Format for

SOCIO-ECONOMIC ANALYSIS

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 non-confidential summary, leaving only one format to use for both the “complete” and the “public” versions of the Socio-Economic Analysis Changes in Instructions and Legal note Addition of a section on Argumentation for the length of the review period and a section on Number of people exposed Addition of an Annex for justifications for confidentiality claims with instructions Changes in the Declaration Formatting and editorial changes
2.0	Change 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 purpose of this document is to provide applicants for authorisation with instructions on how to organise and present their Socio-Economic Analysis (SEA). 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 format asks the applicant/authorisation holder to present SEA in support of the application for authorisation/review report for each use of the Annex XIV substance(s) and to include references to the Chemical Safety Report (CSR), the Analysis of Alternatives, the Substitution Plan and/or other sections of the application as appropriate. Detailed guidance on how to prepare a SEA is contained in the Guidance on Socio-Economic Analysis – Authorisation Process. The How to apply for authorisation guide provides practical information, advice and examples from previous applications.

The "public version" of the SEA 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/review report.

Although this SEA format is aimed to assist applicants/authorisation holders with the preparation of an application for authorisation/review report, it is recommended that other parties, who submit information during the public consultation, document their SEA in a similar way. See Appendix H of the Guidance on SEA – Authorisation Process for further information.

Instructions

Please prepare two versions of the same SEA 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]. 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]) 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 SEA[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 SEA (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.

[1] In this document the term "blanked out" is used as a synonym of the term "redacted" which is often used in that context.
[2] Please enable printing and copying of text for the "complete version" and printing for the "public version"
[3] This annex listing your justifications for confidentiality claims will not be made publicly available as part of the broad information on uses package

For each use applied for, please prepare a zip file containing both the files for the "complete" and the "public" version of the SEA. 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 SEA as part of an application for authorisation/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 SEA, 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[1].

The "complete version" of the SEA 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 and demonstration that this commercial interest is worthy of protection by the non-disclosure of information. Demonstration 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.]

[1] http://www.echa.europa.eu/qa-display/-/qadisplay/5s1R/view/ids/590

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:

The market price of the substance is known only to our customers who are asked to sign non-disclosure and non-compete agreements.

Demonstration of Potential Harm:

Dissemination of the market price will allow our competitors to undercut us on price, or to engage in other predatory practices to encroach on our market. This would severely harm the commercial interests of our corporation.

Limitation to Validity of Confidentiality:

The claim for confidentiality on market price will remain valid indefinitely.

Format for

SOCIO-ECONOMIC ANALYSIS

Legal name of applicant(s):	*[Legal names of applicant(s)/authorisation holders]*
Submitted by:	*[Legal name of submitting applicant/authorisation holders]*
Substance:	*[Include Annex XIV substance name, EC and CAS number]*
Use title:	*[Include use title]* *[This format is for one use. If an application/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

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 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:

[NAME, TITLE]

1. SUMMARY OF SOCIO-ECONOMIC ANALYSIS

Summarise in one or two pages maximum the main conclusions of the Socio-Economic Analysis (SEA).

Depending on the aim of SEA, summarise:

a) the socio-economic benefits of continued use of the Annex XIV Substance;
b) residual risks to human health and the environment of continued use;
c) whether benefits of continued use outweigh the risks to human health and the environment;
d) the factors that RAC[1] and SEAC[2] 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;
e) 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;

If the applicant/authorisation holder has prepared a Substitution Plan[3] for threshold substances, the summary could also include the socio-economic benefits of the proposed phased transition from the Annex XIV substance to the alternative(s).

[1] The Committee for Risk Assessment
[2] The Committee for Socio-economic Analysis
[3] Please note that a Substitution Plan needs to be prepared if the applicant considers that the risks are adequately controlled and there are suitable alternatives (based on Article 60(2)).

