credibility of CBA highly dependent upon the reliability of the information and the choices of the analyst, in terms of geographic and temporal boundaries, data categories, types of impacts reported and valuation method used. It is in fact a **highly malleable technique presented as an objective tool**.[77] Critics have denounced the method as reductionist as well as providing artificial certainty and objectivity.

Similarly, even if the value judgments are not explicit, it does not mean that they are not there. Implicit value judgements prioritise some interests – those of industry incumbents – over others, in a way that is neither transparent nor debated.

The contentious nature of CBA amongst public authorities

In 2018, for example, the German Federal government called for a discussion at political level in the Council and Parliament on the acceptance and consequences of this approach.[78] A recent report from the German Environment Agency notes that even if established monetisation methods are applied in

[74] Franck Ackerman, Pricing the priceless, cost-benefit analysis of environmental protection, p 1568; Cass R. Sunstein, "Is Cost-Benefit Analysis for Everyone?," 53 Administrative Law Review 299 (2001); Baruch Fischhoff, "The realities of risk-cost-benefit analysis", *Science* 2015, Vol. 350, Issue 6260, aaa6516, DOI: 10.1126/science.aaa6516; Lynn, E Blais, Beyond Cost/Benefit: The Maturation of Economic Analysis of the Law and Its Consequences for Environmental Policymaking; John Broome, Trying to Value a Life, 9J. PUB. ECON. 91, 92 (1978); Amy Sinden, The problem of unquantified benefits, Environmental Law, Vol. 49, No. 1 (2019), pp. 73-129

[75] Background paper on the scientific basis of SEAC conclusions – ECHA Secretariat draft for the management board (2021)

[76] Weihsueh A. Chiu, "Chemical risk assessment and translation to socio-economic assessments", OECD Environment Working Papers N°117 (2017)

[77] Keith Miller, "Quantifying Risk and How It All Goes Wrong", Hazards 28, Symposium Series No 163, IChem (2018)

[78] See: Germany's position on the REACH Authorisation procedure (August 2017) at: http://files.chemicalwatch.com/Position%20paper%20on%20authorisation%20August%202017%20%281%29.pdf See also "Germany calls for revamp of socio-economic analyses of authorisation", Chemical Watch, 27 June 2018. Paywalled: https://chemicalwatch.com/68094

the correct way, "the underlying principle can be questioned" and "potentially the comparison of the different effects may not be adequate, from a conceptual perspective".[79]

The implicit value judgements favouring business-as-usual

Discounting[80] - Applicants discount the value of impacts in the future so that they are worth comparatively less than if they had occurred in the present.[81] According to the New Economics Foundation, the choice of discount rates rests on a critical value judgment, which is that the welfare of future generations matters less than the welfare of current generations. Moreover, it gives a poor understanding of the latency of certain effects, notably "where exposure tomorrow could result in impacts many years from now, and those impacts could be accumulative (i.e. only occur over a certain build-up of chemicals in the body)". The choice of a discount rate hence can significantly tip the outcome of the cost-benefit analysis: e.g. with a 4% discount rate (recommended by ECHA), the costs of a restriction over the period 2020-2039 significantly outweigh the benefits. They conclude that it is important that lower discount rates (of 2% or less) be considered the default, and that impacts that typically occur the furthest in the future (e.g. health and environment) are better accounted for in the SEA.

Even setting aside these criticisms, **CBA can be a powerful tool but only in a very data-rich context.**[82] The capacity of this tool to assist in the identification of societal benefits in a process inherently constrained by its information source is an important issue. REACH was adopted with an original weakness in that regard, a weakness that has been reinforced in practice.

Opposition to SEAC making "pre-decisions"

The separation between expertise and politics is always thin when it comes to socio-economic factors. It is also true that SEAC's opinions must be usable by the Commission. However, the Commission has repeatedly required SEAC to enter the political realm by providing a "pre-decision" in the form of a conclusion on the proportionality of an authorisation.[83]

There is hardly consensus around this approach. Members of SEAC themselves have expressed their opposition. During their third meeting, they explained that "socio-economic considerations are easily regarded as political, not scientific or technical considerations, and that SEAC should therefore abstain

