HOW TO FIND AND ANALYSE ALTERNATIVES IN THE AUTHORISATION PROCESS

The main goal of the authorisation process is to promote the replacement of substances of very high concern (SVHC) with substances or technologies that are safer. However, during the "stocktaking conference on authorisation" held in November 2017, it emerged that the authorisation process has not delivered its full potential. In particular, authorisations have been granted even when alternatives did exist, contrary to the requirements of REACH and having negative effects on alternative providers. When an authorisation is granted under Article 60(4) despite the existence of a suitable alternative, it not only violates REACH, it also rewards the laggards and frustrates the frontrunners.

On the basis of the conference on authorisation,[1] experience as observers in the socio-economic committee (SEAC) and extended exchanges with alternative providers, ChemSec and ClientEarth have identified two of the issues in the way SEAC operates, that prevent the authorisation process to fully deliver. [2] First, applicants do not always comply with their obligation to provide ECHA with accurate and comprehensive information on alternatives. The way to find existing alternatives has to be re-thought. Second, SEAC does not use clear and appropriate criteria to assess the feasibility of suitable alternatives. The way that SEAC assesses the feasibility of alternatives needs to be improved. This factsheet aims to explain the current challenges and recommend solutions that could be implemented without changing the existing regulatory framework.

1. https://echa.europa.eu/-/stock-taking-conference-on-applications-for-authorisation
2. This document does not cover the scenario where an authorisation is granted under Article 60(2) (adequate control route). It focuses on the scenario where an authorisation is granted under Article 60(4), which requires that no safer alternatives are available (i.e. technically and economically feasible), and that the socio-economic benefits of using the substance outweigh the risk. The socio-economic assessment is not the subject matter of this document. The analysis does not cover the risk assessment of alternatives either as this falls in the remit of the risk assessment committee (RAC) rather than SEAC.

How to find existing alternatives

1. Demand comprehensive and accurate information from the applicant

Under REACH, companies that apply for authorisation to use an SVHC are obliged to provide the information necessary to assess if an alternative substance or technology is available.

However, it is vital to bear in mind that the unique objective of the applicant is to be granted the authorisation. If the applicant cannot adequately control the risk of its SVHC, its chances of getting an authorisation are zero if SEAC finds suitable alternatives. Companies therefore do not have an incentive to provide a comprehensive and thorough review of information on existing alternatives; they actually have an incentive to do the opposite.[3]

EXAMPLES

Gruppo Colle applied for an authorisation to use sodium dichromate as a mordant in wool dyeing. In its analysis of alternatives, Gruppo Colle listed some potential alternatives, for example a few Lanasol products made by Huntsman. However, the analysis did not include the most relevant substance in the group and based its conclusion on a substance used as a yellow dye, even though the final authorisation was granted for using sodium dichromate for dark colours. Similarly, the applicant listed some alternatives from Dystar in its analysis but omitted Realan Black MF-PV, Dystar's most relevant alternative to sodium dichromate.

In December 2016 ECHA Committees suggested to grant an authorisation for seven years to the consortia of **Henkel, Brenntag_PD, Brenntag_SD, PPG, Akzo** to use chromium compounds in surface treatment for various applications in the aerospace industry. Alternatives to these chromium compounds developed by some of the applicants themselves were not listed in the original analysis of alternatives. These alternatives include chrome-free primers as alternatives to chrome coatings e.g. Metaflex SP 1050 by Akzo, Desoprime™ product group by PPG, Bonderite and Alodine®5700™ or Alodine®T-5900™ by Henkel. The decision of the Commission on this authorisation is still awaited.

☞ *Recommendations to ECHA:*

ECHA should demand that applicants provide accurate and exhaustive information regarding alternatives and remind them that this is a legal obligation.

☞ *Recommendations to SEAC:*

If the applicant does provide relevant information about alternatives SEAC should recommend that authorisation is not granted.

☞ *Recommendations to the Commission:*

If information on available alternatives is discovered after the adoption of the authorisation by the Commission, and in particular if it is discovered that the applicant knew about these alternatives, the Commission should review and/or withdraw the authorisation under Article 61.3 of REACH.

