

How to apply for authorisation

December 2016



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About this guide

The purpose of this guide is to give potential applicants practical advice on how to prepare a 'fit-for-purpose' application for authorisation under the EU REACH Regulation¹, including choosing an appropriate 'use description'. This guide is supplementary to existing ECHA guidance documents and other information on the application for authorisation process.

The European Chemicals Agency (ECHA), with input from the Task Force on the Workability of Applications for Authorisation², has prepared this guide as part of their ongoing efforts to streamline the application for authorisation process. The development of the guide was informed by feedback gathered from past applicants and other interested stakeholders and reflects the experience gained so far from the implementation of the application for authorisation process.

The guide describes the essential information that should be included in an application for authorisation and presents examples from previous applications. It identifies the important documents that applicants should familiarise themselves with before preparing an application. It also outlines some key issues that should be considered when developing an application strategy, gathering information (including supply chain communication) and application planning.

The examples from previous applications are provided to illustrate relevant issues but should not be interpreted as the best or only way of preparing an application for authorisation. Previous applications should always be read in conjunction with the corresponding opinions of the European Chemical Agency's Scientific Committees and decisions by the European Commission as these also provide useful insight into the evaluation of applications and the decision making process.

This guide will be updated from time to time as further experience is gained in the evaluation of applications and from further understanding of the practical challenges faced by applicants. Equally, the guide will be updated in response to any improvements in the implementation of the application for authorisation process or support documentation. For example, an update to the ECHA publication on 'use description in applications for authorisation' is planned for 2017.

This document will be revised in the future in response to improvements in the implementation of the application for authorisation process or to address the needs of applicants. We are therefore interested in getting feedback on both general and specific aspects of this guide. If you think that any information, advice or documents have been omitted, or if you have any suggestions for improvement, please let us know through this feedback survey:

<https://www.webropol-surveys.com/S/FC35E2491162B840.par>

If you have any questions, you can email us at:

application-authorisation@echa.europa.eu

¹ Registration, Evaluation, Authorisation and Restriction of Chemicals - (EC) No 1907/2006

² The Task Force consists of representatives from the ECHA Secretariat, the Commission, the Committee for Risk Assessment (RAC), the Committee for Socio-economic Analysis (SEAC) and Member State Competent Authorities (MSCAs) of the following countries: Belgium, Denmark, France, Germany, the Netherlands, Sweden and the United Kingdom.

Key messages

The chapters of this guide clarify the critical issues that should be considered when preparing and documenting an application for authorisation. The key messages from these chapters can be summarised, as follows:

Be sincere and convincing

- Explain realistically and clearly what will really happen if you did not get an authorisation.
- Make sure that you understand and describe clearly the operational conditions and risk management measures and the link between them and exposure levels. Support exposure scenarios with reliable and representative up-to-date information e.g. on workplace exposure and environmental releases.
- 'Own' your application, irrespective of whether you use outside expertise to help to prepare it. The application concerns your business. Anticipate challenges during the opinion making process.

Defining the uses applied for is critical

- Uses define the scope of your application and are therefore the core of your application and the basis for any authorisation granted. Individual uses must be defined clearly and described in detail to minimise the uncertainties that may affect how your application is evaluated. Give the context of your use (within your process, your business, the market and society).
- Do not apply for uses where you know there are suitable alternatives. If there are "sub-uses" where suitable alternatives exist, clearly identify them and state that they are not included in your application.

Describe and analyse the alternatives clearly

- Clearly describe all alternative substances and technologies that you have considered (including beyond business as usual). Analyse the most promising ones and in particular the best alternative.
- Identify if your competitors have substituted or are planning to do so. Describe why you have not chosen to do so and what it would take to do this.

Describe and analyse your operations in a societal context

- Analyse and document clearly what you would do if you do not get the authorisation: for example, use the alternative or relocate production outside the EU. Be clear, as this is a key discussion point.
- Analyse the socio-economic impacts of non-use on your business and your supply chain as a whole, as well as on the users and producers of alternatives. Describe them as well as you can as the Socio-economic Analysis Committee will need to take such information into account.

Remember that an authorisation is subject to review

- Provide the information necessary for the scientific committees to recommend an appropriate time-limited review period for your use, e.g. on alternatives and benefits of continued use.
- The recommended review period may well be shorter than the total amount of time that you consider necessary to transition to an alternative. This is because the review report is used to check, for instance, technical progress relating to the development of alternatives for your use or how you have implemented the conditions of your authorisation.

Plan and organise

- Start early, talk with all those in the supply chain who may be affected directly or indirectly.
- Start with the ECHA web pages on "[how to apply for authorisation](#)".
- Decide early if and where you might need outside expertise.
- Notify ECHA about your plan to submit and ask for a pre-submission information session.
- Use iterations to refine the uses applied for and the analysis needed.
- Determine who would be in the best position in the supply chain to cover your use. Plan how you might apply - individually or with others.
- Be flexible, as you will learn during the preparation of your application, for instance from your customers and suppliers.
- Plan to finalise your application early and use the last month before submission to improve the coherence and readability of your application.

Read and follow the guidance

- In addition to the Guidance Documents use the [checklist for an application for authorisation](#).
- Take into account how ECHA's scientific committees evaluate your applications by reading the relevant notes on "[evaluating applications](#)" on the ECHA website.

Make your application readable and understandable

- Do not overload your application. One (or some) convincing arguments often works well. Define your main arguments in the analysis of alternatives or the socio-economic analysis and then build on it/them.
- Communicate in a way that a non-expert understands you. Information should remain coherent, logical and facts should be demonstrated as far as possible.
- Consider providing a note summarising the key elements of your application.
- Before submitting have an outsider critically review your applications.

1. Introduction

Under the EU REACH Regulation³, it is a general requirement that manufacturers, importers and downstream users shall ensure that the substances they manufacture, place on the market or use do not adversely affect human health or the environment.

In addition to that, companies that use, or place on the market, certain substances of very high concern (SVHC) may need an 'Authorisation' to do so. The aim of Authorisation is to ensure that the risks from SVHC are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable.

Authorisation can be granted for 'specific uses' by the European Commission on the basis of an 'application for authorisation' made to the European Chemicals Agency (ECHA). Where an authorisation is granted by the Commission it is valid until amended or withdrawn, but is subject to time-limited 'review', at which time authorisation holders are required to submit a review report.⁴

1.1 Overview of the authorisation process

1.1.1 When is an authorisation needed

An application for authorisation is required for an SVHC that has been included on [Annex XIV to REACH](#).

The listing of a substance on Annex XIV prohibits use or placing on the market after a specified 'sunset' date, unless the use has been authorised, an application for an authorisation for the use was made before the 'latest application date' but a decision has not been taken yet by the Commission or the use is [exempt](#) from authorisation. Annex XIV of REACH specifies both the sunset date and the latest application date.

The authorisation requirement applies in all countries in the European Economic Area (EEA), regardless of the quantity of the substance used.

Manufacturers, importers, only representatives or downstream users can all apply for an authorisation but there are differences between who in the supply chain is subsequently allowed to use the substance based on who applies. For example, an authorisation by an upstream actor can cover their own use of an Annex XIV substance as well as uses by downstream users within its supply chain. An authorisation held by a downstream user also allows for an immediate supplier to place the substance on the market, but only to supply to the authorisation holder.

Authorisations are always 'use specific'. This means that applications should also always be for an appropriately described specific use (or uses). Appropriate use description is introduced as part of Section 2 of this guide and further elaborated in Section 3.

An application can be submitted to ECHA by a single applicant or a group of applicants

³ Registration, Evaluation, Authorisation and Restriction of Chemicals - (EC) No 1907/2006

⁴ Irrespective of any applications, according to Article 69(2), ECHA considers if the use of an SVHC in both EU made and imported articles poses a risk to human health or the environment. If there is a risk that is not adequately controlled ECHA shall prepare a restriction dossier. In this manner possible risks related to articles can be addressed to complement the authorisation process. For details, see the restriction pages on ECHA's website and Article 69(2) of the REACH Regulation. For example, ECHA has prepared a restriction proposal for four phthalates.

applying together.

There are two possible circumstances under which an authorisation may be granted:

1. **Adequate control:** Applicants must show that the risk from using the substance is adequately controlled, i.e. that the exposure is below the derived no-effect level (DNEL) or the predicted no-effect concentrations (PNEC). Where there are suitable alternatives the application must also include a 'substitution plan'.
2. **Socio-economic benefits outweigh risks and there are no suitable alternatives:** Applications must show that the socio-economic benefits of using the substance outweigh the risks and that there are no suitable alternative substances or technologies. These are the conditions under which the use of a 'non-threshold' substance may be authorised (i.e. substances for which a no-effect level, and thus a DNEL or PNEC, cannot be established). Uses of threshold substances that result in exposures above the DNEL or PNEC may also be authorised under these circumstances.

These different authorisation routes are discussed further in Section 2 of this guide. Potential applicants should be aware that an authorisation cannot be granted for the use of a threshold substance for which adequate control is not shown and there are suitable alternatives.

1.1.2 Information required in an application for authorisation

The information required in an application is contained within a series of 'assessment reports'. The assessment reports that are required in a specific application will depend on whether the applicant can show adequate control of the risks and whether there are suitable alternative substances or technologies available for the use applied for.

The relevant assessment reports for an application for authorisation are:

- **Chemical Safety Report (CSR).** The CSR should always be included in an application and describes how the Annex XIV substance is used and the resulting risks to human health and/or the environment. Unless relevant to the analysis of alternatives, the CSR only needs to address the risks posed by the hazard properties of the substance that are listed on Annex XIV. The CSR describes the exposure scenario/s relevant to the use applied for, comprised of operational conditions (OCs) and risk management measures (RMMs). The CSR also contains the exposure assessment and risk characterisation for the use applied for.
- **Analysis of Alternatives (AoA).** The AoA should always be included in an application and describes the technical feasibility, economic feasibility, availability and risk reduction potential of alternative substances or technologies for the use applied for. The AoA should also include information about relevant research and development activities, including timelines.
- **Socio-economic Analysis (SEA).** The SEA describes what would happen if the applicant or other actors in its supply chain were not able to continue using the substance, and what costs and benefits this would entail. The key issue addressed in the SEA is whether the socio-economic benefits⁵ of the applicant's continued use

⁵ Socio-economic benefits are considered in a broad sense to include impacts on applicants, suppliers, consumers, competitors, market functioning, etc.

of the substance outweigh the risks to human health and the environment. Often, a large part of the benefits are related to the effort and investment required to adopt an alternative substance or technology. As a result of this, the SEA is closely interlinked with the AoA.

- **Substitution plan.** The substitution plan is required in an application where adequate control is shown and alternatives are considered to be suitable. The plan details the timetable for replacement of the Annex XIV substance in the use applied for.

The formats for these assessment reports are available on [ECHA's website](#). As the AoA and the SEA are closely interlinked, it is also possible to report these two analyses in a combined AoA/SEA format. While the information requirements are essentially the same regardless of which format is used, the combined AoA/SEA format might be more appropriate for some applications (and less for others). Specific considerations when using the 'combined format' are discussed in Section 3.4.2.

The SEA is not a mandatory assessment report when a substance is adequately controlled. However, it is recommended that some elements of SEA are reported in these applications as these may provide critical information during the evaluation of an application (e.g. if a substance is subsequently not considered to be adequately controlled). SEA in applications for authorisation under adequate control are discussed in Section 3.4.3.

The information required in each of these assessment reports are discussed further in Section 3 of this guide that describes 'the key elements of an application for authorisation'.

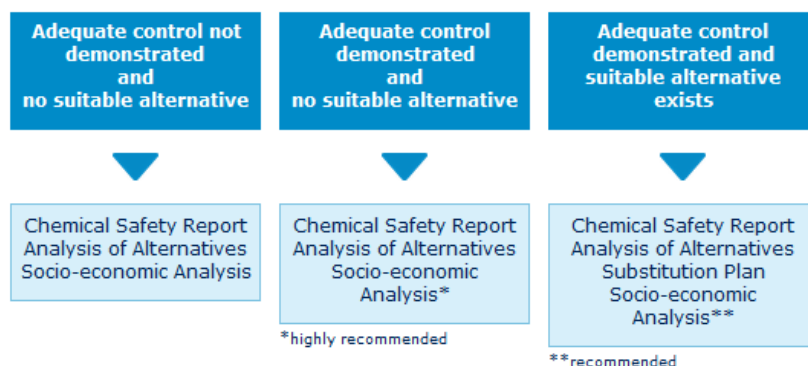


Figure 1.1. Assessment reports for applications for authorisation

1.1.3 Evaluation of applications for authorisation and decision making

ECHA's Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) develop an opinion on each use included in an application for authorisation. This opinion outlines the RAC and SEAC evaluation of an applicant's assessment reports and includes recommendations for any conditions or monitoring arrangements that could be included in an authorisation decision as well as a recommendation on the length of the time-limited review period, should an authorisation be granted for the use.

The RAC and SEAC opinion is based on the application, as well as any information received in the public consultation on possible alternatives. RAC and SEAC can request additional information from an applicant, which is also taken into account.

An indicative timeline for opinion development after submission of an application is outlined in Figure 1.2. Annex 1 presents an example of the letter sent to all applicants after their application is accepted. This letter provides further details of the opinion development timeline for their application, including the likely periods where RAC and SEAC could request an applicant to attend a 'trialogue' meeting, or submit written answers to questions.

Questions can be posed to an applicant after the initial evaluation of an application by RAC and SEAC or in response to information submitted by a 3rd party during the public consultation.

A 'trialogue meeting' may also be organised between the applicant, the Scientific Committees and third parties who have submitted information about potential alternatives in the public consultation. Triologue meetings are an efficient way to exchange and clarify information.

Applicants should plan the resources required to prepare answers to any questions received from the committees and/or participate in a triologue meeting. Responses to written questions are usually requested within 3-4 weeks of receipt.

After RAC and SEAC adopt their draft opinion, applicants can submit written comments on it, but they are not expected to provide new or updated information at this point in the process. Where an applicant chooses to comment, they must provide these within two months of receipt of the draft opinion. RAC and SEAC then take a further two months to adopt their final opinions.

The final decision to grant or not grant an authorisation is taken by the Commission after discussion with Member States in the REACH Committee. The European Commission prepares a draft authorisation decision within three months of receiving the RAC and SEAC opinion from ECHA. Following the draft decision, a minimum of a further three months is generally needed for the vote in the REACH Committee and the subsequent adoption procedure in the Commission. The decision-making process takes at least six months.

ECHA has established 'submission windows' for applications for authorisation that occur throughout the year. When applicants submit their applications within these windows, they ensure that their application will be processed within the shortest time possible. After an application has been submitted, an Authorisation Team Manager (ATM) is appointed from within ECHA. This means that applicants have an identified contact person at ECHA.

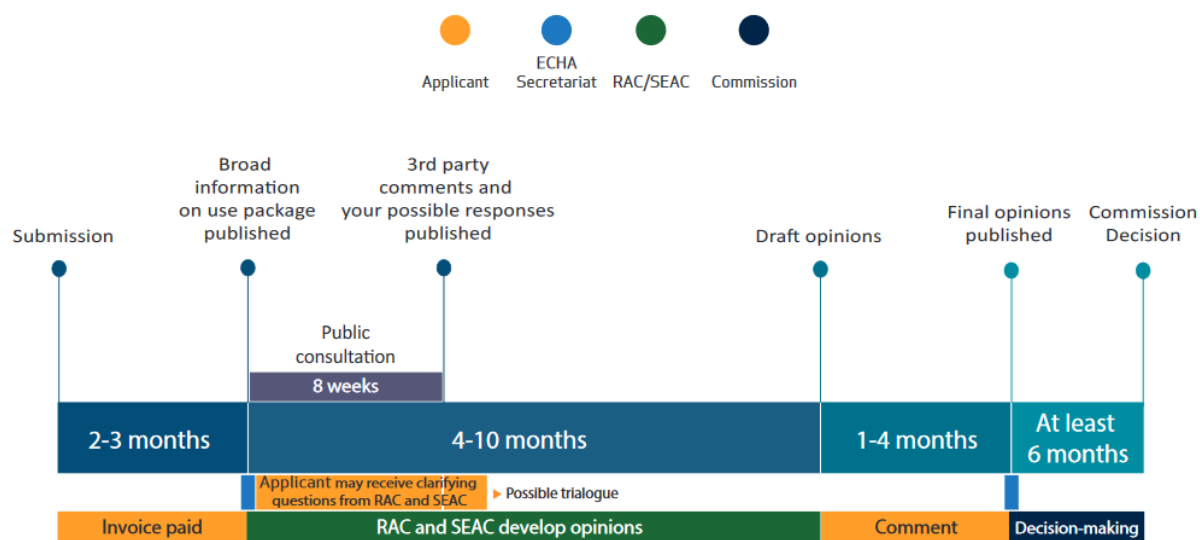


Figure 1.2. Indicative timeline for RAC and SEAC opinion making on an application for authorisation

Further information about how applications are evaluated by RAC and SEAC can be found in the following committee documents:

- [Common approach of RAC and SEAC](#) in opinion development on applications for authorisation (ECHA, 2012a).
- [Working procedure for RAC and SEAC](#) for developing opinions on applications for authorisation (ECHA, 2014a).
- [Setting the review period](#) when RAC and SEAC give opinions on an application for authorisation (ECHA, 2013a).
- [Guidance paper on opinion trees for non-threshold substances](#) (ECHA, 2016). These 'opinion trees' facilitate the interface between RAC and SEAC during opinion making and outlines how the strengths and weaknesses of different applications should be consistently evaluated and how these should correspond with recommendations for additional conditions, monitoring arrangements and the length of the time-limited review period.
- [Publication of information](#) on applications during the opinion-making process (ECHA, 2012b).
- [Participation of applicants, third parties and stakeholder observers](#) in the application for authorisation process (ECHA, 2012c).
- A [checklist for preparing an application for authorisation](#) (ECHA, 2016c) has been developed to assist applicants as they develop their assessment reports.

1.1.4 Obligations after an authorisation has been granted

If an authorisation is granted, the use of the substance will usually be subject to the conditions of use described in the application but may also be subject to certain additional conditions or monitoring arrangements that were not included in the application, but

recommended by RAC or SEAC or imposed by the Commission. Conditions of use and any monitoring arrangements will be specified in the decision.

1.1.4.1 Authorisation holders

Authorisation holders must comply with the conditions of the decision. If they place the substance or a mixture containing the substance on the market they must include the authorisation number on the label and pass on information about the authorisation. They have to inform their customers without delay in an updated extended safety data sheet (eSDS). The eSDS should include relevant exposure scenarios, as amended (where appropriate) by the authorisation decision, and any additional conditions and monitoring arrangements imposed by the authorisation decision on their downstream users (e.g. any reporting obligations for preparing the review report).

Those additional conditions and monitoring arrangements should be included in Section 15 of the eSDS.

Where the authorisation holder is also the registrant, they may also have to update the registration dossier.

1.1.4.2 Downstream users covered by the authorisation of an upstream actor

Downstream users of an Annex XIV substance covered by the authorisation of an upstream actor (e.g. their supplier) must comply with the conditions of the authorisation decision and notify to ECHA their use of the substance within three months of the first supply of the substance (this is known as an Article 66 notification and is made using [ECHA's website](#)).

ECHA will keep a register of these notifications and provide these to Member State Competent Authorities. Downstream users should also keep in touch with their suppliers and provide them with any information required for a review report, if necessary.

If a downstream user further supplies the substance, either on its own (following re-packaging) or in a mixture, they also have to pass on the information about the authorisation (in the eSDS and the label) without delay. The eSDS should include relevant exposure scenarios detailing the applicable operational conditions and risk management measures, to their customers, as well as any additional conditions and monitoring arrangements imposed by the authorisation decision on the latter (e.g. reporting obligations for preparing the review report). Those additional conditions and monitoring arrangements should be included in Section 15 of the eSDS.

1.1.4.3 Time-limited review

All authorisation decisions are subject to a time-limited review period. To continue using the substance after the end of the review period, a review report must be submitted to ECHA at least 18 months before the end of the review period. Therefore, efforts to identify and analyse suitable alternatives should continue after an authorisation has been granted for a use.

1.2 Relevant existing guidance documents and support

Guidance documents and other support materials for potential applicants are available on ECHA's website. These documents provide detailed technical guidance that is relevant to specific aspects of an application for authorisation (which is beyond the scope of this guide):

- ECHA's online [support pages on how to apply for authorisation](#) provide a quick overview of the necessary steps from an applicant's point of view.
- The [guidance on the preparation of an application for authorisation](#) (ECHA, 2011a) provides information about the authorisation process and describes the main elements of an application for authorisation.
- The [guidance on the preparation of socio-economic analysis for authorisation](#) (ECHA, 2011b) provides specific and detailed guidance on how to prepare a socio-economic analysis.
- The [guidance on information requirements and chemical safety assessment](#) provides guidance on how to prepare a CSR.
- ECHA has published over 80 [Questions and Answers \(Q&As\)](#) on the application for authorisation process.
- ECHA has also held several training seminars and workshops to clarify issues related to the application for authorisation process. The presentations and other material used in these events are available on [ECHA's website](#).
- Before submitting an application for authorisation, applicants can [request a pre-submission information session \(PSIS\)](#) with ECHA to ask questions regarding the regulatory and procedural aspects related to the application.

2. Developing an application strategy

At the outset of preparing an application for authorisation, it is useful to develop an application strategy and plan how, when and by whom the information necessary for assessment reports will be collected and analysed.

Certain aspects of an application, such as the analysis of alternatives or the collection of workplace exposure data (which may require workplace exposure monitoring) can, based on the experience of previous applicants, take a significant length of time to complete, which should be taken into account during planning.

Below is a list of issues that companies may want to consider when developing their strategy. It is important to appreciate that the preparation of an application, including the development of an application strategy, is likely to be most efficiently conducted as an iterative process.

Therefore, throughout the process, applicants should review their strategy to ensure that it remains appropriate. For example, an applicant should review the number of uses that will be required in an application after an initial data gathering exercise (i.e. an initial scoping study).

