ECHA
EUROPEAN CHEMICALS AGENCY

Submission of information on alternatives by interested third parties for the public consultations on alternatives for Applications for Authorisation

Instructions & Format

Version	Changes	Date
Version 2.0	Updated instructions and template how to organise the information by using “Complete version” and “public version”. Included section regarding the categorisation of the comments.	November, 2015
Version 1.0	First version.	March, 2013

Legal notice

This document provides practical and technical guidance on submitting information for the public consultation on alternatives to an Annex XIV substance use applied for in Applications for Authorisation. However, users are reminded that the text of the REACH Regulation and any related EU legislation are the only authentic legal references and that the information in this document does not constitute legal advice. The European Chemicals Agency does not accept any liability with regard to the contents of this document.

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If you have questions or comments in relation to this document please send them (quote the reference and issue date) using the information request form. The information request form can be accessed via the Contact ECHA page at: http://echa.europa.eu/contact
http://echa.europa.eu/contact

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A. INTRODUCTION

A.1. Preamble

The purpose of this document is to provide interested third parties with further guidance on submitting information for the public consultation on alternatives to an Annex XIV substance use applied for in Applications for Authorisation under Title VII of the REACH Regulation. The document consists of instructions about:

a) how to technically submit information on alternatives (via a secure webform on ECHA's website) and
b) how to organise the information to be submitted (using "*complete version*" and "*public version*").

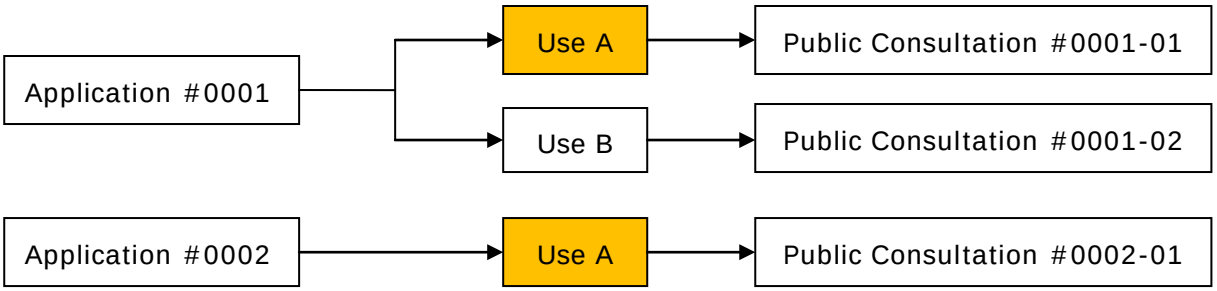
A.2. Purpose of the public consultation on alternatives

The public consultation for Applications for Authorisation is defined in article 64.2 of the REACH Regulation. Its purpose is to gather additional information on possible alternatives for the uses applied for. The information submitted by interested third parties will be taken into account in the development of the opinion for the relevant Applications for Authorisation by the Committee for Risk Assessment (RAC) and the Committee for Socio-Economic Analysis (SEAC).

Each public consultation on alternatives will last eight weeks.

A separate public consultation is held for each combination of a use and application. Therefore, Applications for Authorisation for several uses will have several concurrent public consultations. As there may be several separate applications for the same or similar use, there may be several public consultations on the same or similar use. Please see Figure 1 below for an example.

Figure 1: Sample organisation of the public consultations by application and use[1]



[1] In rare cases, it may be necessary to open separate consultations for each combination of a substance, use and application, e.g., there may be two separate consultations for Application 001, Use A, Annex XIV substance 1 and Application 001, Use A, Annex XIV substance 2 (if Use 2 covers 2 Annex XIV substances).

B. PREPARATION OF YOUR SUBMISSION

B.1. How to submit information during the public consultation on alternatives?

Interested third parties can submit information via a secure webform on ECHA's website. The webform gathers minimum information about the 'alternative' to facilitate the publication of the submitted information in an organised manner.

According to the *Guidance on the preparation of an application for authorisation*, an alternative is defined as another substance or a technique (e.g. a process, procedure, device, or modification in end product) or a combination of technical and substance alternatives to an Annex XIV substance. For example, a technical alternative could be a physical means of achieving the same function of the Annex XIV substance or perhaps changes in the production, process or product that removes the need for the Annex XIV substance function altogether.

Detailed information on the alternative and further analysis on its suitability to replace the Annex XIV substance for a specific use should be provided in an attachment to the webform, using the *format for third party submission of information on alternatives*. Appendix I shows the format, which outlines the information on alternatives that the Committees will find beneficial for the assessment of Applications for Authorisation. Please follow the format and provide information on all topics to the extent possible, although all meaningful submissions will be given consideration.

Your submission should always contain a *"public version"* attachment. If you wish to provide further information which should not be made public you have the possibility to submit a *"complete version"* in addition to the *"public version"* [2].

Submitting information on alternatives in a "*public version*" is important in order to allow ECHA to fully utilize the information provided. Instances where the *"public version"* plays an important role are:

a) to ask applicants follow-up questions

According to the REACH Regulation the technical and economic feasibility is determined from the applicant's perspective (Art. 60.5, Art. 62.4.e). Therefore, RAC and SEAC will likely require the applicants to respond to whether the alternatives identified in the third party submissions are technically and economically feasible for them.

b) to communicate the final opinion of RAC and SEAC on the granting of an authorisation

The ECHA Committees will formulate their opinion on the availability of suitable alternatives by taking into account the "*complete version*" of your submission, if one is provided. However, when preparing their final opinion on the granting of an authorisation for the uses applied for, the Committees can refer only to the "*public version*" attachment.

The "*public version"* parts of the submissions will also serve to improve transparency and to enhance the publicly available information on possible alternatives to the Annex XIV substances. They will be published on ECHA's website with the objective to facilitate the progressive substitution of the substances of very high concern (SVHC) with suitable alternative substances or technologies.

