Format for

ANALYSIS OF ALTERNATIVES

and

**Socio-economic analysis**

Please note: Instructions in blue are applicable to the Review Report

**Version 3.01**

October 2021

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| --- | --- |
| **Version** | **Changes** |
| 3.01 | Updated links in footnotes |
| 3.0 | Adaptations made to the instructions and format in response to the conclusions of the General Court’s judgments in cases T-837/16 and T-108/17. Changes include reordering and renaming of some sections, clarifications of instructions, inclusion of new instructions, adding of a section specifying the substitution plan, and deletion of the table on distributional impacts. Minor changes in terminology were made to be consistent with SEAC’s opinion format (e.g., “costs of non-use” instead of “benefits of continued use”). Annex on confidentiality has been substantially updated. |
| 2.0 | Adaptations include:  Consultations, market and business trends, analysis of the substance function (addition of the description and technical requirement for the products), environmental impact, assessment of shortlisted alternatives. Reordering of some sections. |
| 1.2 | Adaptations for review report |
| 1.1 | Correction of formatting issue in the table of content, addition of list of abbreviations, list of tables and list of figures |
| 1.0 | First version (merger of former formats for Analysis of Alternatives and Socio-economic Analysis) |

Preamble

The purpose of this format is to provide applicants seeking an authorisation as well as authorisation holders submitting a review report with instructions on how to organise and present their analysis of alternatives (“AoA”), socio-economic analysis (“SEA”) and – where needed – a substitution plan (“SP”), in the same document (“AoA-SEA”).[[1]](#footnote-2)

The SEA part should describe, among other aspects, the societal cost implied by their non-use of the Annex XIV substance, the residual risks to human health and the environment of continued use, whether the societal cost of non-use outweighs these risks to human health and the environment, and the factors that the ECHA’s scientific committees should take into consideration in their recommendation of a review period. Detailed guidance on how to prepare a SEA is contained in the [Guidance on Socio-economic Analysis – Authorisation Process](https://echa.europa.eu/documents/10162/23036412/sea_authorisation_en.pdf/aadf96ec-fbfa-4bc7-9740-a3f6ceb68e6e) (“SEA Guidance”).

The AoA part should show whether there are any suitable alternative substances or technologies to the Annex XIV substance use applied for that are available for the applicant(s), or in general. In case that suitable alternatives are available **in general**, i.e., available in the EU market, they must include a substitution plan into their SEA detailing out future activities to support the transition to the alternative(s) irrespective of whether the authorisation is submitted under “adequate control route” (i.e., pursuant Article 60(2) of REACH) or the “SEA route” (pursuant Article 60(4) of REACH). Detailed guidance on how to prepare an AoA is contained in the [Guidance on the preparation of an application for authorisation](https://echa.europa.eu/documents/10162/13643/authorisation_application_en.pdf/8f8fdb30-707b-4b2f-946f-f4405c64cdc7) (“AfA Guidance”) in Chapter 3 and Appendix 3, 4 and 5.

Applicants may also want to consult the [How to apply for authorisation guide](https://echa.europa.eu/documents/10162/13637/apply_for_authorisation_en.pdf/bd1c2842-4c90-7a1a-3e48-f5eaf3954676) which provides practical information, advice and examples from previous applications. Detailed instructions on use descriptions can be found in the guide on [How to develop use descriptions in applications for authorisation](https://echa.europa.eu/documents/10162/13566/uses_description_in_auth_context_en.pdf/14b5f647-1778-47de-8178-2e2dad170424). Answers to common questions about the authorisation process can be found in [ECHA’s Q&As](https://echa.europa.eu/support/qas-support/browse?p_p_id=journalqadisplay_WAR_journalqaportlet&p_p_lifecycle=0&_journalqadisplay_WAR_journalqaportlet_topic=REACH&_journalqadisplay_WAR_journalqaportlet_scope=Authorisation&_journalqadisplay_WAR_journalqaportlet_backURL=https%3A%2F%2Fecha.europa.eu%2Fsupport%2Fqas-support%2Fbrowse%3Fp_p_id%3Djournalqadisplay_WAR_journalqaportlet%26p_p_lifecycle%3D0%26p_p_state%3Dnormal%26p_p_mode%3Dview). Finally, applicants find specific information on the evaluation of their applications for authorisation by the Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) on [ECHA’s website](https://echa.europa.eu/fi/applying-for-authorisation/evaluating-applications).

Instructions

It is highly recommended to prepare a public version of the AoA-SEA document for each use applied for. If an applicant makes confidentiality claims, then they must prepare two versions of the same AoA-SEA document for each use applied for: one “complete version” should contain confidential business information (marked as such) and another “public version” should blank out or use ranges for confidential business information.[[2]](#footnote-3)

ECHA will publish on its website the “public version” as a part of the information provided for the stakeholder consultation. Save your work in a separate (unprotected) Word (or pdf or rtf) file. To ensure that blanked out parts cannot be removed by technical means, it is best to provide the “public version” as a scanned document (pdf image).[[3]](#footnote-4)

The two versions of the format need to be identical apart from the parts containing confidential business information that are blanked out in the “public version”. In this “public version” each blanked out part should be clearly referenced with a number and this reference should be made visible. This is to allow an unambiguous link with your justifications for why the information should not be made publicly available. These justifications need to be provided in an annex to the “complete version” of the AoA-SEA document.[[4]](#footnote-5) Further instructions on blanking out and justifications for confidentiality are provided in the Legal Note and in the Annex to this format. The same approach should be taken for all documents provided as annexes (except for the annex with the justifications for confidentiality).

In the context of the preparation of the package on broad information on uses applied for, and with a view of having a meaningful stakeholder consultation on possible alternatives, ECHA reserves the right to reject unsubstantiated or non-motivated claims of confidentiality and to require meaningful information (e.g., ranges) in the “public version”. Information on environmental emissions and exposure to humans of SVHCs cannot be claimed confidential.

For each use applied for, prepare a zip file containing both the “complete” and the “public” version of the AoA-SEA document. Attach the zip file to the relevant use section in the IUCLID file, section 3.10 – Application for authorisation of uses.

Legal Note

This format is intended solely for the purpose of facilitating the preparation of an Analysis of Alternatives, a Socio-economic Analysis and – where needed – a substitution plan as part of an application for authorisation or a review report under Title VII of the REACH Regulation. Providing the information specified in this format does not preclude possible requests for more information under Article 64 of the REACH Regulation.

The “public version” will be part of the package on broad information on uses applied for to be published on ECHA’s website for the purpose of the stakeholder consultation on possible alternatives. It is the applicants’ responsibility to ensure that no confidential business information is present in this document. ECHA does not assume any liability for damages resulting from the publishing of confidential information that you may have included in the “public version”. For further information on the preparation of the broad information on uses package, please see ECHA’s Question and Answer [#590](https://echa.europa.eu/support/qas-support/qas?p_p_id=journalqasearch_WAR_journalqaportlet&p_p_lifecycle=0&p_p_state=normal&p_p_mode=view&_journalqasearch_WAR_journalqaportlet_mvcPath=%2Fhtml%2Fsearch%2Fview_qa.jsp&_journalqasearch_WAR_journalqaportlet_articleUuid=62270cd7-4547-4229-9ddc-0b3c56349012&_journalqasearch_WAR_journalqaportlet_backURL=https%3A%2F%2Fecha.europa.eu%2Fsupport%2Fqas-support%2Fqas%3Fp_p_id%3Djournalqasearch_WAR_journalqaportlet%26p_p_lifecycle%3D0%26p_p_state%3Dnormal%26p_p_mode%3Dview%26_journalqasearch_WAR_journalqaportlet_keywords%3D%26_journalqasearch_WAR_journalqaportlet_formDate%3D1630390368730%26_journalqasearch_WAR_journalqaportlet_basicSearch%3Dfalse%26_journalqasearch_WAR_journalqaportlet_topic%3D%26_journalqasearch_WAR_journalqaportlet_from%3D%26_journalqasearch_WAR_journalqaportlet_doSearch%3Dtrue%26_journalqasearch_WAR_journalqaportlet_to%3D%26_journalqasearch_WAR_journalqaportlet_uniqueIds%3D0590).[[5]](#footnote-6)

Please note that the “complete version” of the AoA-SEA is subject to Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents and Regulation (EC) No 1367/2006 regarding the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making, and Access to Justice in Environmental Matters to Community institutions and bodies.

