#

Format for

ANALYSIS OF ALTERNATIVES
AND SOCIO-ECONOMIC IMPACTS

 use in THE PRODUCTION OF legacy spare parts/in the repair of articles and complex products no longer produced

**Legal name of applicant:** *[Legal name of applicant]*

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

**Use title:**  *[Include use title][[1]](#footnote-2)*

**Date:** *[Include the date of submission]*

CONTENTS

PURPOSE OF THIS FORMAT

1. Use applied for 4

1.1. Role of the applicant 4

1.2. Use applied for 4

1.3. Description of the articles or complex products and the legacy spare parts 4

1.4. Analysis of substance function 5

1.5. Information for the length of the review period 5

2. Annual QUANTITY used 5

3. Justification 6

3.1. The article or complex product is no longer produced by the sunset date and the Annex XIV substance was used in its production 6

3.2. The article or complex product cannot function as intended without the spare part 6

3.3. The spare part cannot be produced without the substance, or the article or complex product cannot be repaired otherwise than by using the substance 7

3.3.1 Identification and suitability of alternatives 7

3.4. Conclusion 9

4. Analysis of impacts 9

4.1. Human health or environmental impact (risk associated with continued use) 9

4.2. Socio-economic benefits of the use applied for 10

4.3. Conclusion 11

Annex – Justifications for Confidentiality Claims 12

**PURPOSE OF THIS FORMAT**

This document provides a format for the analysis of alternatives and the socio-economic analysis to be used in applications for authorisation for uses of substances in the production of legacy spare parts or in the repair of articles or complex products no longer produced as well as in review reports[[2]](#footnote-3) concerning an authorisation granted for such uses, submitted in accordance with Commission Implementing Regulation (EU) 2021/876 of 31 May 2021[[3]](#footnote-4). Therefore, this simplified application format can only be used where the use applied for fulfils all the conditions in Article 1(a) or 1(b) of that Regulation.

**Declaration**

We, the Applicant, declare that we are aware of the fact that 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]) this 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.

We further declare that the use applied for fulfils the conditions of a use [in the production of legacy spare parts] [in the repair of articles or complex products no longer produced], as defined in the Commission Implementing Regulation (EU) 2021/876 of 31 May 2021 laying down rules for the application of Regulation (EC) No 1907/2006 as regards applications for authorisation and review reports for the uses of substances in the production of legacy spare parts and in the repair of articles and complex products no longer produced and amending Regulation (EC) No 340/2008.

Signature: Date, Place:

[NAME, TITLE]

# Use applied for

We, the applicant, need to use [Annex XIV substance name] [to produce spare parts for the repair of] [for the repair of] articles or complex products that are no longer produced by the sunset date referred to in Annex XIV and for which the substance was used in their production (referred to hereinafter as [“production of legacy spare parts”] [“repair of articles or complex products no longer produced”]).

## Role of the applicant

Our role in the supply chain is: [check the correct option below]

Upstream [ ]  manufacturer

 [ ]  importer

 [ ]  only representative

 [ ]  formulator

Downstream [ ]  downstream user

The use is performed by:

 [ ]  the applicant

 [ ]  downstream users of the applicant

## Use applied for

*[Provide the use title as in the cover page.]*

## Description of the articles or complex products and the legacy spare parts

*[Provide a succinct description of the articles or complex products associated with the use applied for, including an identification of the relevant legacy spare parts (in case the application is for the production of legacy spare parts) and type approvals related to the application (including dates and relevant legislation/standard). If needed, please use an Annex for the technical details.]*

## Analysis of substance function

*[Provide a description and analysis of the function of the substance (i.e. the task or job that the Annex XIV substance is performing, such as processing aid, extraction solvent, degreasing agent, corrosion inhibitor, swelling-agent or surfactant) and a justification for the need to use the substance (e.g. critical substance properties related to the desired function, quality criteria,* *process and performance constraints, customer requirements or legal requirements for technical acceptability) (required).]*

## Information for the length of the review period

*[Provide information about the remaining lifetime of the articles or complex products, as well as possible justifications related to the requested review period.]*

# Annual QUANTITY used

We are using the following quantity of the substance annually in the use applied for (in kg):

*[Indicate the average annual quantity used for the use applied for. If the quantity is confidential, indicate a meaningful range in brackets [x – y kg]. Provide the same amount as stated in section 9.4.1 of the CSR.]*

# Justification

Below we demonstrate that the articles or complex products are no longer produced by the sunset date that the substance was used in their production and that [the spare parts are needed for their repair, because the articles or complex products cannot function as intended without these spare parts and that the spare parts cannot be produced without that substance] [the Annex XIV substance is needed for their repair, because the articles or complex products cannot be repaired otherwise than by using that substance].

## The article or complex product is no longer produced by the sunset date and the Annex XIV substance was used in its production

*[Provide the justification demonstrating that the article or complex product (e.g. car, aeroplane):*

* *is no longer produced by the sunset date and*
* *that the Annex XIV substance was used in its production.]*

## The article or complex product cannot function as intended without the spare part

*[In case the application is for the production of legacy spare parts, provide the justification demonstrating that the article or complex product (e.g. car, aeroplane) cannot function as intended without the spare part]*

## The spare part cannot be produced without the substance, or the article or complex product cannot be repaired otherwise than by using the substance

*[Provide the justification demonstrating that:*

* *such spare part cannot be produced without the substance,*

*or*

* *the article or complex product cannot be repaired otherwise than by using the substance.]*
1.

### Identification and suitability of alternatives

The following sections underpin section 3.3.