[2] Please keep in mind that it is the responsibility of the submitter to ensure that no confidential information is included in the "public version" of the provided comments. ECHA will not check whether confidential information was removed.

B.2. Evaluation of the submissions for the public consultation on alternatives

Once submitted, the Committees will evaluate the submitted information/analysis on possible alternatives to the Annex XIV substance. It will be assessed in terms of its:

- ***relevance***, i.e., whether the submission is relevant for the consultation (application case) as described in the broad information on uses package published on ECHA's website for the purpose of a public consultation on alternatives for the uses applied for authorisation;
- ***quality and clarity***, i.e., whether sound and well-justified methodology and assumptions are included.; and
- ***completeness***, i.e., whether the technical and economic feasibility of using an alternative as well as its capability to reduce the overall risk in comparison to the Annex XIV substance are discussed.

B.3. What submitted information will be published on ECHA's website?

The non-confidential information interested third parties submit via the webform will be published on ECHA's website. The webpage Comments submitted to date shows the information that will be published unless you have marked it confidential by clicking the relevant checkboxes.

The following information submitted via the webform on public consultation will always be considered non-confidential and will be published automatically on ECHA's website:

- the submission type, i.e., whether the submission is on behalf of an organisation, or a company or an individual;
- type of organisation or company and its role in the supply chain;
- type of alternative: substance (on its own or in a mixture) and technical alternative: (a technology, process, procedure, device, modification of end product, or other solutions; or a combination of a substance/mixture and a technology, process, procedure, device, modification of end product, or other solutions);
- generic name of the alternative and/or brief description of the technical alternative;
- classification and labelling information, according to the Classification, Labelling and Packaging Regulation (CLP), the Dangerous Preparations Directive (DPD), or the Globally Harmonised System (GHS);
- type of comment; and
- the "*public version"* attachment.

Third parties can mark the following information confidential: name (and country of legal establishment) of your organisation/company, EC, CAS and IUPAC name of the alternative substance. If this information is not marked confidential by the submitter, it will be published automatically on ECHA's website after submission.

Personal information (first and last name, email address and country of the submitter) and information marked confidential (submitted in the "*complete version*" attachment or flagged confidential in the webform fields by clicking the checkboxes) will not be published on our website.

In this document, a "technical alternative" is defined as an adaptation or a change in the technology, process, procedure, device, modification of end product or other solutions necessary to replace or remove the need for the Annex XIV substance for the use applied for by the applicant.

B.4. How to prepare a "*public version*" and a "*complete version*" of your submission?

If all the information of your submission can be made public there is no need to prepare a "*complete version*" of your submission, the "*public version*" is sufficient. However, if you wish to provide further information which should not be made public, you have to prepare a "*complete version*" in addition to the "*public version*".

In this case, the two versions of the document should be identical apart from the fact that the parts containing confidential 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 to the "*complete version*" of your submission (do not include this annex in the "*public version*"). Further instructions on blanking out and justifications for confidentiality are provided below and in the Annex to this document. The same approach should be taken for all documents provided as annexes to submission (except for the annex with the justifications for confidentiality).

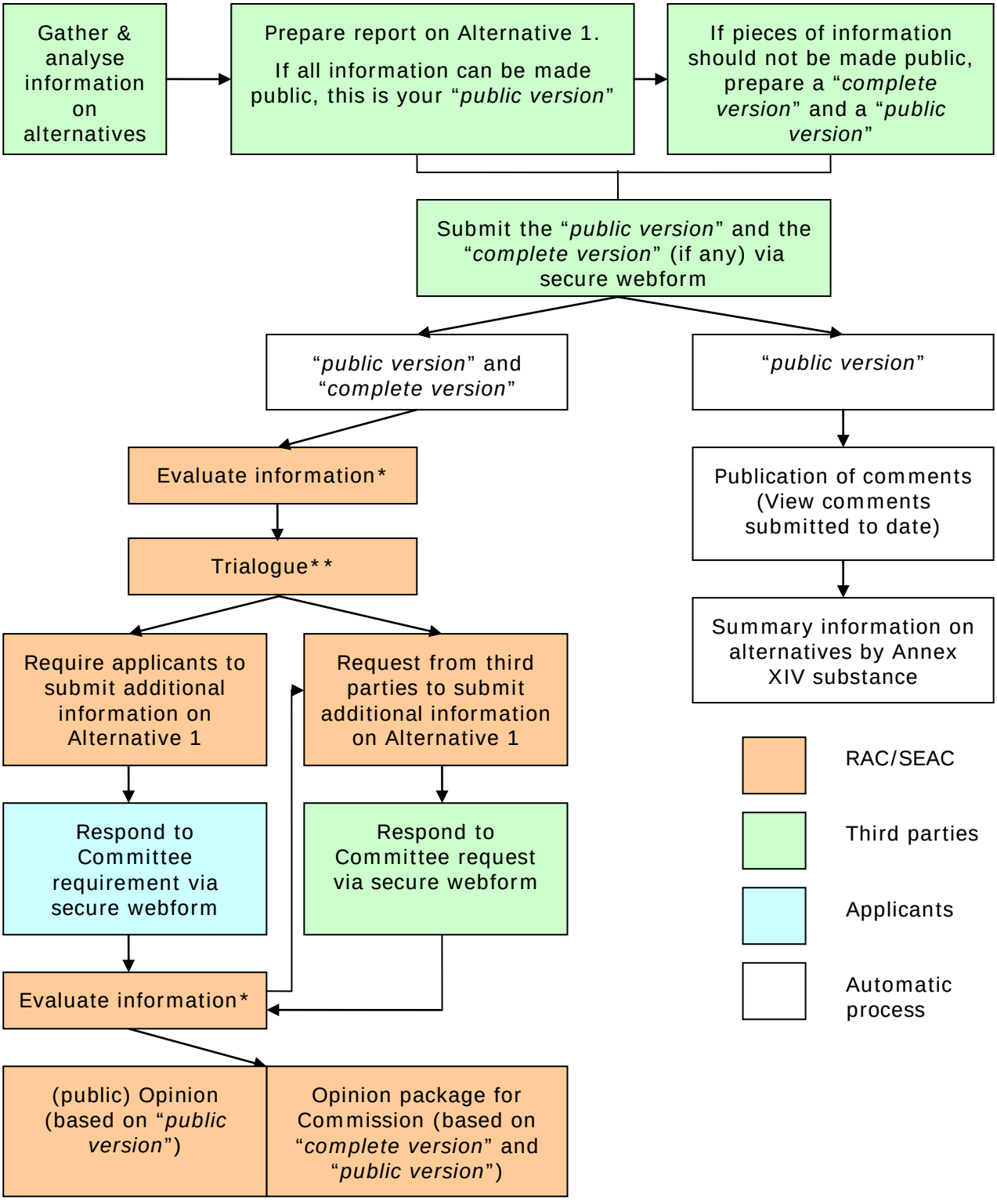
In summary, if you wish to submit information which should not be made public: prepare two versions of your contribution: one version – i.e. the "*complete version*"– that contains confidential information and another – "*public version*" – where confidential information is blanked out. Save your work in a separate (unprotected) 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).