The justifications and motivations for not disclosing specific information in the “public version” will play a crucial role in ECHA’s assessment of what information should be disclosed following an access to documents request under the aforementioned Regulations. This holds without prejudice to ECHA’s final decision on the disclosure of the requested document in accordance with the aforementioned regulations.

Instructions for how to provide a justification for confidentiality

Your justification needs to contain the following three elements:

Demonstration of Commercial Interest:

[Description of the nature of the applicant’s commercial interest, which would be harmed by the disclosure of the information and demonstration that this commercial interest is worthy of protection. Description of any specific measures the applicant has taken to keep the information claimed confidential secret to date.]

*Example 1: “We have sourced supplies of a new generation of low flammability solvents and built relationships with our supplier over many years. Mixtures of these solvents and the Annex XIV substance can be used at 150°C in a specific process developed in-house to manufacture end-products with a much higher degree of quality compared to our competitors, which is the unique selling point for our end-products. Our new generation mixtures in combination with our new technique (not yet patented) provide end-products with a level of quality much higher than that possible with commonly known mixtures and production techniques. This provides us with a distinct competitive advantage on the relevant markets.”*

[Existence of contractual clauses requiring confidential treatment can serve as evidence of existence of a commercial interest that needs protecting as well as to illustrate commercial harm that disclosure of the information could result in.]

*Example 2: “We bought the process that includes the manufacturing step applied for under a legal non-disclosure claim from a non-European company (named ABC Ltd.) under a license agreement. The process involves a new surface coating technique which is unknown to our competitors using chemical vapor deposition (CVD) technology, whereby the coating underlayer and specific properties of the CVD process are covered by the non-disclosure agreement to protect the commercial interest of the licensor. As set out in the license agreement, there is a strong commercial interest in maintaining information on the process confidential (please see the relevant clause(s) of the agreement annexed). Disclosure of the information on the technique would negatively impact the value of the acquired know how and would also negatively impact the interest of the licensor, who may no longer be able to licence the know how if it became publicly available. Furthermore, disclosure would make our company subject to heavy contractual penalties as set out in the annexed contractual provisions.”*

Demonstration of Potential Harm:

[Explanation of why release of the information claimed confidential would be likely to cause potential harm to the commercial interest and the specific nature of those harmful effects. A causal link between disclosure and such harmful effects should be clearly made.]

*Example 1: “The dissemination of the exact temperature of the process will reveal to our competitors the existence of new generation solvents and/or the existence of our new technique that can be used at higher temperatures than those commonly known. This would allow our competitors to attempt to buy the same solvents and/or begin to attempt to copy our novel production technique, thereby harming our market position, our commercial interest and would deprive the financial investments that we have made over the past 5 years of its value.”*

Limitation to Validity of Claim:

[The period for which the claim will be valid: until a certain date, until the occurrence of a particular event (which should be clearly specified), or indefinitely and the motivation for why this is the case.]

*Example 1: “The exact temperature should remain confidential until 1 January 2022, which is the expected date for the use of Annex XIV substance under this high temperature technique to be patented and the market to be mature enough.”*

Format for

ANALYSIS OF ALTERNATIVES

and

**Socio-economic analysis**

**Legal name of applicant(s):** [Legal names of applicant(s)/authorisation holder(s)]

**Submitted by:**  [Legal name of submitting applicant/authorisation holder]

**Date:** [Date when the document was completed, normally the date of submission]

**Substance:**  [Include Annex XIV substance name, EC and CAS number]

**Use title:**  [Include the use title. Note that this format is for one use. If an application has several uses, a separate document needs to be prepared for each use.]

**Use number:**  [Include the number for this use as stated in section 3.10 of the IUCLID application for authorisation dossier under the "Use concerned by the request" field.]

**CONTENTS**

[Please generate table of contents.]

**TABLES**

[Please insert here the list of tables.]

**FIGURES**

[Please insert here the list of figures.]

**LIST OF ABBREVIATIONS**

[Please insert here the list of abbreviations.]

# DECLARATION

We, the Applicant [Authorisation Holder], are aware of the fact that further evidence might be requested by ECHA to support the information provided in this document.

Also, we request that the information blanked out in the “public version” of the Analysis of Alternatives and Socio-economic Analysis is not disclosed. We hereby declare that, to the best of our knowledge as of today ([DATE]), the information is not publicly available, and, in accordance with the due measures of protection that we have implemented, a member of the public should not be able to obtain access to this information without our consent or that of the third party whose commercial interests are at stake.

Signature: Date, Place:

# SUMMARY

[Summarise (max. 2 pages) the main conclusions of the AoA and SEA:

* The use applied for, the function of the substance, end-uses, markets, etc.;
* The steps taken to identify possible alternatives to the substance function (incl. R&D efforts, providers of alternatives, costs of adopting, etc.);
* Identification of potential alternatives and the availability and suitability of these alternatives for the substance function in the use applied for;
* If alternatives do not exist or are considered not to be suitable for the use applied for, a summary justifying this conclusion;
* If alternatives were identified as currently not suitable for the use applied for, the key actions needed to make immature alternatives suitable and available, the timescale for these actions, and the conditions under which substitution could become feasible both from a technical and economic perspective;
* If alternatives were identified that are suitable and available in general, but not from the perspective of the applicant(s) or their downstream users (if relevant), the conclusions of the substitution plan[[6]](#footnote-7) of activities proposed to support the possible transition to an identified alternative in future;
* If an alternative has been identified which the applicant(s) propose(s) to adopt but which requires more time than is available before the Sunset Date [end of the Review Period], a summary of the substitution plan of activities and a timeline to support the substitution to this alternative is required;
* A brief description of the continued use scenario – what the applicant(s) expect(s) to do if an authorisation is granted;
* A brief description of the most likely non-use scenario – what the applicant(s) expect(s) to do if an authorisation is not granted;
* An overview of the societal cost of discontinuing the use of the Annex XIV Substance (i.e., the socio-economic benefits of continued use);
* Residual risks to human health and/or the environment of continued use and, where relevant, of non-use of the Annex XIV substance;
* A conclusion as to whether the societal costs of discontinuing the use of the Annex XIV Substance outweigh the risks to human health and the environment.]

# AIMS AND SCOPE

(See Chapter 3.9 of the AfA Guidance and Chapter 2 of the SEA Guidance)

[Introduce the applicant(s)/downstream users. Define the aim of the AoA and SEA. Set the scope of the SEA in terms of temporal and geographic boundaries, relevant market(s) and supply chains, and the types of impacts to be covered. When you determine the temporal scope of the SEA, consider the full period over which you expect to be impacted. In the identification of relevant supply chains, consider physical flows related to inputs and outputs from the use applied for and economic flows through affected markets because of continued use of the Annex XIV substance or the transition to a possible alternative.]

