Format for

**ANALYSIS OF ALTERNATIVES**

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

**Version 3.2**

**May 2017**

|  |  |
| --- | --- |
| **Version**  | **Changes**  |
| 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 AlternativesChanges in Instructions and Legal noteAddition of a section on Annual tonnageAddition of an Annex for justifications for confidentiality claims with instructionsChanges in the DeclarationFormatting 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 AnnexChanges in Preamble, Instructions and Legal noteInclusion of Instructions for justifications for confidentialityChange to Summary sectionFormatting 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 Analysis of Alternatives 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-1). 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-2)) 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 Analysis of Alternatives[[3]](#footnote-3). 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 to your Analysis of Alternatives (except for the annex with the justifications for confidentiality).*

 *ECHA may assess your justification for example in the context of the preparation of the package on broad information on uses applied for and when preparing the public version of the Committees’ opinion.*

*For each use applied for, please prepare a zip file containing both the files for the “complete” and the “public” version of the Analysis of Alternatives. Attach the zip file to the relevant use section in the IUCLID 5 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-4).*

*The “complete version” of the Analysis of Alternatives is subject to Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents. 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 Regulation. If your justification is sufficient and falls under one of the exceptions envisaged in Regulation 1049/2001, there will in principle be no need to request further clarification from you why access to part or the whole of the “complete version” should be refused.*

**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]*

**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]*

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**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, [Applicant’s/Authorisation holder’s name], 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.*

*In the event no possible alternatives were identified, briefly indicate the steps taken to identify possible alternatives and include a summary of your argumentation why such alternatives do not exist. 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.]*

# ANALYSIS OF SUBSTANCE FUNCTION

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

*[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, customer requirements or legal requirements for technical acceptability. Include any obstacles or difficulties identified or expected in relation to finding an alternative fulfilling or replacing the equivalent function of the Annex XIV substance.*

*Present the list of essential criteria for fulfilling the substance function 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 by linking the criteria to the function, tasks and conditions under which the substance is used in the specific use applied for.]*

# Annual Tonnage

*[Indicate the average annual tonnage used for the use applied for[[5]](#footnote-5). If the tonnage is 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 Analysis of Alternatives the confidential tonnage figure can be blanked out, just leaving the tonnage band visible to the public. If you indicate bands, use the standard ones below[[6]](#footnote-6) unless you prefer to be more precise:*

*<1 tonne per year*

*1-10 tonnes per year*

*10-100 tonnes per year*

*100-1000 tonnes per year*

*>1000 tonnes per year*

*Example 1- with standard tonnage band:*

*Confidential average annual tonnage for use 1: 25 tonnes per year[[7]](#footnote-7)*

*Annual tonnage band for use 1: 10-100 tonnes per year[[8]](#footnote-8)*

*Example 2 – with applicant’s specific, more precise tonnage band:*

*Confidential average annual tonnage for use 1: 25 tonnes per year[[9]](#footnote-9)*

*Annual tonnage band for use 1: 20-30 tonnes per year][[10]](#footnote-10)*

# IDENTIFICATION OF POSSIBLE ALTERNATIVES

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

## List of possible alternatives

*[List all possible alternatives included in the scope of your Analysis of Alternatives.]*

## Description of efforts made to identify possible alternatives

1.

### Research and development

*[Include information on past and/or planned research and development activities undertaken in an effort to identify possible alternatives. 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.]*

#### Substitution effort 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, aiming at substituting the use of the Annex XIV substance.]*

### Data searches

*[Describe the extent and results of data searches on possible alternatives. Include information on past and/or planned research and development activities aiming to identify possible alternatives.]*

### Consultations

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

* *(the parts of) the supply chain(s) consulted;[[11]](#footnote-11)*
* *other organisations contacted;*
* *possible alternatives that have been identified through this process and evidence of (non)availability of alternatives.]*

# SUITABILITY AND AVAILABILITY OF POSSIBLE ALTERNATIVES

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

**ALTERNATIVE 1**[[12]](#footnote-12)

## Substance ID and properties[[13]](#footnote-13)

*[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 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.]*

## Technical feasibility

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

*[Present a transparent analysis of the technical feasibility of the alternative in terms of the possible provision of an equivalent function to the Annex XIV substance. Show how the criteria for equivalent function were applied to the possible alternative to determine its technical feasibility. 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 (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.*

*In the event 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[[14]](#footnote-14)

*(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 issues and 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.*

*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[[15]](#footnote-15)

*(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 not only the risks in relation to the hazards that were the basis for placing the Annex XIV substance on the candidate list but also other 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. 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[[16]](#footnote-16)

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

*[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 5.1-5.6 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.*

*In the event the Analysis of Alternatives concluded that there are no available suitable alternatives, present a list of actions that you will undertake to identify and develop a suitable and available alternative. Specify the timeframe within which these actions will be undertaken.]*

# REFERENCES

*[Provide list of references]*

Annex – Justifications for ConfidentialiTy Claims[[17]](#footnote-17)

 *[Include your justifications for confidentiality for each blanking that you have carried out in the “public version” of the Analysis of Alternatives[[18]](#footnote-18). Give a clear numbered reference to each blanked out item. 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.]*

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| *Blank # 1* | *…* | *….* |
| *Blank # 2* | *…* | *…* |
| *…* | *…* | *…* |

***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..*

*[…]*

*Page 11*

***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[[19]](#footnote-19);*
* *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-1)
2. Please enable printing and copying of text for the “complete version” and printing for the “public version” [↑](#footnote-ref-2)
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-3)
4. <http://www.echa.europa.eu/qa-display/-/qadisplay/5s1R/view/ids/590> [↑](#footnote-ref-4)
5. Aggregated annual tonnage in case of several applicants [↑](#footnote-ref-5)
6. These tonnage band are usually not considered confidential [↑](#footnote-ref-6)
7. Figure can be blanked in the public version [↑](#footnote-ref-7)
8. The tonnage band is left visible in the public version [↑](#footnote-ref-8)
9. Figure can be blanked in the public version [↑](#footnote-ref-9)
10. The tonnage band is left visible in the public version [↑](#footnote-ref-10)
11. Sharing and publishing supply chain specific information may be subject to competition rules. [↑](#footnote-ref-11)
12. 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-12)
13. When the alternative is a technique, the appropriate title is: Description of technique. [↑](#footnote-ref-13)
14. Link to Section 3.2: Economic impacts of the Socio-economic analysis (SEA) format. [↑](#footnote-ref-14)
15. Link to Section 3.1: Human health and environmental impacts of the Socio-economic analysis (SEA) format. [↑](#footnote-ref-15)
16. Link to Section 3.2: Economic impacts of the Socio-economic analysis (SEA) format. [↑](#footnote-ref-16)
17. This annex will not be made publicly available as part of the broad information on uses package [↑](#footnote-ref-17)
18. 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-18)
19. Sharing and publishing supply chain specific information may be subject to competition rules. [↑](#footnote-ref-19)