2.1 Establish the starting point

Applicants should initially ask themselves the following questions, which will help them to establish if they need to apply for authorisation, and, if so, whether they have the necessary information to prepare an application:

- Are there suitable alternatives to the Annex XIV substance and would it be possible to substitute to them? The [information on substituting hazardous chemicals](#) on ECHA's website may be a helpful starting point when considering this. Are there any competitors that avoid the use of the Annex XIV substance?
- How important is the Annex XIV substance to our business and our supply chain, and why? What makes it unique and indispensable for us?
- What R&D activities have we carried out on substituting the Annex XIV substance? What more can be done and by when to find a suitable and available alternative?
- If we do not obtain an authorisation, what is the most realistic alternative way forward for the company and its supply chain?
- What relevant data do we have on worker exposure and environmental releases of the Annex XIV substance, e.g. from existing workplace risk assessments or surveillance monitoring, environmental permit requirements, REACH registration dossiers or extended safety data sheets? Is this data robust and representative of the use that we are considering applying for? Do we need to perform or collect (additional) measurements?
- Are risks for human health and the environment controlled in line with the general requirements under REACH (Article 14(6) and Annex I, Sections 6.4 and 6.5)? If the substance is used at the workplace, have the principles of the hierarchy of

control⁶ been adhered to? Are releases to the environment minimised, e.g. through the application of best available techniques (BAT) under the Industrial Emissions Directive (IED)⁷ or by avoiding wide dispersive uses with high potential for release to the environment? Is there scope to further improve operational conditions, or risk management measures to reduce workplace exposures, consumer exposures, or releases to the environment?

2.2 Consider how to apply

An application for authorisation may be made by the manufacturers, importers, only representatives and/or downstream users of the Annex XIV substance. They can apply for their own use or for the downstream uses that they intend to place the substance on the market for. In addition, an application can cover the placing of the substance on the market by an immediate supplier (see Figure 2.1 below).

Therefore, as a first step, companies that require an authorisation should try to find out whether others in the supply chain intend to apply for the same use⁸. Downstream users should find out if their use is covered, or is intended to be covered, in an application prepared by a supplier (upstream actor). This is similar to the practice under REACH registration where manufactures/importers are responsible for the registration of substances for downstream uses, but downstream users can notify registrants of their uses.

Where an application will be made for a downstream use by an upstream actor in the supply chain, a downstream user may either rely on this application, or submit an application for their own uses. The latter may be of interest to a downstream user where they are reluctant to share confidential business information (CBI) with their supplier or would prefer to keep their supply options open.

Downstream users should carefully consider any request for information (e.g. on operational conditions, risk management measures, suitability of alternatives or socio-economic information). This is because downstream user information is likely to be critical in ensuring that an authorisation is granted and that all appropriate conditions of use are included.

⁶ Hierarchical system used to minimise or eliminate exposure to chemical hazards as described in the Chemical Agents Directive (98/24/EC) and Carcinogens and Mutagens Directive (2004/37/EC). Protection and prevention measures that should be used by employers to reduce risks to a minimum include, in order of decreasing effectiveness (priority): substitution, engineering controls (that avoid or minimise release, such as closed systems), collective protection measures at source (e.g. adequate local extraction or general ventilation), administrative (organisational) controls (such as hygiene measures and demarcation of risk areas) and individual protection measures, including personal protective equipment (PPE).

⁷ <http://eippcb.jrc.ec.europa.eu/reference/>

⁸ The ECHA [‘partner service’ for applicants](#) might be helpful in finding other companies or consortia to partner with.

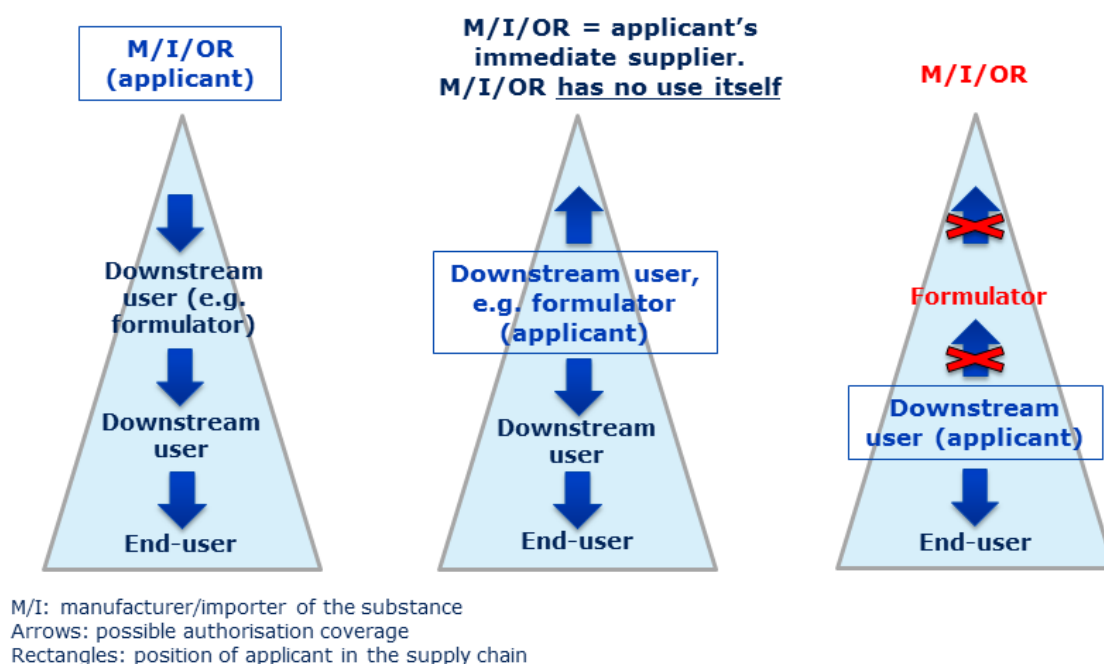


Figure 2.1. Supply chain coverage in applications for authorisation

Manufacturers, importers or only representatives may also group together to prepare a 'joint application' for the uses of their downstream users. Similarly, groups of downstream users undertaking the same use can prepare a joint application⁹.

While there may be benefits in preparing the assessment reports (or parts of them) as part of a group, the final decision on whether to submit a joint application or a series of company specific individual applications should only be taken once the analysis is complete and it is clear if the uses and arguments (as described in the CSR, AoA and SEA) of all the members of the group are compatible.

There may also be CBI issues and competition law that influence the decision to apply jointly or individually.

Some of the potential advantages (+) and disadvantages (-) relevant to deciding how to apply are outlined in the boxes below.

⁹ When establishing any group to prepare an authorisation application, carefully consider whether to discuss with relevant industry associations; whilst they are not users of the substance themselves (and thus are not applicants) they often have access to relevant information or communication networks with downstream users that could be useful when preparing an application. Equally, companies that assemble end products from component parts produced using an Annex XIV substance (but which do not contain the Annex XIV substance) are not users of a substance (and cannot apply), but are likely to have relevant information for an application and would be affected in the event that an authorisation was not granted.

Application by a single downstream user	
Advantages	Disadvantages
<ul style="list-style-type: none"> + The scope of the analysis can be simple and it is straightforward to present specific data in the application (e.g. on exposure, suitability of alternatives, markets, profits etc.). + If the authorisation is granted, the applicant has flexibility regarding where to purchase the substance. 	<ul style="list-style-type: none"> – The applicant needs to allocate all the resources needed to develop assessment reports and submit an application (e.g. possible cost of support provided by external experts, application fee).

Applications by multiple downstream users	
Advantages	Disadvantages
<ul style="list-style-type: none"> + Possibility to share knowledge, e.g. about alternatives. + Potential cost savings in the development of assessment reports (e.g. literature review, methodologies). + If the authorisation is granted, the applicant has flexibility regarding where to purchase substance 	<ul style="list-style-type: none"> – The management of confidential information and the necessary organisation and coordination across several companies may represent an administrative burden and cost. – If there are significant differences between companies (e.g. in RMMs applied, exposure or suitability of alternatives) then the decision to grant an authorisation, the conditions of the authorisation or the length of the review period could be driven by the ‘lowest common denominator’.
<p>Issues to consider:</p> <ul style="list-style-type: none"> • Ensure that each use is adequately defined – clearly establish which are the final uses applied for and the use conditions for each of them. • Ensure that the data in the application (CSR, AoA, SEA) is representative, and is reported in sufficient detail to allow RAC and SEAC to evaluate it. The concept of representativeness is elaborated in Section 3. • Identify uncertainties and minimise them where possible, especially if they are considered to be important. Where they cannot be minimised their significance should be analysed. • Contractual framework, project management and agreement on the decision-making processes within the group. • Working procedures for managing confidential business information both during the preparation of the assessment report and in response to potential questions from RAC and SEAC (compliance with competition law may require involvement of an independent third party to protect confidentiality). • If the decision is taken to submit a joint application, carefully consider the comparability of uses (in terms of OCs and RMMs, suitability of alternatives, risks and benefits) between all the applicants. Joint applications are likely to be evaluated on the basis of the “lowest common denominator”, which could be based on a single member of a joint application. Would such a situation be acceptable? 	

When downstream users apply, either individually or jointly, there is an additional element to consider. It is important to determine if there is an additional, intermediate step taking place in the EU between their use of the substance and its manufacturing or import, such as the formulation of a mixture, as this will also need to be authorised.

Applications by upstream actors	
Advantages	Disadvantages
<ul style="list-style-type: none"> + Efficient if the application is well designed at an appropriate scale, allowing flexibility of supply (for downstream users) within complex and multi-layered supply chains. This may be beneficial for companies who do not have the capacity to pursue their own applications (e.g. SMEs). + If well organised, it may be overall less expensive for the supply chain than multiple individual applications. This is because the necessary technical expertise to develop assessment reports can be resourced as a single project. + Possibility to cover several types of downstream uses and/or the entire 'depth' of complex supply chains in a single application (potentially with multiple uses). 	<ul style="list-style-type: none"> – Extensive data collection likely to be required from supply chains that may be complex and multi-layered. Complex coordination required among actors at all levels of the supply chain. Management of CBI. – Extensive effort likely to be required to ensure 'representative data' (on RMMs, exposure/emissions, alternatives, socio-economic aspects) and minimise uncertainties. – Should a use be described broadly (e.g. encompassing multiple "sub-uses" that have different potential for substitution, RMMs or exposure levels), this could affect the conditions, the length of the review period or even whether an authorisation is granted e.g. if evaluation is driven by the 'lowest common denominator' or if it is difficult to show that there are no suitable alternatives across the whole use.
<p>Issues to consider for applicants (upstream actors):</p> <ul style="list-style-type: none"> • Ensure that each use is adequately defined – clearly establish which are the final uses applied for and the use conditions for each of them. • Data collection – mapping the supply chain and planning the data collection should begin early. Previous applicants' experience has shown that this task is likely to have practical challenges (e.g. identifying contacts, multilingual respondents) and may require several rounds of consultation to obtain the information needed. • Involve any relevant distributors early in the process, as they may be able to provide useful information about downstream users. • Ensure that the data in the application (CSR, AoA, SEA) is representative, and is reported in sufficient detail to allow RAC and SEAC to evaluate it. The concept of representativeness is elaborated in Section 3. • Identify uncertainties and minimise them where possible, especially if they are considered to be important. Where they cannot be minimised their significance should be analysed (important in all applications but those applications covering many downstream users are particularly prone to uncertainties). • Consider if using an independent third party to manage the upstream flow of information would be needed to protect CBI and respect competition law. 	
<p>Specific issues for downstream users that are asked to help prepare an application.</p> <ul style="list-style-type: none"> • If you need to continue using the Annex XIV substance you need to ensure that the authorisation covers your particular conditions of use. This means that the application needs to take account of your particular use conditions, alternatives assessment and socio-economic considerations. Therefore, endeavour to provide any data requested by the upstream actor as it could be critical in ensuring that an authorisation is granted or that your particular use is included. • You may not be able to play an active role in presenting and defending your own data, which will be evaluated together with the data provided by other downstream users. If there are key differences between downstream users (e.g. in RMMs applied, exposure or suitability of alternatives), you may have a stronger case when applying on your own rather than as part of an upstream actor application. 	

Consider a two-level application strategy

Based on the experience in the application process, it seems that a two level application strategy could be helpful, although it has not yet been used.

In such a strategy, manufacturers, importers or only representatives would apply for a 'Level 1' authorisation for their own use of the substance as well as downstream users undertaking formulation uses, here called 'formulators'.

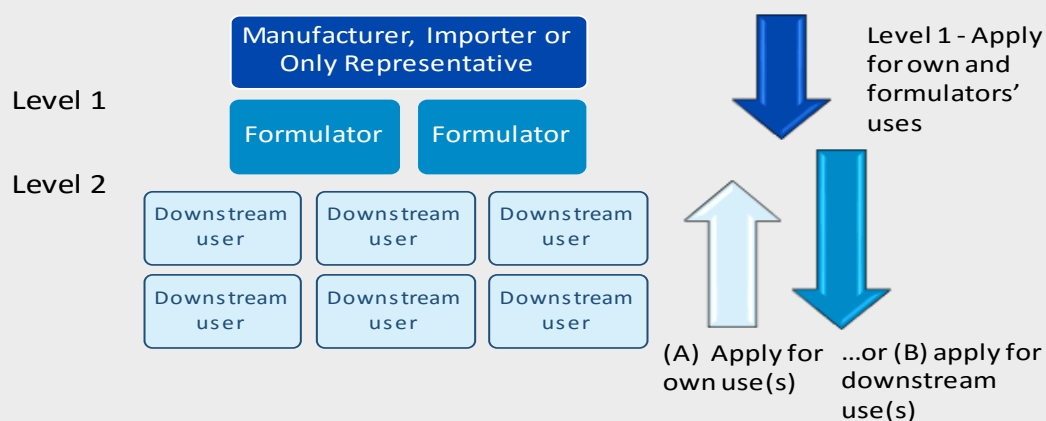
In 'Level 2' applications,

(A) downstream users (including end users) of the formulators would apply for their own uses,

Or

(B) alternatively, formulators could apply for the uses of their downstream users.

Level 2 applications could be made simultaneously with Level 1 applications. The following figure illustrates the strategy:



The advantage in this strategy is that the actors applying can provide specific information on their use and bring additional clarity to the applications. This way of working may also reduce possible problems related to the handling of confidential business information (CBI) and competition law.

A two level application strategy would probably need to be developed jointly by all the main actors in a supply chain. It would require a different way of organising the work to prepare the individual applications as coherent packages. The coverage of the applications would be the same as in other ways of applying.

2.3 Consider the scope of your application and the number of uses

The scope of an application is defined by the uses applied for and is influenced by several elements, including:

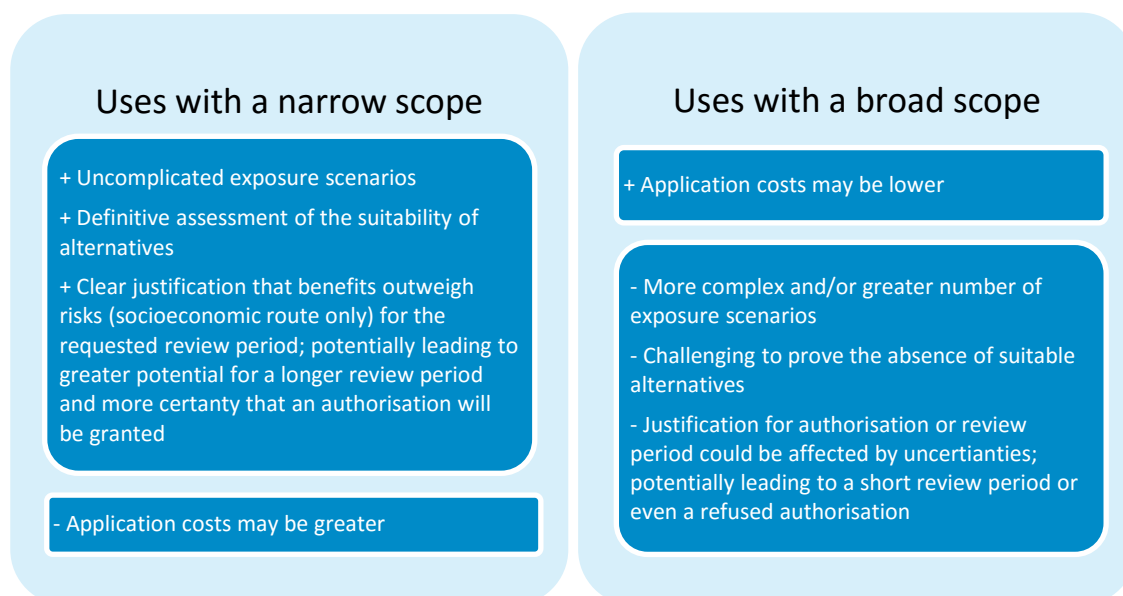
- The number of different market sectors covered.
- The number of different legal entities covered.
- Diversity of end products¹⁰ manufactured using the Annex XIV substance.

Defining the scope of an authorisation application should ideally be an iterative process. Certain uses may be included, excluded or refined when preparing an application depending on the available information, including analysis of relevant operational conditions, risk management measures, worker and general population exposures and the suitability of alternatives within different markets.

When defining uses, the following should be considered:

- The diversity of operational conditions (OCs) and risk management measures (RMMs) implemented at all the different sites to produce the end products included in the uses; can this diversity in OCs and RMMs be reflected in a single use?
- The suitability of alternatives within the different markets and diversity of end products covered by the uses. If technical requirements vary across different markets or end products this may influence the suitability of alternatives; can this diversity in the suitability of alternatives be reflected in a single use? The broader the scope of a use is, the less straightforward it is likely to be to show that there are no suitable alternatives available for all the articles/sites covered.
- The diversity of responses to a refused authorisation and related socioeconomic impacts within the different markets and end products covered. Can this diversity in supply chain responses be reflected in a single use?

These aspects are further developed in Section 3 of this guide.



¹⁰ End products, for the purposes of authorisation, include articles, components of articles and other substances on their own or in mixtures (e.g. polymers, active pharmaceutical ingredients)

2.4 Consider whether you need external expert advice or support

Preparing an application for authorisation requires expertise across various disciplines, such as occupational hygiene, environmental exposure assessment, product development, process engineering and socioeconomic analysis.

Whilst applicants are likely to have significant expertise in some, if not all, of the necessary areas of expertise, sometimes they could benefit from additional expertise in a particular area. Furthermore, the coordination of consortia often requires particular expertise, especially when considering how to collate and analyse confidential business information (CBI).

Any decision on whether external expert advice or support is required when preparing an application should consider:

- What the applicant's internal capabilities and capacities are (including internal know-how and available resources);
- What the additional expertise would be used for, such as:
 - advice on application strategy and submitting an application;
 - assistance with data-gathering;
 - assistance with specific parts of an application;
 - support after submission (e.g. responding to questions from RAC and SEAC, support in a potential dialogue); and/or
 - management of CBI (this is particularly important for applications by upstream actors and for joint applications by several downstream users).

Regardless of whether external expert support is needed or not, the applicants should always 'own' their application as they are usually the ones who best know their use.

If applicants decide to outsource specific parts of the application, they should ensure that connections between the assessment reports are considered. For example, the AoA and SEA are highly integrated and it is therefore important that links between these reports are maintained.

2.5 Use of confidential business information

It may sometimes be appropriate for applications to include CBI. However, the merits of including it in an application should always be considered on a case-by-case basis, specifically:

- CBI should only be provided when it significantly adds to the argument being made. Remember that any material submitted to ECHA as part of an application for authorisation can be subject to an "[access to documents request](#)" by a third party.
- CBI can be 'redacted' (blanked) from the public versions of assessment reports (i.e. those used for the public consultation). However, each instance where confidentiality is claimed requires a specific justification. ECHA advises against redacting large blocks of text from assessment reports so that public versions of documents remain coherent. Only the specific CBI in the text should be redacted and, where possible, non-confidential information should also be provided e.g. a

tonnage range. Further information on how to redact and justify CBI in assessment reports is provided in the [relevant formats on ECHA's website](#).

- Care should be taken when redacting information from documents, so that it cannot be recovered from the public versions.

2.6 Detail and depth of analysis in "fit-for-purpose" applications

ECHA's *Guidance on SEA (ECHA, 2011b)* states that the analysis undertaken should be '*as robust as needed to support the conclusion*' and that '*the level of detail should be proportionate to the problem in hand*'. Similarly, the Commission impact assessment guidelines state that '*...the more significant and the more likely the impacts are expected to be, the deeper the analysis should be...*'.

Therefore, within the context of an application for authorisation, the level of information and analysis necessary to justify an authorisation should be balanced against the human health or environmental impacts posed by the uses applied for. This concept can be referred to as a 'fit-for-purpose' application for authorisation. All parts of an application (i.e. CSR, AoA and SEA) should be prepared with this concept in mind.

Applications should be as concise as possible and only contain relevant information for opinion and decision-making. Where it is appropriate, consider focusing on one, or a limited number of, well described and justified "key" arguments in assessment reports.

The need for including detailed secondary argumentation should always be determined by evaluating the strength of the key arguments. Secondary information, if provided, can always be described to a lesser extent (e.g. qualitatively rather than quantitatively, if appropriate).

Such an approach will aid applicants, ECHA's scientific committees and decision makers. The [checklist for preparing an application for authorisation](#) (ECHA, 2016c) provides advice on the information that should be included in an application (and where supporting information and justification should be provided).

3. Key elements of an application for authorisation

3.1 Use applied for

An authorisation for an Annex XIV substance is **always granted for a specific use**. Therefore, a critical, if not the most critical, element in preparing an application is the description of the uses applied for. Individual applications can include several uses, each supported with their own set of assessment reports.

The clear definition of every single use in an application is required regardless of the number of uses applied for and the applicant's role in the supply chain. Where uses are not appropriately described, there are likely to be difficulties in showing that there are no technically and economically feasible alternatives within the scope of a single use. This could adversely affect the conditions of an authorisation, the length of the review period or even whether an authorisation is granted.

The sections below introduce how the uses that comprise an application for authorisation should be described. The ECHA publication on [how to develop the description of uses in the context of authorisation](#) (ECHA, 2011c) provides further information on this process.

3.1.1 Use description

A use description in an application for authorisation contains the following elements:

- The name of the use applied for.
- A description of the use in relation to exposure scenarios.
- A description of the use in relation to an analysis of alternatives.