# ANALYSIS OF ALTERNATIVES

## SVHC use applied for

### Description of the function(s) of the Annex XIV substance and performance requirements of associated products

(See Chapters 3.2, 3.3, 3.5.1 and Appendix 4 of the AfA Guidance)

[Provide a detailed description of the exact function that the Annex XIV substance has (and where and how, i.e., under what conditions, that function must be performed) in a particular use. This will allow you to look for other ways of performing that function.

Present detailed information on the precise functions performed by the Annex XIV substance. Include a description and outcome of the process where the use is applied and under what process conditions the function must be performed. Examples of functional requirements may include critical substance properties related to the desired equivalent function, quality criteria, process, and performance constraints.[[7]](#footnote-8)

Discuss tolerances of these requirements (i.e., acceptance ranges) for the product(s) or process concerned and back them up by technical specifications of your customers wherever possible. If several industrial/market sectors are concerned and if they have different technical requirements, the discussion should reflect this variety. If the variety is substantial, separate uses and apply for them individually.[[8]](#footnote-9)

For some upstream uses (e.g., mixing, formulation, re-packaging) the Annex XIV substance itself is unlikely to have a function at this stage because the substance function may be only relevant at the “next-stage” use performed by the downstream users. It might hence not be meaningful to define an alternative for such uses.]

### Market analysis of products manufactured with the Annex XIV substance

[Present the products that have been produced with and may contain the Annex XIV substance (clarify whether that is the case). Describe the market sectors where these products are commercialised, in the EU and elsewhere, detailing who the main producers (companies or sectors) and consumers of these products are.[[9]](#footnote-10)

Describe the market environment as of today, i.e., at the time of submitting the application (the review report). If the number of products or processes associated with the use of the Annex XIV is very high (e.g., many hundreds of different products), please define meaningful markets, underpinned by reasonably foreseeable combinations of processes, products, technical requirements, and market sectors. Technical requirements may relate, for instance, to:

* Regulatory or legal requirements for technical acceptability (e.g., maximal regulatory limits or regulatory approval by national authorities);
* Internationally recognised standards for technical performance (e.g., EN or ISO standards);
* Certification requirements;
* Customer specifications.

Please provide the necessary documentation supporting information on customer specifications and why they are relevant. This may include customer surveys, summaries of discussions with customers, market analysis reports or sectoral technical standards. Whenever possible, provide the web links for relevant documentations as well as for the tests used in the relevant sectors for verifying products’ compliance with those standards.

Consider recent or anticipated changes (e.g., if the substance has been entered in Annex XIV, uses have been authorised, new restrictions that were introduced for the substance) in regulatory, technical, and economic trends impacting the relevant supply chain(s) for the use of the Annex XIV substance.

Describe your own position in the relevant market (segment) vis-à-vis competitors, suppliers and downstream users. Provide as detailed information as you can to describe the circumstances under which you operate (including the presence or absence of economic and regulatory market barriers). Describe the extent to which alternative substances or technologies have been used in relevant market (segment).]

### Annual volume of the SVHC used

[Indicate the average annual tonnage used by the applicants or their downstream users for the use applied for. If changes in use volumes are anticipated, provide a volume trend over time. If you can justify why the tonnage should be confidential, indicate in addition to the confidential tonnage figure a reasonable tonnage band. The tonnages indicated in this section should be consistent with the ones assumed for the Exposure Scenarios provided in the Chemical Safety Report of your application. In the “public version” of the AoA-SEA document, the confidential tonnage figure can be blanked out, just leaving the tonnage band visible. If you indicate bands, you should report at a minimum the ones listed below:[[10]](#footnote-11)

* <1 kg per year
* 1-10 kg per year
* 10-100 kg per year
* 100 kg-1 tonne per year
* 1-10 tonnes per year
* 10-100 tonnes per year
* 100-1 000 tonnes per year
* >1 000 tonnes per year

However, to provide as meaningful information as possible, please consider using more precise bands. For example, if the actual (confidential) annual tonnage for the use applied for is 24 tonnes per year, you may indicate in the “public version” a tonnage band of say 20-30 tonnes or 15-35 tonnes per year.]

## Efforts made to identify alternatives

[It is very important to provide as much detail as possible about the efforts you have made to identify and prioritise/select alternatives and assess them with respect to their suitability as substitutes for the Annex XIV use applied for.]

### Research and development

[Include information on past, current and/or planned R&D activities undertaken to identify possible alternatives. In review reports, the progress towards finding an alternative for the use applied for within the period since the authorisation was granted shall be described.]

### Consultations with customers and suppliers of alternatives

[Document the consultations undertaken during the preparation of the application for authorisation. When you consulted third parties, include company names and contact details (including e-mail addresses) but do not provide names of persons. Provide as much details as possible about companies that provide alternative substances, technologies, or services to meet the function of the substance use applied for.

As relevant, provide details of how you have consulted (parts of) the supply chain(s), in particular your customers and/or downstream users and any other organisations contacted. Provide information about any surveys you have done with your customers and other actors regarding the (non-)availability of similar products made without the Annex XIV substance that can act as a substitute.

Describe how you assessed your customers’ acceptance of alternatives that you have been investigating (e.g., by running customers’ surveys, performing market analysis, or indicating the relevant sectoral technical standards, pre-agreed performance criteria, etc.). Assess specifically whether your customers would be willing to accept a change (e.g., a limited loss) in product performance that might be associated with the use of a safer alternative compared to the Annex XIV substance. If no loss in performance is acceptable, justify why.

Please also provide details of other organisations such as trade associations, consumer interest groups etc. that you have contacted.

Report any information about companies that possibly have already substituted the Annex XIV substance in the use applied for. Provide a summary in this section and use Appendix 1 for details. Technical and economic details gathered through these consultations should feed into the relevant sections of the AoA and SEA.]

### Data searches

[Building on Section 3.2.1 and 3.2.2, describe the extent and the results of data searches on possible alternatives. Include detailed and meaningful information on past and/or planned research and development activities aiming to identify possible alternatives.]

### Identification of alternatives

[List all alternative substances and/or technologies for the use applied for that you have identified. Present a list of key criteria that served as the basis for the assessment of these alternatives. Justify why these criteria are the most relevant for the selection of potential alternatives and, where possible, use quantitative parameters in addition to qualitative criteria. Make sure to include alternatives already used by competitors within the relevant supply chains.

Make sure that you do not only consider possible alternative chemicals. An alternative to the Annex XIV substance can also be a different technology or even a change in the process that eliminates the need for the Annex XIV substance. For example, if the substance is used for improving the durability and reliability of your equipment, a possible change in maintenance, repair and overhaul (MRO)’s activities may render the use of the substance redundant. Similarly, in some cases the production process might be adapted in a way that eliminates the need for the Annex XIV substance.]

### Shortlist of alternatives

[For ease of reference, document the shortlisted alternatives in Table 1. Based on the essential criteria identified in Section 3.2.4, develop a shortlist of possible alternatives for a more in-depth analysis. Describe the basis for the selection. If there is an alternative that is available and suitable in general (i.e., there are other companies in the EU that already use this alternative for a similar use contributing to products sold in the same market segment as those produced using the Annex XIV substance), these should be included in the shortlist.[[11]](#footnote-12) Also, briefly explain why alternatives that were not included in the shortlist do not merit further examination.]

