Format for

**ANALYSIS OF ALTERNATIVES**

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

**Version 4.0**

**February 2019**

|  |  |
| --- | --- |
| **Version** | **Changes** |
| 4.0 | Adaptations include:  Consultations, analysis of the substance function (addition of the description and technical requirement for the products), assessment of shortlisted alternatives. Reordering of some sections. |
| 3.2 | Adaptation for review report |
| 3.1 | Addition of a list of abbreviations, list of tables, list of figures , instructions for appendices |
| 3.0 | Deletion of the confidential annex, leaving only one format to use for both the “complete” and the “public” versions of the Analysis of Alternatives  Changes in Instructions and Legal note  Addition of a section on Annual tonnage  Addition of an Annex for justifications for confidentiality claims with instructions  Changes in the Declaration  Formatting and editorial changes |
| 2.0 | Separation of non-confidential and confidential analysis in two documents: a non-confidential Analysis of Alternatives report and a Confidential Annex  Changes in Preamble, Instructions and Legal note  Inclusion of Instructions for justifications for confidentiality  Change to Summary section  Formatting and editorial changes |
| 1.0 | First version |

**Preamble**

The Analysis of Alternatives is part of the package on broad information on uses applied for. As such, it will be published on ECHA’s website for the purpose of the public consultation on alternatives for each application for authorisation. The same format will also be used by authorisation holders submitting a review report in order to continue using the substance in question after the end of the review period.

The purpose of this document is to provide the applicants for an authorisation and authorisation holders submitting a review report with instructions on how to organise and present their Analysis of Alternatives. The analysis should show whether there are any suitable alternative substance(s) or technology(ies) to the Annex XIV substance(s) for the uses applied for. The format asks the applicant to present a detailed Analysis of Alternatives for each use applied for and to include references to the Chemical Safety Report, the Substitution Plan, the Socio-Economic Analysis and/or other sections of the application as appropriate. Detailed guidance on how to prepare an Analysis of Alternatives is contained in the [Guidance on the preparation of an application for authorisation](https://www.echa.europa.eu/documents/10162/13637/authorisation_application_en.pdf/6571a0df-9480-4508-98e1-ff807a80e3a9) in Chapter 3 and Appendix 3, 4 and 5. The [How to apply for authorisation guide](https://echa.europa.eu/documents/10162/13637/apply_for_authorisation_en.pdf/bd1c2842-4c90-7a1a-3e48-f5eaf3954676) provides practical information, advice and examples from previous applications.

**Instructions**

Please prepare two versions of the same AoA document for each use applied for: one version – i.e. the “complete version”– that contains confidential business information and another – “public version” – where confidential business information is blanked out[[1]](#footnote-2). ECHA will publish on its website the “public version”as a part of the information provided for public consultation. Save your work in a separate (unprotected[[2]](#footnote-3)) Word (or pdf or rtf) file. To ensure that blanked out parts cannot be removed by readers by technical means it might be safer that you provide the “public version” as a scanned document (PDF image).

The two versions of the document should be identical apart from the fact that the parts containing confidential business information 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 made visible. This is to allow an unambiguous link with your justifications for why the information should not be made publically available. These justifications should be provided in an annex of the “complete version” of the AoA[[3]](#footnote-4). Further instructions on blanking out and justifications for confidentiality are provided below and in the Annex. 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 view to having a meaningful public consultation on alternatives, ECHA reserves the right to reject unsubstantiated claims and to require meaningful information (e.g. ranges) in the public version.

For each use applied for, please prepare a zip file containing both the files for the “complete” and the “public” version of the AoA. 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 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 public consultation on alternatives. It is your responsibility to ensure that no confidential business information is present in this public version. ECHA does not assume any liability for damages resulting from the publishing of confidential information you may have included in the “public version”.

If information falling under the broad information of uses is not available in the “public version” of the Analysis of Alternatives, ECHA reserves the right under Article 64(2) of the REACH Regulation to supplement this “public version” for the purpose of the public consultation on alternatives with the necessary information from the “complete version”. For further information on preparation of the broad information on uses package, please see ECHA’s Question and Answer #590[[4]](#footnote-5).

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 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 for not disclosing the information in the “complete 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 is 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 should 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.]