3. This was flagged by the paper prepared by the Netherlands and submitted to REACH REFIT. "REACH Forward Applicants, especially those that manufacturer or import the substance, usually have no incentive or knowledge to fully describe the benefits of alternatives, particularly when these involve changes in technologies, processes or business models outside his current practice or scope of use." Page 9 at https://ec.europa.eu/growth/sectors/chemicals/reach/review_en

2. Increase the visibility of the public consultation

REACH does not ignore the risk that applicants may not provide accurate or comprehensive information on alternatives. That is why Article 64(2) requires ECHA to organise a public consultation on the documents submitted by the applicant, in order to receive information from third parties which could help to scrutinise the accuracy and exhaustiveness of the application.

SEAC currently assumes that if alternatives exist, the public consultation will reveal it. SEAC assumes that alternative providers will see the public consultation as an opportunity to promote their product or technology and that competitors will also use the opportunity to promote a better solution.

ChemSec is in frequent contact with alternative providers, including through the management of "ChemSec Marketplace", the meeting platform for alternative providers and chemical users. Feedback provided by these contacts reveals that relevant third parties frequently do not know about the public consultation.

Most companies do not routinely check the ECHA website, and, because they do not receive information about the public consultation from another source, they remain unaware of its existence. This is true for competitors, alternative providers, as well as for customers, who could also be a source of useful information.

EXAMPLE

In the **Gruppo Colle** authorisation case, the providers of suitable alternatives only found out about the public consultation at a very late stage of the process, which meant that SEAC was missing key information when it gave its opinion.

The Netherlands and Sweden, in their contribution to REACH REFIT, underlined the fact that information on alternatives is seldom submitted during the public consultation and that additional sources of information are needed.[4]

☞ *Recommendations to ECHA:*

- Make information on the public consultation more readily available on ECHA's website.
- Have a web page dedicated to "alternative providers" or "innovators for safer alternatives" on the ECHA site.
- Provide a "go-to" person or department at ECHA, who alternative providers could contact to either ask for guidance on the authorisation process or to provide information.
- Advertise public consultation through specialised professional channels, including LinkedIn, fairs, etc.
- Create a system where third parties could register interest in being notified about information on regulatory activity concerning specific SVHCs.

None of these changes in administrative practice requires legislative change. It requires work from an IT perspective and more outreach resources allocated to the ECHA "substitution" team.

4. See the support papers submitted alongside their contribution at https://ec.europa.eu/growth/sectors/chemicals/reach/review_en

3. Get relevant information from third parties

Currently, the public consultation is the only safeguard used by ECHA against the bias of the applicant's information. Unfortunately, it has not functioned as such. This is either because information about the public consultation does not reach the relevant third parties as described above, or because alternative providers are not always able or willing to contribute for commercial reasons. Many alternative providers, and sometimes competitors, may run the risk of endangering business relationships by participating in the public consultation and the trialogue, since the applicant could be a potential customer. In any case, voluntarily contributing to the public consultation or trialogue would mean arguing against their potential customer.

One alternative provider, Oerlikon, clearly explained at the stocktaking conference held in November 2017, that applicants for authorisation are often "high potential customers" to alternative providers.

There is therefore a need to complement the "passive" public consultation with more "proactive" and targeted consultation.

It is impossible for SEAC and ECHA to be experts on each SVHC and their possible alternatives. However, it is possible for ECHA to identify and contact people who are most likely to know about potential alternatives.

Examples of relevant contact persons/groups

- Experts from academia who specialise in the substance or group of substances and/or the relevant sectors
- Companies advertising on ChemSec Marketplace
- NGOs that have worked on substitution, such as SubsPort partners
- Industry groups created to find sustainable solutions for their sectors, such as ENCORD for the construction sector, and Zero Discharge of Hazardous Chemicals, ZDHC, for textiles.

☞ *Recommendations to ECHA:*

- Build a database, linked to the Candidate List, with information on experts from academia and the private sector who specialise in the substance or substance group and/or the relevant sectors;
- Organise workshops that would allow potential applicants and alternative providers to meet;
- Involve experts on a case-by-case basis, when an application for authorisation is received.

4. Supplement the public consultation with proactive contacts with relevant third parties

In addition to the "passive" public consultation consisting in waiting for third parties to contribute voluntarily, there is a need for a more "proactive" and targeted consultation to check the accuracy and exhaustiveness of the information given by the applicant. One way to obtain this information could be to follow the practice of the Commission under EU merger law.

Getting information from competitors, suppliers and customers: lessons from EU merger law

When companies apply for an authorisation to merge with or acquire another business, they may need to request an approval from the Commission first. In order to obtain the approval, they have to provide an analysis of their market so that the Commission can decide whether the transaction would lead to a "substantial lessening of competition" and, on this basis, clear or refuse it. This requires the companies to provide information on the markets they operate in and to estimate their market power in terms of market shares before and after the merger/acquisition.