Where there are many different end products with the same technical requirements produced with the same process (e.g. different models of electrical connector), uses do not need to be described at the level of each and every end product. In these cases, it is likely to be sufficient in an application to describe the 'type of end product' manufactured.

However, if such a 'type of end product' approach is taken, it is important to ensure that there are no differences in the technical requirements within the group of end products relevant to the suitability of alternatives.

Please remember

- *Opinions and decisions are made by ECHA's committees and the Commission per use.*
- *As part of evaluating an application, ECHA does not further sub-divide a "broad" use into a greater number of "narrow" (sub)uses, e.g. with different recommendations for the length of the review period. Therefore, to avoid obtaining an authorisation with a short time-limited review period, applicants should try to avoid incorporating 'sub-uses' where suitable alternatives are already available, or are likely to become available within a short period after the sunset date, within the scope of a single use. In such cases, applicants should consider splitting an application into a greater number of uses, as appropriate.*

3.1.2 Use name

Under most circumstances the use names in an authorisation application need to be more specific than those used in registration dossiers. A use name should, ideally, include the following three elements:

- the function of a the substance;
- the end product; and
- the market sector.

Examples of use names from previous applications

- *Yara France's application for the use of diarsenic trioxide.*
 - [Industrial use of diarsenic trioxide as a processing aid to activate the adsorption and desorption of carbon dioxide by potassium carbonate from synthesis gas formed in the production of ammonia.](#)
- *Blue Cube Germany Assets GmbH & Co KG's (Formerly DOW Deutschland) application for the use of trichloroethylene.*
 - [Use of trichloroethylene as extraction solvent for bitumen in asphalt analysis](#)
- *Federal Mogul Burscheid GmbH's application for the use of chromium trioxide.*
 - [Functional chrome plating of piston rings for automotive engines as applied in the segments light vehicle petrol, light vehicle diesel, middle range diesel and heavy duty.](#)
- *Gentrochema BV's application for the use of sodium dichromate.*
 - [Use of sodium dichromate for the electrolytic passivation of tin plated steel for the packaging industry.](#)
- *Eli Lilly's S.A. – Irish Branch's application for the use of 1,2-dichloroethane (EDC).*
 - [Industrial use as a reaction medium and solvating agent in mediating subsequent chemical transformation reactions leading to the manufacture of an active pharmaceutical ingredient, raloxifene hydrochloride.](#)
- *GE Healthcare Bio-Sciences AB's application for the use of 1,2-dichloroethane (EDC).*
 - [Industrial use of 1,2-dichloroethane as an emulsifying solvent in the manufacture of porous particles for beaded chromatography and cell culture media.](#)

3.1.3 Describe the use for the exposure assessment

Main principles:

- One use applied for should, ideally, be described in one exposure scenario. However, there could be good reasons to have more than one exposure scenario e.g. where a use covers more than one industrial process such as spraying and immersion.
- The exposure scenario is a clearly defined set of OCs and RMMs, which lead to the exposure levels that are used for risk characterisation and possible impact assessment. In applications for authorisation by upstream actors, the exposure scenario also describes the conditions of use that need to be communicated to the downstream users through the extended safety data sheet. Downstream users, in turn, must operate within the boundaries of the exposure scenario to be covered by the authorisation.
- REACH does not require one exposure scenario per individual site where a use takes place. However, in applications for authorisation that are intended to cover multiple sites (either generic or specific sites in applications covering many downstream users) variability between sites should be taken into account.

See Section 3.2 for further details on the CSR for applications for authorisation.

3.1.4 Describe the use for the analysis of alternatives

Uses should be described at an appropriate scale. ECHA recommends that uses are described in such a way that it includes:

- 1. A clear set of technical criteria/specifications/functional requirements.** For example, some applicants (see examples below) made a single application, but with several different uses separated on the basis of the technical function that the substance performs and the level of technical performance that is required in the articles produced using the substance in relation to international standards. In several other applications by upstream actors, "matrix" approaches (see examples below) have been used to identify under which specific technical conditions or requirements the potential alternatives are not technically and economically feasible (thereby establishing the scope of the use).

And, if appropriate

- 2. Restricted to a single industry sector of use.** For example, an application for authorisation for a generic industrial process such as surface treatment could define uses based on specific industry sectors: e.g. automotive, aviation, tooling, cosmetic. This is because each sector has its own peculiarities in terms of technical specifications, quality standards, qualification/certification timelines, substitution costs etc., which are relevant to determine the feasibility of potential alternatives. The definition of an industry sector may be challenging. However, the "Sector of Use" descriptor in ECHA's R.12 guidance on use description may be a useful starting point.

It is essential to differentiate uses on the basis of different substitution potential (including timelines). However, if this exercise results in many uses, applicants should consider grouping them in a coherent manner e.g. short-term vs long-term substitution

possibilities/goals. Any grouping approach needs to be fully justified. See Section 3.3 for further details on the AoA for an application for authorisation.

Examples from previous applications

- *Blue Cube Germany Assets GmbH & Co KG's (Formerly DOW Deutschland) application for the [use of trichloroethylene in industrial parts cleaning by vapour degreasing in closed systems where specific requirements \(system of use parameters\) exist](#). This application is an example of how a "matrix" can be used to define the scope of the use applied for.*
- *Souriau sas's application comprised three uses of chromium trioxide for producing specialised electrical connectors (plugs and sockets). This application is an example of how 'similar' functions can be differentiated into separate uses based on different technical performance requirements (relevant to different markets):*
 1. *[Industrial use of a mixture containing hexavalent chromium compounds for the conversion of cadmium coated circular and rectangular connectors in order to achieve a higher level of performances than the requirements of international standards as well as to withstand harsh environments and high safety applications \(such as in the military, aeronautic, aerospace, mining, offshore and nuclear industries or for the application in safety devices for road vehicles, rolling stock and vessels\)](#).*
 2. *[Industrial use of a mixture containing hexavalent chromium compounds in conversion coating and passivation of circular and rectangular connectors in order to meet the requirements of international standards and special requirements of industries subject to harsh environments](#).*
 3. *[Industrial use of a mixture containing chromium trioxide for the etching of composite connectors used by industries subject to harsh environments, to mainly ensure adhesive deposit to meet the requirements of international standards](#).*

Please remember:

- *Do not include "sub-uses" (e.g. certain end products) within a use where :
 - *The Annex XIV substance is no longer used to produce them.*
 - *Suitable alternatives can be implemented before the sunset date.*
 - *There are different timelines for substitution – in such a case, consider a separate use.**
- *Uncertainties in relation to the scope of the use may lead to a shortening of the review period for the whole use or potentially not granting an authorisation.*

3.2 Chemical safety report

The chemical safety report describes the use of the substance and the risks to human health and/or the environment arising from its intrinsic properties specified in Annex XIV.

The information provided in the CSR is evaluated by RAC. As the hazard and physical properties of Annex XIV substances are already well known, the critical sections of the CSR in an application for authorisation are generally considered to be Sections 9 (exposure assessment) and 10 (risk characterisation).

If an applicant uses the relevant [reference derived no-effect level \(DNEL\) or dose-response relationship](#) for the Annex XIV substance published by RAC, it does not need to provide (or request and pay for access to the registration dossier) additional hazard or physico-chemical data, unless these data are relevant to either the assessment of alternatives or exposure modelling¹¹.

The use of these reference values helps RAC to evaluate of the applications in a transparent, consistent and efficient manner. It also helps to reduce an applicant's uncertainty about how their applications will be evaluated.

The use of an alternative dose-response relationship or DNEL value is acceptable, but should be supported with detailed information justifying why an alternative approach is considered to be appropriate. If RAC disagrees with the alternative values submitted, this may affect the conclusion of RAC on the appropriateness and effectiveness of the risk management measures in the application.

The [Guidance on information requirements and chemical safety assessment](#) is relevant for preparing a chemical safety report for an application for authorisation. The following specific guidance should be reviewed before preparing an application for authorisation:

- Part D - Framework for exposure assessment (ECHA, 2016e).
- Part E – Risk Characterisation (ECHA, 2016f).
- Use description (R.12; ECHA, 2015a).
- Risk management measures and operational conditions (R.13; ECHA, 2012d).
- Occupational exposure estimation (R.14; ECHA, 2016g).
- Consumer exposure assessment (R.15; ECHA, 2016h).
- Environmental exposure estimation (R.16; ECHA, 2016i).
- Uncertainty assessment (R.19; ECHA, 2012).

¹¹ Exposure modelling approaches, such as the EUSES model, require information on the physico-chemical properties of the substance (such as its boiling point).

Did you know?

- *Instead of submitting a complete CSR, ECHA recommends that where RAC reference DNEL or dose-response relationships are used by an applicant, only Sections 9 and 10, i.e. the exposure scenarios and the risk characterisation are included in an application for authorisation. Since many downstream users do not have access to the registration CSR for the Annex XIV substance, this simplification means that they do not need to buy a letter of access to report hazard data (relevant physico-chemical and environmental fate data used for modelling must be included in Chapter 9 if Chapters 1-8 are not included).*
- *Where applications for authorisation are made for substances listed in Annex XIV to REACH on the basis of their PBT properties, an assessment of worker exposure is only required where substances fulfil REACH Annex XIII criteria for “toxicity” based on human health endpoints.*

The practical guidance on [preparing a downstream user chemical safety report](#) (ECHA, 2015b) may be useful for certain applicants. Equally, the practical examples and [annotated formats](#) on ECHA's website for [chemical safety reports](#) (ECHA, 2012f) and [exposure scenarios for communication](#) (ECHA, 2014b) are likely to provide useful additional information for applicants.

However, remember that this guidance was principally developed for REACH registration and that CSRs provided to support an application for authorisation are generally expected to contain more detailed and specific information.

In addition, upstream actors preparing applications for downstream uses should review the approaches developed as part of the CSR/ES roadmap to describe sector “[Use maps](#)”.

The use map concept was developed to improve the quality of the information on use and conditions of use communicated in the supply chain for REACH registration. Nonetheless, certain aspects of the approach are likely to be useful in an application for authorisation by an upstream actor, particularly those elements that aim to ensure that chemical safety assessments reflect relevant and realistic information on uses and conditions of use.

However, as already noted, applicants should be aware that the level of detail and information generally anticipated in an application for authorisation is greater than that for REACH registration.

ECHA also regularly publishes [questions and answers \(Q&As\)](#) on specific aspects of the application for authorisation process on its website, including chemical safety assessment, which should be checked regularly.

3.2.1 Key elements of the chemical safety report

3.2.1.1 Overview of the use

In addition to the exposure scenarios and exposure estimates, it is important that readers of the CSR (e.g. RAC, Member States and the Commission) have a clear understanding of the underlying process, the substance function within it (the role of the Annex XIV substance) and the specific tasks leading to exposure of workers, consumers and the environment (including indirect exposure of the general population through the environment).

As a rule, prior knowledge or a detailed technical understanding of a particular industrial process or technology by members of RAC, SEAC or the authorities should not be assumed.

The overview of the use should also clearly describe if the use is conducted at the applicant's own site (or sites), or if the use is to be conducted by other legal entities further along the substance supply chain (downstream users).

Advice to applicants

- Provide a narrative description of the use (process broken down by individual tasks, if appropriate) to compliment the descriptions of operational conditions and risk management measures provided in the exposure scenario (see Section 3.2.1.2).
- Ensure that it is clear who is exposed (which workers, consumers, environment, general population through the environment), how exposure arises and the relevant routes of exposure. Consider if bystanders are also likely to be exposed.
- Consider using diagrams, pictures or even videos to ensure that your descriptions are logical and clear. Think about asking somebody who is not familiar with your use to review your description to ensure that it is understandable¹².
- Where a use is expected to occur further along the supply chain (by downstream users), further information should be included in the application. In these cases, the description should include the likely number of different legal entities or sites that are expected to undertake the use and also characterise any relevant diversity across them, for example:
 - in terms of the scale (tonnage used);
 - the number of exposed workers;
 - population indirectly exposed through the environment;
 - the process technology used (e.g. manual vs automatic, closed vs open systems);
 - geographical distribution within the EU;
 - relevant differences in occupational safety and health requirements (e.g. Member State specific occupational limit values)¹³.

This information is also very important when considering the number and complexity of the exposure scenarios that will be required to describe the use

¹² Consider confidentiality issues (including figures and photographs) at an early stage, for example by taking pictures that illustrate the relevant task (e.g. taking a sample), but do not include confidential information irrelevant to the task (e.g. the size of a tank in the background).

¹³ These data are also likely to be useful for the socio-economic analysis.

applied for (see Section 3.2.1.2 below).

- As a rule, the more diverse the downstream OCs and RMMs are, the more exposure scenarios (or contributing scenarios) and exposure datasets will be required to adequately describe it.

Examples from previous applications

- *Vlisco's application for authorisation for the [use of trichloroethylene \(TCE\) as a solvent for the removal and recovery of resin from dyed cloth](#). This application is an example of how the underlying process and function of an Annex XIV substance can be described within a CSR for an application for authorisation by a downstream user.*
- *Blue Cube Germany Assets GmbH & Co KG's (formerly DOW Deutschland) application for the [use of trichloroethylene as an extraction solvent for bitumen in asphalt analysis](#). This application is an example of how the underlying process and function of an Annex XIV substance can be described within a CSR for an application for authorisation by an upstream actor.*

3.2.1.2 Developing appropriate exposure scenarios (OCs and RMMs)

An exposure scenario is the set of operational conditions (OCs) and risk management measures (RMMs) that, together, describe the use of an Annex XIV substance and the measures taken to control exposures of humans (including workers and consumers) and the environment.

The exposure scenario is sub-divided into environmental, worker and consumer contributing scenarios. Several worker contributing scenarios (WCS) can be used to distinguish between the exposure potential of different tasks within a single multi-step industrial process (e.g. sampling, material transfer, unloading of end products from racks or jigs) or to distinguish between different groups of workers (e.g. process vs maintenance workers).

Operational conditions (OCs) are:

- The processes (or tasks) involved, including the equipment used, the physical form in which the substance is used, the concentration of the substance and any other operational parameters relevant to exposure potential, such as operating temperature, concentration, pressure, flow rate, level of automation, indoor or outdoor use.
- The activities of workers related to the processes (such as sampling or transfer) and their **duration** per event and **frequency** (e.g. events/shift¹⁴ for daily activities, such as sampling; events/year for infrequent tasks such as unloading incoming raw material). These considerations are relevant to estimate the combined (cumulative) exposure for specific [groups of] workers.

¹⁴ It is important to clearly state whether frequency relates to one shift or to one day (e.g. three shifts of workers in a process run 24 hours a day). Also, the duration should be specific, e.g. duration per event, duration per shift.

- The activities of consumers and the duration and frequency of their exposure.
- The duration and frequency of emissions of the substance to different environmental compartments and sewage treatment systems and the dilution in the receiving environmental compartment.

Risk management measures (RMMs) are:

- The measures to reduce or avoid direct and indirect exposure of humans (e.g. industrial and professional users, consumers and general population) and the environment. These can be technical measures (e.g. closed systems), measures to capture releases at the place of origin (e.g. local exhaust ventilation, general mechanical ventilation, wastewater treatment processes, stack emission abatement technologies used), organisational measures (e.g. access control, training) and personal protective equipment (e.g. gloves, clothing, respiratory protective equipment).
- The waste management measures to reduce or avoid exposure of humans and the environment to the substance during waste disposal and/or recycling.

It is important that the exposure scenarios developed for a use capture all of the tasks likely to result in human exposure (including infrequent tasks performed by workers such as maintenance) and release to environmental compartments and sewage treatment systems. Where relevant, exposure scenarios should also be described for consumer and article service-life stages.

Exposure scenarios for threshold substances should ensure that risks to humans and the environment are adequately controlled.

Exposure scenarios for PBT/vPvB substances should recommend risk management measures for downstream users, which minimise exposures and emissions to humans and the environment, throughout the life-cycle of the substance for the use applied for¹⁵.

Capturing the variability in OCs and RMMs across a use and understanding how these link to workplace exposures and environmental releases is essential to ensure the “representativeness” of the exposure scenario. Evaluating the representativeness of an exposure assessment is one of the key elements in RAC’s opinion on an application.

The exposure scenario and worker contributing scenarios (WCS) should be sufficient to credibly capture the diversity of OCs and RMMs that are likely to occur both within an individual site and across different downstream user sites undertaking the use. An applicant needs to show that the exposure scenarios accurately represent the variability of downstream user OCs and resulting exposures.

As the ‘scale’ of an application increases (e.g. the number of sites increases or the diversity of articles produced increases) the exposure scenario **must** adequately capture any

¹⁵ REACH, Annex I, 6.5

corresponding variability in the OCs and RMMs that will be applied by downstream users and consumers. This can be achieved by either ensuring that a sufficient number of exposure scenarios are developed, or by including sufficient worker contributing scenarios within the exposure scenario.

Approaches for exposure scenario “scaling”¹⁶ could also be used. However, any scaling approach would need to be fully justified and communicated appropriately to downstream users if an authorisation was granted.

Equally, applications covering multiple actors could also consider the merit of adopting or promoting business models that ensure that the conditions of use described in the exposure scenario for a use are applied by downstream users (e.g. a ‘chemical leasing’ model, or similar contractual arrangement before supplying to a downstream user).

An applicant may choose to apply for an authorisation based on operational conditions and risk management measures (and resulting exposures) that are known to be more stringent (resulting in a greater level of protection for workers, consumers or the environment) than those that are known to be applied across the EEA. Under these circumstances, any authorisation would not necessarily cover all downstream users. Downstream users that cannot comply with the OCs and RMMs described in an application for authorisation by an upstream actor in their supply chain can apply for an authorisation for their own use.

Such an approach could have the benefit of increasing overall standards of risk management across an industry sector (as some downstream users would need to enhance their operational conditions and risk management measures to benefit from an authorisation). However, the exposure scenario is still expected to be fully described and justified using reliable and representative exposure data.

If this approach is employed, the impact on the relevant population (user base) of downstream users should be discussed in the application (e.g. the proportion of existing downstream users that are likely to be able to achieve the proposed conditions of use).

Where uses are not described in sufficient detail, RAC may conclude that the uncertainties in the exposure scenarios are significant, which may lead to a recommendation that an authorisation is not granted, a recommendation for either conditions for the authorisation, and/or that the authorisation is reviewed within a short period of time.

Advice to applicants

- Ensure that the selection of RMMs respects the principles of the hierarchy of control¹⁷. RMMs should be described appropriately e.g. where a spray cabin is used the type of cabin (down-flow/cross-flow) should be described. Similarly, descriptions of PPE should include technical information, such as glove material, breakthrough time, mask and filter type, APF, EN standards etc.
- Where an exposure scenario is sub-divided into a series of worker contributing

¹⁶ Exposure scenario scaling is described in Chapter 4 and Appendix 2 of [ECHA's Guidance for downstream users](#) (ECHA, 2014c).

¹⁷ Hierarchical system used to minimise or eliminate exposure to chemical hazards as described in the Chemical Agents Directive (98/24/EC) and Carcinogens and Mutagens Directive (2004/37/EC). Protection and prevention measures that should be used by employers to reduce risks to a minimum include, in order of decreasing effectiveness (priority): substitution, engineering controls (that avoid or minimise release, such as closed systems), collective protection measures at source (e.g. adequate local extraction or general ventilation), administrative (organisational) controls (such as hygiene measures and demarcation of risk areas) and individual protection measures, including personal protective equipment (PPE).

scenarios (WCSs), ensure that the logic of this sub-division is clear and that a sufficient number of different WCSs are developed to reflect the different tasks in a process, and the diversity of appropriate OCs and RMMs. In general, each WCS should comprise a single (or closely related) task associated with a single set of OCs and RMMs (and related exposure data, see the section below). It is unlikely that processes with differing exposure potential, such as automated and manual tasks, can be adequately described within a single WCS.

- Environmental contributing scenarios should encompass the diversity of relevant operational conditions, such as the annual tonnage and operating days per year.
- OCs and RMMs (both for worker and environmental contributing scenarios) should be described in detail, including the effectiveness of RMMs and a justification for this effectiveness. For environmental releases, consider both point and diffuse (fugitive) emission sources.
- In addition to technical RMMs such as LEV or the use of PPE, the exposure scenario should also describe the appropriate organisational RMMs that are in place, such as policies and procedures for access control, preventative maintenance, training requirements as well as programmes for leak detection and repair.
- Ensure that any reasonably expected changes to OCs and RMMs are incorporated into exposure scenarios e.g. due to planned increase/decrease in production or the upgrade of RMMs.

Examples from previous applications

- *Novartis' application for authorisation for the [use of diglyme as a solvent in the manufacturing process of an intermediate for the further conversion into a pharmaceutical compound used in medicinal products for treatment of respiratory diseases](#). This application is an example of a worker exposure scenario for a downstream user.*
- *BASF's application for authorisation for [the industrial use of 1,2 dichloroethane \(EDC\) as a recyclable solvent and extraction agent in a closed system for purification of 1,2,5-trioxane](#). This application is an example of environmental exposure scenario for a downstream user.*
- *Blue Cube Germany Assets GmbH & Co KG's (Formerly DOW Deutschland) application for the [use of trichloroethylene in industrial parts cleaning by vapour degreasing in closed systems where specific requirements \(system of use parameters\) exist](#). This application is an example of how operational conditions and risk management measures can be established for downstream users in an application for authorisation by an upstream actor. In this application, parts cleaning with TCE would only be possible by downstream users with parts cleaning machines compliant with ESCA (European Chlorinated Solvents Association) Type III standard, or higher.*

Please remember:

REACH Annex I 0.8 states that: “The level of detail required in an exposure scenario will vary substantially from case-to-case, depending on the use of a substance, its hazardous properties and the amount of information available to the manufacturer or importer”.

In the context of authorising substances on Annex XIV, e.g. non-threshold carcinogens, the broadness of an exposure scenario needs to be carefully considered. If it is not possible to credibly link OCs with coherent RMMs to expected exposures in the workplace, then the scale of the exposure scenario (and possibly the application itself) is too broad.