Table 1: Shortlisted alternatives.

|  |  |  |  |
| --- | --- | --- | --- |
| **Number** | **Alternative name** | **CAS or EC Number (where applicable)** | **Description of alternative** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

## Assessment of shortlisted alternatives

### Alternative 1: [name]

#### General description of Alternative 1

[For alternative substances, include their substance identity (i.e., chemical name, IUPAC name, CAS/EINECS number, or other identifiers listed in Section 2, Annex VI of REACH.)

For technical/process alternatives, describe the technology/process considered to achieve the equivalent function of the Annex XIV substance, or to possibly remove the need for the Annex XIV substance function altogether by other changes to the process or end product. Note that in some uses limited performance losses may be acceptable.

In case the alternative requires both the use of an alternative substance and a new technology/process, please describe how this composite alternative replaces the function of the Annex XIV substance.]

#### Availability of Alternative 1

(Guidance: Chapter 3.10 of the Guidance on the preparation of an application for authorisation)

[Discuss in a clear and transparent manner whether alternative 1 is available (in the required quantity) without undue delay in the EU taking into account the sunset date of the Annex XIV substance.]

#### Safety considerations related to using Alternative 1

(AfA Guidance: Chapters 3.7 and 3.9)

[Present an assessment of whether the use of alternative 1 can be considered safer when compared to the use of the Annex XIV substance in the use applied for. Compare the hazard profile of alternative 1 with the Annex XIV substance.[[12]](#footnote-13) Report all relevant physico-chemical properties of alternative 1 and indicate whether the alternative is classified according to the (CLP) Regulation (EC) No 1272/2008.

If this is the case, report hazard classes and the relevant category codes. Also support your analysis with any relevant scientific study on its hazard profile. Where useful, present the findings in a table summarising the outcomes of the comparative hazard assessment. Report any difficulties or uncertainty in the assessment.

In case the alternative requires the use of several chemicals, please describe the hazard profile of each of them.

Finally indicate if information on exposure from alternative 1 is available or possible to estimate. If that is the case, indicate whether the use of alternative 1 would imply a constant or different level of exposure when compared to the exposure to the Annex XIV substance in the use applied for and conclude, where permissible, whether the shift to this alternative would lead to an overall risk reduction.]

#### Technical feasibility of Alternative 1

(AfA Guidance: Chapters 3.6 and 3.9)

[Present a transparent analysis of the technical feasibility of this alternative. Show how the criteria for equivalent function were applied to the possible alternative to determine its technical feasibility and how the information gathered in the consultation and from your own research activities was integrated in the assessment.

Whenever possible, include relevant use quantitative parameters (e.g., for density, viscosity, or even measures of effectiveness such as viral clearance) in addition to qualitative criteria, when comparing the potential alternatives to the Annex XIV substance.

Document the methodology, data sources, assumptions made and their effects on the conclusions on the technical feasibility of the possible alternative.

Discuss the process changes required for possible transfer to the alternative substance or technique (e.g., the requirements for equipment, risk management measures, energy, personnel changes and training needs, raw materials, waste, etc.) and how these affect the technical feasibility of the alternative. Where appropriate, you may also discuss climate or circularity considerations.

If other firms in your market already use alternative substances and/or technologies, make sure to provide justifications as to why your situation is different from these companies from a technical or economic perspective, and whether these alternative substances and/or technologies are technically feasible for you[[13]](#footnote-14).

If you conclude that the alternative is not technically feasible from your perspective, discuss possible actions (including R&D, production trials, capital investment, etc.) and timeframe within which technical feasibility might be achievable. Include any obstacles or difficulties identified or expected in the development/identification of a technically feasible alternative.

Make sure that you also describe the economic implications that would be triggered by a possible change in product performance and explain whether you could put in place any activity or implement any change in the process that could mitigate/avoid those economic impacts.

If the alternative could not be implemented before the Sunset Date (end of the Review Period), include activities which might be used to bridge the period until the alternative comes on stream (e.g., outsourcing, stockpiling, temporary closure).]

#### Economic feasibility of Alternative 1

(AfA Guidance: Chapters 3.8 and 3.9 and SEA Guidance Chapter 3.5 and Appendix 1)

[Describe direct and indirect changes in production costs and revenues associated with the use of alternative 1 compared to the use of the Annex XIV substance as applied for.

Detail the parameters used in the assessment of economic feasibility of the alternative (e.g., the raw material price of an alternative substance, or the investment cost for setting up an alternative process or technology, additional investments costs, changes in productivity, personnel costs, etc.).

Include intangible costs or cost savings that may result from switching to the alternative (e.g., increments or reductions in costs accruing from risk management measures, waste management, energy consumption, etc.). Where possible, present a comparative cost analysis of using the Annex XIV substance versus the use of alternative 1.

If alternative 1 cannot be implemented by the Sunset Date (end of the Review Period), but its implementation is foreseen in the future, include the costs of any activities which might be needed to bridge the period until it can replace the Annex XIV substance.

Detail the methodology, the sources of the data, the assumptions and sensitivities in the analysis and their impact on the conclusions of the assessment. Clearly set out the boundaries of the assessment (i.e., in terms of your supply chain) and show the reasoning for the setting of these boundaries.

There may be other firms in your market, offering similar products able to satisfy the same needs as your products and already use alternative substances and/or technologies. If so, be sure to provide justifications as to why your situation is different from these other companies from an economic perspective and why these alternative substances and/or technologies are not economically feasible for you.8

If you conclude that alternative 1 is not economically feasible by the sunset date, discuss developments that could make them feasible in the future. List any obstacles or difficulties identified or expected and specify under which conditions substitution could become feasible from your perspective.

Where relevant, make sure to link the technical assessment of the alternative with the conclusions on its economic feasibility. In particular, explain what economic implications would be triggered by a loss in product performance and whether you could put in place any activity or implement any change in the process that could mitigate/avoid those economic impacts.]

#### Suitability of Alternative 1 for the applicant and in general

(AfA Guidance: Chapters 3.10 and 3.11)

[Conclude on the availability and suitability of Alternative 1 for you and in general. Note that if you identify alternative 1 as an alternative suitable in general in the EU as defined by the Commission note on suitable alternatives6, then the adoption of this (or another) suitable alternative needs to be discussed in Section 4.1.]

### [Provide similar information for all shortlisted alternatives]

## Conclusion on shortlisted alternatives

[Identify the most promising alternative(s) from the shortlisted alternatives. Summarise briefly why this/these alternative(s) cannot be implemented before the sunset date.]

# SOCIO-ECONOMIC ANALYSIS

## Continued use scenario

### Summary of substitution activities

[Provide a summary of max. 300 words of your substitution activities.]

### Conclusion on suitability of available alternatives in general

[Based on the criteria provided by the European Commission’s note on “suitable alternatives available in general & requirement for a substitution plan”6, conclude on the suitability of shortlisted alternatives discussed in section 3. This will be decisive, as you either have (in case you find there are suitable alternatives available in general) or do not have (in case you find there are no suitable alternatives available in general) to provide a substitution plan as indicated in section 4.1.3. In the latter case you should present an R&D plan as indicated in section 4.1.4]

### Substitution plan

(AfA guidance: Chapter 4)

[If the AoA concluded that because of technical and/or economic limitations available alternatives are not suitable for the use applied for before the Sunset Date (or the end of the Review Period), but that these alternatives are **generally available** in the EU (i.e., used by competitors), you must present a substitution plan. This plan needs to include a list of actions that you will undertake to develop and implement the alternative suitable for other actors, or any other alternative that you have identified and that is more suitable for the use applied for. In the latter case, you have to justify why the alternative suitable for other actors, is not suitable for your specific use.