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 explained.]

Limitation to Validity of Claim:

[The period of time 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.]

**Example:**

Demonstration of Commercial Interest:

We have sourced supplies of a new generation of low flammability solvents and build relationships with our supplier over many years. Mixtures of these solvents and 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.

Demonstration of Potential Harm:

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 Confidentiality:

The exact temperature should remain confidential until 1 January 2019, 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

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

**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 use title]

[This format is for one use. If an application or a review report has several uses, separate documents would need to be prepared]

**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 insert here the 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

The Applicant [Authorisation holder] is aware of the fact that evidence might be requested by ECHA to support information provided in this document.

Also, we request that the information blanked out in the “public version” of the Analysis of Alternatives 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:

[NAME, TITLE]

# SUMMARY

[Present a summary of the findings and conclusions of the analysis regarding the identification of possible alternatives and the suitability and availability of these alternatives for the use applied for.

Briefly indicate the steps taken to identify possible alternatives (including 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.

In the event there are no suitable and available alternatives, summarise the actions needed to make possible alternatives suitable and available and the timescale for these actions. Indicate whether the implementation of possible alternatives would lead to an overall reduction of risk.]

# CONSULTATIONS

[Document the consultations undertaken during the analysis. Include when you consulted third parties, their names and contact details (including e-mail addresses) but do not provide names of persons. In particular provide the details of

* Companies providing the alternatives substance, technology or service

As relevant, provide details of how you have consulted the supply chain(s), in particular your clients and downstream users. Provide information about the surveys you have done with your customers about the availability of similar products made without the Annex XIV substances. Please also provide details of other organisations contacted. Report any information about companies that possibly have already substituted. Provide a summary in this section and use Appendix 1 for details.

The details of these consultations should be documented in the relevant sections of the Analysis of Alternatives and SEA.]

# ANALYSIS OF THE SUBSTANCE FUNCTION(S) and TECHNICAL REQUIREMENT(S) for the PRODUCT(S) [[5]](#footnote-6)

(Guidance: Chapter 3.2, 3.3, 3.5.1 and Appendix 4 of the Guidance on the preparation of an application for authorisation)

[An alternative is a possible replacement for the Annex XIV substance. It should be able to replace the function that the Annex XIV substance performs. The alternative could be another substance or it could be a technique (e.g. a process, procedure, device, or modification in 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 Annex XIV substance or perhaps changes in production, process or product that removes the need for the Annex XIV substance function altogether.[[6]](#footnote-7)

A detailed and specific knowledge of the exact function that the Annex XIV substance is doing (and where and how, i.e. under what conditions, that function must be performed) for a particular use, will allow the applicant to look for other ways of performing that function. This may be by using another substance or technology or by changing the process or end product. In the latter cases it is possible that the original function of the substance may become redundant.[[7]](#footnote-8)]

## Description of the technical function provided by the annex XIV substance

[Present detailed information on the precise functions or tasks 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.[[8]](#footnote-9)]

## Description of the product(s) resulting from the use of the annex XIV substance

[The purpose of this section is to give the reader an understanding of the products and that have been produced through the use of the Annex XIV substance, as well as their related market sectors.

Present the products that have been produced through the use of the substance and which may contain the Annex XIV substance. Describe also the market sectors where these products are commercialised, in the EU and elsewhere, detailing who the main producers (either companies or sectors) and users of these products are. [[9]](#footnote-10)]

## Description of the technical requirements that must be achieved by the product(s) made with the substance

[Provide a detailed description of the technical requirements, including tolerances of these requirements (i.e. an acceptable range) for the product(s) or process concerned.

If several industrial/market sectors are concerned and if they have different technical requirements, the description should reflect this variety. If the variety is substantial, separate uses applied for and analysis of alternatives should be prepared[[10]](#footnote-11).