[79] German Environment Agency (UBA), "Assessment of the Authorisation Process under REACH", Final Report, Olaf Wirth, Antonia Reihlen, Dirk Jepsen and Dirk Bunke (2021), pp. 83-84. See at: https://www.umweltbundesamt.de/sites/default/files/medien/5750/publikationen/2021-03-03_texte_41-2021_advancing_reach_ap_5-4.pdf
[80] The New Economics Foundation "Discounting future damages – Do socio economic assessments in chemicals policy underplay future impacts?" (2019): https://chemtrust.org/wp-content/uploads/nef-discounting-future-damage-comp.pdf
[81] Appendix D "Discounting", in ECHA Guidance on the preparation of socio-economic analysis as part of an application for authorisation
[82] O.Renn, Risk governance, Coping with uncertainty in a complex world, Routledge, 2008 p.18: "The economic risk concept constitutes a consistent and coherent logical framework for situations in which decisions are being made by individuals, and in which decision consequences are confined to the decision-maker".
[83] Minutes of First Meeting of SEAC (2008): "given the 3-month time limit it would be impossible for the COM to carry out itself such an Impact Assessment. The importance to link the opinions of the SEAC to the Commission's Impact Assessment Guidelines was therefore emphasised."

from expressing whether it is for or against the proposal".[84] The European Parliament reached the same conclusion: SEAC's role "is not to provide conclusions on the proportionality of an authorisation when the risk to society is not adequately controlled".[85]

Another intrusion into the political sphere happens when SEAC gives a positive opinion despite crippling data gaps or uncertainty, an error nearly all the resolutions of the European Parliament on authorisation have denounced. The authorisation system makes the applicant bear the burden of proof and the risk of remaining non-negligible uncertainties.[86] Nevertheless, in practice, applicants tend to rely on uncertainties to downplay impacts that are not quantifiable or for which data is lacking.[87] Significant data gaps must be treated as a conformity issue[88] or, at least, like other types of uncertainties: as a justification for reaching no conclusion or a negative conclusion. Not drawing the consequences from significant uncertainties identified in a SEAC conclusion makes it considerably harder for the Commission and the Member States to take a decision that will stand up to scrutiny, as any departure from SEAC's opinion is legal but must be thoroughly justified.[89]

2.2 A disproportionately resource-intensive tool

The resources required to use a decision-making tool are, ideally, proportionate to the importance of its role in delivering the policy objective. The balance set initially by REACH has however been disturbed by what is happening in practice.

How the balance between resources and role set by REACH was thrown off

Under the socio-economic route, because the risks concerned are uncontrolled or uncontrollable, they are also unacceptable. The SEA aims to support the political decision on whether this risk is nonetheless tolerable, because of what the activities in question bring to society. SEA is a crucial part of the decision-making process, but **it is ECHA's practice, pushed by the Commission, that leads to using more resources than needed:**

- Applicants do not have to submit a SEA under the "adequate control" route.[90] In practice, however, SEAC and the Commission made the process more resource-intensive by establishing a de facto obligation always to submit a SEA, even when applying under this route.[91]
- If the applicant fails to meet the burden of proving that no alternatives are suitable, because of gaps in the application or contradictory information, the SEA should not be considered by SEAC since the criteria are cumulative. In practice, however, the SEA is always considered in detail, as

[84] Minutes of Third Meeting of SEAC (2009)
[85] European Parliament resolution of 25 November 2015 on draft Commission Implementing Decision XXX granting an authorisation for uses of bis(2-ethylhexhyl) phthalate (DEHP) under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (D041427 — 2015/2962(RSP))
[86] Judgment of the Court (First Chamber) of 25 February 2021, *European Commission v Kingdom of Sweden,* Case C-389/19, para 35
[87] See, as an example, the information submitted as part of Chemservice's application for authorisation for uses of chromium trioxide (2015): 9317c309-8c2f-e18c-f58c-fa5275bab1c6 (europa.eu)
[88] Within the meaning of Art. 60(7) REACH
[89] Judgment of the General Court of 7 March 2019, *Kingdom of Sweden v European Commission*, T-837/16, para.69
[90] Art. 62(5)(a) REACH says that the applicants "may" include a SEA in their application.
[91] ECHA "strongly advises" applicants under the adequate control route to provide a SEA in their application, considering that it could be relevant "in setting the review period or any conditions for the authorisation" (main Guidance on SEA in authorisation, p. 4). This is the substitution plan, including detailed information on the investment cycle, which should have been systematically included in all applications for which an alternative exists, and which should have played this role.

if to salvage poor applications. This was, for example, the case of *Ormezzano* and the big chromium VI consortium, which met with opposition from the Parliament.[92]

- If the applicant fails to include other key information related to the risk in its application, it should also not be considered in conformity or rejected as unreliable – accurate data on exposure is, for example, essential for the SEA. However, this has not happened in practice.
- Due to the uncertainties about the information provided by the applicants and the lack of guidance to SEAC on how to deal with these uncertainties, clarifications are frequently needed during the opinion development process. This affects the efficiency of the process and increases ECHA's workload.[93]

ECHA and the Commission have created undue work for themselves and for applicants. They have done so by changing the role of the SEA **from a precondition of authorisation to a mere justification for the length of the review period, or to a tool for saving defective applications**. It has not only created more work, but it also undermines REACH's main objective to protect human health and the environment.