Similarly to the authorisation process under REACH, and more specifically the analysis of alternatives:

- The companies that apply for merger clearance are tempted to, and sometimes do, present the market in a way that is not accurate;
- A merger case relies on a complex analysis of markets where input from companies is indispensable, and estimations may vary from one company to the other;
- The Commission does not have in-house experts on each sector concerned;
- Customers or suppliers are key third parties for defining the boundaries of a market in the context of merger control, but they may be in a delicate position that could discourage them from providing data (voluntarily) when this data runs contrary to the interests of their business partner;
- Competitors may have an interest in presenting the information requested in a way that would not help their competitors to obtain clearance.

As a result of this, the Commission needs to check the facts submitted by the applicant and collect information from third parties who may not have an interest in participating voluntarily. In order to do this, in practice, the Commission notably requires the company that is applying for merger clearance to provide a list of their main competitors and customers, with their contact details.[5] In complex cases, they also request lists of the main suppliers. This contact list is then used by the case team of the Commission to send eQuestionnaires.[6] In simple cases, they may do short phone interviews instead. The information gathered this way is used to carry out a "reality check" on the accuracy of the information provided by the applicant.

This is how for example the Commission was in a position to contradict the data provided by BASF in 2009 in the context of its acquisition of CIBA:

> *"The Commission's market investigation indicated that the market structure as assumed by BASF and described in the table is not correct. The competitor Toagosei (Japan) does not have any sales in the EEA and sells DMA3 only in Japan. Also, the Italian DMA3 producer 3F Chimica does not sell DMA3 on the merchant market. In consequence, the only producers selling DMA3 on the merchant market in the EEA are Arkema, BASF and Ciba. The concentration thus leads to a reduction of three to two players on the merchant market for DMA3. Indeed, in the market investigation customers expressed concerns about the fact that post-merger they would be left with only two suppliers: BASF and Arkema".* [7]

Such a proactive consultation is an incentive for applicants to be accurate in the data they provide and the argument they make to obtain clearance. It is also a way to ensure that key third parties are involved in the decision-making process. A company is more likely to respond to a personal and formal request from the Commission (or ECHA) than to contribute voluntarily and proactively to a public consultation.

☞ *Recommendations to ECHA:*

- Request that applicants for authorisation provide a "contact detail list" of their main competitors, customers and suppliers (when relevant), in order to check the reliability of the applicants' analysis of alternatives.
- Directly consult competitors, customers and suppliers, for example by sending questionnaires to these contacts, asking targeted questions. The questions could include the cost and timeline of the transition for companies that have made the substitution, as well as the potential financial impact of the authorisation on competitors and alternative providers.

5. See http://ec.europa.eu/competition/mergers/template.xlsx; Council Regulation (EC) No 139/2004)s 20 January 2004 on the control of concentrations between undertakings (OJ L 24, 29.01.2004, p. 1–22), Article 11; Commission Regulation (EC) No 802/2004 of 21 April 2004 implementing Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings (OJ L 133, 30.04.2004, p. 1–39), Annex I point 8.15.
6. http://ec.europa.eu/competition/mergers/equestionnaire_en.html
7. http://ec.europa.eu/competition/mergers/cases/decisions/m5355_20090312_20212_en.pdf

- Organise a cross-institution workshop with DG competition (merger units) staff to share experience and good practices in assessing contradictory information from companies.
- Provide a "go-to" person or department at ECHA, who alternative providers could contact to either ask for information or provide information.

This change of administrative practice does not require legislative change. ECHA has engaged in proactive consultation during the restriction process.[8] During the authorisation process, ECHA also has the power to require additional information from applicants,[9] and has the obligation to critically assess the analysis of alternatives provided. In practice, it could for example rely on Article 111 of REACH to issue compulsory forms listing the information needed. In other words, ECHA already has the power to implement these recommendations. It will however require more support from ECHA to SEAC members and thus more resources internally allocated to the "substitution" team.

5. Give third parties the information they need to contribute meaningfully

Through our exchanges with alternative providers, we learned that alternative providers have lost trust in the authorisation process, something which was confirmed by the discussions during the stocktaking conference.[10] Their feeling is that it is "all for nothing": even if they spend time and resources on contributing to the public consultation, their contributions are disregarded. Their motivation to participate suffers as a result.