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 categories, underpinned by reasonably foreseeable combinations of processes, products, technical requirements and market sectors. The technical requirements of the articles need to rely on, for instance:

- Legal requirements for technical acceptability;

- Internationally recognised standards for technical performance (e.g. EN or ISO standards);

- Certification requirements;

- Customer requirements.] [[11]](#footnote-12)

# Annual Tonnage

[Indicate the average annual tonnage used for the use applied for. Please consider any future variation of quantities used. If you can justify why the tonnage should be confidential, indicate besides this confidential tonnage figure a tonnage band. The tonnages indicated in this section should be consistent with the ones mentioned in the Exposure Scenarios provided in the Chemical Safety Report. In the “public version” of the AoA the confidential tonnage figure can be blanked out, just leaving the tonnage band visible to the public. If you indicate bands, you may use at a minimum the standard ones below[[12]](#footnote-13):

<1 tonne per year

1-10 tonnes per year

10-100 tonnes per year

100-1000 tonnes per year

>1000 tonnes per year

However, to provide as meaningful information as possible please use as precise bands as possible, for instance:

If the actual (confidential) annual tonnage for use is 25 tonnes per year, you may use in the “public version” as a tonnage band of 20-30 tonnes per year.]

# IDENTIFICATION OF POSSIBLE ALTERNATIVES

(Guidance: Chapter 3.5 of the Guidance on the preparation of an application for authorisation)

## Description of efforts made to identify possible alternatives



### Research and development

[Include information on past and/or planned research and development activities undertaken in an effort to identify possible alternatives (including your suppliers and customers). This is particularly important in cases where no possible alternatives are identified.

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.]

### Data searches

[Building on Section 2, describe the timing, extent and results of data searches on possible alternatives. Include meaningful information on past and/or planned research and development activities aiming to identify possible alternatives.]

## Identification of known alternatives

[List all possible alternatives substances and/or techniques included in the scope of your Analysis of Alternatives.

Based on Sections 3 and 4, present the list of essential criteria, that served as the basis for the assessment of the alternatives. Justify why these criteria are the most relevant for the selection of the possible alternatives.

Describe the link with the relevant parts of the Socio-economic Analysis where you describe what would happen if an authorisation is not granted, i.e., “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, the Analysis of Alternatives and the Substitution Plan.

If necessary, in the Socio-economic Analysis, formulate several “non-use” scenarios by describing the likely response of actors in the relevant supply chains under each different set of assumptions. Describe the differences under each scenario and discuss the likelihood of each scenario occurring. Justify the selection of the scenario(s) analysed.]

# SUITABILITY AND AVAILABILITY OF POSSIBLE ALTERNATIVES

[Organise the analysis of suitability and availability of alternatives by possible alternative:]

**ALTERNATIVE 1**[[13]](#footnote-14)

## Substance ID and properties (or Description of alternative technique)

[For substance alternatives, include their substance identity (i.e., chemical name, IUPAC name, CAS/EINECS number, or other identifiers listed in Section 2 of Annex VI) and a summary table of properties relevant for the overall risk to human health and the environment (e.g., physico-chemical properties, classification and labelling information, etc.).

For technical alternatives, describe the technology 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.]

## Technical feasibility

(Guidance: Chapter 3.6 and Chapter 3.9 of the Guidance on the preparation of an application for authorisation)

[Based on the consultations (Section 3) and the technical requirements (Section 4) present a transparent analysis of the technical feasibility of the 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 was integrated in the assessment.

Support your analysis with information on research and development activities. Document the methodology, data sources, assumptions made, uncertainties 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, waster, etc.) and how these affect the technical feasibility of the alternative.

If substitution has already happened in your market, provide justifications as why your situation is different from other companies using the alternative (see also section 5.3.1.3)[[14]](#footnote-15).

If it is concluded that the alternative is not technically feasible, discuss possible actions (including R&D, production trials, etc.) and timeframe within which technical feasibility can be achieved. Include any obstacles or difficulties identified or expected in the development/identification of a technically feasible alternative.]

## Economic feasibility and economic impacts [[15]](#footnote-16)

(Guidance: Chapter 3.8 and Chapter 3.9 of the Guidance on the preparation of an application for authorisation as well as Chapter 3.5 and Appendix 1 of the Guidance on SEA – Authorisation process)

[Describe the direct and indirect costs and revenues associated with the placing on the market or using of the Annex XIV substance and the alternative. Discuss possible liability or reputational issues associated with using the Annex XIV substance as well as the less tangible benefits that can result from the transferral to the alternative. Present the results of the comparative cost analysis of the current use of the Annex XIV substance versus the alternative.