The result: transferring issues to the Commission

When the SEA is used to "save" defective applications by the Committees, the issues simply move on to the political stage. Such applications should be rejected. A positive opinion from SEAC has not erased their issues. For the most contentious applications, a positive opinion on the SEA has not helped to secure the majority needed for a consensual political decision. This explains the shocking delays in the adoption by the Commission of a final decision on some applications: for example, *Deza* (76 months since the opinion), *REACH law* (42 months), *Ormezzano* (49) and *Gerhardi* (52), are still pending three years after our first report on the issue.[94]

2.3 Recommendations

Commission and ECHA secretariat → Do not ask SEAC members to conclude on whether the socioeconomic benefits of continued use outweigh the risks, or, in short, whether an authorisation is 'justified'

[92] European Parliament resolution of 29 November 2018 on the draft Commission implementing decision granting an authorisation for certain uses of sodium dichromate under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Ilario Ormezzano Sai S.R.L.); European Parliament resolution of 1.7.2020 on the draft Commission implementing decision partially granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (REACHLaw Ltd) for certain uses of chromium trioxide, 2020 (D066992/01 – 2020/2670(RSP)); European Parliament resolution of 24 October 2019 on the draft Commission implementing decision partially granting an authorisation for a use of chromium trioxide under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Cromomed S.A. and others), (D063690/01 – 2019/2844(RSP))

[93] German Environment Agency (UBA), "Assessment of the Authorisation Process under REACH", Final Report, Olaf Wirth, Antonia Reihlen, Dirk Jepsen and Dirk Bunke (2021), p. 75

[94] See ClientEarth report (2018): https://www.documents.clientearth.org/wp-content/uploads/library/2018-12-11-clientearth-call-for-action-on-unreasonable-delays-and-lack-of-transparency-in-the-adoption-of-authorisations-and-restrictions-under-reach-ce-en.pdf

→ Include in the Opinion template an opportunity to reach a negative opinion in case of non-negligible uncertainties on key information[95]

→ Update guidance and practice to stop requiring SEA for applications under the adequate control route

→ Adopt another approach to the conformity check that allows for the rejection of dossiers with substantive gaps on key information

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SEAC members

→ Oppose requests from the Commission or ECHA secretariat that go against REACH and intrude on the independence of SEAC or the quality of SEAC's work

→ Use the conformity check or SEAC's power to provide a negative opinion to flag non-negligible/substantial uncertainties

[95] The most recent version of the Opinion template (v. 4.0, Sept. 2021) requires SEAC to make the distinction between negligible and non-negligible uncertainties, which is a significant improvement compared to the previous template. The Opinion template now reads: "{If non-negligible uncertainties exist} SEAC acknowledges that there are remaining non-negligible uncertainties in the available information that may affect its conclusions"

3 Looking ahead – SEA and the REACH reform

REACH has been misinterpreted in the framing and application of SEA. Would it have become an ideal tool if REACH had been complied with? There are reasons to doubt it.

The over-reliance on applicants' data is a structural weakness. The data may be hard to get or may not be available at all,[96] and when it is available, applicants will always be tempted to build a case favourable to their micro-economic perspective. There is also a practical difficulty for the Commission to look beyond SEAC's opinion in every case.

It is without doubt indispensable to take into account socio-economic factors when deciding which uncontrolled risks are tolerable, but there are more direct and less resource-intensive ways to do so. Furthermore, a broader understanding of the "societal" impact of authorisation is needed, one that is not limited to economic impacts but also includes social considerations. That includes aspects such as, *inter alia*:

→The distribution of impacts and benefits across different parts of the population (workers, consumers, people living near the factory that produces the substance etc.).