2. AIMS AND SCOPE OF SEA

(Guidance: Chapter 2 of the Guidance on SEA – Authorisation process)

2.1. Aims and scope of SEA

[Define the aim of SEA. Set the scope of SEA in terms of temporal and geographic boundaries, relevant supply chains, and types of impacts to be covered. Consider the impact triggering and impact realisation period in the determination of the temporal scope of SEA. In the identification of relevant supply chains, take into account physical flows related to inputs and outputs from the use applied for and economic flows through affected markets as a consequence of continued use of the Annex XIV substance or the transition to a possible alternative.]

2.2. Definition of "applied for use" scenario

[Describe the assumed parameters of the socio-economic environment under the "applied for use" scenario, i.e., of continued use of the Annex XIV substance for the use applied for and under the conditions described in the Chemical Safety Report (CSR). Consider recent or anticipated changes (e.g., the substance has been entered in Annex XIV) in regulatory, technical and economic trends impacting the relevant supply chain(s) for the use of the Annex XIV substance. Document assumptions by citing relevant sources of information (supply chain consultations, data searches, information on R&D, etc.), including the assessment presented in the CSR.]

2.3. Definition of "non-use" scenario

[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, 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) to be analysed in greater detail in SEA.]

2.4. Information for the length of 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) (available at http://echa.europa.eu/documents/10162/13580/seac_rac_review_period_authorisation_en.pdf.) establishes how the Committees intend 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.]

3. ANALYSIS OF IMPACTS

3.1. Human health and environmental impacts

(Guidance: Chapter 3.1, 3.2, 3.3 and appendices A, B, C, F and G of the Guidance on SEA – Authorisation process)

[Present the differences between the "applied for use" and "non-use" scenarios in emissions, exposure and human and/or environmental risks relating to the Annex XIV substance and possible alternatives. Identify the human health and environmental endpoints that are affected. Reference the sections of the CSR and the Analysis of Alternatives that are used as the starting point for the assessment of human health and/or environmental impacts for the purpose of SEA.

Present the assessment of human health and environmental impacts in qualitative, semi-quantitative or quantitative terms, i.e., the impact of granting an authorisation stemming from the remaining risk associated with continued use of the Annex XIV substance. Indicate the significance of the impacts qualitatively and quantitatively. Quantify if possible and reasonable to do so. Monetise (using unit values) the quantified impacts.

Discuss the certainty and confidence in the description and possible quantification and valuation of the impacts. Include all relevant assumptions and uncertainties.]

3.1.1 Number of people exposed

[Indicate the number of people (likely) exposed to the Annex XIV substance. Distinguish figures between industrial workers, professionals and general population.]

3.2. Economic impacts

(Guidance: Chapter 3.1, 3.2, 3.4 and appendices A, B, C, G and I of the Guidance on SEA – Authorisation process)

[Describe the economic impacts of not granting an authorisation for continued use of the Annex XIV substance by comparing the "applied for use" and the "non-use" scenarios. As SEA should examine socio-economic impacts on society, consider including in the analysis broader socio-economic considerations than those discussed in Section "5.3 Economic feasibility" and Section "5.5. Availability" of the Analysis of Alternatives.

Present a quantitative assessment of the economic impacts of continued use of the Annex XIV substance for the applicant and the Annex XIV supply chain: i.e., the costs (or savings) to society associated with the transition from the Annex XIV substance to possible alternative(s). Report possible costs and savings to other supply chains if an authorisation is not granted and a transition to a possible alternative may be anticipated. Include all relevant assumptions and uncertainties.

Discuss the significance of the impacts as well as the certainty and confidence in the description and possible quantification of economic impacts. Include all relevant assumptions and uncertainties.

If the applicant has prepared a Substitution Plan for threshold substances, give references to the sections that are used as the starting point for the assessment of economic impacts in SEA.]

3.3. Social impacts

(Guidance: Chapter 3.1, 3.2, 3.5 and appendices A, B, C and G of the Guidance on SEA – Authorisation process)

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

If relevant, present an assessment of the social benefits of granting an authorisation, i.e., the avoided social costs of not granting an authorisation, in qualitative, semi-quantitative or quantitative terms. Discuss the significance of the impacts as well as the certainty and confidence in the description and possible quantification of the impacts. Include all relevant assumptions and uncertainties.]