In the list of actions, identify important dependencies, milestones etc. and their implications for the substitution plan, and describe all the conditions that need to be met for a successful substitution.

Please remember that a substitution plan is “a commitment to take the actions needed to substitute the Annex XIV substance with a suitable alternative substance or technology within a specified timetable”6, that means you have to provide the conditions for substitution to be potentially successful. Where applicable, explain why you do not foresee to have fully substituted the use applied for by the end of the review period being sought.

Bear in mind the following points when preparing your substitution plan:

* You should always discuss those alternatives that are deemed to be suitable and available in general. You may also discuss other alternatives, for instance, ones that are not yet readily available but seem promising. In any case, the actions taken to identify each of the alternatives discussed should be clearly listed.
* Uses should be as specific as possible.8 For uses that are broad by their very nature (e.g., in certain upstream applications) and where substitution may happen in stages, ensure to undertake substitution planning for each (group of) utilisation(s) for which there are suitable alternatives available in general. For those (groups of) utilisations for which suitable alternatives are not available in general, the applicant does not have to submit a substitution plan. However, the conclusion about availability and suitability of alternatives has to be duly justified. For example, Cr(VI) may be used as an etching agent and for the decorative coating of plastic parts. It is then necessary to differentiate the utilisation based on the technical function of the SVHC in different process steps (i.e., one would expect at least two substitution plans – one for etching and one for coating). In certain cases, it may also be useful to further differentiate by sector. For example, separate substitution plans may be needed for plating on plastics for automotive parts and for parts of sanitary appliances.

The substitution plan should be meaningful (i.e., it should explain how the applicant, or its downstream users intend to switch from the current use of the Annex XIV substance to an alternative substance or technology), relevant to the scope of your application and linked to, that is following from, the conclusions of the AoA. A good way to picture this is to consider the AoA to cover all substitution-related activities in the past up until the date of submission of your application, whereas the substitution plan should cover all substitution-related activities from the date of submission until at least the end of the review period being sought.

Use the following headers to structure the substitution plan.]

#### Factors affecting substitution

(Guidance: Chapter 4.3.1 and Appendix 6 of the Guidance on the preparation of an application for authorisation)

[Describe the factors that influence the actions needed and/or the timing of substitution of the Annex XIV substance with the selected/identified alternative(s). This could include the outcome of R&D and testing, availability of the alternative, market considerations impacting the economic feasibility of the alternative, process changes and other considerations related to technical feasibility, etc. Draw on the analysis presented in Section 2 and Section 5 of the AoA. Include references to the AoA and/or the Chemical Safety Report as appropriate.]

#### List of actions and timetable with milestones

(Guidance: Chapters 4.3.2, 4.3.3, 4.3.4, and 4.3.5 and Appendix 6 of the Guidance on the preparation of an application for authorisation)

[Describe in detail how the substitution plan will be implemented. Present the rationale behind each action towards substitution and its timetable. Indicate phasing (if relevant) and key milestones identifying the completion of key actions to allow progress to be measured. Present the start and end dates for the identified actions and a justification for the time allotted for the actions to be implemented. Consider how the length of the review period might impact the completion of the substitution, and how it corresponds to the substitution plan and the potential need for re-authorisation after the review period, should the authorisation be granted. Discuss dependencies, uncertainties and factors that may hinder or accelerate the substitution, as well as how they have been addressed in the plan and timetable for substitution.

The required content of the substitution plan and the concreteness of the commitment to substitute will depend on several factors:

* Where a suitable alternative is available in general will become feasible for the applicant or his downstream users within a certain timeline, the substitution plan should contain a corresponding clear and credible timeline to substitute the use of the substance. The substitution plan may be updated as part of a review report, and justification provided regarding the reason why it was updated.
* Where substitution depends on the results of ongoing research, development or testing, the substitution plan should contain a commitment to undertake the necessary actions to undertake research on, develop or test alternatives to make them technically and economically feasible for the applicant, with a clear timetable, following the indications provided in this document and the ECHA Guidance on the preparation of an application for authorisation7. For actions later in that timetable, it is accepted that those may depend on the outcome of earlier actions.
* Where a suitable alternative available in general cannot become technically or economically feasible for the applicant in the short or medium term, the applicant should still submit a substitution plan, explaining why substitution can only take place over a longer time horizon (e.g., when building a new plant or after the end of lifetime of the product). Obviously, such a long-term substitution plan also needs to have a credible timeline. However, it is understood that steps towards substitution are less certain and the time it takes for each step to be finalised is necessarily indicative.
* If an authorisation holder does not manage to achieve substitution within the scheduled timetable, it should provide the justified reasons for such delays in the updated substitution plan as part of the review report; e.g., if a R&D programme did not lead the alternative to achieve the required key functionalities or if the construction of the necessary machinery or equipment has not been finalised for specific reasons, etc. ]

#### Monitoring of the implementation of the substitution plan

(Guidance: Chapter 4 and Appendix 6 of the Guidance on the preparation of an application for authorisation)

[Describe the system in place (or to be put in place) for monitoring and documenting the progress of the implementation of the identified actions included in this substitution plan.]

#### Conclusions

[Summarise your commitments towards substitution (when possible) of the Annex XIV substance with the selected/identified alternative(s), the timetable for the transition to an alternative, milestones and critical factors influencing the substitution.]

#### References

[Where applicable, provide list of references.]

### R&D plan

If the AoA concluded that there are **no** suitable alternatives available in general, you should still consider presenting a plan including a list of research and other actions that you will undertake to identify, develop, and implement a suitable alternative in the future. Specify the timeframe within which these actions will be undertaken. Identify important dependencies, milestones, etc. analogues to a substitution plan. This kind of R&D plan is likely to be less concrete than a substitution plan since there are no suitable alternatives available in general in the EU market.

To present the R&D plan use the same headers as for the substitution plan as a starting point. Case-specific deviations and additions from this structure are possible.]

## Risks associated with continued use

(SEA Guidance: Chapters 3.1, 3.2 and 3.3 and appendices A, B, C, F and G)

[Present human health and/or environmental risks associated with the continued use of the Annex XIV substance as identified in the CSR (and where relevant in the AoA) of your application. Consider the implication of non-use on the risks identified. Present the assessment of human health and environmental impacts in qualitative, semi-quantitative or quantitative terms. When relevant, estimate the number of statistical disease cases or environmental emissions or other negative impacts associated with the use applied for. Quantify the societal economic burden of health and/or environmental impacts of the use scenario (by considering tangible and intangible costs) where this is possible and sensible to do.]

### Impacts on humans

[In case the relevant endpoint concerns human health, indicate the number of people directly and indirectly exposed to the Annex XIV substance. Thereby distinguish between industrial workers, professionals, as well as the general population and consider the exposure time, the tasks frequency, the accumulated risks, etc.]

### Impacts on environmental compartments

[Where relevant, describe the (likely) impacts to the environment such as ecological impairments (biodiversity and functioning), negative impacts on the quality of water, air and soil), greenhouse gas emissions, water and energy consumption, etc.]

### Compilation of human health and environmental impacts

[Compile all impacts on human health and the environment that are expected from continued use of the Annex XIV substance (compared to the situation of ceasing the substance use) and, where possible, monetise the quantified impacts using unit values[[14]](#footnote-15). Use Table 2 to report estimated impacts on human health and Table 3 to report estimated impacts on the environment.]