One solution is to give more weight to the information that third parties contribute, a matter discussed in section 2. Another is for ECHA to make sure that third parties know which information will be seen as relevant and usable by SEAC in its assessment of the suitability of alternatives as presented by the applicant.

In order for an alternative provider (or other third party) to send usable information to SEAC, they must receive the information they need to assess whether their alternative would be suitable to perform the task of the SVHC. This requires being provided with the necessary information and in particular information on the function of the chemical and of the product or process in which the chemical is used. This means seeing beyond the narrow "function of the chemical", and look at the "end-use function". [11]

The function of the chemical would be, for example for a substance such as BPA when used in thermal paper, "transfer proton to the dye, triggering a conformational change that exhibits colour". That information would allow third parties to assess whether their alternative can be used as a "drop-in" chemical alternative to the SVHC, and to select the information best suited to prove that it can. But most of the time, applicants stop there and do not look at alternative materials or processes that do not require the use of the SVHC.

That is why the "end-use function" must also be specified in the application. The "end-use function" would be, for example for BPA in thermal paper, the creation of a printed image on paper. That information is needed for third parties to assess whether their technology or chemical can perform the task of the SVHC in the end-product or process, or make its use redundant. On the basis of this information, they can also select the information best suited to prove that it can. Broadening the analysis of alternative to the end-use function is necessary in order to comply with the REACH objective to substitute SVHCs with "alternative chemicals or technologies".[12]

This is also why the applicant needs to collect and give information on the "function as service" (e.g. for BPA in thermal paper: providing consumers with a record of sale). That is needed to push third parties downstream (if the most downstream company is not the user of the chemical), i.e. the company putting on the market the end-product, to question whether an alternative product (e.g. electronic ticket as opposed to printed ticket) could fulfil the need of their client, and make redundant the end-product manufactured using SVHC.

8. In the context of restrictions, ECHA has experience in pro-actively contacting companies to seek their opinion on potential exemptions, thereby inviting comments that aim to lower the level of protection of a restriction proposal. ECHA should apply the same eagerness to finding alternatives.
9. Article 64(3) REACH provides SEAC with the power to conduct such targeted public consultations: *"The Committee for Socio-economic Analysis may, if it deems it necessary, require the applicant or request third parties to submit, within a specified time period, additional information on possible alternative substances or technologies."*
10. https://echa.europa.eu/documents/10162/23551137/rudiger_schafer_en.pdf/840₂0373–584e-e9ab-f626–5c478786dd20
11. See J.A. Tickner, J.N. Schifano, A. Blake, C. Rudisill and M. J. Mulvihill, Advancing safer alternatives through functional substitution (2014) Environmental science and technology.
12. REACH, Article 55

ECHA guidance acknowledges the broader meaning of an "alternative"[13] and the need for alternative providers "to be in a position to understand the use most fully."[14] However, this dimension is usually missing in current applications for authorisation. Third parties need information beyond the "chemical function". When this information is kept confidential,[15] is missing or inadequate,[16] alternative providers are not given the means to assess whether their substance is an adequate alternative. Besides existing alternatives, the detailed description of function could be a key that triggers companies to innovate future solutions.

EXAMPLE

The application submitted to obtain an authorisation to use **HBCDD** exemplifies the problem, as it did not define essential criteria related to the function of the end-products (aka articles) for the manufacture of which the SVHC was used – making it more difficult for alternative provider to provide evidence demonstrating that the function can be fulfilled by other means, and for SEAC to consider alternative technologies. [17]

In addition, alternative providers (and other third parties) also need to know what SEAC will consider as an available and feasible alternative for that specific use, and how third-party information will be taken into account – because only then will they be in a position to provide the information that SEAC needs. SEAC has not yet developed a clear set of criteria to evaluate alternatives. Guidance exists and offers clues, but is not always followed. Currently, third parties are left in the dark on what information they are supposed to provide: they need to be given extra support.

The 'How to analyse alternatives' part of this report gives recommendations on how to improve the methodology used by SEAC to evaluate alternatives.