3.4. Wider economic impacts

(Guidance: Chapter 3.1, 3.2, 3.6 and appendices B.4, D.4, G of the Guidance on SEA – Authorisation process)

[Report possible differences between the "applied for use" and "non-use" scenarios in terms of wider economic impacts. Impacts may comprise of effects on international trade, competition and economic development. Present an assessment of these impacts considering their significance as well as any uncertainties of the analysis. Include all relevant assumptions.]

4. COMBINED ASSESSMENT OF IMPACTS

4.1. Comparison of impacts

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

[Combine the assessment of different impacts (discussed in Section 3: Analysis of impacts) that could potentially arise as a result of not granting an authorisation for continued use of the Annex XIV substance. Compare the different types of impacts using an appropriate SEA method (e.g., ranging from qualitative assessment to a fully monetised cost-benefit analysis) to be able to draw conclusions on the net impacts of not granting an authorisation. Ensure impacts are comparable and have not been double counted.]

4.2. Distributional impacts

(Guidance: Chapter 4.2 of the Guidance on SEA – Authorisation process)

[If relevant, present an assessment of the distributional impacts of the "applied for use" vs. the "non-use" scenario. Discuss the distribution of the socio-economic costs and benefits in terms of supply chain stages, geographic span, and social or eco-system groups affected.]

4.3. Uncertainty analysis

(Guidance: Chapter 3.7, 3.8, and 4.3 and appendix E of the Guidance on SEA – Authorisation Process)

[Summarise the key sources of uncertainties based on the selected methodology and assumptions made in SEA. Indicate their importance to the overall conclusions of SEA.
Ensure all assumptions and data sources are summarised in one section of SEA.]

5. CONCLUSIONS

[Make overall conclusions regarding the aims of SEA. Depending on the aim of SEA, give the conclusions of the following points:

a) the socio-economic benefits of continued use of the Annex XIV Substance;
b) residual risks to human health and the environment of continued use;
c) whether benefits of continued use outweigh the risks to human health and the environment;
d) the 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;
e) 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;

If the applicant has prepared a Substitution Plan[4] for threshold substances, summarise also the socio-economic benefits of the proposed phased transition from the Annex XIV substance to the alternative(s). In addition, summarise the argumentation in support of any other research goals that you set out to prove with SEA in support of your application for authorisation/review report.]

6. REFERENCES

[Provide list of references]

[4] Please note that a Substitution Plan needs to be prepared if the applicant considers that the risks are adequately controlled and there are suitable alternatives (based on Article 60(2)).

ANNEX – JUSTIFICATIONS FOR CONFIDENTIALITY CLAIMS[5]

[Include your justifications for confidentiality for each blanking that you have carried out in the "public version" of the Socio-Economic Analysis[6]. 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.]

Blanked out item reference	***Page number***	***Justification for blanking***
Blank #1	…	….
Blank # 2	…	…
…	…	…

Example:

Public version of the SEA:

Page 23:

Economic impacts

With view of the margin in our sector of [Blank #1]%), a refused authorisation is estimated to result in a loss of revenues of around €10 million per year and a loss of annual profit of €[Blank #2] . (Table 3.23).

Table 3.23: Estimated change in revenues in 2017-2020 if authorisation was not granted (€m)

	2017	*2018*	*2019*	*2020*
Sales	*Blank #3*			
Fixed costs				
Recurrent costs				
Change in revenue	*-11*	*-10*	*-9*	*-8*

[…]

[5] This annex will not be made publicly available as part of the broad information on uses package

[6] 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.

Table of justification for confidentiality in the Annex of the complete version of the Socio-Economic analysis:

Blanked out item reference	***Page number***	***Justification for confidentiality***
Blank #1	*23*	*[insert here your justification]*
Blank # 2	*23*	*[insert here your justification]*
Blank # 3	*23*	*[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[7];*
- *other organisations contacted;*
- *any other relevant information related to consultations]*

_____

Additional appendices

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

[7] Sharing and publishing supply chain specific information may be subject to competition rules.