Format for

**Socio-Economic Analysis**

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

**Version: 4.0**

**February 2019**

|  |  |
| --- | --- |
| **Version** | **Changes** |
| 4.0 | Major adaptations to be consistent with the revised opinion format and other modifications in several sections, including:  Preamble (justification of the confidentiality claims), legal note (reference to Regulation No 1367/2006), declaration (request for evidence), summary (inclusion of distributional costs, R&D efforts), aim and scope (markets), section on market and business trends (reference to companies using alternatives), section on impact of granting the authorisation (additional instructions and addition of tables to report the impacts), conclusions (cfr. summary), Annex – Justifications for Confidentiality Claims (reference to size of the blanking, link to commercial interest threats and public consultation on alternatives). |
| 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](https://echa.europa.eu/documents/10162/23036412/sea_authorisation_en.pdf/aadf96ec-fbfa-4bc7-9740-a3f6ceb68e6e). 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.

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 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-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 SEA[[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 (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 SEA. 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 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[[4]](#footnote-4).

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 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.]

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]

**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/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 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 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]

# 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:

1. the socio-economic benefits of continued use of the Annex XIV Substance, including distributional impacts;
2. residual risks to human health and the environment of continued use;
3. whether benefits of continued use outweigh the risks to human health and the environment;
4. the factors that RAC[[5]](#footnote-5) and SEAC[[6]](#footnote-6) 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;
5. 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[[7]](#footnote-7) 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).

# Aims and scope of SEA

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

## Aims and scope of SEA

[Define the aim of SEA. Set the scope of SEA in terms of temporal and geographic boundaries, relevant market(s) and 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.]

## Market and business trends including the use of the substance

[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, uses have been authorised) in regulatory, technical and economic trends impacting the relevant supply chain(s) for the use of the Annex XIV substance.

Describe the position of the applicants on the market, vis-à-vis competitors, suppliers and downstream users. Provide as detailed information as you can to describe the circumstances in which you operate. Describe the extent to which alternatives techniques or substances have been used in relevant markets, on the basis, among other sources, of the consultations referred to in Section 3.

If an alternative is used by other companies (including competitors) the applicant needs to appropriately justify why this alternative is not suitable and available for him.

Describe current, past and projected sales figures, profits, prices or any other relevant information. 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.]

## 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.]

## 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.]

## 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.]

# impacts OF GRANTING AUTHORISATION

## Human health and/or environmental impacts

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

[If relevant, present the assessment of human health and/or 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.]

### Number of people exposed

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

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

### Impact on the environment

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

Where relevant, describe the (likely) impacts to the environment such as ecological impairments (biodiversity and functioning), impairments to the quality of water, air and soil), impacts on climate change, water consumption, etc.

For quantified human health impacts, please summarise the data presented in this section in the table below.]

**Table X: Summary of additional statistical <endpoint> cases:**

[Summarise the monetised excess risk of fatal and non-fatal endpoints in separate tables]

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Excess <endpoint> risk**2 | **Number of exposed people** | **Estimated statistical <endpoint> cases** | **Value per statistical <endpoint> case** | **Monetised excess risk per year1** |
| Workers | | | | | |
| Directly exposed workers3 |  |  |  |  |  |
| Indirectly exposed workers4 |  |  |  |  |  |
| Sub-total |  |  |  |  |  |
| General population | | | | | |
| Local |  |  |  |  |  |
| Regional |  |  |  |  |  |
| Sub-total |  |  |  |  |  |
| **Total** |  |  |  |  |  |
| Latency(years) |  | | | | |

Notes:

1. Annualised to a typical year based on the time horizon used in the SEA;
2. Excess risk is estimated over a lifetime working exposure (typically 40 years) and via the environment over a typical lifetime exposure (typically 70 years);
3. Directly exposed workers perform tasks described in the worker contributing scenarios, typically based on 8 hour Time Weighted Average (TWA) of a representative worker;
4. Indirectly exposed workers (bystanders) do not use the substance;

[If no information is available (e.g. on value per statistical case) please indicate this by “n.a.”.