Please note that the ECHA Committees will formulate their opinion on the availability of suitable alternatives taking into account your "*complete version*" attachment, if one is provided. However, when asking the applicant(s) for clarifications on possible alternatives and when preparing the final opinion, the Committees can refer only to the information submitted by you which has been deemed non-confidential. For this reason, please ensure that you provide a comprehensive "*public version*" of your submission.

B.5. Consultation process from a third party perspective

Figure 2 below describes the process for the preparation, submission, and processing of the information on alternatives for the public consultation on Applications for Authorisation.

Figure 2: Overview of the process on public consultation on alternatives for Applications for Authorisation



* The information submitted during the public consultation is evaluated in conjunction with the information submitted in the application for authorisation.
**The RAC and SEAC rapporteurs may request a discussion with the applicant(s) on technical or scientific issues in their application. Stakeholder observers and/or third parties who have submitted information on alternatives as part of the public consultation may also be invited. See *Participation of applicants, third parties and stakeholder observers in the application for authorisation process*.

B.6. Justification for confidentiality

Please note that any information submitted to ECHA is subject to Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents. Therefore, interested third parties submitting confidential information during the public consultation on alternatives are required to provide a justification for confidentiality in an annex to their "*complete version*" attachment ("Annex – Justifications for confidentiality claims"). If the submitter's justification is sufficient and falls under one of the exceptions envisaged in Regulation 1049/2001, there will in principle be no need to request further clarification from the submitter why a request for access to part or all information marked confidential in the submission should be denied.

The submitter's justification for confidentiality should contain the following three elements:

Demonstration of Commercial Interest:
[Description of the nature of the third party commercial interest and demonstration that this commercial interest is worthy of protection by the non-disclosure of information. Demonstration of any specific measures the submitter 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.]

The following is an example of how third parties can write their justification for confidentiality:

Demonstration of Commercial Interest:
We have sourced supplies of a new generation of low flammability solvents. Mixtures of these solvents and the Annex XIV substance can be used within a specific range of 150-165°C in a particular process developed in-house to manufacture end-products with a much higher degree of quality compared to our competitors, which is the unique selling point for our end-products. Our new generation mixtures in combination with our new technique (not yet patented) provide end-products with a level of quality much higher than that possible with commonly known mixtures and production techniques. This provides us with a distinct competitive advantage on the relevant markets.

Demonstration of Potential Harm:
The dissemination of the temperature range of the process will reveal to our competitors the existence of new generation solvents and/or the existence of our new technique that can be used at higher temperatures than those commonly known. This would allow our competitors to attempt to buy the same solvents and/or begin to attempt to copy our novel production technique, thereby harming our market position, our commercial interest and would deprive the financial investments that we have made over the past 5 years of its value.

Limitation to Validity of Confidentiality:
The temperature range should remain confidential until 1 January 2016, which is the expected date for the use of Annex XIV substance under this high temperature technique to be patented and the market to be mature enough.

B.7. Additional guidance and information sources to prepare your submission

Interested third parties are advised to begin their preparation for submission of information on alternatives by consulting the *Guidance on the preparation of an application for authorisation*. The overall context within which third parties may wish to provide information on alternatives is discussed in *Chapter 5. Guidance for third parties on submitting information on alternative substances or technologies.* Guidance on how to conduct an analysis of alternatives is included in *Chapter 3. Planning for substitution: guidance on analysis of alternatives*. Although this chapter is directed primarily at applicants for authorisation, interested third parties may find useful advice on how to gather and analyse information on alternatives.

The ECHA webpage on Authorisation (http://www.echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation) contains information on the identification of SVHCs, recommendations for inclusion in the Authorisation list and Annex XIV (the Authorisation list). These pages can provide third parties with background information on the substances included on Annex XIV.

Information on ongoing consultations is available on the ECHA webpage *Consultations: Applications for Authorisation* (http://www.echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/applications-for-authorisation). It is important that your submission is tailored to the specific consultation on the use applied for. Detailed information on the use can be accessed from the button “Details” in the Consultation table. See section C.2 of this document for further details.

C. INSTRUCTIONS TO SUBMIT YOUR COMMENTS

To submit information on alternatives follow the steps described below:

C.1. Review the ongoing consultations for Applications for Authorisations published on our website **Consultations: Applications for Authorisation** (http://www.echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/applications-for-authorisation)

Sort the table by clicking on the arrows beside each column title to find consultations for the same substance, applicant, or use.

Each consultation represents a separate combination of use applied for and application.[3] For instance if an application is made for three uses of the same substance, three consultations will be initiated. Therefore if ECHA has received different applications at the same time for the same substance and same (or similar) uses, it is theoretically possible to have several ongoing consultations that appear similar but actually correspond to different applications.

