Format for

SUBSTITUTION PLAN

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

Version 4.0

June 2020

Version	Changes
4.0	Changes in response to the conclusions of the General Court's judgments in cases T-837/16 and T-108/17
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

According to REACH Article 62(4)(f), if an authorisation applicant's/holder's Analysis of Alternatives shows that suitable alternatives are available, the application/review report should include a Substitution Plan with a timetable of proposed actions by the authorisation applicant/holder. This applies whether or not the authorisation applicant/holder can demonstrate adequate control of risks. According to Article 60(5), the technical and economic feasibility of alternatives for the applicant is only one factor, among others, playing a role in determining their suitability for substituting the Annex XIV substance. The General Court's judgments in cases T-837/16 and T-108/17 provide criteria to determine what a suitable alternative is. In response, the Commission services have contacted several applicants, requiring them to submit a substitution plan for their uses applied for and explaining the situation in detail[1]. Please note that a suitable alternative as defined by the criteria set out by the General Court presents de facto an obligation to submit a substitution plan. A substitution plan is not required where there are no suitable alternatives.

This document provides authorisation applicants/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) within a specified timetable. It is important to consider that the expectation towards a Substitution Plan depends on the specific use the applicant applies for and on the conclusions of the Analysis of Alternatives.

a) *If the Analysis of Alternatives identifies an alternative which (based on preliminary or conclusive studies) is expected to be implemented within a foreseeable time period after the Sunset Date/end of the current review period (due to economic or other use-specific constraints), the Substitution Plan should set out the steps it will do to switch to the alternative.*

b) *If the Analysis of Alternatives identifies a suitable alternative for the use applied for/authorised, which is available in general in the EU but not feasible for the authorisation applicant/holder and/or for its downstream users[2], the Substitution Plan should set out what it will do in the future (assuming the authorisation is granted/extended) to try and make that alternative (or another alternative) suitable from its (and its downstream users') perspective.*

The format asks the authorisation applicant/holder to present a detailed Substitution Plan which is meaningful and relevant to the scope of the use (or to a specific utilisation) of the Annex XIV substance, where an alternative has been identified for adoption.

Where a suitable alternative has been identified for a use but is deemed not currently feasible for the authorisation applicant/holder, the format asks for a detailed Substitution Plan with a clear and credible timeline of the steps it will take to try and make that alternative (or another identified alternative) technically and economically feasible from its and its downstream users' perspective. It is, however, acknowledged that whilst a Substitution Plan is a commitment to take the actions needed to substitute the Annex XIV substance with a suitable alternative substance or technology within a specified timetable, it is not mandatory to have substituted the use of the substance by the end of the review period as long as this is duly justified.

[1] See the following Commission note: https://echa.europa.eu/documents/10162/13637/ec_note_suitable_alternative_in_general.pdf/5d0f551b-92b5-3157-8fdf-f2507cf071c1.

[2] Downstream users covered by the application/authorisation submitted/granted to an actor up their supply chain in line with Article 56 (2) of REACH.

When a detailed description of all steps is not possible because later steps in the substitution process are contingent on the initial steps being successful, then subsequent actions can be presented in an outline form. Moreover, the authorisation applicant/holder may choose to investigate several alternatives in parallel and only choose at a later stage the most suitable one amongst them. This is acceptable as long as the actions towards identifying and investigating the alternatives are clearly listed.

The format asks for 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[3], in Chapter 4 and Appendix 6.

If the Analysis of Alternatives concludes that there is no suitable alternative which is available in general in the EU, a Substitution Plan is not required. However, the authorisation applicant/holder might still wish to include a R&D plan that describes what research (and eventually substitution activities) it plans to undertake towards substitution.

Instructions

It is recommended that the authorisation applicant/holder prepares only a single version of the Substitution Plan which does not include any confidential information. However, if it is strictly necessary to include confidential information, prepare two versions of the same Substitution Plan for each use applied for: a 'complete version' that contains confidential business information and another 'public version' where confidential business information is blanked out[4].

ECHA will publish on its website the public version as part of the information provided for external consultation. Save your work in a separate (unprotected[5]) Word (doc), Acrobat (pdf) or rich text file (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, except that the parts containing confidential business information are blanked out in the public version. In the 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 to be made to your justifications why the information should not be made publicly available. These justifications should be provided in an annex to the complete version of the Substitution Plan[6]. 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).