#### List of alternative substances/technologies

We have searched for alternative substances and technologies that could replace [Annex XIV substance name] for the purpose of our use and have identified the following potential alternatives:

*[Provide the name and a brief description of each alternative substance or technology, add additional rows as needed.]*

|  |  |  |  |
| --- | --- | --- | --- |
| ***Number*** | ***Name*** | ***Type*** | ***Brief description (including CAS number and classification, if relevant)*** |
| 1 |  |  Substance Technology |  |
| 2 |  |  Substance Technology |  |
| … | … | … | … |

#### Suitability of alternatives

There are no suitable alternatives available[[4]](#footnote-5) to [produce legacy spare parts] [repair articles or complex products no longer produced] and therefore [the spare part cannot be produced without the substance] [the article or complex product cannot be repaired otherwise than by using the substance].

We have assessed the alternatives listed in section 3.3.1.1 and concluded that none of the alternatives are suitable because at least one of the following reasons applies for each alternative:

1. *The alternative is not technically feasible as it does not provide the same function at the level of technical performance necessary for the use applied for.*
2. *The alternative is not technically and economically feasible as it requires extensive testing and requalification or other specific legislative measures.*
3. *The alternative is not economically feasible.*
4. *The alternative does not lead to reduced overall risks to human health and the environment.*
5. *The alternative is not suitable because of other reasons (if so, please explain the reasons in the justifications below).*

*[Link each alternative listed in section 3.3.1.1 to at least one reason for non-suitability. In the justification column, provide the relevant technical, cost-related, risk-related or availability-related information why the alternative is not considered suitable. Add additional rows if needed. Alternatives with the same reason for non-suitability and the same justification may be grouped in one row.]*

|  |  |  |
| --- | --- | --- |
| ***Alternative(s)*** | ***Reason(s) for non-suitability*** | ***Justification*** |
|  | [ ]  a [ ]  b [ ]  c [ ]  d[ ]  e |  |
|  | [ ]  a [ ]  b [ ]  c [ ]  d[ ]  e |  |
| … | … | … |

## Conclusion

We have provided justifications that:

* The article or complex product is no longer produced by the sunset date and the Annex XIV substance was used in its production.
* The article or complex product cannot function as intended without the spare part (in case the application is for the production of legacy spare parts).
* [The spare part cannot be produced without the substance][, or] [the article or complex product cannot be repaired otherwise than by using the substance].

We have concluded that there are no suitable alternatives for the use applied-for. Taking into account the above, we have not prepared a substitution plan.

# Analysis of impacts

## Human health or environmental impact (risk associated with continued use)

We have considered the human health or environmental impact arising from the use of the Annex XIV substance with respect to the intrinsic properties specified in Annex XIV. Based on the information in the Chemical Safety Report (CSR) or extended Safety Data Sheet (eSDS), the human health or environmental impact of continued use is described as follows.

*[Provide a succinct description of the human health or environmental impact of the use of the Annex XIV substance with respect to the intrinsic properties specified in Annex XIV (required).]*

## Socio-economic benefits of the use applied for

We have considered the economic and social impacts of no longer being able to use [Annex XIV substance name] and have concluded that a refused authorisation would lead to additional costs or other negative economic impacts for our company, customers and/or society. By continuing the use of the substance, we would avoid these impacts; thus there would be a socio-economic benefit. The justification demonstrated under section 3 is hereby also taken into account.

*[Provide a succinct description of the economic and social benefits of the use applied for. Please include the economic and social impacts in case the authorisation is not granted i.e. what would happen to your company, customers, consumers and/or society if the authorisation was not granted (required). This should consider both positive and negative impacts. If available, provide estimates of the additional costs or other relevant impacts that would arise in the event of a refused authorisation. A justification should also be included demonstrating that the conditions set out in points (a) or (b) of Article 1 of this Regulation as appropriate have been fulfilled (you can refer to section 3, as appropriate).]*

## Conclusion

We have assessed the human health or environmental impacts associated with the continued use of the Annex XIV substance (section 4.1) and the socio-economic impacts that would occur in the event of a refused authorisation (section 4.2). Having compared the risk with the socio-economic benefits of the continued use of the substance, as described in these sections, we have concluded that the socio-economic benefit of the use of the substance outweighs the risk arising from its use.

# Annex – Justifications for Confidentiality Claims[[5]](#footnote-6)

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

1. If there is a formulation step, which is an integral part of the production of legacy spare parts or the repair of articles and complex products no longer produced, it is possible to include both uses in a single document. [↑](#footnote-ref-2)
2. This format may be adapted for the purpose of review reports. For review reports, please also submit an Explanatory note, available here: <https://echa.europa.eu/documents/10162/13637/explanatory_note_format_review_en.docx> [↑](#footnote-ref-3)
3. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2021.192.01.0003.01.ENG&toc=OJ%3AL%3A2021%3A192%3ATOC> [↑](#footnote-ref-4)
4. In paragraphs 72 and 73 of the EU General Court’s judgment of 7 March 2019, (Case T-837/16) the Court has provided key criteria to identify what a ‘suitable alternative’ is. Such an alternative should be safer (entailing a lower risk for human health and/or the environment). ‘Suitability’ is also not limited to the existence of an alternative *in abstracto* or in laboratory or exceptional conditions but relates to the availability of alternatives technically and economically feasible in the EU. Furthermore, the analysis concerning the feasible alternatives must be carried out from the perspective of the production capacities for those alternative substances and of the feasibility of those alternative technologies, as well as in the light of the legal and factual requirements for putting them into circulation. [↑](#footnote-ref-5)
5. This annex will not be made publicly available as part of the broad information on uses package. [↑](#footnote-ref-6)