☞ *Recommendations to ECHA:*

- ECHA needs to require from the applicants a description of the three dimensions of the "function" beyond the "chemical function" and make it public, as is already called for in the guidance on the preparation of the application for authorisation. [18]
- As the starting point is a clear and meaningful definition of all the uses included in the application and a general description of the product or process in which the substance is used, ECHA needs to apply its 2017 guidance on the definition of use. [19]
- Reject undue confidentiality claims on information that is indispensable for third parties to contribute meaningfully.
- Organise meetings with alternative providers, as early as possible in the process, to explain which information is needed from them.
- Have a web page dedicated to "alternative providers" or "innovators for safer alternatives"[20] and provide a "go-to" person or department at ECHA, who alternative providers could contact to either ask for guidance or provide information.

☞ *Recommendations to SEAC:*

- Recommend the rejection of applications that are not specific enough to allow third parties to assess whether their alternatives would be suitable in application of Article 60(7).
- State the criteria which will be used to evaluate the suitability of alternatives.

None of these changes in administrative practice requires legislative change.[21] It requires work from an IT perspective and more resources allocated to the ECHA "substitution" team.

13. ECHA Guidance on the preparation of an application for authorisation, January 2011, p. p.57 https://echa.europa.eu/documents/10162/23036412/authorisation_application_en.pdf
14. Guidance on the preparation of an application for authorisation, p.84
15. See for example the application for authorisation submitted by Micrometal (p. 44–46)
16. Application for authorisation regarding DEHP in recycled PVC
17. See for more details the contribution of EEB to the public consultation on the application for autorisation.
18. Guidance on the preparation of an application for authorisation, p. 90 for example.
19. https://echa.europa.eu/documents/10162/13566/uses_description_in_auth_context_en.pdf
20. A similar format to the current tab "are you a consumer" on ECHA's home page, linked to a special page for consumers, could be used for inspiration.
21. The current rules on transparency (Regulation (EC) No 1049/2001; Regulation (EC) No 1367/2006), read in conjunction with REACH, allow for the publication of this information.

How to analyse alternatives

1. Keep the burden of proof on the applicant

REACH places the burden of proof on the company or companies that apply for authorisation to prove that the use applied for cannot be achieved without the SVHC. This means this is the responsibility of the applicant(s) to prove that there are no technically and economically feasible alternatives available for each specific use. In practice, however, SEAC tends to shift the burden of proof from the applicant to third parties by assuming that if a company decides to invest resources in the authorisation process, it is reasonable to assume that there is no suitable alternative. This logic is expressed explicitly for economic feasibility in the guide *"How the Committee for Socio-Economic Analysis will evaluate the economic feasibility in applications for authorisation"*, in which it is affirmed that *"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 submit an authorisation application"*.[22]

This assumption goes directly against the EU legislator's decision to place the burden of proving that no suitable alternative is available on the applicant. It is also unsound. Behavioural economics has revealed the fragility of the "rational economic agent" model[23] on which it relies. More generally, experience of the authorisation process has proved that applicants apply even when an alternative is already in use, even widely. This was confirmed by Sweden's comments submitted in the REACH REFIT consultation: "authorisations are granted despite availability of relevant alternatives" – an observation shared by Denmark and the Netherlands.[29]

EXAMPLE

In the **DCC lead chromate** case, evidence was brought in the public consultation that alternative pigments were used efficiently for many years for road markings (e.g. in Sweden). [24] The authorisation for use of lead chromates was flagged by Denmark under the REACH REFIT as an example of an authorisation granted to some industries for uses that other industries have already phased out.[25]

Gruppo Colle[26] did not include relevant alternatives in its analysis. It also rejected the arguments of third parties that submitted proof that the major and similar companies in the market have already successfully substituted the SVHC with alternatives that fulfil the same quality requirements.

Similarly, in the **Lanxess** case, the applicant fully rejected the arguments presented by the alternative providers, affirming that its alternative was feasible for applications in the automotive industry. [27] Volkswagen however released a new model with the technology a few months later, using a solution from an alternative provider, Oerlikon Balzers.[28]

REACH does require SEAC and then the Commission to consider "the technical and economic feasibility of alternatives for the applicant".[30] However, this provision cannot be interpreted in isolation. REACH also requires SEAC and the Commission to take into account information on alternatives provided by third parties.[31] In addition, according to REACH, the authorisation process aims to promote substitution, not to protect inefficient economic operators that did not invest in alternative solutions early enough.[32]

Both REACH and past experiences from the authorisation process therefore require that more weight is given to information from third parties that reveal the existence of alternatives and to shift back the burden of proof on to the applicant.