In the context of the preparation of the package on broad information on uses applied for, and with a view to having a meaningful stakeholder consultation on alternatives, ECHA reserves the right to reject unsubstantiated confidentiality claims and to require meaningful information (e.g. ranges) in the public version of the Substitution Plan.

[3] https://echa.europa.eu/documents/10162/23036412/authorisation_application_en.pdf.

[4] In this document the term 'blanked out' is used as a synonym of the term 'redacted' which is often used in similar contexts.

[5] Please enable printing and copying of text for the complete version and printing only for the public version.

[6] 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 version 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.

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 authorisation applicant's/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 authorisation applicant/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. The 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 authorisation applicant(s)/ holder(s)]*
Submitted by:	*[Legal name of submitting authorisation applicant/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/authorisation has several uses which are NOT connected, separate documents should 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

The Applicant [Authorisation Holder] 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 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. One of the following scenarios is likely to apply:

- *If the authorisation applicant/holder has identified an alternative for possible implementation to replace the Annex XIV substance for the use applied for/authorised, state the alternative and indicate the section in the Analysis of Alternatives which discusses the alternative in detail.*

- *If the authorisation applicant/holder has identified a suitable alternative which is available in general, but which is not (yet) technically or economically feasible for replacing the Annex XIV substance in the use applied for/authorised, state the alternative and indicate the section in the Analysis of Alternatives which discusses the alternative in detail.*

- *If the authorisation applicant/holder has concluded that there is no suitable alternative which is available in general, but wishes to include a R&D plan to outline the proposed efforts to develop one (or several) that might become suitable in the future for possible implementation, indicate the section(s) in the Analysis of Alternatives which discusses the alternative(s) 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/identified alternative(s). This could include the outcome of R&D and testing, 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 in detail how the Substitution Plan will be implemented. Present the rationale behind each action towards substitution and its timetable. Indicate phasing (if relevant) and key milestones identifying the completion of key actions 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 actions to be implemented. Consider how the length of the review period might impact the completion of the substitution, and how it corresponds to the Substitution Plan and the potential need for re-authorisation after the review period, should the authorisation be granted. Discuss dependencies, 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.

The required content of the substitution plan and the concreteness of the commitment to substitute will depend on several factors:

- *Where it is clear that a suitable alternative that is available in general will become feasible for the applicant or his downstream users within a certain timeline, the substitution plan should contain a corresponding clear and credible timeline to substitute the use of the substance. The substitution plan may be updated as part of a review report, and justification provided regarding the reason why it was updated.*

- *Where substitution depends on the results of ongoing research, development or testing, the substitution plan should contain a commitment to undertake the necessary actions to undertake research on, develop or test alternatives to make them technically and economically feasible for the applicant, with a clear timetable, following the indications provided in this document and the ECHA Guidance on the preparation of an application for authorisation[7]. For actions later in that timetable, it is accepted that those may depend on the outcome of earlier actions.*

- *Where it is clear that a suitable alternative available in general cannot become technically or economically feasible for the applicant in a short or medium term, the applicant should still submit a substitution plan, explaining why substitution can only take place over a longer time horizon (e.g. when building a new plant or after the end of lifetime of the product). Obviously, such a long-term substitution plan also needs to have a credible timeline. However, it is understood that steps towards substitution are less certain and the time it takes for each step to be finalised is necessarily indicative.*

- *If an authorisation holder does not manage to achieve substitution within the scheduled timetable, it should provide the justified reasons for such delays in the updated substitution plan as part of the review report; e.g., if a R&D program did not lead the alternative to achieve the required key functionalities or if the construction of the necessary machinery or equipment has not been finalised for specific reasons, etc.*

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 towards substitution (when possible) the Annex XIV substance with the selected/identified alternative(s), the timetable for the transition to an alternative, milestones and critical factors influencing the substitution.]

[7] https://echa.europa.eu/documents/10162/23036412/authorisation_application_en.pdf.

5. REFERENCES

[Provide list of references]

ANNEX – JUSTIFICATIONS FOR CONFIDENTIALITY CLAIMS[8]

[Include your justifications for confidentiality for each blanking that you have carried out in the public version of the Substitution Plan[9]. 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:

Figure 3.2 Prediction of the price evolution of the alternative substance

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

[9] ECHA may assess your justification in the context of the preparation of the package of information containing broad information on uses applied for and other information made available for external 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 (EC) No 1049/2001.

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;*[10]
- *other organisations contacted;*
- *any other relevant information related to consultation.]*

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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.]

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