Format for

ANALYSIS OF ALTERNATIVES

and

**Socio-economic analysis**

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

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

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

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

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

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

**CONTENTS**

[Please generate table of contents.]

**TABLES**

[Please insert here the list of tables.]

**FIGURES**

[Please insert here the list of figures.]

**LIST OF ABBREVIATIONS**

[Please insert here the list of abbreviations.]

# DECLARATION

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

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

Signature: Date, Place:

# SUMMARY

[Insert text here]

# AIMS AND SCOPE

[Insert text here]

# ANALYSIS OF ALTERNATIVES

## SVHC use applied for

[Insert text here]

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

[Insert text here]

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

[Insert text here]

### Annual volume of the SVHC used

[Insert text here]

## Efforts made to identify alternatives

### Research and development

[Insert text here]

### Consultations with customers and suppliers of alternatives

[Insert text here]

### Data searches

[Insert text here]

### Identification of alternatives

[Insert text here]

### Shortlist of alternatives

[Insert text here]

**Table X: Shortlisted alternatives**

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

## Assessment of shortlisted alternatives

### Alternative 1: [name]

[Insert text here]

#### General description of Alternative 1

[Insert text here]

#### Availability of Alternative 1

[Insert text here]

#### Safety considerations related to using Alternative 1

[Insert text here]

#### Technical feasibility of Alternative 1

[Insert text here]

#### Economic feasibility of Alternative 1

[Insert text here]

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

[Insert text here]

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

## Conclusion on shortlisted alternatives

[Insert text here]

# SOCIO-ECONOMIC ANALYSIS

## Continued use scenario

### Summary of substitution activities

[Insert text here]

### Conclusion on suitability of available alternatives in general

[Insert text here]

### Substitution plan

#### Factors affecting substitution

[Insert text here]

#### List of actions and timetable with milestones

[Insert text here]

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

[Insert text here]

#### Conclusions

[Insert text here]

#### References

[Insert text here]

### R&D plan

[Insert text here]

## Risks associated with continued use

[Insert text here]

### Impacts on humans

[Insert text here]

### Impacts on environmental compartments

[Insert text here]

### Compilation of human health and environmental impacts

[Insert text here]

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

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

Notes:

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

Table X: Summary of remaining releases to the environment.

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

## Non-use scenario

[Insert text here]

### Summary of the consequences of non-use

[Insert text here]

### Identification of plausible non-use scenarios

[Insert text here]

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

[Insert text here]

## Societal costs associated with non-use

### Economic impacts on applicants

[Insert text here]

### Economic impacts on the supply chain

[Insert text here]

### Economic impacts on competitors

[Insert text here]

### Wider socio-economic impacts

[Insert text here]

### Compilation of socio-economic impacts

[Insert text here]

Table X: Societal costs associated with non-use

|  |  |
| --- | --- |
| **Description of major impacts** | **Monetised/quantitatively assessed/qualitatively assessed impacts** |
| 1. **Monetised impacts** | **€ [per year1] [Over x years]** |
| Producer surplus loss due to ceasing the use applied for  *OR*  Investment and/or additional production costs related to the adoption of an alternative |  |
| Relocation or closure costs |  |
| Loss of residual value of capital[[1]](#footnote-2) |  |
| Social cost of unemployment16 |  |
| Spill-over impact on surplus of alternative producers17 |  |
| Please specify |  |
| **Sum of monetised impacts** |  |
| 1. **Additional quantitatively assessed impacts** | **[Per year] [Over x years]** |
| Please specify |  |
| 1. **Additional qualitatively assessed impacts** |  |
| Please specify |  |

## Combined impact assessment

[Insert text here]

Table X: Societal costs of non-use and risks of continued use

|  |  |  |  |
| --- | --- | --- | --- |
| **Societal costs of non-use** | | **Risks of continued use** | |
| Monetised impacts  (€ [per year1] [over x years]) |  | Monetised excess risks to directly and indirectly exposed workers  (€ [per year2] [over x years]) |  |
| Additional quantitatively assessed impacts  ([per year][over x years]) |  | Monetised excess risks to the general population  (€ [per year2] [over x years]) |  |
| Qualitatively assessed impacts  ([per year][over x years]) |  | Qualitatively assessed risks  ([per year][over x years]) |  |
| **Summary of societal costs of non-use** |  | **Summary of risks of continued use** |  |

Notes:

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

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

|  |  |
| --- | --- |
|  | **[Per year4] [Over x years]** |
| Total costs1 (€) |  |
| Total releases2 (kg) |  |
| Ratio3 (€/kg) |  |

Notes:

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

## Sensitivity analysis

[Insert text here]

## Information to support for the review period

[Insert text here]

# CONCLUSION

[Insert text here]

# REFERENCES

[Insert text here]

# ANNEX – JUSTIFICATIONS FOR CONFIDENTIALITY CLAIMS

[Insert text here]

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

# APPENDICES

[Insert text here]

1. If profit losses have not been already accounted for. [↑](#footnote-ref-2)