Format for

SUBSTITUTION PLAN

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 template to use for both the “complete” and the “public” versions of the Substitution Plan Changes in Instructions and Legal note Addition of an Annex for justifications for confidentiality claims with instructions Changes in the Declaration Formatting and editorial changes
2.0	Change to preamble and instructions 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 the applicants for an authorisation/authorisation holders with instructions on how to organise and present their Substitution Plan. The Plan should show the applicant's/authorisation holder's commitment to take the actions needed to substitute the Annex XIV substance(s) with (a) suitable alternative substance(s) or technology(ies) (for uses for which a suitable alternative is available) within a specified timetable. The format asks the applicant/authorisation holder to present a detailed Substitution Plan for each use of the Annex XIV substance(s), where substitution is possible, and to include references to the Chemical Safety Report, the Analysis of Alternatives, the Socio-Economic Analysis and/or other sections of the application as appropriate. Detailed guidance on how to prepare a Substitution Plan is contained in the Guidance on the preparation of an application for authorisation, in Chapter 4 and Appendix 6.

The "public version" of the Substitution Plan 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.

Instructions

Please prepare two versions of the same Substitution Plan 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 Substitution Plan[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 Substitution Plan (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 Substitution Plan. Attach the zip file to the relevant use section in the IUCLID 5 file, section 3.10 – Application for authorisation of uses.

[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

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/authorisation holder'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/authorisation holder 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 developed in collaboration with our supplier a new generation of solvents that can be used in place of the Annex XIV substance. We have also developed a new technique for the use of these new solvents to manufacture end-products with a much higher degree of quality than that possible with commonly known mixtures and production techniques used by our competitors. This will be the unique selling point for our end-products. We have recently filed a patent application to protect our know-how and this patent will not be delivered before January 2017. At that date both our technique and the relevant markets will be mature enough to fully substitute the Annex XIV substance which will provide us with a distinct competitive advantage.

Demonstration of potential harm:

The dissemination of the delivery date of our patent, the identity of the new solvents and the date of their full availability, information on market considerations, and exact timetables of our substitution plan will reveal to our competitors the existence of the new generation solvents and/or the existence of our new technique, and that a patent is pending with indications on the delivery date. This would allow our competitors to attempt to buy the same solvents and/or begin to attempt to copy our novel production technique before our patent is delivered, thereby harming our market position and commercial interest.

Limitation to Validity of confidentiality:

The exact expected date of the delivery of our patent, the identity of the new solvents, and the exact timetables of our substitution plan should remain confidential until 1 January 2018 which is the expected date for the full substitution of the Annex XIV substance in the relevant markets.

Format for

SUBSTITUTION PLAN

Legal name of applicant(s):	*[Legal names of applicant(s)/authorisation holder(s)]*
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 has several uses which are NOT connected, 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 Substitution Plan 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]

INTRODUCTION

[Briefly summarise essential information about the use of the Annex XIV substance (as per the application) and its precise function(s) or task(s) performed. Include references to the Analysis of Alternatives and/or the Chemical Safety Report as appropriate.

State the suitable and available alternative selected to replace the Annex XIV substance for the used applied for. Indicate the section in the Analysis of Alternatives which discusses the alternative in detail.]

1. FACTORS AFFECTING SUBSTITUTION

(Guidance: Chapter 4.3.1 and Appendix 6 of the Guidance on the preparation of an application for authorisation)

[Describe the factors that influence the actions needed and/or the timing of substitution of the Annex XIV substance with the selected alternative (e.g., availability of the alternative, market considerations impacting the economic feasibility of the alternative, process changes and other considerations related to technical feasibility, etc.). Draw on the analysis presented in Section 2 and Section 5 of the Analysis of Alternatives. Include references to the Analysis of Alternatives and/or the Chemical Safety Report as appropriate.]

2. LIST OF ACTIONS AND TIMETABLE WITH MILESTONES

(Guidance: Chapters 4.3.2, 4.3.3, 4.3.4, and 4.3.5 and Appendix 6 of the Guidance on the preparation of an application for authorisation)

[Describe how the Substitution Plan will be implemented. Present the rationale behind each action/step towards substitution and its timetable. Indicate phasing (if relevant) and key milestones identifying the completion of key stages to allow progress to be measured. Present the start and end dates for the identified actions and a justification for the time allotted for the action to be implemented. Discuss uncertainties and factors that may hinder or accelerate the substitution, as well as how they have been addressed in the plan and timetable for substitution.]

3. MONITORING OF THE IMPLEMENTATION OF THE SUBSTITUTION PLAN

(Guidance: Chapter 4 and Appendix 6 of the Guidance on the preparation of an application for authorisation)

[Describe the system in place (or to be put in place) for monitoring and documenting the progress of the implementation of the identified actions included in this Substitution Plan.]

4. CONCLUSIONS

[Summarise your commitments to substitute the Annex XIV substance with the selected suitable and available alternative, the timetable for the transition to the alternative, milestones and critical factors influencing the substitution.]

5. REFERENCES

[Provide list of references]

ANNEX – JUSTIFICATIONS FOR CONFIDENTIALITY CLAIMS[4]

[Include your justifications for confidentiality for each blanking that you have carried out in the "public version" of the Substitution Plan[5]. 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 confidentiality***
Blank # 1	…	….
Blank # 2	…	…
…	…	…

Example:

Public version of the Substitution Plan - Page 4

Prediction of the evolution of the alternative substance price

Considering the current high market demand for the alternative and the limited supply, the market price for this alternative is at the moment very high. However, due to the increasing production capacity which is foreseen in the next five years the alternative market price will decrease which will allow a quicker conversion of all our reactors for processing the alternative substance. The prediction of the price evolution of the alternative is presented in Figure 3.2 below:

Blank #2

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

[5] 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.

Figure 3.2 Prediction of the price evolution of the alternative substance

Table of justification for confidentiality in the Annex of the "complete version" of the Analysis of Alternatives:

Blanked out item reference	***Page number***	***Justification for confidentiality***
Blank #1	*2*	*[insert here your justification]*
Blank #2	*4*	*[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[6];*
- *other organisations contacted;*
- *any other relevant information related to consultation.]*

_____

Additional appendices

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

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