In the last row of the table, describe if and how latency effects were accounted for in the analysis.

Analysis of health impact – 40 years for workers and 70 for general population or for the duration of the review period – the period taken into consideration should be the same as in the assessment of benefits.

Description of methodology, and values used to monetise health and / or environmental impacts. Description of uncertainties.

For environmental impacts, summarise the information from Section 10.2. Environment (combined for all emission sources) of the Exposure Scenario in the CSR. If appropriate, reproduce the relevant table(s) here.]

## Economic impacts

(SEA Guidance: Chapter 3.1, 3.2, 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 “applied for use” and the “non-use” scenarios. As SEA should examine socio-economic impacts on society, include in the analysis broader socioeconomic considerations than those discussed above in Section “Economic feasibility” and “Availability”, such as, for example, the impact on alternative providers.

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. Dicsuss also possible liability or reputation issues associated with maintaining the use of the Annex XIV substance.

You are encouranged to summarise the impacts in table(s) that would feed to the summary table in Section 6.4.]

## Social impacts

(SEA Guidance: Chapter 3.1, 3.2, 3.5 and appendices A, B, C and G).

[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.

You are encouraged to summarise the impacts in table(s) that would feed to the summary table in Section 6.4.]

## Wider economic impacts

(SEA Guidance: Chapter 3.1, 3.2, 3.6 and appendices B.4, D.4, G).

[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.

Please summarise the data presented in this section in the tables below. If no information is available please indicate this by “n.a.”.]

**Table X: Socio-economic benefits of continued use**

|  |  |
| --- | --- |
| **Description of major impacts** | **Quantification of impacts**  **[annualised to € million per year]** |
| **1. Benefits to the applicant(s) and/or their supply chain** | |
| * 1. Avoided profit loss due to investment and/or production costs related to the adoption of an alternative |  |
| * 1. Avoided profit loss due to ceasing the use applied for[[8]](#footnote-8) |  |
| * 1. Avoided relocation or closure cost |  |
| * 1. Avoided residual value of capital |  |
| * 1. Avoided additional cost for transportation, quality testing, etc. |  |
| **Sum of benefits to the applicant(s) and / or their supply chain** |  |
| **2. Quantified impacts of the continuation of the SVHC use applied for on other actors** | |
| * 1. Avoided net job loss in the affected industry[[9]](#footnote-9) |  |
| * 1. Foregone spill-over impact on surplus of alternative producers |  |
| * 1. Avoided consumer surplus loss (e.g. because of inferior quality, higher price, reduced quantity, etc.) |  |
| * 1. Avoided other societal impacts (e.g. avoided CO2 emissions or securing the production of drugs) |  |
| **Sum of impacts of continuation of the use applied for** |  |
| **3. Aggregated socio-economic benefits (1+2)** |  |

# COMBINED ASSESSMENT OF IMPACTS

## 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) 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.

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.”]

**Table X: Comparison of socio-economic benefits and risks of continued use**

|  |  |  |  |
| --- | --- | --- | --- |
| **Socio-economic benefits of continued use** | | **Monetised excess risks associated with continued use** | |
| Benefits to the applicant(s) and/or their supply chain [annualised to € million per year] |  | Monetised excess risks to workers directly exposed in the use applied for [annualised to € million per year] |  |
| Quantified impacts of the continuation of the SVHC use applied for on other actors |  | Monetised excess risks to the general population and indirectly exposed workers [annualised to € million per year] |  |
| Additional qualitatively assessed impacts |  | Additional qualitatively assessed risks |  |
| Aggregated socio-economic benefits  [annualised to € million per year] |  | Aggregated monetised excess risk [annualised to € million per year] |  |

**Table X: Benefit/ risk summary**

|  |  |
| --- | --- |
| Net benefits (€) |  |
| Benefit/monetised risk ratio |  |

[For PBT/vPvB substances, endocrine disruptors and other substances for which human health relevant end points were not estimated, describe the impacts in the table below.]