C.2. Click on Details in the last column of the Consultation table to view detailed **Information on use applied for in Applications for Authorisation**.

C.3. Once you have chosen the use for which you would like to provide comments and have familiarised yourself with all information on the use applied for in the table **Information on**

[3] In rare cases, it may be necessary to open separate consultations for each combination of a substance, use and application, e.g., there may be two separate consultations for Application 001, Use A, Annex XIV substance 1 and Application 001, Use A, Annex XIV substance 2 (if Use 2 covers 2 Annex XIV substances).

use applied for in Applications for Authorisation, note its consultation number and click on **Give comments** in the last row of the table.

⚠ Note the consultation number(s) for which you would like to submit information on an alternative. You will need to specify this number in the **Webform to submit comments**.

You may also wish to review all comments submitted to date for this consultation in order to avoid duplicating submissions. You can do so by clicking **View comments submitted to date** in the last row of the table **Information on use applied for in Applications for Authorisation** (see above).

Consultation

Summary

The following comments have been submitted to date as part of the public consultation on alternatives for Applications for authorisation. ECHA accepts no responsibility or liability with regard to the information (including attachments) presented below.

For details on the public consultation process, please refer to Applications for Authorisation.

Substance name	
EC Number	
CAS Number	
Entry Nr in Annex XIV	
Broad information on use applied for (title)	
Consultation number	
Applicant name(s)	
Consultation period	
Response to comments by applicant	

Comments

#	Submitter	Alternative			Attachments
		General info	Description of technology	Classification and Labelling	
Ref.No: **Date:** **Type of comment:**	**Affiliation:** organisation **Type/ Role in supply chain:** Non-governmental organisation (NGO) **Name of org/company:** **Country:** Sweden	**Type:** **Generic name:** **EC number:** **CAS number:**			Download

C.4. After clicking on **Give comments** from the **Information on use applied for in Applications for Authorisation** web page (see step C.3.), you will be taken to the page **Public consultation on alternatives for Applications for authorisation: Webform to submit comments**.

Public consultation on alternatives for Applications for authorisation: Webform to submit comments

Using the webform below you may submit your comments for the public consultation on alternatives to an Annex XIV substance for the uses for which ECHA has received applications for authorisation. For details on the public consultation process, please refer to Applications for Authorisation webpage.

You are requested to provide basic information on possible alternative(s) in the webform below and more detailed information in a "complete version" and a "public version" of your submission as separate attachments.

Instructions on how to organise and submit the information on alternatives are available in the document:
Submission of information on alternatives by interested third parties for the public consultations on alternatives for Applications for Authorisation

The same document outlines what sections of your submission will be published on ECHA's website.

The following formats can be used to organise in an attachment the "complete version" and the "public version" of the information on the alternative you wish to present:
- Format for third party submission of information on alternatives ("complete version")
- Format for third party submission of information on alternatives ("public version")

☐ I agree with the Terms and Conditions of this webform.

Compulsory fields are marked with an asterisk (*).

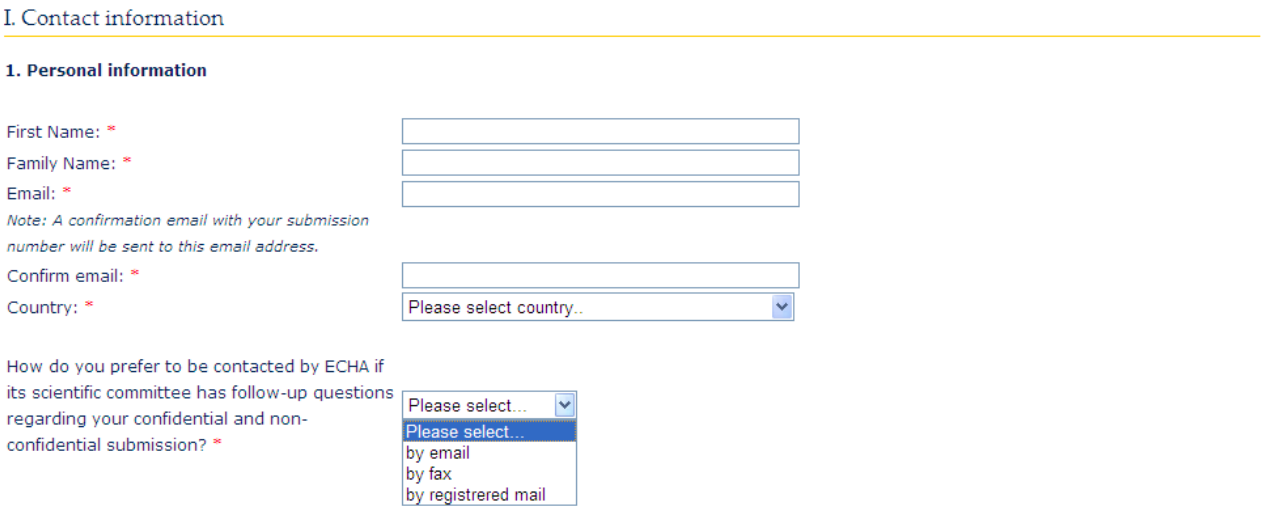
Fill out the secure **webform** by following the steps described below. Fields marked by "*" are mandatory:

C.4.1. Contact information

1. Personal information

Fill in your contact details in the appropriate fields. Select how you would prefer to be contacted by ECHA in the event its scientific committees have follow-up questions. Please note that in order to ask clarifying questions, the Committees may have to refer to confidential information in your submission. Therefore, ensure you select the method that provides the best protection of the confidentiality of the information in your submission.

The personal information in this section will not be published on ECHA's website.