Applicants are advised to separate processes that have differing potential for exposure into different exposure scenarios, contributing scenarios or even uses, rather than group diverse activities together, for example:

- Describe processes such as spraying, brushing, machining and immersion in different contributing scenarios. Whilst these are all surface treatment activities, they are associated with very different OCs and RMMs and have very different potential for exposure.
- Describe closed, fully automatic, production lines in separate contributing scenarios to open, manual systems. Combining these processes would lead to such a large distribution of exposure estimates that evaluation of the appropriateness and effectiveness of RMMs by RAC would become impossible.

3.2.1.3 Estimating worker exposure, including combined exposure

Providing robust worker exposure data is a critical element of the CSR and is a key part of RAC’s evaluation of an application for authorisation.

Sufficiently robust, reliable and appropriately reported exposure data should be available for each worker contributing scenario (WCS). Combined exposure across tasks should also be reported or it should be explained why combined exposure does not occur. Where possible, exposure should be estimated using all available information in a weight-of-evidence approach.

Advice to applicants

- Whilst an estimate of reasonable worst-case exposure¹⁸ is generally suitable for risk characterisation (particularly where the objective is to show adequate control), estimates of more typical (average) exposure should also be presented, as these are more appropriate for undertaking the health impact assessment for the use in the SEA. Assuming that all individuals undertaking a use will be exposed to the reasonable worst-case exposure concentration is likely to overestimate the actual health impacts associated with a use.

¹⁸ R.14 Guidance states that: “In general the 90th percentile value, representing **the reasonable worst case** exposure level of a distribution within a generally suitable dataset (i.e. a dataset corresponding to the conditions described in a contributing scenario), should be used as the exposure value for the risk characterisation”.

- Measured exposure data (concentration in air and/or obtained by biomonitoring) is preferred and special consideration is given to them during the evaluation of applications. Personal measurements of exposure are generally preferred to stationary sampling¹⁹. RAC is able to evaluate exposure measurements only when relevant contextual information is available e.g. tasks performed during sampling, sampling time, standardised sampling method (personal/stationary), analytical method, limit of detection, RMMs in place, etc. Always consider if measurement data can be supported with appropriate modelling data, and *vice versa*, particularly where the measured data is from a single sampling campaign.
- Where data are available from multiple sampling campaigns or different sites, always characterise the distribution of the available measurement data and report appropriate summary statistics (e.g. 90th percentile, average, median). Individual measurement results should, ideally, be provided in an annex to the CSR.
- Exposure modelling²⁰ can often be used to supplement available measured data; and this should be carefully considered. However, care should be taken to ensure that appropriate models (for both the use and the substance) are used. Tier 1 models (e.g. ECETOC TRA) should generally only be used for screening purposes and higher tier tools should be used whenever possible (ART/Stoffenmanager/Riskofderm). Input and output data, and any deviations from default assumptions should always be clearly described and justified (e.g. process temperatures, vapour pressure, dustiness).

Examples from previous applications

- *Grupa Azoty's application for authorisation for [the industrial use of trichloroethylene \(TCE\) as a process chemical in caprolactam purification](#). This is an example of a worker exposure assessment in a downstream user application that used multiple information sources in the exposure assessment e.g. personal exposure monitoring, biomonitoring and modelling.*
- *Abloy Oy's application for authorisation for the [use of chromium trioxide in electroplating of mechanical and electromechanical cylinders, cam and padlocks, electromechanical lock cases and architectural hardware](#). This is an example of a downstream user worker exposure assessment for an inorganic substance where modelling approaches were used to support measured data.*

¹⁹ Measured data is generally preferred (See *R14.6 Guidance*). Personal air sampling describes the individual workers exposure, provided their work-pattern is known. On the other hand, stationary air sampling gives a picture of localised contaminant concentrations, provided the samplers are stationed in relation to the main emission sources and this information is available. Together, personal and static measurements can provide a solid picture of exposure at the workplace. In addition to understanding exposures in a spatial sense, it is also necessary to build up a picture over time to assess stability and potentially a declining trend in exposure. This is especially important for less frequent (few short processes per year) batch processes and for workplaces where there is a variability of processes occurring over time. Measurement data for dermal exposure, where relevant, would equally be preferred to modelled data, but it is recognised that there are technical limitations with the available methods.

²⁰ *R14 Guidance* outlines the appropriate use of some exposure models. RAC has supported applications for authorisation with exposure estimates exclusively from modelling in conjunction with well-managed, closed (gas-tight) systems where exposures were clearly very low (generally below the level of detection for personal sampling). However, many previous applications have shown that for some tasks (PROC codes) models may not overestimate exposures, as previously thought.

"Representativeness"

The responsibility of an applicant is to show that the exposure data provided are "representative" of the tasks described in the CSR and the OCs and RMMs described in an exposure scenario.

An applicant must also ensure that exposure data are of acceptable quality (reliability) and are reported in sufficient detail to allow the variability in exposure levels within individual WCSs and, potentially, between different sites undertaking the same use to be understood.

It is useful to consider "representativeness" across the spatial scales that are relevant in different types of applications for authorisation. In general, the larger the assessment scale is the greater the uncertainty.

- i) A **"task"** is the smallest unit, i.e. a specific process step within a larger "site" where a worker carries out a discrete task-based activity with potential for exposure, e.g. dismantling on a bench, spraying in a booth, filling a container etc. The location where a task takes place might be subject to stationary sampling, but this will not always be appropriate. A task is often the focus of a **"worker contributing scenario"**.

Exposure data can be considered to be representative of the task if they were obtained (including through modelling) whilst it was being undertaken (or using input parameters consistent with the OCs and RMMs associated with the task) and if there are sufficient replicate measurements available to characterise the central tendency (i.e. average) and "reasonable worst case" exposure associated with it.

Given the variability of OCs and RMMs that could be described in an application for authorisation, it is not currently possible to indicate the minimum number of measurements that would be required to determine 'representative exposure' for a given task. However, applicants should take note that it is not the quantity of the measurements that is critical, but the quality of the data and the accompanying contextual information that is key when RAC evaluates the representativeness of exposure data to OCs and RMMs.

- ii) A **"site"** is the location where one or several tasks (WCSs) takes place. To be considered representative it is important that exposure data are available for the tasks that result in the greatest overall exposure, bearing in mind that the combination of exposure level, duration and frequency is often more important when estimating overall exposure than the exposure levels measured during specific, potentially infrequent tasks.
- iii) An application can describe the same tasks performed at **multiple "specific" sites**. In this scenario, the precise OCs and RMMs associated with each task at each site should be described in the application and the representativeness of available exposure data can be presented and discussed in relation to these specific OCs and RMMs.
- iv) An application can describe the same uses across **multiple "generic" sites**. In this case, OCs, RMMs and associated exposure estimates are available for only a limited number of "representative" specific sites. The variability across these representative sites (in terms of process type, size etc.) should correspond to the variability expected in generic sites that will undertake the tasks. This approach is suitable if the exposure scenario is sufficiently detailed and represents OCs and RMMs that can be communicated to downstream users to achieve a defined level of exposure at all sites.

Representativeness implies:

- A strategy for occupational exposure assessment consisting of a series of measurements (ideally carried out over several years).
- Using an appropriate sampling strategy that could consist of a combination of personal and stationary sampling (biomonitoring could also be considered if appropriate to the Annex XIV substance).
- The strategy should cover all relevant tasks, but predominantly those resulting in the greatest overall exposure (the main emission sources should be clearly identified). Variability in exposure due to differences between how individuals conduct tasks should, ideally, also be explored.

In applications intended to cover multiple generic sites (potentially up to several hundred), it will be crucial to provide justification that the range of exposure levels described in the application are representative of the sites intended to be covered by the authorisation i.e. read-across from the “representative” specific sites.

As a first step, it is essential to identify groups of sites that are considered to be sufficiently comparable in terms of the similarity of the OCs and RMMs applied. These sites should be identifiable (although this could subsequently be claimed as CBI). In a second step, exposure data need to be collected and the variability of that data used to prove the comparability of the sites.

When justifying the representativeness of data in these cases, an applicant should communicate the basis upon which they consider the approach to be robust and meaningful. Outline any communication that took place within the supply chain (e.g. survey results and response rate). Discuss the sampling approach used to identify specific sites. Can this be considered as random? If not, the consequence of any geographical or temporal bias should be discussed.

3.2.1.4 Estimating releases to environmental compartments, environmental exposure and indirect exposure of humans (general population) through the environment

The CSR should contain an “environmental contributing scenario” that describes the operational conditions and risk management measures that are relevant to potential releases of an Annex XIV substance to environmental compartments and sewage treatment systems from the use. These releases should be quantified.

Applications for authorisation for Annex XIV substances listed as a result of their human health hazard properties (i.e. carcinogenic, mutagenic, toxic to reproduction (CMR) or equivalent concern) should also assess the risks and impacts resulting from indirect exposure to humans (general population) through the environment.

The assessment of indirect exposure considers exposure resulting from the use of the Annex XIV substance through air, drinking water and food.

Default approaches to indirect exposure assessment consider a local population living in the vicinity of a site as well as a regional population.

Applications for authorisation for Annex XIV substances listed on the basis of “equivalent concern for the environment” will need to estimate concentrations in the environment if adequate control is sought.

Advice to applicants

- Whilst an estimate of reasonable worst-case exposure²¹ is generally suitable for risk characterisation (particularly where the objective is to show adequate control), estimates of more typical (average) exposure should also be estimated, as these are more appropriate for undertaking the health impact assessment in the SEA. Assuming that all members of the general population will be exposed to the reasonable worst-case exposure concentration is likely to overestimate the overall health impacts associated with a use, as many will be exposed to a lower concentration.
- Releases to environmental compartments should be based on representative monitoring datasets, supported with appropriate contextual information and special consideration is given to them during the evaluation of applications. If necessary, releases can be estimated using default release factors from environmental release categories (ERCs). Final release factors can often be refined from initial factors using an appropriate (i.e. use/sector specific) specific environmental release category (SPERC). Other approaches, such as mass-balance methodologies can also be useful for certain types of releases, particularly assessing the magnitude of fugitive releases of volatile substances (e.g. certain solvents). In general, the

²¹ R.14 Guidance states that “In general the 90th percentile value, representing **the reasonable worst case** exposure level of a distribution within a generally suitable dataset (i.e. a dataset corresponding to the conditions described in a contributing scenario), should be used as the exposure value for the risk characterisation”.

factors used to estimate releases detailed in EU technical guidance documents for chemical risk assessments predating REACH (Tables A and B in TGD, 2003) should not be used. These approaches have been superseded by those detailed in contemporary REACH guidance.

- The standard, Tier I modelling tools used in REACH for estimating indirect exposure of humans through the environment and environmental exposure²² use default assumptions that are likely to result in overestimates of exposure and risk, particularly in the local assessment²³. Where adequate control of 'threshold' substances can be shown, despite the use of such assumptions, this is unlikely to cause difficulties during evaluation. However, overestimates of exposure may prevent adequate control from being shown or lead to exaggerated human health impacts in applications for non-threshold substances, particularly where overestimated risk levels are combined with large populations of exposed individuals (e.g. when a use is conducted at many sites across the EU). The magnitude of these health impacts could influence any recommendation on whether to grant an authorisation, the conditions that should accompany an authorisation or the length of the review period. As such, the need to refine exposure estimates derived from using default assumptions should be carefully considered²⁴.
- Refined approaches for exposure assessment have been used by many previous applicants. Approaches have included the use of site-specific dispersion modelling to refine estimates of inhalation exposure at various distances from a site (consistent with the occurrence of populated zones) or undertaking site-specific monitoring of ambient air in the environment surrounding a site. This can be particularly useful where the general population is located significantly further from the site than the default assumption (of 100 metres).
- Alternative approaches will always be necessary when assessing indirect exposure to metals and inorganic substances in food. This is because the approaches used to estimate exposure from food in standard modelling tools are not suitable for these types of substances.

²² ECHA CHESAR tool, or the EUSES model. See Chapter R.16 of ECHA's Guidance.

²³ ECHA's *R.16 Guidance* (environmental exposure assessment) states in Section R.16.4.3.9, in relation to the use of the EUSES model for assessing indirect exposure to humans through the environment, that "In light of these limitations, it is clear that a generic indirect exposure estimation, as described by the calculations detailed in Appendix A.16-3.3.9, can only be used for screening purposes to indicate potential problems. The assessment should be seen as a helpful tool for decision making but not as a prediction of the human exposure actually occurring at some place or time."

²⁴ Refinements should be especially considered where individual cancer risks for the general population are estimated to exceed those that have been previously used as decision points in chemicals risk assessment. ECHA's *R.8 Guidance* reports that cancer risk decision points used for lifetime exposure of the general population are generally in the range of 10^{-5} to 10^{-6} .

Please remember:

- *The default assumptions used in an EUSES local assessment are:*
 - *A site is associated with a standard town, where its releases result in exposure to the local general population (10 000 people). All food and water is from the affected area.*
 - *As a reasonable worst case, the whole population is exposed to the concentration in air estimated to occur at the site boundary (100 metres from a point source). Note, this is not equivalent to assuming that 10 000 people live at the boundary of a site or that local assessment is restricted to the population occurring within 100 metres (or 1 km) of a site.*
 - *Crops, meat and milk are assumed to be from soils affected by deposition within a 1km radius of a point source.*
- *These default assumptions will significantly overestimate exposure for the general population, as most of the population will not live 100 metres from a site, or consume food entirely sourced from the vicinity of the site. Appropriate refinements, where necessary, could include:*
 - *Estimating exposure at the distance from the site where population is known to occur e.g. the distance at which the closest residential building occurs.*
 - *In some cases, more than one PEC will be appropriate. For example, it may be useful to differentiate between the population (size and exposure) occurring immediately adjacent to the site (reasonable worst case) and the population (size and exposure) occurring further away from a site. The geographical extent of analysis could be established relative to achieving “background concentrations”, such as the EUSES “regional concentration”.*

3.2.1.5 Estimating exposure from articles and consumer uses

Where relevant, the CSR should describe human (direct and indirect) and environmental exposure resulting from industrial, professional and consumer uses (including from the uses of articles produced using the Annex XIV substance).

Advice to applicants

- Are OCs (e.g. concentration, duration of use) and RMMs (e.g. size and type of packaging, labelling on packaging, PPE provided or recommended, use instructions) clearly described?
- Ensure that human and environmental exposure estimation (including from articles) has been clearly described and justified and includes all relevant routes of exposure and populations (i.e. direct and indirect exposure to the general population). Modelling or measurement data should be sufficiently supported with contextual information i.e. as described above for worker/environmental exposure.

3.2.1.6 Risk characterisation

Risk characterisation should be undertaken for all relevant endpoints, tasks, routes of exposure and populations (including article service life and consumer uses of mixtures).

Risk characterisation for workers should include an assessment of “combined exposure” for workers that undertake a number of different worker contributing scenarios. Risk characterisation should be undertaken over a duration of time appropriate to the Annex XIV endpoint e.g. for some Annex XIV substances estimating excess risk based on mean exposures over an extended period may be appropriate, whilst for others it will be more important to consider short-term peak exposures.

- Where applicable, risk characterisation for workers should be undertaken based on combined (aggregated) exposure across different tasks (where workers are known to undertake tasks described by multiple worker contributing scenarios) and incorporate all relevant routes of exposure (e.g. inhalation and dermal). This consideration is equally applicable to both threshold and non-threshold substances. Indirectly exposed workers (e.g. those not directly involved in tasks resulting in exposure to Annex XIV substance) should also be taken into account where relevant. Adequate control will be evaluated based on the risk characterisation ratio resulting from combined exposure across all applicable WCSs and routes of exposure. Sensitivity analysis may be prudent where RCR values approach 1.
- For non-threshold substances, ensure that excess risk reported from the dose-response relationship does not include any correction for the length of the “assessment/review period”; such corrections are generally presented in the SEA.
- Risk characterisation for CMRs or equivalent concern substances (identified on the basis of human health hazard properties) should be undertaken for humans exposed indirectly through the environment – taking into account all relevant routes of exposure i.e. inhalation and oral (drinking water and food) routes of exposure.
- Risk characterisation for PBT and vPvB substances should comprise an emissions characterisation (as outlined in Section 4.2 of Annex I to REACH) outlining an estimation of the amounts of substance released to the different relevant environmental compartments from the use (in kg per year). This estimate should be used as the basis of a cost-effectiveness analysis (as described in the SEAC paper on the [evaluation of restriction reports and applications for authorisation for PBT and vPvB substances in SEAC](#) (ECHA, 2016j)). The risk characterisation should also justify how the RMMs applied, or recommended to downstream users, minimise exposures and emissions to humans and the environment, throughout the life-cycle of the substance.
- Risk characterisation for equivalent concern substances (identified based on environmental hazard properties) where it is possible to derive a PNEC should be undertaken for all relevant environmental compartments i.e. water, aquatic sediments, soil.

3.2.1.7 Uncertainty analysis for CSR

Inevitably, there are uncertainties associated with the derivation of exposure scenarios, exposure estimation and risk characterisation. Analysis of uncertainty presented in a separate chapter in the CSR can increase the robustness and transparency of the CSR. Uncertainty analysis is discussed further in [*CSA Guidance Chapter R.19: Uncertainty analysis*](#).

3.3 Analysis of alternatives

The purpose of the analysis of alternatives (AoA) is twofold.

First, the AoA seeks to determine whether there are any suitable alternative substances or technologies to replace the use of the Annex XIV substance applied for.

Second, the AoA may compare these alternatives to other managerial options such as shut-down or relocation to determine what is the most likely non-use scenario.

This provides input for an SEA, e.g. as a starting point for assessing the various options and thereby demonstrating the credibility of the non-use scenario (i.e. identifying the most likely option if the Annex XIV substance can no longer be used).

In the AoA, the applicant analyses the suitability of alternative substances or technologies i.e. their technical feasibility, economic feasibility, availability and risk reduction potential. The analysis should also include information about relevant research and development activities and, where applicable, testing results and the likelihood of alternatives becoming suitable in the future.

Section 3 of the [Guidance on the preparation of an application for authorisation \(ECHA, 2011a\)](#) gives further technical information on how to perform the AoA. SEAC's note on how it assesses [economic feasibility](#) (ECHA, 2013b) in applications for authorisation is also relevant.

3.3.1 Key elements of the analysis of alternatives

3.3.1.1 Substance function and technical requirements

To identify promising alternatives to the use of the Annex XIV substance, it is essential to describe the production process and the function of the substance within it (i.e. the task or job that it performs) clearly as well as the technical and performance requirements that possible alternatives need to meet.

To this end, it might also be important to provide a description of the technical and performance requirements of the end product or service, since these often have a direct impact on the selection of the alternative.

Advice to applicants

- The description of the substance function and technical requirements of the Annex XIV substance and (if relevant) of the end product or service should be concise, and contain explanation for non-experts.
- Describe the process conditions under which the substance is used.
- Do not overstate the technical requirements that alternatives have to fulfil. Often, a drop-in alternative (with the exact same properties as the Annex XIV substance) does not exist, but a combination of different alternative substances or technologies could still replace the Annex XIV substance function. In some cases, having to use

a combination of alternatives may have higher costs. In that case, that should be adequately described as an economic and not a technical feasibility issue.

Example from a previous application

- *Vlisco's application for [the use of TCE](#) is an example of an analysis of alternatives using tables and diagrams to illustrate processes and other key information. Additional information is provided in appendices. The discussion of the substance function is readily comprehensible.*

3.3.1.2 Identification of potential alternatives

When identifying potential alternatives, the applicant should also consider other ways of achieving the function provided by the Annex XIV substance. This may be by using another substance or technology (e.g. by changing the process). If the process can be changed, it is possible that the original function of the substance applied for becomes obsolete or that the substance is no longer needed.

Advice to applicants

- The number and type of alternatives considered in an initial screening step should be indicated. Where a large number of alternative substances are considered during a screening exercise, it is best to list these in an annex to the AoA.
- If known, alternative substances and technologies used by competitors, or by similar processes in non-competing sectors, should be identified as alternatives and their suitability should be assessed.
- The criteria and information sources used at each step of a shortlisting procedure should be clearly described and logical. The reader should be able to understand why a certain alternative has not been considered for further assessment. Applicants are advised to obtain information on alternatives not only from in-house but also from external sources of information and expertise, when available. Applicants should explain the reasoning behind excluding potential alternatives, particularly when an alternative is known to be used by a competitor.
- Any adaptations or changes necessary to replace or remove the need for the Annex XIV substance for the specified use should be considered.

Please remember:

An alternative that is suitable and available for one company may not be suitable or available for the applicant. However, if an alternative used by other companies (including competitors) is known and not considered to be suitable and available for the applicant, this needs to be appropriately justified.

Examples from previous applications

- In Sasol-Huntsman's [analysis of alternatives for the use of DBP](#) the criteria and process for shortlisting alternatives are explained. The applicant evaluated the identified alternatives against key criteria for suitability.
- In Grohe's [analysis of alternative for the use of chromium trioxide](#), a broad range of alternatives was screened, including alternative technologies. Facts were referenced by studies or other evidence-supporting materials.

3.3.1.3 Technical feasibility of alternatives

The technical feasibility of an alternative should be judged based on whether or not (or to what extent) it fulfils or replaces the function of the Annex XIV substance applied for.

Advice to applicants

- Article 60(5)(b) of REACH states that all relevant aspects should be taken into account when assessing the suitability of alternatives, including the technical and economic feasibility of alternatives for applicants. Furthermore, the perspective of the users of the substance (also covered in applications by upstream actors) or, in some cases, of the users of the product that relies on the functionality of the substance applied for is also likely to be relevant. For example, service providers might do surface treatment of products according to the specification of the customer whose requirements will be decisive to judge the technical feasibility of alternatives.
- Beyond drop-in substances, assess how alternative substances, technologies or a combination of them could replace the function of the Annex XIV substance, or the need for it. For example, if an end-product is currently produced in low and high quality grades using the Annex XIV substance, could the different qualities also be produced by different combinations of alternative substances/technologies?
- Beyond alternatives providing the same or higher performance to the end-product or service, also assess alternatives that would lead to lower performance and explain if this is not acceptable and what the expected impact on the end-users is. If the impact is of an economic and not technical nature (e.g. aesthetic issues leading to less customer acceptance of an end-product), consider concluding that the alternative is technically feasible but assess economic consequences in the economic feasibility assessment.
- Describe any legal or other quality requirements that need to be met, e.g. relevant national or international standards, including required levels of properties, or qualification and performance certification requirements.
- If an alternative is found not to be technically feasible, where possible, the applicant should explain what would be required to develop the alternative sufficiently to achieve technical feasibility and justify the time and resources needed to do so (including details of necessary R&D, the required timescales and cost).
- In applications by upstream actors, there may be alternatives that are technically

feasible for some but not all downstream users. If these alternatives are also economically feasible, available and reduce risks, then those downstream users should be excluded from the use.