Detail the methodology, the sources of the data, the assumptions and uncertainties 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.

If substitution already happened in your market, provide justifications as why your situation is different from other companies using the alternative (see also section 6.2)[[16]](#footnote-17).

In the event it is concluded that the alternative is not economically feasible, discuss what it will take to make this alternative economically feasible. Include any obstacles or difficulties identified or expected.]

## Reduction of overall risk due to transition to the alternative[[17]](#footnote-18)

(Guidance: Chapter 3.7 and Chapter 3.9 of the Guidance on the preparation of an application for authorisation)

[Present an assessment of whether the transfer to the alternative would result in reduced overall risks to human health and the environment. In the risk assessment of the alternative, consider all the relevant risks and effects associated with the alternative. These may also be related to other aspects affecting the overall risk reduction capacity of the transfer to the alternative, such as changes in energy or raw material consumption or physical conditions.

Support your analysis with information on research and development activities, including the information based on the consultations (Section 2). Describe the methodology of comparing the risks of the Annex XIV substance and the alternative. Document the data used, its quality and reliability, the assumptions made, the uncertainties in the analysis and their impact on the conclusions of the assessment.

In the event it cannot be concluded that the transition to the alternative will result in an overall risk reduction, discuss possible actions (e.g., gathering of additional hazard data, etc.) and the timeframe within which relevant information can be gathered to conclude on the risk reduction capacity of the alternative. Include any obstacles or difficulties identified or expected in the identification of such an alternative.]

## Availability[[18]](#footnote-19)

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

[Based on Section 2, for suitable alternatives, discuss in a clear and transparent manner whether they are available (in the required quantity) without undue delay (taking into account the sunset date of the Annex XIV substance). In the event it is concluded that the alternative is not available, discuss what it will take to make this alternative available. Include any obstacles or difficulties identified or expected.]

## Conclusion on suitability and availability for Alternative 1

(Guidance: Chapter 3.10 and 3.11 of the Guidance on the preparation of an application for authorisation)

[Conclude on the overall suitability and availability of Alternative 1.

In the cases where the alternative is not suitable and/or available, present a list of actions that would be needed in order to make the alternative suitable and available, including the time frame required for these actions to be implemented as well as potential obstacles. Discuss specifically any research and development activities needed to make the alternative suitable and available.]

**b) ALTERNATIVE 2**

(Repeat sections 6.1-6.6 as shown for Alternative 1. Add additional sections for other alternatives.)

# OVERALL CONCLUSIONS ON SUITABILITY AND AVAILABILITY OF POSSIBLE ALTERNATIVES FOR USE 1

[Present overall conclusions on the suitability and availability of all possible alternatives considered in the Analysis of Alternatives. Rank the alternatives based on their technical and economic feasibility, capacity for reducing the overall risk and their availability.]

# SUBSTITUTION EFFORTS TAKEN BY THE APPLICANT IF AN AUTHORISATION IS GRANTED

[If an authorisation is granted for the use of this substance or prolonged after the submission of a review report, describe which actions you will undertake, including a realistic and well-reasoned estimate of the time needed to substitute aiming at substituting the use of the Annex XIV substance.]

# CONCLUSION

[Present the main conclusions of the analysis regarding the identification of possible alternatives and the suitability and availability of these alternatives for the use applied for.

Briefly indicate the steps taken to identify possible alternatives (including 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.

In the event there are no suitable and available alternatives, summarise the actions needed to make possible alternatives suitable and available and the timescale for these actions. Indicate whether the implementation of possible alternatives would lead to an overall reduction of risk.]

# REFERENCES

[Provide list of references]

Annex – Justifications for ConfidentialiTy Claims[[19]](#footnote-20)

[Include your justifications for confidentiality for each blanking that you have carried out in the “public version” of the AoA[[20]](#footnote-21). Give a clear numbered reference to each blanked out item. Blanked area should be as limited in size as possible, and cover only the information which disclosure presents a direct threat to commercial interests. The size of the blanked out areas should correspond to the size of the text 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 the table below to report the blanked out references, corresponding page number and justification. A legal note and further instructions on how to provide a justification for confidentiality are presented above in this document. In the context of the preparation of the package on broad information on uses applied for, and with view to having a meaningful public consultation on alternatives, ECHA reserves the right to reject unsubstantiated claims and to require meaningful information (e.g. ranges) in the public version].