Table 2: Summary of additional statistical <endpoint> cases for human health.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Excess lifetime <endpoint> risk1** | **Number of exposed people** | **Estimated statistical <endpoint> cases**  **([per year4 ]**  **[over x years])5** | **Value per statistical <endpoint> case** | **Monetised excess risk ([per year4]**  **[over x years])5** |
| Workers | | | | | |
| Directly exposed workers2 |  |  |  |  |  |
| Indirectly exposed workers3 |  |  |  |  |  |
| *Sub-total* |  |  |  |  |  |
| General population | | | | | |
| Local |  |  |  |  |  |
| Regional |  |  |  |  |  |
| *Sub-total* |  |  |  |  |  |
| **Total** |  |  |  |  |  |
| Latency (years) |  | | | | |

Notes:

1. Excess risk is estimated over a typical lifetime working exposure (40 years) and via the environment over a typical lifetime exposure (70 years). As excess risks are likely to be different depending on the task, report the overall minimum and maximum excess risk among of all the tasks carried out by the workers.
2. Directly exposed workers perform tasks described in the worker contributing scenarios, typically characterised by an 8-hour Time Weighted Average (TWA) exposure of a representative worker.
3. Indirectly exposed workers (bystanders) do not use the substance.
4. Per average year during the time horizon used in the analysis.
5. Derived from the lifetime risk of 40 or 70 years.

[For PBT/vPvB substances, endocrine disruptors, and other substances of similar concern for which endpoints and impacts could not be estimated, describe their releases or emissions predicted under the continued use scenario in Table 3.]

Table 3: Summary of remaining releases to the environment.

|  |  |
| --- | --- |
|  | **[Per year] [Over x years]** |
| Total releases/emissions (in kg per period) |  |

## Non-use scenario

(AfA Guidance: Chapter 3.5)

[The non-use scenario is what the applicant(s) will do, and what will happen more generally, if an authorisation is refused and the applicant(s) must stop (or is not allowed to commence) using the Annex XIV substance.]

### Summary of the consequences of non-use

[Summarise what would happen if an authorisation is not granted, i.e., the non-use scenario(s). Address how each link in the relevant supply chains would react to the non-availability of the Annex XIV substance. Document your assumptions by citing relevant sources of information (supply chain consultations, data searches, information on R&D, etc.), including the assessment presented in the CSR, AoA and the substitution plan.]

### Identification of plausible non-use scenarios

[Formulate plausible non-use scenarios by describing the likely response of actors in the relevant supply chains under each different set of assumptions, the differences of each of the identified scenarios, and the likelihood of each scenario occurring.]

### Conclusion on the most likely non-use scenario

[Conclude on the most likely non-use scenario and justify this conclusion.]

## Societal costs associated with non-use

(SEA Guidance: Chapters 3.1, 3.2 and 3.4 and appendices A, B, C, G and I)

[Describe the economic impacts of not granting an authorisation for continued use of the Annex XIV substance by comparing the continued use scenario and the most likely non-use scenario.

Make sure that the continued use scenario incorporates the substitution activities, as described in section 4.1. It is expected that all the economic implications of the substitution activities have been factored in the continued use scenario. As a result, the profit expected in the continued use scenario – which may be lost in the non-use scenario and reported in section 4.4.1 – may be different from the one of the baseline scenario.

Describe the societal costs of the identified non-use scenario which would accrue if authorisation was refused. Detailed analysis of these impacts should be provided in the subsequent sections.

Remember that any cost expected to accrue in both the continued use scenario and non-use scenario should be excluded.

Include all relevant assumptions and present a sensitivity analysis if appropriate.

Discuss the significance of the impacts as well as the confidence in the description and possible quantification of economic impacts.]

### Economic impacts on applicants

[Describe what economic impacts you are expecting in the most likely non-use scenario. Indicate clearly how these are linked to the most likely non-use scenario and how they were quantified. Describe any relevant assumption used in the assessment and report any qualitative impact on you, when relevant.

If you follow SEAC’s approach for assessing changes in producer surplus[[15]](#footnote-16) to gauge the welfare implications of the non-use scenario, make sure to state so and explain how you applied the approach in your specific case. In any case ensure in your assessment that you exclude any transfer payments and that you do not double count cost elements.]

### Economic impacts on the supply chain

[Describe whether the non-use scenario is expected to impact actors along the supply chain, such as your customers and possibly their customers. Report such impacts in a quantitative, and if this is not possible, in a qualitative manner; especially if these impacts are considered important. Please indicate if these impacts are structural or limited in time.

For example, you may be the only supplier of certain products (e.g., certain medicinal products) or you may be the only certified supplier of certain products for your customers. In such situations, the customers may be negatively affected if an authorisation for the use if the Annex XIV substance was refused. This is because they would not have immediate access to suitable alternative products.]

### Economic impacts on competitors

[Report possible impacts on your competitors, while being careful to avoid any double counting of costs. For example, in connection with section 3.3, indicate whether your competitors have already switched to an alternative and how the non-use scenario may impact their business. If you have followed “*SEAC’s approach to assessing changes in producer surplus”* (see section 4.4.1)[[16]](#footnote-17), then all relevant economic impacts on competing firms from the non-use scenario have already been accounted for.]

### Wider socio-economic impacts

(SEA Guidance: Chapters 3.1, 3.2, 3.5, 3.6 and 4.2 and appendices A, B, C, D and G)

[Report possible impacts on workers, consumers, the general public or special population groups. Impacts may include, e.g., unemployment, working conditions, job satisfaction, training and skill development as well as changes in social security.

If relevant, present an assessment of the socio-economic impacts of a refused authorisation, e.g., the societal costs of unemployment[[17]](#footnote-18) or negative spillover effects on other sectors of a regional economy. Other relevant impacts may comprise effects on international trade, competition and economic development.

Where relevant, discuss distributional impacts that would occur under the non-use scenario and could affect different actors in the supply chain, or have a different, geographic span, or affect different social groups or eco-systems differently.

Discuss the significance of these impacts as well as the certainty and confidence in the description and possible quantification of the impacts. Explain all relevant assumptions.]

### Compilation of socio-economic impacts

[Compile all socio-economic impacts that are expected from ceasing the use of the Annex XIV substance (compared to the situation of continuing the substance use) and, where possible, monetise the quantified impacts. Use Table 4 to report your estimates. There may be an overlap between the cost categories. Please avoid double counting. Mark the cost categories that are not relevant for your case with “Not applicable”. When additional costs categories are used, please specify what these comprise.]

Table 4: Societal costs associated with non-use.

|  |  |
| --- | --- |
| **Description of major impacts** | **Monetised/quantitatively assessed/qualitatively assessed impacts** |
| 1. **Monetised impacts** | **€ [per year1] [Over x years]** |
| Producer surplus loss due to ceasing the use applied for  *OR*  Investment and/or additional production costs related to the adoption of an alternative |  |
| Relocation or closure costs |  |
| Loss of residual value of capital[[18]](#footnote-19) |  |
| Social cost of unemployment16 |  |
| Spill-over impact on surplus of alternative producers17 |  |
| Please specify {These could include, e.g., additional costs for transportation or quality testing} |  |
| **Sum of monetised impacts** |  |
| 1. **Additional quantitatively assessed impacts** | **[Per year] [Over x years]** |
| Please specify {These could include, e.g., the number of non-treated patients or additional tonnes of greenhouse gas emissions} |  |
| 1. **Additional qualitatively assessed impacts** |  |
| Please specify {These could include, e.g., consumer surplus loss due to inferior quality, higher price or reduced quantity” |  |

Notes:

1. Per average year during the time horizon used in the analysis.

## Combined impact assessment

(Guidance: Chapter 4.1 and appendix D, E, and F of the Guidance on SEA – Authorisation process)

[Combine the assessment of different impacts that are expected from non-authorisation of the use applied for (as discussed in Section 4.4) and compare them to the remaining risks associated with the continued use of the Annex XIV substance (as discussed in Section 4.2). For the comparison, use an appropriate SEA method (ranging from a qualitative assessment of impacts to a fully monetised cost-benefit analysis) to draw conclusions on the impacts of granting or refusing an authorisation. Ensure that impacts are comparable and have not been double counted.