22. Page 2 of the document, 2013, https://echa.europa.eu/documents/10162/13580/seac_authorisations_economic_feasibility_evaluation_en.pdf
23. See for example Richard H. Taler's and Cass Sustein's work.
24. https://echa.europa.eu/documents/10162/18074545/a4a_comment_520_1_attachment_en.pdf
25. See Denmark's contribution to REACH REFIT https://ec.europa.eu/growth/sectors/chemicals/reach/review_en
26. https://echa.europa.eu/applications-for-authorisation-previous-consultations/-/substance-rev/15704/del/50/col/synonymDynamicField_302/type/asc/pre/4/view
27. https://echa.europa.eu/documents/10162/eec3aab4–3f49–48be-822b-b9f32d510e30
28. https://www.oerlikon.com/stories/2016/04/21/how-material-advances-put-the-vw-tiguan-in-the-technology-fast-lane/
29. See the papers submitted in addition to their contributions, https://ec.europa.eu/growth/sectors/chemicals/reach/review_en
30. REACH Article 60(5)(b).
31. REACH Article 60(4)(c) and 64(4)(b).
32. REACH Article 55.

In practice, this means that when a relevant alternative is already in use on the market, SEAC should apply a presumption that the alternative is technically and economically feasible. This presumption may be rebutted by the applicant, but only with detailed evidence establishing how its unique circumstances justify non-alignment with the best practices of the market. In other word, the level of evidence required from the applicant must be higher than when substitution has not already happened on the market.

In practice, this presumption means that if there is information demonstrating that an alternative performing the function of the SVHC is already in use, SEAC can only legally recommend not to grant authorisation.[33] An exception may be made only if the applicant submits detailed, specific and objective evidence that, because of attributes which differentiate it from all other companies that have already made the substitution, the substitution is not feasible (yet).

The decision tree (see page 11) illustrates how SEAC should assess the information received from the applicant against information received from third parties. It covers the situation where third parties bring evidence that an alternative is already in use on the market. Other scenarios would require an adaptation of the decision tree as the level and type of proof to be brought by the applicant must vary in light of the stage where the development of the alternative is at (already in use, placed on market but not used yet, in development, etc.).[34] The decision tree ensure that SEAC keeps the burden of proof on the applicant, and that SEAC requires applicants to follow a consistent methodology to assess alternatives, in line with REACH's requirements and the objective of the authorisation process.

☞ *Recommendations to SEAC:*

- Abandon the assumption that if a company applies for an authorisation, it is reasonable to assume that there is no alternative.
- Use a decision tree, such as the one proposed below, which keeps the burden of proof on the applicant.
- Raise the level of evidence required from the applicant when an alternative is already in use on the market – a requirement which can already be found in the guidance. [35]

2. Clarify the methodology for analysing alternatives

The two main guidance documents on the authorisation process[36] and the new "checklist"[37] give useful indications of how the analysis of alternatives, and in particular the analysis of the feasibility of the substitutes, should be set up and assessed. But they do not set clear boundaries. In practice, SEAC tends to accept any methodology followed by the applicant instead of requiring a consistent approach.

EXAMPLE

– The guidance recognises the need for the analysis to consider broader alternatives than drop-in substitutes as required by REACH,[38] but this is rarely done by applicants.

– The performance of an alternative may be considered inferior to the performance of the SVHC, when assessed on core technical requirements. However, even then, the alternative might make the function of the SVHC redundant, or be good enough to maintain the end-product or end-service function. This is why the guidance explicitly requires that the technical feasibility of the alternative should be assessed against the function to be performed, and not

33. Irrespective of the conclusion of the socioeconomic assessment, and pending the assessment of the risk of using the alternative scrutinised by RAC.
34. The starting point of this decision tree is that there is evidence from third parties that an alternative is currently used. There are other scenarios possible, i.e. an alternative is on offer but no company uses it yet. So this decision tree needs to be adapted depending on the information provided by third parties bearing in mind that the burden of showing that there are no suitable alternatives is on the applicant.
35. See for example, How to apply for authorisation, a step-by-step guide for applicants, October 2017, ECHA https://echa.europa.eu/documents/10162/13637/apply_for_authorisation_en.pdf/bd1c2842–4c90–7a1a-3e48-f5eaf3954676 p. 44.
36. How to apply for authorisation, a step by step guide for applicants October 2017, ECHA https://echa.europa.eu/documents/10162/13637/apply_for_authorisation_en.pdf/bd1c2842–4c90–7a1a-3e48-f5eaf3954676, ECHA Guidance on the preparation of an application for authorisation, January 2011, https://echa.europa.eu/documents/10162/23036412/authorisation_application_en.pdf
37. Checklist for preparing an application for authorisation or a review report, May 2017, https://echa.europa.eu/documents/10162/13637/afa_applicants_checklist_en.pdf
38. Article 55, 60(4)(d), 60(5).

against the performance of the SVHC. However, in practice, the latter is more common, which reduces the range of potential alternatives and violates REACH. This was for example what happened in the lead chromate case. The applicant compared the performance of the alternatives, in terms of durability of the end product (yellow paint), with the performance of the SVHC, without defining a benchmark, i.e. how durable the end product produced by using the chemical needs to be.