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**Example**:

Public version of the Analysis of Alternatives:

[…]

Page 6

**Annual Tonnage**

Confidential average annual tonnage for use 1: . [Blank #1] .

Annual tonnage band for use 1:10-100tonnes per year

This tonnage represents the applicant’s total annual tonnage for its three factories located in the EU..

[…]

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**Alternative X**

[…]

* Technical feasibility

The alternative was tested during four years in our factory of Villecity. The tested mixture called [Blank #2] was supplied by [Blank #3] in drums of [Blank #4] litres. The detailed results of the tests carried out are presented in Table 4.2 below:

Table 4.2 Results of Alternative X technical feasibility

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[…]

Table of justification for confidentiality in the Annex of the “complete version” of the Analysis of Alternatives:

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| **Blanked out item reference** | **Page number** | **Justification for confidentiality** |
| Blank #1 | 6 | [insert here your justification] |
| Blank #2 | 11 | [insert here your justification] |
| Blank #3 | 11 | [insert here your justification] |
| … | … | … |

# APPENDIXES

## Appendix 1 Consultations

[Document the consultations undertaken during the analysis. Include details on:

* (the parts of) the supply chain(s) consulted[[21]](#footnote-22);
* other organisations contacted;
* possible alternatives that have been identified through this process and evidence of (non)availability of alternatives.]

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

## Additional appendices

[Include other information that you consider relevant for the Analysis of Alternatives, e.g., list of data sources, data collection approach, summary of assumptions, methodologies, etc.].

1. In this document the term “blanked out” is used as a synonym of the term “redacted” which is often used in that context. [↑](#footnote-ref-2)
2. Please enable printing and copying of text for the “complete version” and printing for the “public version” [↑](#footnote-ref-3)
3. This annex listing your justifications for confidentiality claims will not be made publicly available as part of the broad information on uses package [↑](#footnote-ref-4)
4. <http://www.echa.europa.eu/qa-display/-/qadisplay/5s1R/view/ids/590> [↑](#footnote-ref-5)
5. See How to develop use descriptions in applications for authorisation, Chapter 2.1 [↑](#footnote-ref-6)
6. Guidance on the preparation of an application for authorisation, Chapter 3.2 [↑](#footnote-ref-7)
7. Guidance on the preparation of an application for authorisation, Chapter 3.5 [↑](#footnote-ref-8)
8. Guidance on the preparation of an application for authorisation Appendix 4 [↑](#footnote-ref-9)
9. See How to develop use descriptions in applications for authorisation p. 8 and 9 as well as the Guidance on the preparation of an application for authorisation p.121, 122. [↑](#footnote-ref-10)
10. See ‘How to apply for authorisation’ chapter 3.1.4 and ‘How to develop use descriptions in applications for authorisation’ chapter 3. [↑](#footnote-ref-11)
11. See How to develop use descriptions in applications for authorisation p. 8 and 9 as well as the Guidance on the preparation of an application for authorisation Appendix 4 [↑](#footnote-ref-12)
12. These tonnage bands are usually not considered confidential [↑](#footnote-ref-13)
13. If the Annex XIV substance is replaced by a group of several substance and/or techniques, include the analysis for the group as a whole in one section. [↑](#footnote-ref-14)
14. See How to apply for authorisation, a step by step guide for applicants p.44. [↑](#footnote-ref-15)
15. Link to Section 3.2: Economic impacts of the Socio-economic analysis (SEA) format. [↑](#footnote-ref-16)
16. See How to apply for authorisation, a step by step guide for applicants p.44. [↑](#footnote-ref-17)
17. Link to Section 3.1: Human health and environmental impacts of the Socio-economic analysis (SEA) format. [↑](#footnote-ref-18)
18. Link to Section 3.2: Economic impacts of the Socio-economic analysis (SEA) format. [↑](#footnote-ref-19)
19. This annex will not be made publicly available as part of the broad information on uses package [↑](#footnote-ref-20)
20. 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 public 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 1049/2001. [↑](#footnote-ref-21)
21. Sharing and publishing supply chain specific information may be subject to competition rules. [↑](#footnote-ref-22)