Summarise the data presented in this section in the tables below, as relevant. If no information is available (e.g., on value per statistical case) please indicate this by “n.a.”]

[For substances that pose a risk to human health, compile the impacts in Table 5.]

Table 5: Societal costs of non-use and risks of continued use.

|  |  |  |  |
| --- | --- | --- | --- |
| **Societal costs of non-use** | | **Risks of continued use** | |
| Monetised impacts  (€ [per year1] [over x years]) | {report the monetised net impacts of granting an authorisation; should be consistent with the total reported in Table 4; fill with ‘not available’ if there are none} | Monetised excess risks to directly and indirectly exposed workers  (€ [per year2] [over x years]) | {report the monetised risks to workers in case of granting an authorisation; should be consistent with Table 2; fill with ‘not available’ if there are none} |
| Additional quantitatively assessed impacts  ([per year][over x years]) | {report additional quantitatively assessed impacts that were not monetised, e.g., number of patients treated; should be consistent with the information reported in Table 4;fill with ‘not available’ if there are none} | Monetised excess risks to the general population  (€ [per year2] [over x years]) | {report the monetised risks to indirectly exposed workers/general population in case of granting an authorisation; should be consistent with Table 2; fill with ‘not available’ if there are none} |
| Qualitatively assessed impacts  ([per year][over x years]) | {report qualitatively assessed impacts, e.g., availability of treatment for patients with disease A; should be consistent with the information reported in Table 4; fill with ‘not available’ if there are none} | Qualitatively assessed risks  ([per year][over x years]) | {report qualitatively assessed risks, e.g., risks associated with releases of the Annex XIV substance to the environment; fill with ‘not available’ if there are none} |
| **Summary of societal costs of non-use** | {list the most important elements from the above rows in a bullet point manner} | **Summary of risks of continued use** | {list the most important elements from the above rows in a bullet point manner} |

Notes:

1. Annualised to a typical year based on the time horizon used in the analysis.
2. Per average year during the time horizon used in the analysis.

[For PBT/vPvB substances, endocrine disruptors, and other substances of similar concern for which endpoints and impacts could not be estimated, describe the societal costs of non-use together with the releases or emissions predicted under the continued use scenario, and derive the corresponding cost-effectiveness ratio in Table 6.]

Table 6: Costs of non-use per unit of release.

|  |  |
| --- | --- |
|  | **[Per year4] [Over x years]** |
| Total costs1 (€) | {should be consistent with Table 4} |
| Total releases2 (kg) | {should be consistent with Table 3} |
| Ratio3 (€/kg) |  |

Notes:

1. “Total costs” (in case of non-authorisation) = Societal costs of non-use
2. “Total releases” are from Table 3.
3. “Ratio” = Total costs/Total releases.
4. Annualised to a typical year based on the time horizon used in the analysis.

## Sensitivity analysis

(SEA Guidance: Chapters 3.7, 3.8 and 4.3 and appendix E)

[Summarise the key assumptions of the selected methodology and highlight which of those assumptions are particularly relevant for the conclusions derived in the SEA. Where relevant, conduct sensitivity analysis adopting reasonable worst-case assumptions. Ensure all assumptions and data sources are documented in one section of the SEA.

Discuss the certainty and confidence in the description and possible quantification and valuation of economic, social, health or environmental impacts. Again, make sure to explain all relevant assumptions.]

## Information to support for the review period

[Provide information for the length of the review period. The note “Setting the review period when RAC and SEAC give opinions on an application for authorisation” ([SEAC/20/2013/03](https://echa.europa.eu/documents/10162/13580/seac_rac_review_period_authorisation_en.pdf/c9010a99-0baf-4975-ba41-48c85ae64861)) establishes the criteria the Committees apply to recommend to the Commission the length of the review period. Thus, any information or argumentation that would facilitate the opinion making in this regard should be documented here.]

# CONCLUSION

[Draw overall conclusions on the AoA and SEA based on:

* The steps taken to identify potential alternatives (incl. R&D efforts) and alternative providers, including a summary of your argumentation why such alternatives do not exist, or are not yet available or suitable for your use;
* Assessment of potential alternatives and their suitability and availability for the use applied for;
* If no suitable and available alternatives were identified, a substitution plan detailing the actions needed to make possible alternatives suitable and available and the timescale for these actions;
* Whether the implementation of possible alternatives would lead to an overall reduction in risk.
* The socio-economic benefits of continued use of the Annex XIV substance;
* Residual risks to human health and the environment of continued use;
* Whether the socio-economic benefits of continued use outweigh the risks to human health and the environment;
* Any factors that RAC and SEAC in their opinion as well as the Commission in its decision should take into consideration when defining the operating conditions, risk management measures, and/or monitoring arrangements for an authorised use;
* Any factors that RAC and SEAC in their opinion and the Commission in its decision should take into consideration when assessing the duration of a review period.

# REFERENCES

[Provide a complete list of references.]

# ANNEX – INSTRUCTIONS ON HOW TO DOCUMENT CONFIDENTIAL AND PUBLIC INFORMATION

[Information on environmental emissions and exposure to humans of SVHCs cannot be claimed confidential.

A legal note at the beginning of this format summarises ECHA’s recommendations for handling confidentiality issues. Further instructions on how to provide a justification for confidentiality are presented in this annex.

In the context of the preparation of the package on broad information on uses applied for, and with view to having a meaningful stakeholder consultation on alternatives, ECHA reserves the right to reject unsubstantiated claims and to require meaningful information, e.g., in form of informative ranges[[19]](#footnote-20), in the public version. For the reporting of profit margins and other sensitive business information, applicants are advised to consider the “*Guidance on the preparation of public versions of Commission Decisions adopted under the Merger Regulation*”.[[20]](#footnote-21)

Always include justifications for each item that you have claimed as confidential in the “public version” of the AoA-SEA.[[21]](#footnote-22) Give a clear numbered reference to each piece of information claimed confidential through blanking out and giving ranges. Blanked-out items should be limited to a minimum and cover only that information for which disclosure presents a direct threat to commercial interests. The size of blanked-out text/figure should correspond to the actual size of the text/figure which has been blanked out (e.g., if an entire page has been blanked out, it should be visible in the “public version” that an entire page has been blanked out). Use Table 7 to report the blanked-out references, corresponding page numbers and their justification.

Table 7: Template for providing justifications for confidentiality claims.

|  |  |  |
| --- | --- | --- |
| **Blanked out item reference** | **Page number** | **Justification for confidentiality** |
| Blank # 1 | … | …. |
| Blank # 2 | … | … |
| … | … | … |

If the blanking out concerns qualitative information, make sure that the public version still contains enough public information to constitute a meaningful non-confidential summary of the redacted information. If what is visible after blanking out is not understandable to the reader without the confidential information, include a non-confidential description/summary of what has been blanked out next to the blanked-out area [in square brackets].

The confidential version of the AoA-SEA document needs to be identical to the non-confidential one, except with the confidential information readable but marked in yellow.]

**Examples**:

*Example 1: Figures*

**Public version of the AoA-SEA:**

Annual Tonnage

The applicant uses [Blank #1] [10-100 tonnes] of substance of per year. This tonnage represents the applicant’s total annual tonnage for its three factories located in the EU.