**Table X: Cost of non-use per kg and year (for PBT/vPvB substances and endocrine disruptors)**

|  |  |
| --- | --- |
|  | **Per year** |
| Total cost (€)[annualised to € million per year] |  |
| Total emissions (kg) |  |
| Ratio (€/kg) |  |

Notes:

1. “Total cost” (of non-authorisation) = Benefit of authorisation
2. “Total emissions” (if authorisation is granted) = Estimated emissions to the environment, kg per year from Section 10.2 of the CSR
3. “Ratio” = Total cost/Total emissions
4. Annualised to a typical year based on the time horizon that you used in the analysis

## Distributional impacts

(SEA Guidance: Chapter 4.2)

[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.

This analysis can be summarised in tables such as the one below.

Adapt the table below to your circumstances.]

**Table X: Distributional impacts**

|  |  |  |
| --- | --- | --- |
| **Affected group1** | **Economic impact** | **Health and environmental impact** |
| **Economic operator** | | |
| Applicant |  |  |
| Suppliers of alternatives in the EU |  |  |
| Suppliers of alternatives outside the EU |  |  |
| Competitors in the EU |  |  |
| Competitors outside the EU |  |  |
| Customer group 1 (identify2) |  |  |
| Customer group 2 (identify) |  |  |
| Public at large in the EU (identify) |  |  |
| **Geographical scope** | | |
| Region or Member State x |  |  |
| Region or Member State y |  |  |
| **Within the applicant’s business** | | |
| Employers/Owners |  |  |
| Exposed workers |  |  |
| Non-exposed employees |  |  |

Notes:

**1** Adapt the groups as relevant for your application.

**2**Identify group or groups as relevant. These may comprise the downstream or end users of the substance or the final customers of the products.

Severity of impacts: either monetary [annualised to € million per year] or using scale high (+++ or ---), medium (++ or --), low (+ or -) or not applicable (n/a)

## Uncertainty analysis

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

[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.

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

# CONCLUSIONs

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

1. the socio-economic benefits of continued use of the Annex XIV Substance;
2. residual risks to human health and the environment of continued use;
3. whether benefits of continued use outweigh the risks to human health and the environment;
4. 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;
5. 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[[10]](#footnote-10) 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.]

# REFERENCES

[Provide list of references]

Annex – Justifications for ConfidentialiTy Claims[[11]](#footnote-11)

[Include your justifications for confidentiality for each blanking that you have carried out in the “public version” of the SEA[[12]](#footnote-12). 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]

|  |  |  |
| --- | --- | --- |
| **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 |

[…]

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[[13]](#footnote-13);
* 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.]

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. The Committee for Risk Assessment [↑](#footnote-ref-5)
6. The Committee for Socio-economic Analysis [↑](#footnote-ref-6)
7. 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)). [↑](#footnote-ref-7)
8. Profit losses to be counted in only for the first [x] years, see SEAC note on economic surplus changes (not yet available). [↑](#footnote-ref-8)
9. Job losses to be accounted for only for the arithmetic mean period of unemployment in the concerned region/country as outlined in the SEAC paper on the valuation of job losses (See [The social cost of unemployment](https://echa.europa.eu/documents/10162/13555/seac_unemployment_evaluation_en.pdf/af3a487e-65e5-49bb-84a3-2c1bcbc35d25) and [Valuing the social costs of job losses in applications for authorisation](https://echa.europa.eu/documents/10162/13555/unemployment_report_en.pdf/e0e5b4c2-66e9-4bb8-b125-29a460720554)). [↑](#footnote-ref-9)
10. 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)). [↑](#footnote-ref-10)
11. This annex will not be made publicly available as part of the broad information on uses package [↑](#footnote-ref-11)
12. 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-12)
13. Sharing and publishing supply chain specific information may be subject to competition rules. [↑](#footnote-ref-13)