Example from a previous application

- *Blue Cube Germany Assets GmbH & Co KG's (formerly DOW Deutschland) [analysis of alternatives for the use of TCE](#) is an example of how the identified possible alternative substances can be assessed, including the reasoning on which they are excluded. An economically and technically viable alternative technique is identified based on specific criteria.*
- *Eli Lilly's [analysis of alternatives for the use of EDC](#) contains a description of the European Medicines Agency's regulatory framework and what variations to the applicant's marketing authorisations would be required if it changed over to an alternative.*

Please remember:

The effort required to perform a meaningful assessment of technical feasibility will vary depending on the specific nature of the process. Nevertheless, it is good practice to state how much effort (in terms of time and resources) has been going into the testing of a particular alternative substance or technology before it is dismissed as technically infeasible.

3.3.1.4 Economic feasibility of alternatives

The assessment of the economic feasibility of an alternative focuses on changes in the costs and revenues of those actors currently using the Annex XIV substance if they adopted the alternative (substance or technology).

This means that both the investment in new equipment and the cost of producing the good or product with the alternative should be taken into account (however avoiding double counting of cost transferred down the supply chain).

Whilst the economic feasibility of alternatives has important links with the SEA, it should focus on the economic viability of the alternatives to the applicant, as well as the downstream users of the substance. For this assessment, the concept of economic feasibility is about changes in net costs, taking account of the changes in both costs and revenues of adopting an alternative, including consideration of differences in performance or quality. It does not equate to an individual firm's ability to afford to pay for any increases in net cost, which might be associated with an alternative.

Advice to applicants

- The economic feasibility assessment of alternatives should focus on alternatives that are technically feasible, or are likely to become technically feasible within the period of the analysis conducted. Typically, the focus would be on investment, raw material and labour costs but there may also be other relevant costs (e.g. costs to comply with other legislations). For drop-in alternatives, the costs will typically comprise mainly of raw-material costs, whilst investment costs may be dominant when the production process requires substantial changes.
- The economic feasibility assessment can be based on typical costs within a sector. Detailed specifications for new plants will usually not be required.
- Take into account that the price of newly developed alternative substances or technologies may decrease over time if the respective production volumes increase.
- When assessing the economic feasibility of alternatives, applicants should not only consider the cost of implementing the alternatives, but also the cost savings related to the use of the alternative linked to avoiding the use of the Annex XIV substance e.g. costs related to worker protection expenses, monitoring of emissions, disposal costs, etc.
- Further information on the calculation of compliance costs is available in Appendix I of the [Guidance on the preparation of socio-economic analysis](#) (ECHA, 2011b). See also the note on [how SEAC evaluates economic feasibility in applications for authorisation](#) (ECHA, 2013b).

Please remember:

It is good practice to analyse the market you operate in to obtain a good picture of production costs and constraints faced by the respective industry before economic infeasibility of an alternative is claimed.

Example from a previous application

- Sasol Huntsman's [analysis of alternatives for the use of dibutyl phthalate](#) monetises important cost categories (plant modifications and loss of profit during shutdown) and discusses other impacts qualitatively.
- In Boliden Kokkola's [analysis of alternatives for the use of diarsenic trioxide](#), technically feasible alternatives were identified. Nevertheless, the analysis demonstrated that the alternatives were not suitable for the applicant because they were not economically feasible.

3.3.1.5 Availability of alternatives

An alternative can generally be regarded as available when it is reasonably accessible before the sunset date, available in the required quantity and developed enough to allow implementation.

The availability assessment should also consider the time needed to fulfil the relevant legal requirements (e.g. marketing authorisation obtained by the European Medicines Agency, REACH registration or obligations under the Industrial Emissions Directive).

Advice to applicants

- The key issue is timing. The sunset date is the reference point. Consider that a suitable alternative might not be available in the necessary quantities at the sunset date but that additional volumes could become available in the near future after the sunset date.
- If a technically and economically feasible alternative exists but it is not available in sufficient quantities at the sunset date, an authorisation will be required for the specific time period required to substitute after the sunset date. An application for such an authorisation is sometimes referred to as a “bridging application”.

Example from a previous application

- *In its [analysis of alternatives for the use of HBCDD](#), the applicants concluded that an alternative would be technically and economically feasible once available in sufficient quantities and testing and certification has been completed. Based on the information provided in the public consultation and the dialogue, [SEAC concluded in its opinion](#) that the alternative would be available earlier than outlined in the applicant's analysis of alternatives and recommended a shortening of the review period requested by the applicant.*

Please remember:

Applicants are advised to outline their current and future plans to substitute the use of the Annex XIV substance. This information is taken into account in setting the review period.

For applicants that have not identified a suitable alternative, this means describing:

- Past, current and future activities related to the identification of possible alternatives (monitoring of literature/patents, communication with suppliers and customers, research institutes, academics etc.).
- The estimated time that would be required for testing any identified alternatives candidates (lab scale, semi-industrial pilot, production scale) and the time needed for any relevant certification, qualification or regulatory approval.
- R&D capacities and time optimisation (taking into account whether parallel activities or tests are possible or not).

For applicants that have identified a preferred alternative that they believe will be suitable in the future and are applying for the time period required to substitute ('bridging application'), this means describing:

- As above but with more detailed timelines, including justifications regarding the estimated time that will be required for the various actions

More information is available in Chapters 3 and 4 of the [Guidance on the preparation of an application for authorisation](#).

3.3.1.6 Risk reduction potential of alternatives

A suitable alternative must result in a reduced overall risk to human health and the environment compared with the use of the Annex XIV substance.

Advice to applicants

- If an alternative substance is equally or more hazardous than the Annex XIV substance concerned (e.g. as established by its harmonised classification, or presence on the Candidate List), this is generally sufficient to show that it is not a suitable alternative and no additional feasibility assessment is normally necessary.
- Exceptions could be if the alternative would be used in far lower quantities or in ways where the exposure and risks could be substantially reduced or eliminated compared to the Annex XIV substance, or if the use of the alternative would be important in the "non-use" scenario described in the socio-economic analysis (in which case their impact on human health and/or the environment should also be considered).
- Assessing the risks of alternative substances may be conducted using a tiered approach starting from a comparison of the hazardous properties and, if necessary, possibly ending in a full assessment of the risks arising from the alternatives. A comprehensive risk assessment of an alternative is generally only needed if the

alternative is technically and economically feasible but the applicant rejects it because of its risk potential.

Example from a previous application

- Grupa Azoty's [analysis of alternatives for the use of trichloroethylene for the manufacture of caprolactam](#) contains a comprehensive evaluation of risks of alternative substances.
- Vlisco's application for authorisation for the [use of trichloroethylene \(TCE\) as a solvent for the removal and recovery of resin from dyed cloth](#). This application is an example of a hazard-based assessment of the overall reduction of risk of an alternative.

3.4 Socio-economic analysis

The socio-economic analysis describes what would happen if the applicant or other actors in its supply chain were no longer able to use the substance, and what the impacts to the applicants and other affected actors would be.

The key issue addressed in the analysis is whether the socio-economic benefits of the applicant's continued use of the substance outweigh the risks to human health and the environment.

Socio-economic benefits relate to the value added of the continued use, including wider social impacts, such as the functioning of the market and the securing of jobs. These benefits have to be balanced against the environmental and human health impacts.

Figure 3.1 illustrates the purpose of the socio-economic analysis as a tool to balance the (monetised) risks to human health and the environment against the socio-economic impacts if the substance is no longer used by the applicant. As can be seen, key elements of the socio-economic analysis are taken directly from the CSR (particularly those related to the risks of continued use) and the AoA (particularly those related to the impacts expected under the non-use scenario).

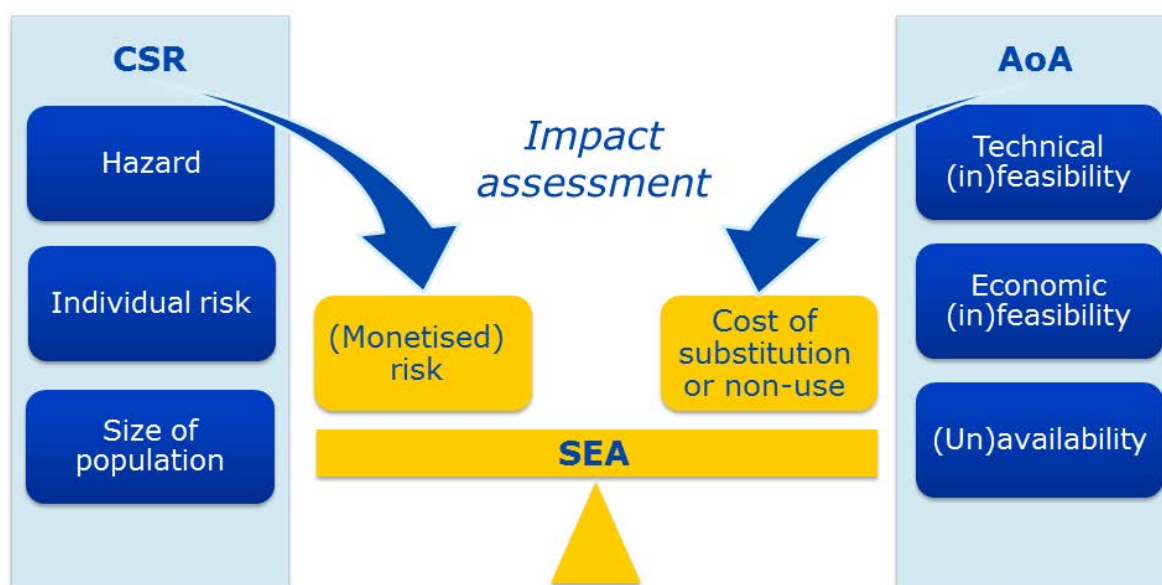


Figure 3.1. Links between SEA, AoA and CSR

Applicants should not only consider the impacts on them, but explain the anticipated reaction of the market to changes in the product/service affected in terms of quality, performance, price, availability and value added to society. For example, would another company take over the market share with a safer product or service? If this would be possible, what would it mean in terms of consumer prices? These are questions applicants should address as part of their SEA.

The [Guidance on the preparation of a socio-economic analysis for an application for authorisation](#) (ECHA, 2011b) provides more information on this.

3.4.1 Key elements of the socio-economic analysis

3.4.1.1 Applied-for-use scenario

The applied-for-use scenario describes the (baseline) situation if the authorisation is granted. In the socio-economic analysis it is compared against the non-use scenario to determine what the impacts on both the applicant and society would be if the authorisation is not granted.

Advice to applicants

- The applied-for-use scenario should provide an overview of the market and supply chains related to the use of the substance (e.g. volumes sold, the market structure etc.). Any future changes (e.g. in relation to production capacity, market forecasts, regulatory drivers or the risks associated with the use) that would affect the costs or benefits of continued use should also be outlined. In a nutshell, an applicant is encouraged to present their business logic to SEAC.

Example from a previous application

- In Eli Lilly's [socio-economic analysis related to the use of EDC](#), the applied-for-use scenario is defined based on the applicant's projections of its future market share.
- Grohe's [socio-economic analysis for the use of chromium trioxide](#) describes the business drivers and the strategic implications of the applied-for-use scenario.

3.4.1.2 Risks of continued use

The risks of continued use are typically made up of the expected impacts to human health and the environment. In the case of human health impacts, the corresponding excess risks derived in the CSR and the estimation of the number of exposed people provide the basis for quantifying these impacts.

Advice to applicants

- The use of the [RAC reference DNELs and dose-response relationships](#) simplifies the applicant's work and facilitates the evaluation of the health impact assessment and valuation.
- The risk of continued use is often assessed for the "excess risk" caused by the substance impact (i.e. the difference in risk between the applied-for-use and the non-use scenarios).
- To monetise human health impacts, applicants can use the findings of an ECHA study on [willingness-to-pay \(WTP\) to avoid certain health impacts](#) (ECHA, 2016k; ECHA, 2016l). The WTP estimates outline people's willingness to reduce the risk of dying or avoiding illness, and is one methodological approach for the valuation of human health impact.
- It is usually very difficult to quantify or monetise the impact of substances identified

as persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB). However, there are means to report such impacts as well and applicants applying for such substances are advised to read SEAC's note on the [evaluation of applications for PBT and vPvB substances](#). (ECHA, 2016j).

- In principle, impact assessment should be based on the central tendency of exposure and population data, or the underlying distribution of data. Upper values derived from risk assessment (such as the reasonable worst-case scenario) may be useful for showing the robustness of the conclusions arrived at (e.g. as part of a sensitivity analysis) but would not be appropriate as the only reference for health impact assessment in the SEA. Taking as the sole assumption that all individuals undertaking a use will be exposed to the reasonable worst-case exposure concentration is likely to overestimate the overall health impacts associated with a use.

Example from a previous application

- *Eli Lilly's [socio-economic analysis related to the use of EDC](#) is an example of how human health impacts can be estimated and monetised.*

Please remember:

The dose-response functions proposed by RAC measure excess risk in different units – some express risk in terms of fatal cancer whilst others express risk in terms of cancer incidence. Applicants are, therefore, well advised to check the respective RAC dose-response relationships and to account for these definitional differences in their health impact and socio-economic assessment.

3.4.1.3 Non-use scenario

The non-use scenario describes what would happen if the authorisation was not granted. The impact assessment is based on the difference between the applied-for-use scenario and the non-use scenario.

Advice to applicants

- An applicant should approach the development of the non-use scenario as a business case, starting by outlining the available options and analysing the potential practical implications on their business as well as the key cost drivers related to each option. This should be done based on the applicant's actual business and market context and is likely to require the involvement of the applicant's management team.
- The non-use scenario is based on the most likely response of the applicant if the authorisation was not granted. The AoA should provide a good starting point for developing non-use scenarios, but adopting an alternative does not need to be the

most likely non-use scenario.

- In any case, it will be of utmost importance that the non-use scenario taken forward by the applicant is credible and analytically justified, particularly if the non-use scenario is shut-down or complete relocation. Often the analysis of alternatives will have to contain a thorough analysis of economic feasibility of alternatives to show that accepting the loss of market shares and foregoing the adoption of alternative substances or technologies would be plausible. If competitors use alternatives, a thorough justification of why users covered by the application in question cannot move to the alternative should be provided.
- In addition to outlining what the applicant would do, the non-use scenario should also describe how other relevant actors in the supply chain (e.g. suppliers, downstream users, end-users, consumers) and competitors would react to a refused authorisation. For example, is it possible that customers modify their certification schemes to allow applicants to switch over to an alternative? Alternatively, could customers adopt an alternative end-product so that the use of the Annex XIV substance would no longer be needed (e.g. changing expanded polystyrene insulation requiring a flame retardant listed on Annex XIV to mineral wool insulation)? Equally, would customers choose to import articles or finished products from outside the EU? Would a refused authorisation affect competitors positively? Would there be any impacts on the quality, price or quantity supplied of the service or product produced within the use applied for?

Example from a previous application

- *H&R Ölwerke Schindler GmbH's [socio-economic analysis related to the use of EDC](#) presents four options that the applicant would have if the authorisation was not granted, including a change-over to an alternative. Based on a brief description of the practical implications and/or the costs of each option, the applicant justifies one of them as the selected non-use scenario.*

Please remember:

The analysis of alternatives outlines and assesses the applicant's options, with the objective of identifying the non-use scenario. A good non-use scenario is a link between the conclusions of the analysis of alternatives and the argumentation in the socio-economic analysis.

3.4.1.4 Scope of the analysis

Based on the possible reactions in the non-use scenario, the applicant should describe the scope of the analysis, including its geographical and temporal boundaries.

Advice to applicants

- It is recommended that the focus of the assessment is on impacts affecting actors in the European Economic Area (EEA).
- Relevant impacts should be at least qualitatively described, regardless of where they occur, and it should be clear from the analysis where these impacts occur.
- All affected actors in the relevant supply chains need to be considered, including suppliers, downstream users, consumers and competitors.
- From a company perspective, the relevant time period for assessing economic impacts is usually that over which an operation is expected to run (i.e. the investment cycle). For human health and environmental impacts to be meaningfully compared to the economic impacts, they should be assessed over the same time period (typically this will be the review period applied for), whilst allowing for any latency of impacts to be taken into account.
- All monetised costs and benefits should be price-adjusted to a base year (typically the year before submission).

Example from a previous application

- Grohe's [socio-economic analysis related to the use of chromium trioxide](#) is an example of a non-use scenario where the applicant would relocate outside the EEA to a site of the same owner. The analysis considered impacts both inside and outside the EEA, but they were all linked in economic terms to the EEA.

3.4.1.5 Benefits of continued use (or the cost of the non-use scenario)

The benefits of continued use are typically assumed to be the economic and social impacts, as well as potential trade, competition and wider economic impacts that would occur if the authorisation is not granted (the non-use scenario).

Advice to applicants

- The starting point for the SEA should be the impact on the applicant and its supply chain. However, applicants also need to take a broader view than only their own operations. The use of a substance might be critical to one company, but its suppliers, customers or competitors might easily live without it or *vice versa*. Applicants should distinguish between costs to their supply chain (often called "private costs") and costs to society as a whole (often called "social costs"). The ultimate focus of the SEA is on estimating authorisation impacts taking society's perspective.
- All major impacts should be identified, but the conclusions should be based on net impacts:
 - If an operation is closed down, there may be "savings" for the company as well.
 - Alternative production means could be more expensive but result in benefits

as well (e.g. in terms of energy consumption or quality). Therefore, not switching to an alternative might involve an opportunity cost, which should be considered.

- A surplus loss to one actor in the supply chain may result in surplus gains to others (e.g. competitors that supply or use alternatives).
 - Resources 'freed up' (e.g. due to relocation), might be used in other productive activities where they contribute to the generation of value.
- The benefits of continued use are often most practically assessed following the compliance costs guidance ([Appendix I of the guidance on the preparation of socio-economic analysis](#) [ECHA, 2011b]).
- The assessment of potential costs to the applicant may be presented as net changes in operating profits made from the use of the substance (rather than the corresponding net changes in revenues). In case of temporary shut-down, other approaches, such as the value added foregone concept, may be equally appropriate.
- Where the non-use scenario is expected to result in unemployment, the applicant should assess the social cost of these changes (i.e. the cost from society's perspective), keeping in mind that jobs lost at one site might be compensated in the long run by jobs created at another site. In a [note on the social cost of unemployment](#) (ECHA, 2016m), SEAC suggests an approach for doing this (which may need to be adapted on a case-by-case basis). In short, the social cost of job loss consists mainly of the temporary productivity loss and the opportunity cost of being unemployed.
- All data should be traceable and verified by appropriate references and it should be possible to reproduce the results. One way of ensuring transparency is to provide spreadsheets of the calculations made as part of the application.
- Under the socio-economic route for authorisation, applicants need to show that the benefits of continued use (i.e. the costs of non-use) outweigh the risks. Under this basic premise, it is accepted that the lower and more certain the health and environmental impacts of continued use are, the less effort and detailed information is likely to be required when estimating the benefits. Where impacts are very low and uncertainties are not significant, it could be sufficient to qualitatively explain the general socio-economic impacts of the non-use and limit the number of elements to be quantified and/or monetised. Nevertheless, the basic premise is that the benefits must be shown to outweigh the risks. See Section 4.1 for more information.
- On the other hand, in cases with larger impacts on human health and/or the environment or larger uncertainties relating to these impacts, a more developed analysis as well as a robust uncertainty analysis of key assumptions will be required to convincingly show that the benefits of continued use outweigh the risks. This may be particularly relevant if:
 - there is not a good understanding of the potential risks to human health or the environment;
 - there is a large population at risk of being exposed to the substance;
 - the use scope is broad (e.g. in terms of end-products or industry sectors).

Examples from previous applications

- In Vlisco's [socio-economic analysis related to the use of TCE](#), the benefits of continued use are investigated and compared with the costs in a methodologically acceptable way. Many arguments are referenced by studies or other evidence-supporting materials.
- Grohe's [socio-economic analysis related to the use of chromium trioxide](#) estimates the social impacts in terms of the costs of temporary unemployment of redundant workers, based on the expected duration of the unemployment. In terms of the economic impacts, the applicant presents the costs to the applicant and adjusts them to provide a net economic welfare analysis.
- LANXESS Elastomers' [socio-economic analysis for the use of sodium dichromate](#) contains a structured argumentation for a temporary shutdown.

Please remember

The socio-economic impacts of an authorisation are measured in terms of producer and consumer surplus. This means that it is not solely the impact of the authorisation on the applicant which matters to society, but also the impacts on its suppliers, customers, consumers and competitors, as well as human health and the environment. The applicant needs to bear the overall societal perspective in mind when assessing the benefits of continued use.

3.4.1.6 Uncertainty analysis for SEA

An uncertainty analysis tests whether different assumptions or estimates could affect the conclusions and, if so, how significant this effect may be. The uncertainty analysis is important to ensure that the conclusions would not change under different assumptions.

Advice to applicants

- Assumptions and uncertainties should be described throughout the application. Uncertainties do not in themselves invalidate the conclusions but they need to be described and, where possible, minimised.
- Uncertainties are a factor in the review period. The more uncertainty, the harder it is to make the case for authorisation (or for the length of the review period). It is therefore in the applicants' interest to identify the uncertainties and to understand what their potential impact on the conclusions could be (e.g. through a sensitivity analysis). For example, uncertainties in the risk assessment may result in increased human health impacts, not only for workers but also for the general population exposed indirectly through the environment. In many previous applications, the potential exposure of the local general population has been a stronger human health impact driver than that of workers.

Examples from previous applications

- Eli Lilly's [socio-economic analysis related to the use of EDC](#) contains a table identifying key uncertainties, alternative assumptions and their potential impact on the conclusions.
- The [socio-economic analysis related to the use of chromium trioxide](#) by Kromatek and others contains a Monte Carlo simulation of the inputs concerning industry employment, industry value added, industry output and initial job loss.