I. Contact information

1. Personal information

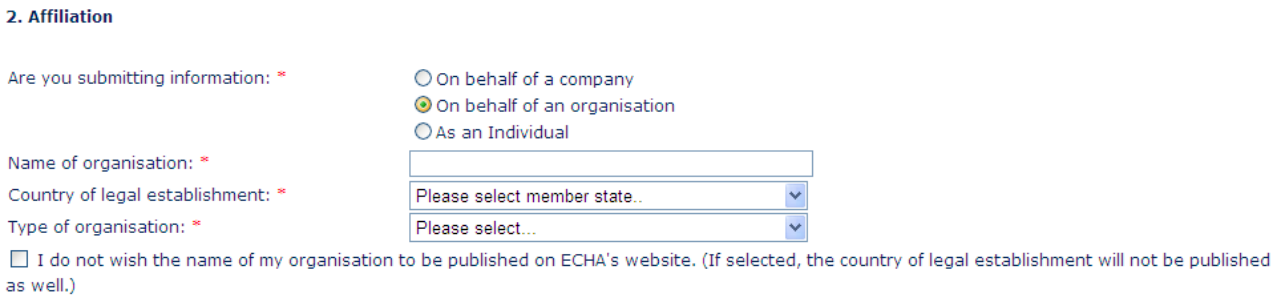
First Name: *
Family Name: *
Email: *
Note: A confirmation email with your submission number will be sent to this email address.
Confirm email: *
Country: * Please select country..

How do you prefer to be contacted by ECHA if its scientific committee has follow-up questions regarding your confidential and non-confidential submission? *
Please select...
Please select...
by email
by fax
by registrered mail

2. Affiliation

Select whether the information you are submitting is on behalf of a company, organisation, or an individual. Your selection will be published on ECHA's website.

Your selection will open additional fields for you to fill out the name of your company or organisation, role in the supply chain or organisation type, and country of legal establishment. The role in the supply chain or organisation type will always be published on ECHA's website. Tick the selection box below if you do not wish your company or organisation name to be published on ECHA's website. In this case, the country of legal establishment will not be published as well.



C.4.2. Comments

1. Alternative

The purpose of this section is to provide minimum information about the alternative to facilitate the publication of the submitted info in an organised manner. Detailed information on the alternative and further analysis on its suitability to replace the Annex XIV substance for a specific use should be provided in an attachment using the *Format for third party submission of information on alternatives.*

The webform is designed for submission of information on one alternative at a time that can be applicable to one or several ongoing consultations. After you submit the information for the first alternative, you will be given the opportunity to add another alternative that is applicable to one or several ongoing consultations. This step can be repeated.

1.1. Type of alternative

Select the appropriate checkbox(es). Multiple selections are accepted depending on the possible cases described below.

a) Alternative is a substance on its own: Select **Substance** and **On its own**, if your alternative is a substance that is used on its own to replace the Annex XIV substance for the use in question (i.e., "drop-in" or "direct" substitute).[4] You can also select **Technical alternative**, if you wish to also describe any adaptations or changes in the technology, process, procedure, device, modification of end product or other solutions necessary to replace or remove the need for the Annex XIV substance for the use applied for by the applicant.

[4] Consult for information on EC/CAS or chemical name: http://echa.europa.eu/information-on-chemicals.

1. Alternative

1.1 Type of Alternative

Is the alternative: *
Note: For instructions on how to define your alternative, please consult the document: Guide to third party submission of information on alternatives.

- ☑ Substance
  - ◉ on its own
  - ○ in a mixture
- ☑ Technical alternative (i.e., an adaptation or a change in the technology, process, procedure, device, modification of end product or other solutions)

1.2. Information on the Alternative

Generic name of alternative substance (non-confidential):*

EC Number: ☐ Tick the box if confidential

CAS Number: ☐ Tick the box if confidential

IUPAC Name: ☐ Tick the box if confidential

Classification & Labelling information according to:*

- ○ Classification, Labelling and Packaging (CLP) Regulation
- ○ Globally Harmonised System (GHS)
- ○ Dangerous Preparations Directive (DPD)

Classification and Labelling information on the alternative substance:*

Brief description of the Technical alternative:*
Note: Use this field if you have selected "Technical alternative" in section 1.1. Type of Alternative

b) Alternative is a mixture: Select **Substance** and **In a mixture**, if your alternative is a mixture or a group of substances that can replace the Annex XIV substance for the use in question. You can also select **Technical alternative**, if you wish to also describe any necessary changes to the technology, process, procedure, device, modification of end product or other solutions.

1. Alternative

1.1 Type of Alternative

Is the alternative: *
Note: For instructions on how to define your alternative, please consult the document: Guide to third party submission of information on alternatives.

- [x] Substance
  - ( ) on its own
  - (•) in a mixture
- [x] Technical alternative (i.e., an adaptation or a change in the technology, process, procedure, device, modification of end product or other solutions)