**Confidential version of the AoA-SEA:**

Annual Tonnage

The applicant uses 65 tonnes [10-100 tonnes] of substance of per year. This tonnage represents the applicant’s total annual tonnage for its three factories located in the EU.

*Example 2:* Referring to particular chemicals

**Public version of the AoA-SEA:**

For the inactivation of enveloped viruses, the company uses a solvent-detergent pair. The 4-tert-OPnEO is used as the detergent and is paired with [Blank #2] [organophosphorous compound widely used in many industrial applications] as the solvent.

**Confidential version of the AoA-SEA:**

For the inactivation of enveloped viruses, the company uses a solvent-detergent pair. The 4-tert-OPnEO is used as the detergent and is paired with Tri-n-butyl phosphate (TnBP) [organophosphorous compound widely used in many industrial applications] as the solvent.

*Example 3: Text descriptions*

**Public version of the AoA-SEA:**

Market trials with alternative 1:

The applicant undertook market trials with products manufactured with Alternative 1 with ten of their customers. Customers reported [Blank #3] [description of exact technical problems with alternative 1 experienced by customers, which resulted in their rejection of the products]

**Confidential version of the AoA-SEA:**

Market trials with alternative 1:

The applicant undertook market trials with products manufactured with Alternative 1 with ten of their customers. Customers reported that the surface of the products deteriorated at a rate 5 times higher than those produced with the substance currently used. This meant the products manufactured with the alternative were not considered to provide a suitable performance and were rejected. [description of exact technical problems with alternative 1 experienced by customers, which resulted in their rejection of the products]

# APPENDICES

[Include other information that you consider relevant for the analysis of alternatives and socio-economic analysis (including the substitution plan, if relevant), e.g., list of data sources, data collection approach, summary of assumptions, methodologies, etc.]

\_\_\_\_\_\_\_

1. The AoA and the SEA are part of the package on broad information on uses applied for. As such they will be published on ECHA’s website for the purpose of the stakeholder consultation on alternatives for each application for authorisation. [↑](#footnote-ref-2)
2. In this format the term “blanked out” is used as a synonym of the term “redacted” which is often used in that context. Please ensure that it is not possible to copy text that has been blackened or otherwise obliterated. ECHA does not take any responsibility for unobliterated information that is marked as public. [↑](#footnote-ref-3)
3. Please enable the search function as well as printing and copying of text for the “complete version” and printing for the “public version”. [↑](#footnote-ref-4)
4. Justifications for confidentiality claims will not be made publicly available as part of the broad information on uses package. [↑](#footnote-ref-5)
5. See [https://www.echa.europa.eu/web/guest/support/qas-support/qas]( https://www.echa.europa.eu/web/guest/support/qas-support/qas). [↑](#footnote-ref-6)
6. See the [Commission note on suitable alternatives available in general & requirement for a substitution plan](https://echa.europa.eu/documents/10162/13637/ec_note_suitable_alternative_in_general.pdf/5d0f551b-92b5-3157-8fdf-f2507cf071c1) for criteria when a substitution plan is needed. [↑](#footnote-ref-7)
7. See [Guidance on the preparation of an application for authorisation](https://echa.europa.eu/documents/10162/13643/authorisation_application_en.pdf/8f8fdb30-707b-4b2f-946f-f4405c64cdc7), Appendix 4. [↑](#footnote-ref-8)
8. See [How to apply for authorisation](https://echa.europa.eu/documents/10162/17229/apply_for_authorisation_en.pdf), chapter 3.1.4 and [How to develop use descriptions in applications for authorisation](https://echa.europa.eu/documents/10162/13566/uses_description_in_auth_context_en.pdf/14b5f647-1778-47de-8178-2e2dad170424), chapter 3. [↑](#footnote-ref-9)
9. See [How to develop use descriptions in applications for authorisation](https://echa.europa.eu/documents/10162/13566/uses_description_in_auth_context_en.pdf/14b5f647-1778-47de-8178-2e2dad170424), p.8-9 as well as the [Guidance on the preparation of an application for authorisation](https://echa.europa.eu/documents/10162/13643/authorisation_application_en.pdf/8f8fdb30-707b-4b2f-946f-f4405c64cdc7), p.121-122. [↑](#footnote-ref-10)
10. Such tonnage bands are not considered confidential information, see the Annex. [↑](#footnote-ref-11)
11. In that case, applicant(s) will have to provide a substitution plan to set out activities to be undertaken to support the potential adoption of such alternatives in the future. [↑](#footnote-ref-12)
12. See for instance, OECD Substitution Toolbox, available at <http://oecdsaatoolbox.org>. Relevant hazard data can be found e.g., on ECHA’s website at <https://echa.europa.eu/information-on-chemicals>. [↑](#footnote-ref-13)
13. See also [How to apply for authorisation](https://echa.europa.eu/documents/10162/17229/apply_for_authorisation_en.pdf), p.44. [↑](#footnote-ref-14)
14. For a compilation of health-related unit values, see [(SEAC/32/2016/5.2)](https://echa.europa.eu/documents/10162/13637/seac_reference_wtp_values_en.pdf/403429a1-b45f-4122-ba34-77b71ee9f7c9). [↑](#footnote-ref-15)
15. See [SEAC/52/2021/03](https://echa.europa.eu/documents/10162/0/afa_seac_surplus-loss_seac-52_en.pdf/5e24c796-d6fa-d8cc-882c-df887c6cf6be?t=1633422139138)  [↑](#footnote-ref-16)
16. See [SEAC/52/2021/03](https://echa.europa.eu/documents/10162/0/afa_seac_surplus-loss_seac-52_en.pdf/5e24c796-d6fa-d8cc-882c-df887c6cf6be?t=1633422139138)  [↑](#footnote-ref-17)
17. See [(SEAC/32/2016/04)](https://echa.europa.eu/documents/10162/17086/seac_unemployment_evaluation_en.pdf/af3a487e-65e5-49bb-84a3-2c1bcbc35d25?t=1549885930050). [↑](#footnote-ref-18)
18. If profit losses have not been already accounted for. [↑](#footnote-ref-19)
19. Informative ranges would protect the applicant’s business information whilst still providing an order-of-magnitude estimate of the actual figures, e.g., an annual tonnage of 536 kg should be described by a range no wider than 100-1 000 kg, preferable would be a range of 200-800 kg. Similar ranges should be applied to other relevant information such as profit figures, price margins, etc. [↑](#footnote-ref-20)
20. For reporting of profit margins, see Annex I of the “[*Guidance on the preparation of public versions of Commission Decisions adopted under the Merger Regulation, European Commission*](https://ec.europa.eu/competition-policy/system/files/2021-03/guidance_on_preparation_of_public_versions_mergers_26052015.pdf)”. For absolute profit figures, one possible approach is to take the natural logarithm of the market share (in percent points) and multiply by 10. This would give the range around your absolute profit. For instance, if you made €0.4m and your market share was 12%, your perturbation range would be about 25%. Hence, you should put an interval around €0.4m that spans €0.1m; e.g., [€0.3-€0.5m] or [€0.25-€0.45m]. [↑](#footnote-ref-21)
21. ECHA may assess your justification for example in the context of the preparation of the package of information containing broad information on uses applied for and other information made available for stakeholder consultation and when preparing the public version of the Committee’s opinion. Furthermore, the justification will help ECHA when processing Access to Documents Requests under Regulation (EC) 1049/2001. [↑](#footnote-ref-22)