– The arguments of the applicant should rely on objective, verifiable data. But in practice, they are generally accepted during the last stage of the procedure (trialogue) at face value, in a situation where it is their word against the word of alternative providers, with the benefit of the doubt given to the applicant.

This leads to analysis which do not adopt the method needed to achieve REACH's objective and is required by the guidance, and, when such analyses are accepted by SEAC and the Commission, to illegal authorisations.[39] Neither the analysis of technical feasibility nor the analysis of economic feasibility have been in line with what is needed to achieve REACH's objective. The evaluation of economic feasibility in particular has suffered from a narrow scope, when a number of elements should actually be taken into account. These aspects are not further elaborated on in this paper, but ChemSec has previously touched upon this subject in several reports and position papers.[40]

This lack of clarity on what is required for an alternative to be considered suitable leads also to a disengagement of alternative providers and contributes to the feeling that this is all for "nothing".

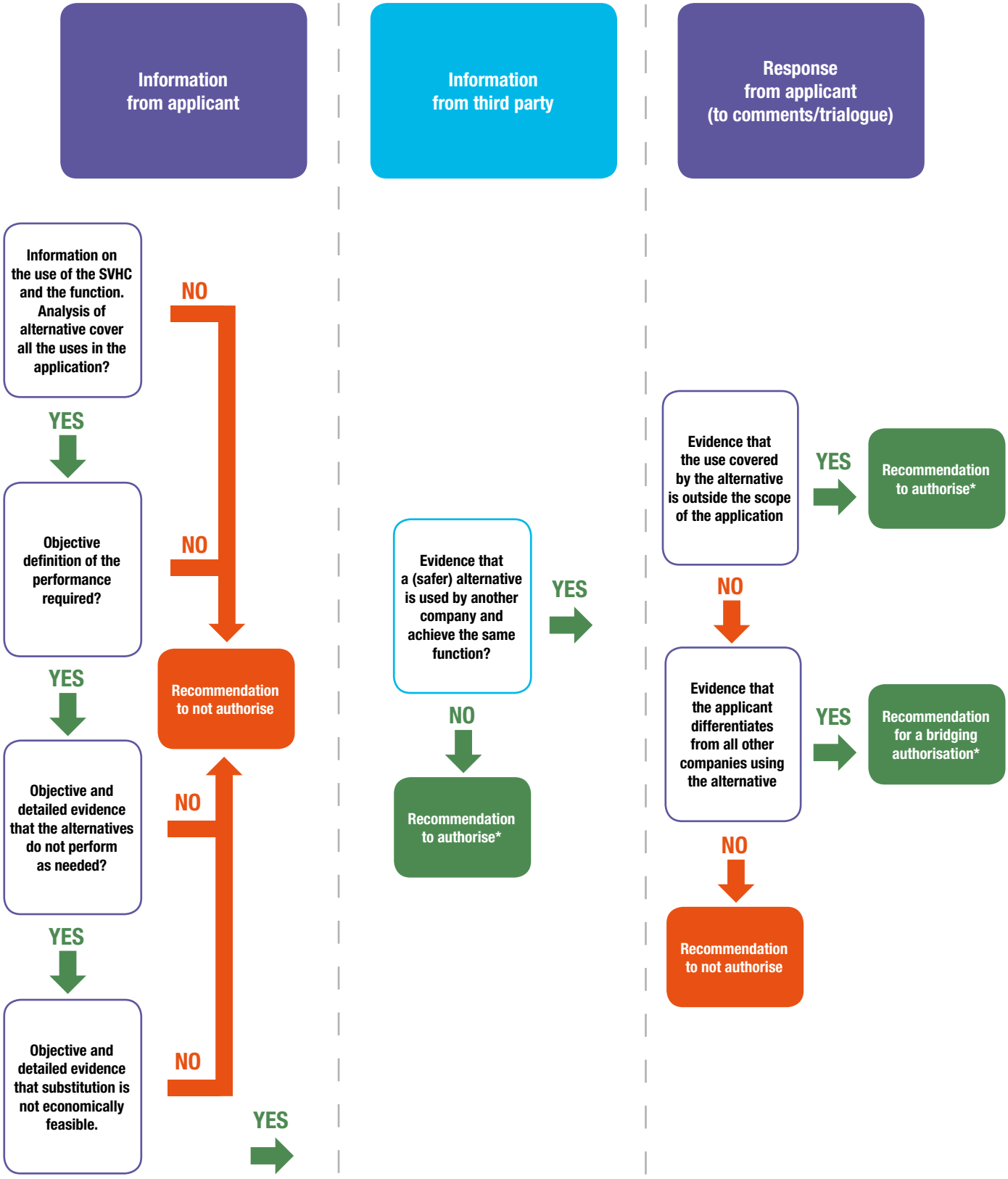
☞ *Recommendations to SEAC:*

- Require that the analysis of alternatives covers all the "uses" applied for which may vary depending on the end-use of the product or process.
- Require that technical requirements are based on the desired equivalent function (as defined in section 1.5[41]) to fulfil, and not on the SVHC performance.[42]
- Make sure the definition of technical requirements is based on evidence – avoid arguments taken at face value. For example, the following definitions could be used:
  - Legal requirement for technical acceptability (safety, etc.);
  - Critical performance related to the desired function objectively documented by performance certification requirements, including tolerances of these requirements (i.e. an acceptable range);
  - Process constraints, for example documented by certification requirements, including tolerances of these requirements (i.e. an acceptable range);
  - Customer requirement, but only if 1) duly documented 2) representing all or a representative majority of customers 3) with proof that the requirements were based on the customers' knowledge of the potential impact of SVHC use with no adequate control and of the performance of the relevant alternative;
  - Standardised performance test;
  - Tests by applicant but audited by independent third party.
- Make sure economic feasibility is evaluated in compliance with REACH and the guidance on the preparation of AfA, which make it clear that the fact that using the alternative costs more than using the SVHC is not enough to consider the latter not economically feasible.[43]