1.2. Information on the Alternative

Generic name of alternative substance (non-confidential):*

EC Number: [ ] Tick the box if confidential

CAS Number: [ ] Tick the box if confidential

IUPAC Name: [ ] Tick the box if confidential

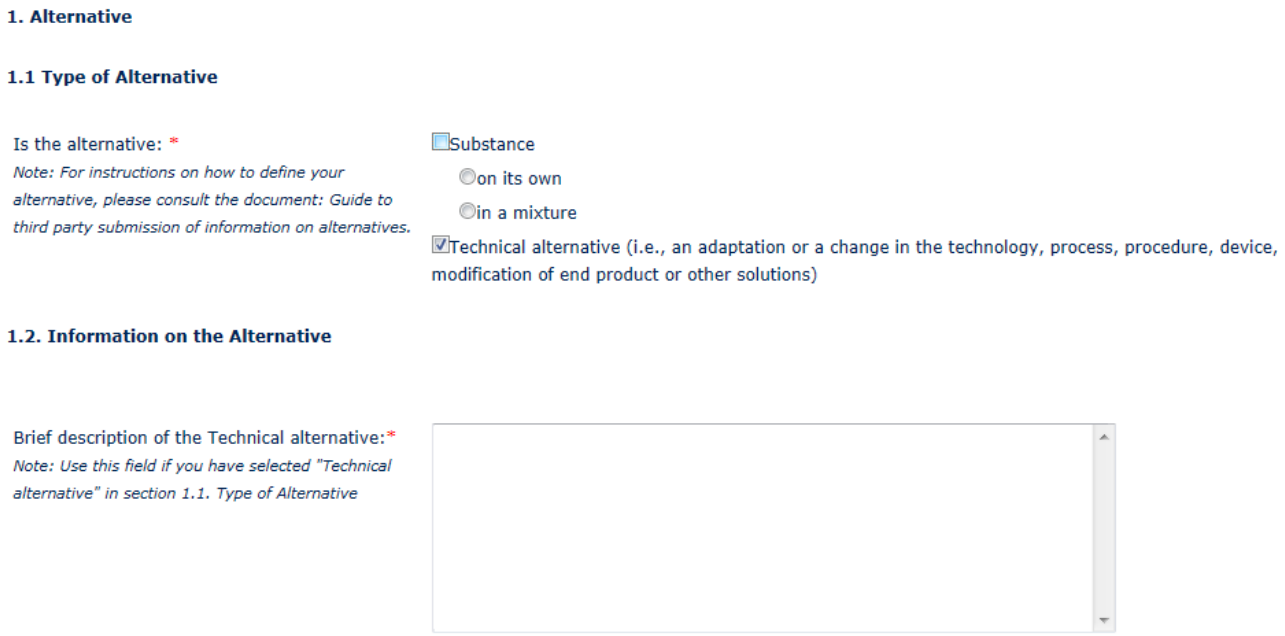
Classification & Labelling information according to:*

- ( ) Classification, Labelling and Packaging (CLP) Regulation
- ( ) Globally Harmonised System (GHS)
- ( ) Dangerous Preparations Directive (DPD)

Classification and Labelling information on the alternative substance:*

Brief description of the Technical alternative:*
Note: Use this field if you have selected "Technical alternative" in section 1.1. Type of Alternative

c) Technical alternative: Select only **Technical alternative** if the alternative can be defined as adaptations or changes in the technology, process, procedure, device, modification of end product or other solutions necessary to replace or remove the need for the Annex XIV substance for the use applied for by the applicant.



Please note that the **Generic name of the alternative substance** and the **Brief description of the Technical alternative** are always non-confidential and therefore, will be published on ECHA's website **Comments submitted to date**.

1.2. Information on the Alternative

Depending on the case you defined in section **1.1. Type of Alternative**, provide the following information (please refer to the screen shots provided above):

a) Alternative substance on its own: provide a generic and non-confidential name of the substance (this could also be the trade name under which the alternative substance is commercialised).

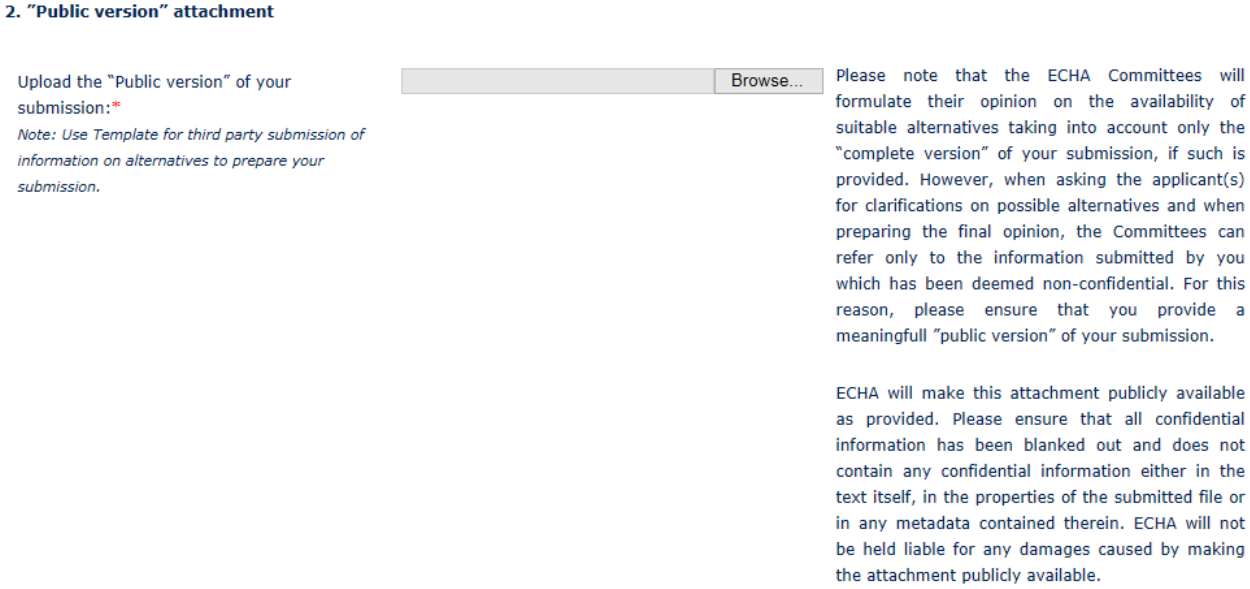
b) Alternative is a mixture: provide a generic and non-confidential name of the **active** substance in the mixture. Describe all constituents and impurities of the mixture in the attachment, following the template for submitting information on alternatives. You could also indicate the trade name under which the mixture is commercialised.

For cases a) and b), provide exact EC and/or CAS numbers and IUPAC in the relevant fields. Select the confidential tick box if you consider these substance identifiers as confidential information. See c) below if you have also selected **Technical alternative** in section **1.1. Type of Alternative**. Indicate the classification of the alternative (substance(s) or mixture(s)) preferably according to the Classification, Labelling and Packaging (CLP) Regulation, the Globally Harmonised System (GHS) criteria, or the Dangerous Preparations Directive (DPD) for mixtures. (Make the necessary selection.)

c) Technical alternative: provide a **Brief description of the Technical alternative** (non-confidential), which briefly outlines the adaptations or changes in the technology, process, procedure, device, modification of end product or other solutions necessary to replace or remove the need for the Annex XIV substance for the use applied for by the applicant.