→The societal importance of the end-product, i.e. its contribution to identified "essential" societal objectives. This criteria is currently being investigated by the Commission.[97]

→The vulnerability of the groups affected by a potential continued use (e.g. pregnant women, low-income communities, infants etc.). The *Natural Resources Defense Council* proposed a definition of vulnerability that is worth referring to.[98]

→The vulnerability of the environment polluted (e.g. is the continued use of the substance likely to affect a protected area, the abiotic environment, or a particularly sensitive organism/species?)

Because of the structural limitations we identified, **we propose for the REACH reform to end the use of SEA.** This, however, does not mean that the various impacts of authorisation should not be taken into account. As argued above, the accommodation of societal concerns is absolutely fundamental for ensuring that the law adequately reflects evolving societies.[99] They should, however, be taken into account differently and less on a case-by-case basis.

What we propose relies on **four pillars**:

First, the modification of the role and functioning of the SVHC listing. The Candidate list triggers new obligations. From the listing, companies must send to ECHA detailed notification of their use (relying on but going beyond their efforts done under SCIP and Article 7 REACH). Companies that do not comply are not eligible for authorisation later on. The listing also triggers a fee for the user, which grows over time.

[96] ECETOC Technical Report N°113, Environmental Impact Assessment for Socio-Economic Analysis of Chemicals: Principles and Practice, Brussels (2011)
[97] See Commission paper CA/61/2020 'Essential uses' submitted to the 37th meeting of CARACAL on 17 November 2020
[98] According to the NRDC, vulnerable people are those who "1) have been disproportionately impacted by toxic chemicals; and/or 2) have an increased likelihood of adverse health effects from toxic chemicals due to greater susceptibility and/or exposure; and/or 3) have been, and continue to be, marginalized and excluded from processes and decisions that affect them. These populations include those that are exposed to toxic chemicals in their workplaces; low-income communities; communities of color; fence line neighborhoods; communities that rely on subsistence for at least a portion of their diet (such as indigenous people of the Arctic); and infants, children, and pregnant women." See the NRDC report "Selecting safer alternatives to toxic chemicals and ensuring the protection of the most vulnerable: A discussion draft", 2017 (available online).
[99] Ludivine Petetin, The Precautionary Principle and Non-Scientific Factors in the Regulation of Biotech Foods, 8 EUR. J. Risk REG. 106 (2017).

The goal is to have stronger incentive for substitution and to increase predictability on what the next regulatory steps entail and require.

Second, a cooperative stage funded by the fees paid by SVHC users is added. This cooperative stage will include some support to help companies identify alternative and build an effective substitution plan. A SEAC working group could play a valuable support/advisory role on the identification of what a credible substitution plan is. It will also include getting a market analysis of uses and alternative as well as best practice in risk management by an independent consultant (paid by ECHA using fees). A SEAC working group could help the process by guiding the collection of relevant data. The goal is to break the information asymmetry which undermines the process today. SEAC will benefit from having best practices to use as benchmark for the claims and performance of the applicants on technical and economic feasibility, and an overview of the market to consider the societal impact.

Third, a dramatic decrease of the number of cases eligible for authorisation. The identification of the uses in the cooperative stage will ground an early reflection and political decision on essential uses eligible for authorisation. In addition, the need to apply – which means the number of applications – is reduced by adopting transition periods up to 7 years for the uses fitting pre-set criteria[100] using a restriction. It is only exceptionally that an individual application for a non-renewable transition period beyond 7 years (from the entry on the candidate list) and up to 12 years can be submitted and granted. Rejected decisions – after preliminary investigation or full analysis – are granted a 1-year grace period to soften the effects. The goal is to change the approach to socio-economic impacts, from micro-economic to societal, which unveils the assumptions and choices on what is a politically acceptable impact.

Fourth, a considerable simplification of the process and criteria. Only one route for authorisation, no socio-economic assessment.

To be able to continue using an SVHC for a **non-renewable, limited period of time**, we propose:

The applicant must prove that:	1. The **best available risk reduction measures** are in place; 2. There are **not yet any technically or economically feasible** alternatives;[101] and 3. There is a substitution strategy, thoroughly detailed in a **Substitution Plan.**
Socio-economic factors are taken into account differently	1. The affordability of the substitution, including the impact on the quality and quantity of the jobs offered, is taken into consideration **as part of the analysis of the economic feasibility of alternatives** or of **the substitution plan.** 2. The pre-authorisation stage will deliver a **benchmark of best practices, a mapping of uses and alternative,** as well as **decisions on what should or should not be considered an eligible use.**

[100] The uses and exposure need to be fully known after the cooperative stage, the uses are not the main contributors to overall emissions, are critical and without alternatives.

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