3.4.1.7 Review period justification

All authorisations have a time-limited review period. The duration of the review period is determined on a case-by-case basis. As part of the application, applicants should present clear justifications to support the recommendation regarding the length of the review period considering their specific circumstances.

The [note on setting the review period when RAC and SEAC give opinions on an application for authorisation](#) (ECHA, 2016n) describes how the length of the recommended review period is determined, outlining the criteria used as a starting point when recommending a normal (seven years), short (e.g. four years) and long (12 years) review period.

Advice to applicants

- The evaluation of the applicant's justifications regarding the length of the review period has proven to be an important aspect of opinion development. Committees will not recommend a review period that is longer than the period justified in the application for authorisation.
- Provide sufficient information to support the recommendation of the length of the review period. Consider the following elements:
 - When will there be suitable alternatives (and what is the timeline for any necessary research, development, industrialisation or certification)?
 - What are the remaining risks associated with the use and can these be further reduced?
 - What would the socio-economic impact be if a shorter review period was specified in an authorisation decision (and the applicant would need to submit a review report sooner than anticipated or stop its use)?
- The time horizon of the SEA should generally not be shorter than the review period that the applicant has provided justifications for.

Example from a previous application

- BASF's [socio-economic analysis for the use of EDC](#) contains a table listing the applicant's arguments regarding the length of the review period based on the committees' note on setting the review period.

3.4.2 Use of the combined AoA/SEA format

Section 3.4.1 focused on the use of stand-alone formats for the AoA and the SEA.

ECHA also provides a combined AoA/SEA format, which might be more appropriate for some applications (and less so for others). This section briefly outlines relevant considerations when selecting the appropriate reporting formats for an application.

When using the stand-alone formats for AoA and SEA, the role of the AoA is to assess 'technical' alternatives in terms of their technical and economic feasibility and to present supporting information about R&D efforts undertaken or necessary to develop a suitable alternative.

The SEA reports a socio-economic analysis of the non-use scenario. However, it is not always clear how the non-use scenario has been identified and substantiated.

In downstream user applications it can be beneficial to use the combined format as the role of the AoA in the combined format is to identify the non-use scenario as the most likely (generally the least cost) way of complying with the requirement to cease use by the sunset date. Therefore, it includes both substitution and 'managerial' options (e.g. relocation of a production line outside of the EEA).

The role of the SEA in the combined format is then solely to assess the socio-economic impacts of the non-use scenario, whether this is the use of an alternative or some other managerial option. In a nutshell, the combined format:

- focuses on what an applicant could do to comply with the requirement to cease use by the sunset date in the event that an authorisation is not granted. It allows the non-use scenario to be identified directly and acknowledges that there is always something which could be done, even if it is to shut down;
- allows a 'can do' approach to assessing the alternatives by encouraging applicants to think about what it would take to make substitution work;
- involves estimating costs for the most likely candidates for the non-use scenario, and facilitates the identification of the least-cost option;
- justifies the choice of the non-use scenario, as it provides evidence on whether it is feasible and that its costs are well-founded (and generally lower than the other options);
- encourages a more extensive and practical assessment of what the applicant's options are—including combining activities such as temporary shutdown while other options are developed for implementation—and may feed directly into their R&D plan and the review period argumentation;
- retains the applicant's appraisal of technical and managerial options in the AoA, whilst the SEA adopts a societal perspective.

These characteristics have to be viewed against the complexity of an application. For an application by an upstream actor, the combined format may be too demanding in terms of information requirements from the downstream users that seek coverage by the application (i.e. the diversity of specific non-use scenarios may be too complex to integrate in the combined format). The decision to use separate or combined assessment report formats should therefore be determined on a case by case basis.

3.4.3 SEA for threshold substances

If adequate control of a threshold substance can be convincingly shown, then the applicant is not required to include an SEA in their application.

However, there may still be reasons to include socio-economic considerations within an application showing adequate control. Such argumentation might help the applicant to substantiate that the benefits of continued use outweigh the associated risks if RAC concludes that the risks are *not* adequately controlled.

In addition, certain elements of an SEA (or an appropriate section on economic feasibility within the AoA) may help substantiate the recommendation for the [length of the review period](#).

If the applicant believes that they have shown adequate control then there will be no identified (monetised) health impacts to evaluate and against which to compare the costs of non-use. In such cases, applicants may consider undertaking an appraisal of the benefits of continued use and the potential harm to workers and/or the general population and show that the former is in all likelihood outweighing the latter. This would be to ensure that the information required to conclude whether socio-economic benefits outweigh the risks is available.

One way of doing so is by means of a 'break-even analysis', which compares the benefits of continued use to the social cost of one case of the health impact of primary concern for the Annex XIV substance (e.g. of one case of infertility). For this purpose, a robust assessment of the benefits of continued use of the substance (as described under Section 3.4.1.5), is divided by the appropriate [willingness-to-pay value for the health endpoint of concern](#).

If this ratio is larger than the number of workers exposed, the applicant has shown that the benefits outweigh the risks. If the ratio is smaller than the number of workers exposed, it is recommended to provide scientific arguments that the number of cases required to break even would not occur given the prevailing worker exposure levels.

3.5 Consider summarising key elements for the reader

The documents that are prepared for an application are self-standing and follow their own internal logic. The readers of these documents – such as ECHA's scientific committees, third parties, the staff of the Commission and Member States – have sometimes had difficulties in easily understanding what the application has really been about. Some applicants have written a note summarising their application²⁵. This has been helpful.

ECHA is considering preparing a format that would standardise how applicants could summarise the key elements of their application. It might, therefore, make such a format public in mid or late 2017. In the meantime, it would be good for the applicants to consider including a note summarising the key elements for the reader in their applications.

²⁵ See for instance: <https://echa.europa.eu/documents/10162/2e8325e9-85c5-484d-b355-87563918a416>

4. Applications for uses with specific characteristics

This section outlines specific issues that should be considered when preparing applications for authorisation for uses that have specific characteristics. The current version of the guide contains a single sub-section on 'applications for uses with minimal expected health impacts'.

This section of the guide will be elaborated in subsequent versions of this guide, notably in response to any simplified approaches for applications for authorisation for low quantity uses and legacy spare parts that are currently being considered by the Commission.

4.1 Applications for uses with minimal expected health impacts

Experience with the evaluation of applications for authorisation by RAC and SEAC has established that, in some cases, applicants can reliably show that the use of Annex XIV substances results in low impacts to society²⁶.

Where human health and environmental impacts arising from the use of an Annex XIV substance are small and the benefits are likely to be greater by many orders of magnitude, applicants should consider if a simplified socio-economic analysis is sufficient to show that the benefits of continued use outweigh the risks.

For example, the overall benefits of continued use could be described qualitatively, with only some key elements quantified (such as the costs of substituting or temporary unemployment) where these are sufficient by themselves to show that the benefits of continued use outweigh the risk. However, it must always be remembered that such considerations do not relieve applicants of their general duty under REACH to ensure that risks are properly controlled.

Both of ECHA's scientific committees understand that the level of information and analysis necessary to justify an authorisation should be in line with the magnitude of the expected human health and/or environmental impacts posed by the use, also taking into account the level of uncertainty.

SEAC has adopted several opinions on applications for authorisation where the costs of substituting have been taken as the "minimum benefits" of continued use when concluding that the benefits outweigh the risks, rather than an extensive evaluation and analysis of the economic benefits of a use. One example is [Grupa Azoty's application for authorisation for the industrial use of trichloroethylene \(TCE\) as a process chemical in caprolactam purification.](#)

Whilst these applications are likely to require limited quantitative information and analysis for some aspects of the SEA (i.e. costs outlined in the non-use scenario), the CSR, the AoA and describing the human health and environmental impacts of continued use in the SEA should be prepared as per any application for authorisation. The sections of this practical guide on chemical safety assessment and the [applicant's checklist for applications for authorisation](#) provide further advice on appropriate methodology, data and justification for adequately describing exposure, risk and impacts in an application for authorisation.

As a starting point, applicants should consider if their description of operational conditions

²⁶ In some previous applications for authorisation, the monetised costs to society of continued use (through expected impacts on workers and the general population) were in the order of tens to hundreds of euro per year, whilst the corresponding benefits were in the range of millions of euros per year.

(OCs), risk management measures (RMMs) and exposure is consistent with the following elements that are indicative of a use with minimal human health and environmental impacts:

- Use in a closed system.
- Worker exposure is well characterised and minimised using appropriate and effective OCs and RMMs, predominately engineering controls, such as containment. Where it is technically feasible, reliable and representative exposure data for all relevant tasks, including tasks with potential for high exposure such as maintenance and sampling, are available and are used for risk assessment.
- Environmental releases are well characterised and minimised using appropriate and effective RMMs. Representative, reliable data on releases to all relevant compartments (including fugitive emissions, where applicable) are available.
- Risk characterisation is undertaken for workers (including potential for combined exposure across tasks) and the general population (through all relevant routes of exposure).
- A mass balance is available describing the flow of the substance through the process and quantifying losses through degradation and disposal and release to environmental compartments (from fugitive and point source emissions e.g. after incineration or wastewater treatment). The mass balance should include losses in products.

Whilst these elements should not be considered exhaustive, experience in RAC has shown that applications for uses that are consistent with these elements, when supported with appropriate data on exposure and releases, can be evaluated by RAC and SEAC as reliably showing that the health impacts, (for workers and the general population through the environment), and the environmental impacts are minimal.

5. Data gathering

Applicants should be prepared to apply an iterative approach in data gathering. The extent and type of data needs will depend on the type of application (adequate control or socio-economic analysis) and the level (single downstream user, multiple downstream users or upstream actor). Some of the issues that need to be considered when planning the data gathering are outlined in the boxes below.

Issues to consider in relation to data gathering

Chemical safety report

It is essential that the processes and tasks covered by the use applied for are described in the CSR and that the underlying assumptions, justifications and conclusions in the exposure assessment are clear.

Relevant information should be available in registration dossiers. However, the actor(s) applying for authorisation should ensure the reliability and representativeness of this information and should consider collecting additional specific information from downstream users on how and where the substance is used, including:

- hazard considerations (if RAC reference values are not used);
- process technologies;
- operational conditions (OCs);
- frequency, duration and overall sequence of tasks;
- scale of operations (including number of workers and production lines);
- risk management measures (RMMs) and their efficiency (relevant for workers and environment) and whether the hierarchy of control principles are applied,
- measured data on exposure and releases to the environment e.g. workplace exposure monitoring or biomonitoring data, data on releases to the atmosphere or wastewater);
- modelled exposure information (workplace, consumer, environment), including applicability considerations of the model, input parameter, output reports,
- combined exposure (e.g. combination of different exposure pathways and WCSs, relevant for different exposed populations) considerations; and
- information about exposure to the general population through the environment (scale of the population, local and regional consideration, different pathways like air, drinking water, food).

Analysis of alternatives

Applicants need to understand why the Annex XIV substance is being used by the actors covered by the application. The AoA needs to reflect the function of the substance both for those using it and for the producers of end-products who may have specific functional requirements that need to be fulfilled.

Consultation with the users of the substance is necessary to gather specific data from their perspective on:

- the function of the substance;
- the process conditions under which it is used;
- specifications/requirements for the substance and the end-products;
- work to identify alternatives (alternative substances/technologies);
- R&D efforts to substitute;
- qualification processes; and
- technical and economic feasibility of alternatives.

Issues to consider in relation to data gathering

When it comes to the availability of alternatives, upstream applicants will need to take a wider view than only those alternatives that are part of or could be part of their own product portfolio. Instead, applicants should consider possible alternatives from the perspective of the use by their downstream users they are applying for, thus outside their portfolio and sector, including changes to process. Cooperation with a representative group of downstream product sectors is helpful for this purpose.

Socio-economic analysis

The applicant will need to identify in their non-use scenario how the various layers of the supply chain (including downstream users, producers of end-products, and consumers) would react if the substance would no longer be available to the supply chain.

When the reactions of actors to non-authorisation are likely to be different within a layer of the supply chain, these reactions should be grouped accordingly in the description of the non-use scenario.

The socio-economic analysis assesses what costs and benefits an authorisation would create for society. Particularly for applications by upstream actors, it is important to note that the value to society of any intermediary good is often related to the value of the final goods or service. Because of this, the main socio-economic benefits of continued use may come from the end-uses rather than from uses higher in the supply chain.

On the other hand, in some cases the end-users may replace uses higher in the supply chain with imports and thus not suffer much, whereas the loss for society may be due to the use higher up in the supply chain.

Therefore, the applicant should consider collecting specific information on:

- How the actors potentially affected (e.g. downstream users, producers of end-products, competitors, alternative providers, other actors in the supply chain, consumers) would react if the authorisation were not granted (including justifications for the reaction), for example:
 - substituting to an alternative;
 - relocating;
 - partial or complete shutdown of business;
 - new opportunities coming with the substituted substance;
 - new opportunities from the alternatives;
 - import of articles or end-products.
- What the economic impacts to the affected actors would be over a specific timeframe and in a common measure (such as lost operating profit in EUR, typically in price level in the year before submission), for example:
 - substitution costs;
 - savings, e.g. related to risk and waste management costs;
 - cost of relocation;
 - decommissioning costs;
 - changes in profit due to changes in market share (to the users of the substance, to other actors in the supply and to competitors);
 - increased profit due to better quality of the end-product leading to greater consumer-surplus (for instance, possibility to advertise on eco/safer products).

Issues to consider in relation to data gathering

- What the social impacts would be, such as:
 - employment: how many jobs would be affected (lost or gained), what types of jobs (position, educational level, age) and their location;
 - effect on consumers, e.g. due to changes in availability or safety of end-products.
- Whether there would be any trade, competition or wider economic impacts;
- Would there be externalities – such as damage to human health or environment or other costs to society caused by not granting the authorisation?

5.1 Advice on data gathering for applications by upstream actors

During the preparation of this guide, ECHA asked previous applicants to give advice on the data gathering for applications by upstream actors. Below is a summary of what they said.

5.1.1 Be prepared for the effort it requires

- *Data gathering along the supply chain is one of the initial and – based on our experience – one of the most difficult tasks to accomplish when preparing an upstream application. This task might be easier when the downstream user using the concerned substance is a direct customer (e.g. short supply chain). But, the longer the supply chain, the more complex the data gathering process. Experience shows that responsiveness decreases with the length of the supply chain.*
- *I think it's always a good idea to talk to the layer that actually uses the substances directly, either by the applicants or through a third party. The information collection is naturally the most effort consuming step.*

5.1.2 Make sure the downstream users understand what information is needed and why

- *Most effort is certainly connected to the data gathering from downstream users as it was often difficult to convince them, that their data is really meaningful and needed. They do often not have the necessary know-how or do not understand the authorisation process or are simply overloaded with their day-to-day business. Applicants have no legal power to enforce the delivery of data from downstream users. Building core groups of 3-5 companies to build-up the base documents reduces the effort. The broader group can then review and comment on the early draft documents.*
- *Consultation requires continuing dialogue with downstream users who need to understand the logic of the SEA to provide meaningful inputs.*
- *Challenges included undertaking extensive and multilingual consultations with a complex and diverse downstream supply chain, and obtaining the necessary supply chain penetration over multiple levels (considering e.g. some distributors exhibited reluctance in passing on further downstream user details due to concerns of being cut out of the supply chain). The 'new' nature of the authorisation process also meant that knowledge in the supply chain was limited, and it was very important that communications did not cause alarm and reduced uncertainty to the extent possible.*

5.1.3 Ensure appropriate legal and organisational mechanisms are in place

- *With particularly complex supply chains, it is important that applicants allocate sufficient time and resources to putting the required mechanisms in place (legal agreements, etc.) including or handling confidential information and conflicting interests.*
- *Compliance with competition law requests that not even the lead applicant is in possession of all the raw data that the application documents are based on. Sharing confidential data with RAC and SEAC without breaking competition law (e.g. not sharing the data with the applicants) turned out to be the biggest challenge.*

5.1.4 Collect as specific data as possible

- *Getting downstream users involved and avoiding having to rely on information that is too generic to be of value were the biggest challenges. Generic information on exposure controls, work to identify alternatives, etc. without this being coupled with insights into what the downstream users are actually doing seems to be leading to a lack of credibility in parts of the authorisation process.*

6. Review report

Authorisations granted are valid until the Commission decides to amend or withdraw them.

Companies that have received an authorisation can re-apply by submitting a review report to ECHA. In other words, authorisation decisions can be extended if it is shown that suitable alternatives are still not available after the review period has come to an end.

According to REACH Article 61(1), if an authorisation holder needs to continue using the authorised substance, they should prepare a review report and submit it to ECHA at least 18 months before the expiry of the time-limited review period.

The process for submitting a review report is outlined in an ECHA note on the [review report for an authorisation](#) (ECHA, 2016n). The content of this note is reproduced verbatim in Sections 6.1 and 6.2 of this guide.

When updating assessment reports within the context of a review report (see below) a key consideration of the authorisation holder should be the revision of the AoA to discuss the progress towards finding an alternative for the use applied for within the period since the authorisation was granted. This could include any dialogue with customers on technical issues or changes to specifications.

In the reviewed SEA, the authorisation holder should explain what actually happened compared to the applied-for-use scenario described in the application and if there are implications that should be considered in the applied-for-use scenario in the review report.

The authorisation holder should also explain how they addressed any conditions, monitoring arrangements or recommendations in the authorisation decision or the opinions of RAC and SEAC, and any efforts made to address uncertainties in the initial application.

6.1 Requirements of the REACH Regulation

Article 61(1) states that an authorisation holder may submit only the number of the current authorisation, however, subject to several conditions²⁷. Applicants have so far always submitted a chemical safety report (CSR) with exposure scenarios, an AoA and a SEA.

The starting point for the review report is the Commission decision. If the CSR or SEA is

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1. Authorisation holder shall submit an update of the analysis of alternatives (AoA) including information about any relevant R&D activity. If the updated AoA shows that there is a suitable alternative available taking into account the elements in Article 60(5), he shall also submit a substitution plan, including a timetable for proposed actions by the authorisation holder.
2. Where the authorisation holder cannot demonstrate that the risk is adequately controlled, he shall also submit an update of the socio-economic analysis (SEA) contained in the original application.
3. If the authorisation holder can now demonstrate that the risk is adequately controlled (which was not the case when applying for authorisation), he shall submit an update of the chemical safety report.
4. If any other elements of the original application have changed, the authorisation holder shall also submit updates of these element(s).

updated, information, which had been provided by the applicant after the original application was submitted, should be included in the review report, if still relevant.

Downstream users (DUs) using a substance in accordance with Article 56(2) of REACH must notify ECHA about their use under a granted authorisation. ECHA encourages DUs to also make this information available for the authorisation holder, where possible. Further details are available [on ECHA's website](#).

The Commission's decisions granting authorisations have normally included the conditions and monitoring arrangements that ECHA's scientific committees²⁸ had recommended. In some cases²⁹, the Commission's decision contained additional conditions over and above those recommended by ECHA and, in some cases, certain recommendations were not taken forward into the decision. ECHA's committees may have given advice to the authorisation holder (in the justification section of the opinion) that was not included in the decision. This advice may be relevant with regard to the review report.

The Commission's decision and the advice from ECHA's committees may affect the exposure scenarios, the AoA and the SEA (including health or environmental impact).

ECHA has issued the reporting formats for an application for authorisation according to Article 111.

In conclusion:

- 1) **AoA:** The authorisation holder must submit an update of the AoA including information about any relevant R&D activity, possible new alternatives and progress made towards substitution by safer alternatives. If the authorisation holder had submitted a substitution plan as part of its original application it must also give an update of it as part of the review report³⁰.
- 2) **CSR:** Where there are conditions or monitoring arrangements relating to the management of the risks in the decisions, the authorisation holder must submit an update of the exposure scenarios in the CSR. If no such conditions or monitoring arrangements have been issued, the exposure scenarios are still expected to be updated if there are changes affecting them. Reasons for this are, for instance: i) progress affecting production technologies and thus, the possibilities to reduce exposure (new risk management measures, variations to operational conditions, quantities used etc.) and ii) improved knowledge of exposure levels (e.g. based on additional measurements).
- 3) **SEA:** As the AoA needs to be updated, the benefits of a granted authorisation may change accordingly. Furthermore, to the extent the exposure scenarios are updated the health or environmental impacts of the granted authorisation may change, too. An SEA or elements of it have been received so far in all applications partly also to give the applicant's reasoning for the duration of the review period. Thus, the authorisation holder may also have to submit an updated SEA or the relevant review period part.
- 4) **Other elements:** The authorisation holder must also submit an update of any

²⁸ Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC)

²⁹ For instance, the Commission's draft decision on uses of recycled DEHP.

³⁰ If the authorisation holder now also concludes that there is a suitable alternative available taking into account the elements in Article 60(5), they must provide a substitution plan.

other element of the original application that has changed or elements that are required by the conditions or monitoring arrangements of the authorisation decision.

6.2 Approach

The approach for the preparation, opinion making and decision making related to the review report needs to follow the requirements of the REACH Regulation (see above) whilst being as practical as possible.

The approach should be such that the authorisation holder would update all relevant elements in the review report using the original application, the opinion, the decision and relevant communication made during the opinion and decision making as the basis. Therefore, the following approach is taken regarding the review reports:

1. The authorisation holder would update all documents submitted in the original application that have changed. The analysis of alternatives has to be updated in all cases. The latest format of the application should be used to facilitate the opinion and decision-making phases. ECHA will issue the formats on its website. The formats for review reports are likely to be the same as the formats for applications.
2. To facilitate public consultation, opinion making and decision making, the authorisation holder is requested to submit one additional document: a note explaining briefly what is different in the original application and the review report. The purpose of this explanatory note is to make it clear what progress has been made since the authorisation was granted. The note would be a reading aid, and would include a summary of the changes and conclusions of the review report and a reference table of where changes have been made. ECHA will issue a format for this explanatory note on its website.
3. The process for handling the review report is essentially the same as for applications for authorisation.

References

EC (2003). Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market.