2. "*Public version*" attachment

Prepare detailed information about the alternative using the Format for third party submission of information on alternatives. Please note that the Annex "Justifications for confidentiality claims" should only be provided in the "*complete version*" attachment, if one is provided. Save your work in an unprotected[5] Word (or pdf or rtf) file.[6] If your "*public version*" contains blanked out parts, it might be safer that you provide it in the format of a scanned document (to avoid removal of the blanks by technical means). Upload your "*public version*" attachment. ECHA will make this attachment publicly available without undue delay on our website. Please ensure that the document does not contain any information which should not be made publicly available. ECHA will not be held liable for any damages caused by making the attachment publicly available.



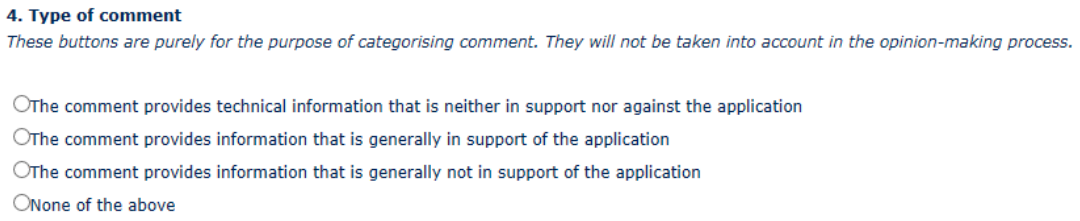
3. "*Complete version*" attachment

Prepare detailed information about the alternative using the Format for third party submission of information on alternatives. Save your work in an unprotected[7] Word (or pdf or rtf) file.[8] Upload your "c*omplete version*" attachment.

[5] Please enable printing.
[6] Several .doc/pdf/rtf files can be submitted in a zip file.
[7] Please enable printing and copying of text.
[8] Several .doc/pdf/rtf files can be submitted in a zip file.

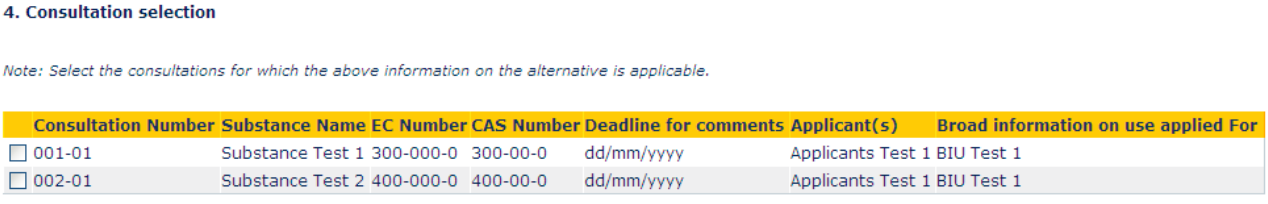
4. Type of comment

By clicking the buttons you may classify your comments as in support, against or neutral. You can also choose not to specify the type of comment by clicking 'none of the above'. The buttons are purely for the purpose of categorising comment. They will not influence how the comment and the information provided in it will be taken into account during the opinion making process.



5. Consultation selection

By clicking on the tick box on the left hand side, select the consultations for which the above information on the alternative is applicable.

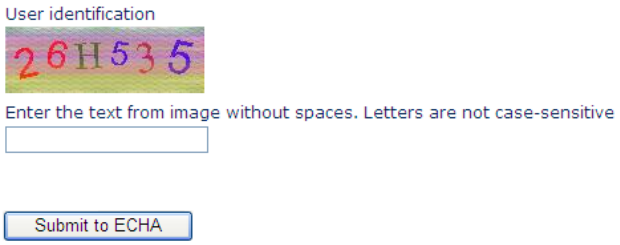


If you wish to double check the details for each ongoing consultation, please refer to ECHA's website **Consultations: Applications for Authorisation** (http://www.echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/applications-for-authorisation)

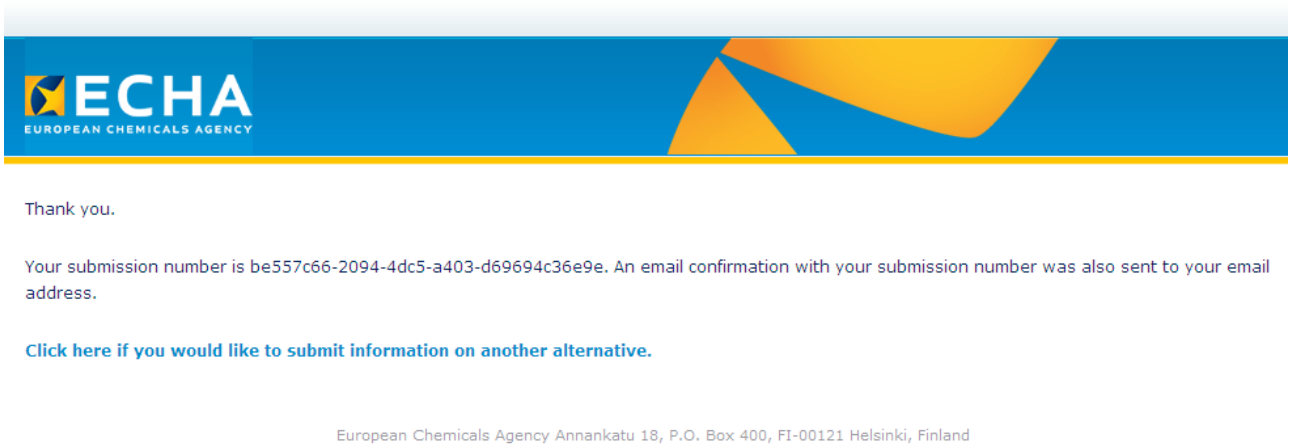
C.5. Submit your information to ECHA

Type the text visible in the user identification box (CAPTCHA) in the field above the **< Submit to ECHA >** button.