These recommendations do not require legislative change, and are in line with the applicable guidance.[44]

39. The lead chromate cases (Action brought on 28 November 2016 – Sweden v Commission (Case T-837/16); Action brought on 12 July 2017 – ClientEarth, ChemSec, EEB and IPEN v Commission (Case T-436/17)) are still pending.
40. See for example http://chemsec.org/publication/authorisation-process,chemicals-business,reach/the-bigger-picture-assessing-economic-aspects-of-chemicals-substitution-2016/ and http://chemsec.org/publication/authorisation-process,reach/3-ways-to-improve-the-socioeconomic-analysis-in-seac-june-2015/
41. Function of the chemical, function of the end-product/end-use, function of as service: what the function of the end-product/service is needed for.
42. Guidance on the preparation of an application for authorisation, p. 81.
43. Guidance on the preparation of an application for authorisation, p 75.
44. The notion of « alternative » under REACH is not defined precisely, but must be interpreted in light of the primary objective of REACH to protect human health and the environment and the objective of the authorisation process to replace SVHCs with safer alternatives.

Decision tree



*provided the societal benefits of the authorisation outweight the risks for human health and the environment

Conclusion

We recommend that ECHA together with SEAC and the Commission:

- **Keep the burden of proof on the applicant**
- **Improve the outreach of the public consultation**
- **Get relevant information from third parties**
- **Supplement the public consultation with proactive contacts with relevant third parties**
- **Give third parties the information they need to contribute meaningfully**
- **Withdraw authorisations when new information about available alternatives is discovered, in particular when it turns out that it was known but not disclosed by the applicant**
- **Clarify the methodology on how to assess available alternatives**

These recommendations have the potential to put the authorisation process back on track, and in full compliance with REACH's objectives. Today, the process tends to reward laggards. If these recommendations are applied, the decision-makers will have the means to sort out the cases where an authorisation is really needed from those where it is not. This is the only way to encourage alternative providers, to take financial risk to find innovative solutions, and to support the companies which have embraced their innovations.

More information at
ChemSec: http://chemsec.org/publication/authorisation-process/
ClientEarth: https://www.clientearth.org/chemicals/

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clientearth.org

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ClientEarth /ChemSec, March 2018