ECHA (2011a). Guidance on the preparation of an application for authorisation. Version 1 (January 2011). ECHA-11-G-01-EN. European Chemicals Agency, Helsinki, Finland.

ECHA (2011b). Guidance on the preparation of socio-economic analysis as part of an applications for authorisation. Version 1 (January 2011). ECHA-11-G-02-EN. European Chemicals Agency, Helsinki, Finland.

ECHA (2011c). How to develop the description of uses in the context of Authorisation. ECHA-11-B-06.1-EN. European Chemicals Agency. Helsinki. Finland.

ECHA (2012a). Common approach of RAC and SEAC in opinion development on applications for authorisation. RAC/20/2012/06 SEAC/14/2012/05. European Chemicals Agency, Helsinki, Finland.

ECHA (2012b). What to make public of opinions on applications for authorisation. RAC/21/2012/11 SEAC/15/2015/05. September 2012. European Chemicals Agency. Helsinki. Finland.

ECHA (2012c). Participation of applicants, third parties and stakeholder observers in the application for authorisation process. RAC/23/2012/06 (Rev. 1) SEAC/17/2012/06 (Rev. 1). European Chemicals Agency. Helsinki. Finland.

ECHA (2012d). Guidance on Information Requirements and Chemical Safety Assessment. Chapter R.13: Risk management measures and operational conditions. Version 1.2. ECHA-12-G-19-EN. European Chemicals Agency. Helsinki. Finland.

ECHA (2012e). Guidance on Information Requirements and Chemical Safety Assessment. Chapter R.19: Uncertainty analysis. Version 1.1. ECHA-12-G-25-EN. European Chemicals Agency. Helsinki. Finland.

ECHA (2012f). An illustrative example CSR. ECHA-12-G-03.1-EN. European Chemicals Agency. Helsinki. Finland.

ECHA (2013a). Setting the review period when RAC and SEAC give opinions and an applications for authorisation. SEAC/20/2013/03. European Chemicals Agency, Helsinki, Finland.

ECHA (2013b). Authorisations – economic feasibility. SEAC/18/2013/03. European Chemicals Agency. Helsinki. Finland.

ECHA (2014a). Working Procedure for RAC and SEAC for developing opinion on the applications for authorisation. RAC/31/2014/07 rev1 SEAC/25/2014/05 rev 1. European Chemicals Agency, Helsinki, Finland.

ECHA (2014b) An illustrative example of the exposure scenarios to be annexed to the safety data sheet. ECHA-14-R-19-EN. ISBN: 978-92-9244-752-6. European Chemicals Agency. Helsinki. Finland.

ECHA (2014c) Guidance for downstream users. Version 2.1. ECHA-13-G-09.1-EN. ISBN: 978-92-9244-013-8. European Chemicals Agency. Helsinki. Finland.

ECHA (2015a). Guidance on Information Requirements and Chemical Safety Assessment. Chapter R.12: Use description. Version 3. ECHA-15-G-11-EN. ISBN 978-92-9247-685-4. European Chemicals Agency. Helsinki. Finland.

ECHA (2015b). How to prepare a downstream user chemical safety report. Practical Guide 17. ECHA-15-B-14-EN. ISBN: 978-92-9247-534-5. European Chemicals Agency. Helsinki. Finland.

ECHA (2016a). Checklist for evaluating chemical safety assessment in applications for authorisation. Version 1.1. European Chemicals Agency. Helsinki. Finland.

ECHA (2016b). Checklist for evaluating socio-economic analysis in applications for authorisation. January 2016. European Chemicals Agency. Helsinki. Finland.

ECHA (2016c). Checklist for preparing an application for authorisation. Version 1. European Chemicals Agency. Helsinki. Finland.

ECHA (2016d). Guidance paper on opinion trees for non-threshold substance in applications for authorisation (AfA). RAC/35/2015/08 SEAC/29/2015/06. January 2016. European Chemicals Agency, Helsinki, Finland.

ECHA (2016e). Guidance on Information Requirements and Chemical Safety Assessment. Part D: Framework for exposure assessment. Version 2.0. ECHA-16-G-07-EN. ISBN 978-92-9495-079-6. European Chemicals Agency. Helsinki. Finland.

ECHA (2016f). Guidance on Information Requirements and Chemical Safety Assessment. Part E: Risk Characterisation. Version 3.0. ECHA-2016-G-04-EN. ISBN 978-92-9495-055-0. European Chemicals Agency. Helsinki. Finland.

ECHA (2016g). Guidance on Information Requirements and Chemical Safety Assessment. Chapter R.14: Occupational exposure assessment. Version 3.0. ECHA-16-G-09-EN. ISBN 978-92-9495-081-9. European Chemicals Agency. Helsinki. Finland.

ECHA (2016h). Guidance on Information Requirements and Chemical Safety Assessment. Chapter R.15: Consumer exposure assessment. Version 3.0. ECHA-16-G-08-EN. ISBN 978-92-9495-080-2. European Chemicals Agency. Helsinki. Finland.

ECHA (2016i). Guidance on Information Requirements and Chemical Safety Assessment. Chapter R.16: Environmental exposure assessment. Version 3.0. ECHA-16-G-03-EN. ISBN 978-92-9247-775-2. European Chemicals Agency. Helsinki. Finland.

ECHA (2016j). Evaluation of restriction reports and applications for authorisation for PBT and vPvB substances in SEAC. SEAC/31/2013/05 Rev. 1. European Chemicals Agency. Helsinki. Finland.

ECHA (2016k). Valuing selected health impacts of chemicals. Summary of the results and a critical review of the ECHA study. European Chemicals Agency. Helsinki. Finland.

ECHA (2016l). Willingness-to-pay values for various health endpoints associated with chemicals exposure. SEAC/32/2016/05.2. European Chemicals Agency. Helsinki. Finland.

ECHA (2016m). The social cost of unemployment. SEAC/32/2016/04. European Chemicals

Agency. Helsinki. Finland.

ECHA (2016n). Review report of an authorisation. Note of 16 September 2016. European Chemicals Agency. Helsinki. Finland.

European Union (1998). Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC). OJ L 131, 5.5.1988, p.11.

European Union (2004). Directive 2004/37/EC of the European Parliament and of the Council on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (sixth individual Directive within the meaning of Article 16(1) of council Directive 89/391/EEC). OJ L 158, 30.4.2004, p. 50.

European Union (2006). Regulation (EC) No 1907/2006 of the European parliament and of the council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/ECC, 93/67/EEC, 93/105/EC and 2000/21/EC. OJ L 396, 30.12.2006, p.1.

Glossary

A glossary of terms used within the guide is provided below. Any words shown in *italics* can also be found within this glossary. ECHA also has an [online glossary of terms relevant to REACH](#) on its website.

Actors in the supply chain	All <i>manufacturers and/or importers</i> (Ms/Is) and/or <i>downstream users</i> (DUs) in a supply chain (Article 3(17)). Within this guide, the term is also used to include consumers and the supply chain for <i>articles</i> . It may additionally refer to actors in the supply chains for alternative substances as well as alternative technologies. See also <i>Supply chain</i> .
Adequate control route	An <i>authorisation</i> shall be granted if it is shown that the risk to human health and the environment from the use of a substance arising from the intrinsic properties specified in <i>Annex XIV</i> is adequately controlled in accordance with Section 6.4 of Annex I {Art. 60(2)} and taking into account Article 60(3). See also <i>Guidance on the preparation of an application for authorisation</i> .
Alternative	An alternative is a possible replacement for an <i>Annex XIV</i> substance. It should be able to replace the function that the <i>Annex XIV</i> substance performs. The alternative could be another substance(s) or it could be a technology (i.e. a process, procedure, device, or modification in an end-product) or a combination of technical and substance alternatives. For example, a technical alternative could be a physical means of achieving the same function of the <i>Annex XIV</i> substance or perhaps changes in production, process or product that removes the need for the <i>Annex XIV</i> substance altogether.
Analysis of alternatives (AoA)	A systematic search for <i>alternatives</i> that can be documented and presented in an application for <i>authorisation</i> . This analysis is the <i>applicant's</i> evidence to show that the <i>technical</i> and <i>economic feasibility</i> of <i>substituting</i> the possible alternatives has been analysed and their risks compared to the <i>Annex XIV</i> substance. The aim of this analysis should be to determine if use of the alternative would lead to an overall reduction in <i>risk</i> . Guidance on conducting an analysis of alternatives can be found in the <i>Guidance on the preparation of an application for authorisation</i> .
Annex XIV	Annex XIV to the REACH Regulation lists all substances subject to authorisation under REACH. The use and placing on the market for a use of substances listed on Annex XIV is prohibited from the " <i>sunset</i> " date unless an authorisation has been granted for that use or unless an exemption applies.
Annex substance	XIV The substance listed on Annex XIV that is the subject of the authorisation procedure.
Applicant	The legal entity or group of legal entities submitting an <i>authorisation application</i> .
Applied for use scenario	/ Term that commonly describes the "baseline" or "business as usual" situation that would arise if the authorisation is granted.

continued use

Article	An object which during production is given a specific shape, surface or design which determines its function to a greater degree than its chemical composition.
Authorisation	System set up under the REACH Regulation under which the use of substances with properties of very high concern and their placing on the market can be made subject to an authorisation requirement. Such substances are included in <i>Annex XIV</i> of the Regulation and may not be placed on the market or used without an authorisation after the <i>sunset date</i> . This authorisation requirement ensures that risks from the use of such substances are either <i>adequately controlled</i> or outweighed by socio-economic benefits. An analysis of alternative substances or technologies is a fundamental component of the authorisation process.
Authorisation application	The documentation submitted to ECHA applying for the use of a substance(s) included in <i>Annex XIV</i> after the “ <i>sunset</i> ” date.
Available (alternative)	Accessible and able to replace the <i>Annex XIV</i> substance.
Baseline scenario	Term that describes the “business as usual” situation that would arise if no additional action were taken. In the application for authorisation, this is called “applied for use” scenario.
Benefits	The positive implications, both direct and indirect, resulting from some action. This includes both financial and non-financial information.
Candidate List	The Candidate List refers to the list of <i>substances of very high concern (SVHCs)</i> from which the substances to be included in <i>Annex XIV</i> (list of substances subject to authorisation) are selected. The Candidate List is established in accordance with Article 59.
Carcinogenic, mutagenic or toxic to reproduction (CMR)	Substances meeting the criteria for classification in the hazard classes carcinogenicity, germ cell mutagenicity or reproductive toxicity category 1A or 1B in accordance with Annex I to Regulation (EC) No 1272/2008. They may be considered to be <i>substances of very high concern (SVHCs)</i> and added to the <i>Candidate List</i> . They may be included in <i>Annex XIV</i> and by that made subject to authorisation requirement. CMRs may be non-threshold (i.e. it is not possible to define a derived no-effect level (DNEL)) or threshold (i.e. it is possible to define a DNEL).
Chemical safety assessment (CSA)	Process aimed at determining the risk posed by a substance and, as part of the exposure assessment, develop exposure scenarios including risk management measures to control the risks. Annex I to the REACH Regulation contains general provisions for performing a CSA. The CSA consists of the following steps: <ul style="list-style-type: none"> - Human health hazard assessment; - Human health hazard assessment of physicochemical properties; - Environmental hazard assessment; and - PBT and vPvB assessment. If, as a result of this hazard assessment, the registrant concludes

	<p>that the substance meets the criteria for classification as dangerous according to Directive 67/548/EEC (for substances) or has PBT/vPvB properties, this triggers further steps in the chemical safety assessment:</p> <ul style="list-style-type: none"> - Exposure assessment; - Risk characterisation.
Chemical safety report (CSR)	The report that documents the chemical safety assessment for a substance on its own, in a mixture or in an article or a group of substances. It details the process and the results of a <i>chemical safety assessment (CSA)</i> . Annex I to the REACH Regulation contains general provisions for performing CSAs and preparing CSRs.
Committee for Risk Assessment (RAC)	An <i>ECHA</i> committee responsible for preparing opinions on applications for authorisation, proposals for restrictions and proposals for classification and labelling and any other questions that arise from the operation of the REACH Regulation relating to risks to human health or the environment. RAC consists of at least one but no more than two members from the nominees of each Member State appointed by the Management Board for a renewable term of three years. The committee members may be accompanied by advisers on scientific, technical or regulatory matters.
Committee for Socio-economic Analysis (SEAC)	An <i>ECHA</i> committee responsible for preparing opinions on applications for authorisation, proposals for restrictions, and any other questions that arise from the operation of the REACH Regulation relating to the socio-economic impact of possible legislative action on substances. SEAC consists of at least one but no more than two members from the nominees of each Member State appointed by the Management Board for a renewable term of three years. The committee members may be accompanied by advisers on scientific, technical or regulatory matters.
Compliance costs	The difference in the cost to the applicant and the up and downstream users (i.e. the supply chain) complying with a "non-use" scenario as compared to the 'applied for use' scenario. Compliance costs include the capital and operating costs that would accrue to the sectors affected by the "non-use" scenario.
Consumer surplus	Denotes the net benefit that a consumer derives from consuming a good. It is equal to the absolute amount the consumer would willingly pay for a good less the amount they actually have to pay (i.e. the market price).
Costs	The negative implications, direct and indirect, resulting from some actions. Includes both financial and non-financial information.
Discounting	A method used to convert future costs or benefits to present values using a <i>discount rate</i> .
Discount rate	Used to convert a future income (or expenditure) stream to its present value. It shows the annual percentage rate at which the present value of a future Euro, or other unit of account, is assumed to decrease over time.

Downstream user	Any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of their industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted under Article 2(7)(c) has to be regarded as a downstream user.
ECHA	The European Chemicals Agency
Economic feasibility	Analysis of the economic implications of the adoption of an <i>alternative</i> . Economic feasibility is normally defined as a situation where the economic benefits exceed the economic costs. For more details on how the concept is applied in authorisation applications; see Section 3.7 in the <i>Guidance on the preparation of an application for authorisation</i> .
Economic impacts	Costs and benefits to manufacturers, importers, downstream users, distributors, consumers and society as a whole.
Environmental impacts	Impacts on all environmental compartments. Covers all use and non-use values of the affected environmental compartments.
Exposure scenario	Set of operational conditions and risk management measures that describe how a substance is manufactured or used during its life-cycle and how exposure of humans and the environment is controlled.
Externalities	The non-market impacts of an activity which is not borne by those who generate them.
Gross profit	Difference between the sales revenue and the variable and fixed costs of producing the product. Fixed and variable costs (also known as "cost of goods sold") include e.g. materials and labour. Gross profit = revenue – variable costs – fixed costs.
Hazard assessment	Hazard assessment consists of using the information about the intrinsic properties of the substance to make an assessment of hazard in the following areas: 1) Human health hazard assessment; 2) Human health hazard assessment of physicochemical properties; 3) Environmental hazard assessment; and 4) PBT and vPvB assessment.
Health impacts	Impacts on human health including morbidity and mortality effects. Covers health related welfare effects, lost production due to workers' sickness and health care costs.
Impacts	All possible effects – positive or negative – including economic, human health, environmental, social and wider impacts on trade, competition and economic development.
Investment cost	Capital or one-off cost that has a lifetime of several years.
Joint application	An application for authorisation made by a number of legal entities forming a group of applicants consisting of manufacturer(s) and/or

	importer(s) and/or downstream user(s) of the Annex XIV substance.
Latest application date	Annex XIV (list of substances subject to authorisation) will specify for each substance included in that annex a date or dates, at least 18 months before the sunset date(s), by which applications for authorisation must be submitted if the applicant wishes to continue to use the substance or place it on the market for certain uses after the sunset date(s) until a decision on the application for authorisation is taken.
Legal entity	Any natural or legal person established within the Community.
Manufacturer / Importer (M/I)	Any natural or legal person established within the Community who manufactures a substance within the Community (manufacturer) or who is responsible for import (importer) (Article 3(9) and (11)). Within this guide, the term is also used for suppliers of alternatives.
Non-threshold substance	A substance for which it is not possible to determine a threshold for toxicological effects (i.e. DNEL or PNEC) in accordance with Annex I to the REACH Regulation.
Non-use scenario	Term that describes the scenario in which an authorisation application for use of a substance is not granted.
Operating cost	Recurrent or variable cost that reappears every year and usually depends on how much a particular machine produces. Examples are raw material costs, labour costs, energy costs or maintenance costs.
Operational condition	Any action, use of tool or parameter state that prevails during manufacture or use of a substance (either in a pure state or in a preparation) that as a side effect may have an impact on exposure of humans and/or the environment. Operational conditions include e.g. physical appearance of preparation, duration and frequency of use/exposure, amount of substance, room size and ventilation rate.
Opportunity cost	The benefit that could have been derived from using a given amount of resources in alternative "non-use" scenario, that is the value of foregone net-benefits created by the "next best" alternative.
Persistent Bioaccumulative Toxic (PBT)	Annex XIII to the REACH Regulation defines criteria for the identification of substances that are persistent, bio-accumulative and toxic (PBTs) and Annex I lays down general provisions for PBT assessment. PBTs are substances of very high concern (SVHCs) and may be included in Annex XIV and by that be made subject to authorisation.
Present value	The future value of an impact expressed in present terms by means of <i>discounting</i> .
Private costs	The costs to a group or sector of implementing a policy. To be distinguished from social costs.
Producers	Denotes the difference between the true cost to a producer of

surplus	producing a good (or volume of goods) and the price at which they can sell the goods.
Rapporteur and co-rapporteur	Members of RAC and SEAC appointed to lead the development of committee opinions on applications for authorisation.
Relocation of production	Relocation of production is used in a generic manner describing either a situation where a production unit closes down in the EU and a new unit is opened up outside the EU, or where a non-EU supplier increases its production to offset reduced/removed production in the EU.
Review period	Authorisations granted will be subject to a time-limited review period.
Review report	To continue using or placing a substance on the market, the holder of the authorisation must submit a review report at least 18 months before the expiry date of the time-limited review period.
Risk assessment	A procedure for determining the risk that a substance poses to health and the environment.
Risk management measures (RMMs)	Any action, use of tool, change of parameter state that is introduced during manufacture or use of a substance (either in a pure state or in a mixture) to prevent, control, or reduce exposure of humans and/or the environment. Such measures thereby control the risks to human health or the environment. Risk management measures include e.g. containment of process, local exhaust ventilation, gloves, waste water treatment, exhaust air filters.
Sensitivity analysis	A "what-if" type of analysis to determine the sensitivity of the outcomes of an analysis to changes in parameters. If a small change in a parameter results in relatively large changes in the outcomes, the outcomes are said to be sensitive to that parameter.
Social costs	Denotes the opportunity cost to society and includes also external costs or externalities.
Social impacts	All relevant impacts which may affect workers, consumers and the general public and are not covered under health, environmental or economic impacts (e.g. employment, working conditions, job satisfaction, education of workers and social security).
Socio-economic analysis (SEA)	The socio-economic analysis (SEA) is a tool to evaluate what costs and benefits an action will create for society by comparing what will happen if one action is implemented compared to the situation where it is not. Under the REACH authorisation procedure, an SEA is a compulsory part of an application for authorisation whenever the risks to human health or the environment from the use of an Annex XIV substance are not adequately controlled. An SEA may be undertaken by an applicant in support of an application when adequate control is proposed. An SEA may also be produced by any third party in support of information on alternatives.
Socio-economic route	An <i>authorisation</i> may be granted if it can be shown that the risk to human health or the environment from the use of the <i>Annex XIV</i>

(authorisation)	substance is outweighed by the socio-economic benefits and if there are no <i>suitable alternative</i> substances or technologies { Article 60(4)}.
Substance function	The function of the <i>Annex XIV</i> substance for the use(s) being applied for is the task or job that the <i>Annex XIV</i> substance performs.
Substances of very high concern (SVHC)	In the context of the REACH Regulation, SVHCs are: <ol style="list-style-type: none"> 1. CMRs category 1 or 2; 2. PBTs and vPvBs meeting the criteria of Annex XIII; and 3. substances – such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties (but not fulfilling the criteria of Annex XIII), for which there is scientific evidence of probable serious effects to human health or the environment which gives rise to an equivalent level of concern to those of other substances listed in points 1 and 2. Such ‘substances of equivalent concern’ will be identified on a case-by-case basis in accordance with the procedure set out in Article 59.
Substitution plan	Proposal including a timetable detailing the replacement of an <i>Annex XIV</i> substance by a <i>suitable alternative</i> substance or technology. The substitution plan must be included in the application for authorisation if suitable alternatives are available. It might also be required within the review of a given authorisation.
Suitable alternative	An <i>alternative</i> that is <i>technically</i> and <i>economically feasible</i> for replacement of the <i>Annex XIV</i> substance where transferral to the alternative results in reduced overall risks to human health and the environment (as compared to the <i>Annex XIV</i> substance) taking into account risk management measures and operational conditions. It must also be available (e.g. can be accessed in sufficient quantity and quality).
Sunset date	Date specified in <i>Annex XIV</i> to the REACH Regulation for each substance from which the placing on the market and the use of that substance must be prohibited unless an exemption applies or an authorisation is granted, or an authorisation application has been submitted before the application date also specified in <i>Annex XIV</i> , but the Commission decision on the application for authorisation has not yet been taken.
Supply chain	Network of organisations, people, activities, information and resources that participate in the production, delivery and sale of substances i.e. <i>manufacturers/importers (Ms/Is)</i> and/or <i>downstream users</i> , including articles containing <i>Annex XIV</i> . It also refers to supply chains for alternative substances or technologies. See also <i>Actors in the supply chain</i> .
Technical feasibility	Relates to an <i>alternative</i> substance or technology which is capable of fulfilling or replacing the function of the <i>Annex XIV</i> substance, without compromising the functionality delivered by the substance and its use in the final product. See also <i>Guidance on the preparation of an application for authorisation</i> .

Third party or interested third party	Any organisation, individual, authority or company other than the applicant, <i>ECHA</i> or the <i>Commission</i> with a potential interest in submitting information on <i>alternatives</i> or other information, e.g. on socio-economic benefits arising from use of the <i>Annex XIV</i> substance and socio-economic implications of a refusal to authorise.
Dialogue	Meeting between applicants, RAC and SEAC Rapporteurs and interested third parties held after the public consultation on an application for authorisation to discuss specific aspects of an application.
Uncertainty	This is a state characterising a situation where related parameters are not known or fixed or certain. It stems from a lack of information, scientific knowledge or ignorance and is a characteristic of all predictive assessments. Uncertainty can have a significant effect on the type and amount of evidence that must be collected in an assessment and taken into account in communicating the outcome.
Unsuitable alternative	An alternative that has been analysed as part of the <i>analysis of alternatives</i> where it is shown that the alternative is not technically or economically feasible, is not available for use or does not reduce risks.
Upstream actor	An actor that is able to apply for a use performed by a downstream user further along their supply chain. Applications by upstream actors are sometimes referred to as "upstream applications".
Very persistent and very bioaccumulative (vPvB)	Substances of very high concern, which are very persistent (very difficult to break down) and very bioaccumulative in living organisms. Annex XIII to the REACH Regulation defines criteria for the identification of vPvBs, and Annex I lays down general provisions for their assessment. vPvBs may be included in Annex XIV and thereby be made subject to authorisation.
Wider economic impacts	Impacts that have macro-economic implications. Such impacts may include trade, competition, economic growth, inflation, taxes and other macro-economic effects.

List of abbreviations

AoA	Analysis of alternatives
ATM	Authorisation team manager
CBI	Confidential business information
CMR	Carcinogenic, mutagenic or toxic for reproduction
CSA	Chemical safety assessment
CSR	Chemical safety report
DNEL	Derived no-effect level
DU	Downstream user
ECHA	European Chemicals Agency
ECS	Environmental contributing scenario
ES	Exposure scenario
EU	European Union
IED	Industrial Emission Directive (Directive 2010/75/EU)
IUCLID	International Uniform Chemical Information Database
M/I	Manufacturer/importer
MS	Member State
MSCA	Member State competent authority
OC	Operational conditions
PBT	Persistent, bio-accumulative and toxic
PEC	Predicted environmental concentration
PNEC	Predicted no-effect concentration
PSIS	Pre-submission information session
Q&A	Question and answer
R&D	Research and development
RAC	Risk Assessment Committee
RCR	Risk characterisation ratio
REACH	Registration, Evaluation, Authorisation and restriction of Chemicals
RMM	Risk management measure
SEA	Socio-economic analysis
SEAC	Socio-economic Analysis Committee
SME	Small and medium-sized enterprises
SVHC	Substance of very high concern
vPvB	Very persistent very bio-accumulative
WCS	Worker contributing scenario
WTP	Willingness to pay

Annex 1 – Opinion development timeline



82 (93)

Helsinki, 09 June 2016

Example applicant

Example address
Example address

Submission number: **xxxxxxxx-xx**Application upload date: **14/03/2016**Communication number: **AFA-x-xxxxxxxxxx-xx-xx/x****Subject: Main steps and timelines for your application for authorisation**

Dear Sir/Madam,

I have the pleasure of informing you that your application for authorisation has passed the business rules check and has been accepted for further processing.

As you applied before the latest application date, your application benefits from the transitional arrangements under Article 58(c)(ii). In other words, you can continue to use the substance even after the sunset date until the Commission has issued its decision, provided that you pay the invoice on time.

An indicative timeline for processing your application is provided below.

Further information on the authorisation procedure is available on ECHA's website at: <http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation/afa>.

If you need further clarification on any of these issues, please contact me at: firstname.lastname@echa.europa.eu.

Yours sincerely,

*(e-signed)*³¹

Risk Management Implementation Unit

³¹ As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

Indicative timeline for your application

The table below outlines the subsequent stages in the processing of your application and highlights when you should be prepared to provide further information. The table includes **indicative** timelines. Precise dates, deadlines and requests for further information will be sent to you in REACH-IT. Please ensure that you regularly check your REACT-IT mailbox. In exceptional cases, we will send you messages through email.

Indicative date	Main steps
30 September 2016	<p>Initial proposal for the 'Broad Information on Uses' package for public consultation</p> <p>ECHA will prepare an initial (draft) version of the Broad Information on Uses (BIU) package that will be used for the public consultation on your application. This will usually be based on the text proposed by you for the "general description of use" and also comprise the non-confidential versions of the following assessment reports:</p> <ul style="list-style-type: none"> • Part A, Section 1 (succinct summary of risk management measures and operational conditions) of the Chemical Safety Report • Sections 9 and 10 of the chemical safety report • Analysis of alternatives • Socio-economic analysis (where submitted) <p>After receipt of this draft version, you will have 10 days to provide comments.</p>
14 October 2016	<p>Final version of the BIU package and invoice</p> <p>We will prepare the final version of the BIU package based on any comments that you send to us. We will send you the final version for information at the same time as the invoice for the payment of the application fee.</p>
4 November 2016	<p>Extended due date for payment of the invoice</p> <p>Note: provided that the invoice will be paid on time and that the upload date of your application (indicated on the top of this letter) has been by the latest application date applicable for your substance, you will be able to benefit from the transitional arrangements described in Article 58(1)(c)(ii). In other words, if no decision has been taken by the Commission by the sunset date, you will be able to continue to use the substance after the sunset date until the Commission takes the decision.</p>
9 November 2016	<p>Start of public consultation</p>

Indicative date	Main steps
	<p>After the application fee has been received, we will publish the BIU package on ECHA's website: (http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation) and start the public consultation, which lasts for eight weeks.</p> <p>The non-confidential version of any comments received will be regularly published on ECHA's website. You will be invited to respond to these non-confidential comments, although this is not a formal requirement.</p>
<p>28 November - 2 December 2016 & 5 - 9 December 2016 (RAC)</p> <p>21 November 2016 - 25 November 2016 &</p> <p>28 November - 2 December 2016 (SEAC)</p>	<p>1st RAC and SEAC plenary meeting (conformity check and initial opinion development)</p> <p>At the 1st plenary meeting after the application fee is paid, the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) will assess if your application is in conformity (i.e. that application includes all the information specified in Article 62 of the REACH Regulation) and begin their opinion development discussions, led by the rapporteurs assigned to your application.</p>
<p>Beginning of December 2016</p>	<p>Requests for additional information</p> <p>After reviewing your application, RAC and SEAC may request in writing that you provide additional information on possible alternative substances or technologies or clarification on essential points in your application. You will have a short period (three to four weeks generally) to provide written responses to these requests.</p>
<p>4 January 2017</p>	<p>End of the public consultation</p> <p>At the end of the public consultation, we will send you non-confidential versions of any comments that we have received. If you wish to respond to these comments, you must do so within two weeks of the end of the public consultation. The non-confidential version of your responses will also be published on ECHA's website, alongside the original comments. In addition, RAC and SEAC may request further information in response to the public consultation, or if responses to earlier requests for information or clarification were not considered to be adequate. You will have a short period (one to two weeks generally) to respond to these requests.</p>
<p>Beginning of February 2017</p>	<p>Dialogue</p>

Indicative date	Main steps
	<p>A “trialogue” between applicants and the RAC and SEAC rapporteurs may be scheduled to discuss the content of your application (particularly with respect to alternatives). RAC and SEAC rapporteurs will decide if they consider that the triologue is necessary. This decision will be based on the outcome of the public consultation and your responses to any requests for clarification or information. Rapporteurs may also invite third parties that have submitted comments during the public consultation to the triologue. These meetings (usually around three hours long) can be held using WebEx or at ECHA in Helsinki. RAC and SEAC members, as well as accredited stakeholder observers, may also attend the triologue.</p>
<p>March 2017 (RAC)</p> <p>March 2017 (SEAC)</p>	<p>2nd RAC and SEAC plenary meeting (further opinion development)</p> <p>At the 2nd plenary meeting, the draft opinion on your application will be further discussed and may be adopted, in one or both of the committees. If no agreement is reached, the draft opinion will be further discussed in subsequent RAC and SEAC meetings, until it is adopted.</p>
<p>June 2017 (RAC)</p> <p>June 2017 (SEAC)</p>	<p>3rd RAC and SEAC plenary meeting, if necessary</p>
<p>September 2017 (RAC)</p> <p>September 2017 (SEAC)</p>	<p>4th RAC and SEAC plenary meeting, if necessary</p>
<p>After 2nd, 3rd or 4th plenary meeting</p>	<p>ECHA sends the draft opinion to you</p> <p>Once RAC and SEAC have adopted their draft opinion, we will send it to you.</p>
<p>Within: 1 month of the receipt of the draft opinions</p>	<p>Informing ECHA if you wish to comment</p> <p>You will need to decide if you wish to comment on the draft opinion. As it is important to time the commenting correctly, the authorisation team manager will discuss this with you once the draft opinions have been adopted.</p> <p>If you wish to comment, you must inform ECHA within one month from receiving the draft opinion, and send the comments to us within two months from receiving the draft opinion.</p>

Indicative date	Main steps
	Please also inform us if you do not wish to comment. In this case the draft opinion automatically becomes a final opinion.
<p>Within:</p> <p>2 months of the receipt of the draft opinions</p>	<p>If you wish to comment</p> <p>If you comment on the draft opinion, RAC and SEAC rapporteurs will investigate your comments, primarily with regard to clarifying any factual inaccuracies or misunderstandings and may or may not decide to adjust the opinion. It is not the intention that additional new information, e.g. new exposure data or reworked risk and exposure assessments be provided at this stage in the process. RAC and SEAC will take into consideration your comments within the remit given in Article 64(5) of the REACH Regulation.</p>
<p>Within:</p> <p>15 days if you do not comment.</p> <p>2½ months if you wish to send comments.</p>	<p>ECHA sends the opinions to the European Commission</p> <p>Once RAC and SEAC have adopted their final opinion, we will send it to the European Commission for decision making together with any comments that you provided and the response of RAC and SEAC to these comments. We will also upload these documents to ECHA's website. You will get a copy of our letter to the Commission, as will EU Member States.</p>
	<p>Decision making</p> <p>Decision making on applications for authorisation is handled by the European Commission REACH Committee. The decision-making process can be followed through the Comitology Register, where further information is published about the REACH Committee's past and upcoming meetings: http://ec.europa.eu/transparency/regcomitology/index.cfm?do=Search.Search&NewSearch=1</p> <p>The European Commission also publishes information about the expected timing of its decisions on this page: http://ec.europa.eu/DocsRoom/documents/9827</p>

Annex 2 – Links in this document

The 'How to apply for authorisation' guide contains hyperlinks to several documents and webpages embedded into the text. The full links are provided below.

Key messages

How to apply for authorisation: <https://echa.europa.eu/applying-for-authorisation>

Checklist for an application for authorisation:
https://echa.europa.eu/documents/10162/13637/afa_applicants_checklist_en.pdf

Evaluating applications: <https://echa.europa.eu/applying-for-authorisation/evaluating-applications>

Section 1. Introduction

Annex XIV to REACH: <https://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list>

Exemptions from the authorisation requirement:
https://echa.europa.eu/documents/10162/13640/generic_exemptions_authorisation_en.pdf

Application formats: <https://echa.europa.eu/applying-for-authorisation/preparing-applications-for-authorisation>

Common approach of RAC and SEAC:
https://echa.europa.eu/documents/10162/13555/common_approach_rac_seac_en.pdf

Working procedure for RAC and SEAC:
https://echa.europa.eu/documents/10162/13579/rac_seac_wp_opinions_auth_app_en.pdf

Setting the review period:
https://echa.europa.eu/documents/10162/13580/seac_rac_review_period_authorisation_en.pdf

Guidance paper on opinion trees:
https://echa.europa.eu/documents/10162/13637/opinion_trees_non_threshold_subs_en.pdf

Publication of information:
https://echa.europa.eu/documents/10162/13555/public_parts_rac_seac_opinions_en.pdf

Participation of applicants, third parties and stakeholder observers:
https://echa.europa.eu/documents/10162/13555/stakeholder_participation_in_afa_en.pdf

Checklist for an application for authorisation:
https://echa.europa.eu/documents/10162/13637/afa_applicants_checklist_en.pdf

Downstream user notification (Article 66): <https://echa.europa.eu/support/dossier-submission-tools/reach-it/downstream-user-authorised-use>

How to apply for authorisation: <https://echa.europa.eu/applying-for-authorisation>

Guidance on the preparation of an application for authorisation:
<https://echa.europa.eu/guidance-documents/guidance-on-reach?panel=auth-appl#auth-appl>

Guidance on the preparation of socio-economic analysis for authorisation:
https://echa.europa.eu/documents/10162/13637/sea_authorisation_en.pdf

Guidance on information requirements and chemical safety assessment:
<https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>

Questions and answers: <https://echa.europa.eu/support/qas-support/browse/-/qa/700x/view/scope/reach/authorisation>

AfA events: <https://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation/afa>

Request a PSIS:
https://comments.echa.europa.eu/comments_cms/AfA_NotifyAndPresubmit.aspx

Section 2. Developing an application strategy

Information on substituting hazardous chemicals:
<https://echa.europa.eu/regulations/substituting-hazardous-chemicals>

Access to document requests: <https://echa.europa.eu/about-us/the-way-we-work/procedures-and-policies/access-to-documents>

How to redact and justify CBI: <https://echa.europa.eu/about-us/the-way-we-work/procedures-and-policies/access-to-documents>

Checklist for an application for authorisation:
https://echa.europa.eu/documents/10162/13637/afa_applicants_checklist_en.pdf

Section 3. Key elements of an application for authorisation

Use applied for

How to develop the description of uses in the context of authorisation:
https://echa.europa.eu/documents/10162/13566/uses_description_in_auth_context_en.pdf

Yara France's application: <https://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations/-/substance-rev/1606/term>

Blue Cube Germany Assets GmbH & Co KG's application:
https://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations/-/substance-rev/1652/del/50/col/synonymDynamicField_308/type/asc/pre/1/view

Federal Mogul Burscheid GmbH's application: <https://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations/-/substance-rev/12448/term>

Gentochema BV's application: <https://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations/-/substance-rev/13531/term>

Eli Lilly S.A.'s application: <https://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations/-/substance-rev/13534/term>

GE Healthcare Bio-Sciences AB's application: <https://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations/-/substance-rev/13535/term>

Blue Cube Germany Assets GmbH & Co KG's application: <https://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations/-/substance-rev/1647/term>

Souriau sas's application:

1. <https://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations/-/substance-rev/13517/term>
2. <https://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations/-/substance-rev/13522/term>
3. <https://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations/-/substance-rev/13523/term>

Reference DNEL and dose-response relationships: <https://echa.europa.eu/applying-for-authorisation/evaluating-applications>

Chemical safety report

Guidance on information requirements and chemical safety assessment: <https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>

Guidance on preparing a downstream user chemical safety report: https://echa.europa.eu/documents/10162/13655/pg17_du_csr_final_en.pdf

Annotated formats: <https://echa.europa.eu/support/guidance-on-reach-and-clp-implementation/formats>

Practical examples of chemical safety reports and exposure scenarios for communication: <https://echa.europa.eu/support/practical-examples-of-chemical-safety-reports>

Use maps: <https://echa.europa.eu/csr-es-roadmap/use-maps/concept>

Questions and answers: <https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/scope/reach/authorisation>

Vlisco's application: <https://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations/-/substance-rev/1604/term>

Blue Cube Germany Assets GmbH & Co KG's application: <https://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations/-/substance-rev/1652/term>

Guidance for downstream users: https://echa.europa.eu/documents/10162/13634/du_en.pdf

BASF's application: <https://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations/-/substance-rev/12441/term>

Blue Cube Germany Assets GmbH & Co KG's application: <https://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations/-/substance-rev/1647/term>

Grupa Azoty's application: <https://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations/-/substance-rev/1644/term>

Abloy Oy's application: <https://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations/-/substance-rev/13548/term>

Evaluation of restriction reports and applications for authorisation for PBT and vPvB substances in SEAC:

https://echa.europa.eu/documents/10162/13580/evaluation_pbt_vpvb_substances_seac_en.pdf/af4a7207-f7ad-4ef3-ac68-685f70ab2db3

CSA Guidance Chapter R.19: Uncertainty analysis:

https://echa.europa.eu/documents/10162/13632/information_requirements_r19_en.pdf/d5bd6c3f-3383-49df-894e-dea410ba4335

Analysis of alternatives

Guidance on the preparation of an application for authorisation:

https://echa.europa.eu/documents/10162/13637/authorisation_application_en.pdf

Note on economic feasibility:

https://echa.europa.eu/documents/10162/13580/seac_authorisations_economic_feasibility_evaluation_en.pdf

Vlisco's analysis of alternatives:

https://echa.europa.eu/documents/10162/18584504/afa_tce-0014-01-aa_en.pdf

Sasol-Huntsman's analysis of alternatives:

<https://echa.europa.eu/documents/10162/7634e827-c1bf-454e-b878-71d6005a8925>

Grohe's analysis of alternatives: <https://echa.europa.eu/documents/10162/74e68036-01ed-482d-9ec2-b51df4b4f4a4>

Blue Cube Germany Assets GmbH & Co KG's analysis of alternatives:

<https://echa.europa.eu/documents/10162/db868ede-42ad-4914-a928-d8c6991a61f6>

Eli Lilly S.A.'s analysis of alternatives: <https://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations/-/substance-rev/13534/term>

Guidance on the preparation of socio-economic analysis:

https://echa.europa.eu/documents/10162/13637/sea_authorisation_en.pdf

How SEAC evaluates economic feasibility:

https://echa.europa.eu/documents/10162/13580/seac_authorisations_economic_feasibility_evaluation_en.pdf

Sasol Huntsman's analysis of alternatives:

<https://echa.europa.eu/documents/10162/7634e827-c1bf-454e-b878-71d6005a8925>

Boliden Kokkola's analysis of alternatives:

<https://echa.europa.eu/documents/10162/53ff04a3-fc9b-4e53-94e0-a4ec6040ec3e>

Analysis of alternatives for the use of HBCDD:

<https://echa.europa.eu/documents/10162/5164baf4-1f50-45a5-97e2-1c9c7597a692>

SEAC's opinion on HBCDD: <https://echa.europa.eu/documents/10162/0144eda8-0377-4cc6-aa94-c0de9a5a9456>

Guidance on the preparation of an application for authorisation:

https://echa.europa.eu/documents/10162/13637/authorisation_application_en.pdf/6571a0df-9480-4508-98e1-ff807a80e3a9

Grupa Azoty's analysis of alternatives: <https://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations/-/substance-rev/1644/term>

Vlisco's application: <https://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations/-/substance-rev/1604/term>

Socio-economic analysis

Guidance on the preparation of socio-economic analysis:
https://echa.europa.eu/documents/10162/13637/sea_authorisation_en.pdf

Eli Lilly's socio-economic analysis: <https://echa.europa.eu/documents/10162/1964ae5d-5c14-446f-ac42-eadb5ff9130>

Grohe's socio-economic analysis: <https://echa.europa.eu/documents/10162/008a678a-1034-4f32-9b57-3497cf175aa4>

Reference DNELs and dose-response relationships: <https://echa.europa.eu/applying-for-authorisation/evaluating-applications>

Willingness-to-pay to avoid certain health impacts: <https://echa.europa.eu/support/socio-economic-analysis-in-reach/willingness-to-pay-to-avoid-certain-health-impacts>

Evaluation of applications for PBT and vPvB substances:
https://echa.europa.eu/documents/10162/13580/evaluation_pbt_vpVB_substances_seac_en.pdf

Eli Lilly's socio-economic analysis: <https://echa.europa.eu/documents/10162/1964ae5d-5c14-446f-ac42-eadb5ff9130>

H&R Ölwerke Schindler GmbH's socio-economic analysis:
<https://echa.europa.eu/documents/10162/d82579b2-79db-474c-814f-58228f1015c0>

Grohe's application for authorisation:
https://echa.europa.eu/documents/10162/18584504/afa_chromiun_trioxide-0034-01-sea_en.pdf

Guidance on the preparation of socio-economic analysis:
https://echa.europa.eu/documents/10162/13637/sea_authorisation_en.pdf

Note on the social cost of unemployment:
https://echa.europa.eu/documents/10162/13555/seac_unemployment_evaluation_en.pdf/af3a487e-65e5-49bb-84a3-2c1bcbc35d25

Vlisco's socio-economic analysis:
https://echa.europa.eu/documents/10162/18584504/afa_tce-0014-01-sea_en.pdf

Grohe's socio-economic analysis:
https://echa.europa.eu/documents/10162/18584504/afa_chromiun_trioxide-0034-01-sea_en.pdf

LANXESS Elastomers' socio-economic analysis:
https://echa.europa.eu/documents/10162/18584504/afa_sd-0042-01-sea_en.pdf/64219392-e0cd-47a8-beaa-2c2745e3322f

Eli Lilly's socio-economic analysis: <https://echa.europa.eu/documents/10162/1964ae5d-5c14-446f-ac42-eadb5ff9130>

Socio-economic analysis of Kromatek and others:
<https://echa.europa.eu/documents/10162/20e1f807-803e-456f-818b-6e02d0025a3d>

Note on setting the review period:

https://echa.europa.eu/documents/10162/13580/seac_rac_review_period_authorisation_en.pdf/c9010a99-0baf-4975-ba41-48c85ae64861

BASF's socio-economic analysis: <https://echa.europa.eu/documents/10162/8974152b-a4d7-4fee-ae13-a5ab0dc8eaad>

Length of the review period:

https://echa.europa.eu/documents/10162/13580/seac_rac_review_period_authorisation_en.pdf/c9010a99-0baf-4975-ba41-48c85ae64861

Willingness-to-pay value for the health endpoint of concern:

https://echa.europa.eu/documents/10162/13637/seac_reference_wtp_values_en.pdf/403429a1-b45f-4122-ba34-77b71ee9f7c9

Section 4. Applications for uses with specific characteristics

Grupa Azoty's application: <https://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations/-/substance-rev/1644/term>

Applicant's checklist for applications for authorisation:

https://echa.europa.eu/documents/10162/13637/afa_applicants_checklist_en.pdf/70190e64-dead-49ce-1d10-a9016d48b74f

Section 6. Review report

Review report of an authorisation:

https://echa.europa.eu/documents/10162/13637/authorisation_review_report_en.pdf/cbc94819-bdb8-4d98-8687-7372df779bcf

Further information on downstream user notifications:

<https://echa.europa.eu/support/dossier-submission-tools/reach-it/downstream-user-authorised-use>

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