Click the **< Submit to ECHA >** button to submit your comments to the public consultations selected above.



Your comment is considered submitted once you a submission number is displayed and that you receive a confirmation email. If you do not receive such a message, please submit your comment again.



C.6. Add another alternative

After submitting you can enter information on another alternative. From the confirmation page, click the link of the text: "**Click here if you would like to submit information on another alternative**." Your personal information does not need to be re-entered if you do not close your browser before you continue with entering the information on the next alternative.

The webform is designed for submission of information on one alternative at a time that can be applicable to one or several ongoing consultations. After you submit the information for the first alternative, you will be given the opportunity to add another alternative that is applicable to one or several ongoing consultations. This step can be repeated.

APPENDIX:

FORMAT

for third party submission of information on alternatives for

Applications for Authorisation

Legal name of submitter(s): *[Insert the legal name(s) of submitter(s)]*

TABLE OF CONTENTS

DECLARATION[9]

We, [Submitter's name], request that the information blanked out in the "public version" of this third party submission of information on alternatives 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 the information claimed confidential without our consent or that of the third party whose commercial interests are at stake.

Signature: Date, Place:

[NAME, TITLE]

[POSTAL ADDRESS INCLUDING COMPANY/ORGANISATION NAME]

[TELEPHONE NUMBER AND EMAIL ADDRESS]

[9] This Declaration is necessary only for "complete version" if you submit one.

Please provide information on the following topics if possible.

1. ALTERNATIVE ID AND PROPERTIES

(You may find the following guidance useful for this section: Guidance for identification and naming of substances under REACH and CLP)

[If the alternative is a substance, describe it by the following sections of Annex VI of the REACH Regulation: 2.Identification of the substance, 3.Information on manufacture and uses, 4.Classification and labelling and 5.Guidance on safe use. With respect to the latter, you can include the safety data sheet (SDS) and relevant exposure scenarios, if available.

Similarly, if the alternative is a mixture, include identification and classification of each of its constituents, classification of the mixture, and guidance on safe use (e.g., an SDS of the mixture).

For "technical" alternatives, describe the adaptations or changes in the technology, process, procedure, device, modification of end product or other solutions necessary to replace or remove the need for the Annex XIV substance for the specified use.

If the alternative is a combination of a substance/mixture and "technical" alternative, please provide all of the above.

Provide a summary table of properties relevant for the overall risks comparison of the alternative with the Annex XIV substance (i.e., toxicological profile and physico-chemical properties)".

Ensure that the information you provide in this section is consistent with the information you provided in the webform. Document the data sources used, their quality and reliability, the assumptions made, the uncertainties in the analysis and their impact on the conclusions of the assessment.]

2. TECHNICAL FEASIBILITY

(You may find the following guidance useful for this section: Chapter 3.6 and Chapter 3.9 of the Guidance on the preparation of an application for authorisation)

[Shows that the alternative you propose can replace or remove the need for the Annex XIV substance for the use(s) for which you are submitting comments. Relate your discussion to the information included in the webpage: Information on use applied for in Applications for Authorisation, at a minimum to the use name, the use descriptors, key elements of the conditions of use of the Annex XIV substance, the exposure scenario and Section 2.Analysis of substance function in the applicant's Analysis of Alternatives report (non-confidential).

Describe the precise functions or tasks performed by the alternative for the use(s) in question. Include a description and outcome of the process and under what process conditions the function must be performed. Show how the alternative meets the functional requirements for the use(s) of the Annex XIV substance it is replacing/eliminating. Examples of functional requirements may include: critical substance properties related to the desired equivalent function, quality criteria, process and performance constraints, customer requirements or legal requirements for technical acceptability.

Discuss any adaptations or changes in the technology, process, procedure, device, modification of end product or other solutions necessary to replace or remove the need for the Annex XIV substance for the specified use (e.g., the requirements for equipment, risk management

measures, energy, personnel changes and training needs, raw materials, waste, etc.) and how these affect the technical feasibility of the alternative.

Include any other benefits (corporate image, compliance legislation, worker safety, relation with community, etc.) and obstacles or difficulties identified or expected in relation to removing or replacing the need for the Annex XIV substance for the specified use.

Support your analysis with information on research and development activities. Document the methodology, data sources and their reliability, assumptions made, uncertainties and their effects on the conclusions on the technical feasibility of the alternative.]

3. ECONOMIC FEASIBILITY

(You may find the following guidance useful for this section: Chapter 3.8 and Chapter 3.9 of the Guidance on the preparation of an application for authorisation as well as Chapter 3.5 and Appendix 1 of the Guidance on SEA – Authorisation)

[Estimate the direct and indirect costs and revenues associated with the transitioning to the alternative you propose. Relate your discussion to the information included in the webpage: Information on use applied for in Applications for Authorisation, at a minimum to the section "Economic feasibility" in the public versions of the applicant's Analysis of Alternatives and Socio-economic analysis.

Detail the methodology, the sources of data and its quality and reliability, the assumptions and uncertainties in the analysis and their impact on the conclusions of the assessment. Clearly set out the boundaries of the assessment (i.e., in terms of your supply chain) and show the reasoning for the setting of these boundaries.]

4. HAZARD AND RISKS OF THE ALTERNATIVE

(You may find the following guidance useful for this section: Chapter 3.7 and Chapter 3.9 of the Guidance on the preparation of an application for authorisation)

[Describe the risks to human health and the environment associated with the use of the alternative for which you are providing comments. Relate your discussion to the information included in the webpage: Information on use applied for in Applications for Authorisation, at a minimum to the exposure scenarios and section "Reduction of overall risk due to transition to the alternative" in the public version of the applicant's Analysis of Alternatives. Please note that the information on ECHA's dissemination site could also contain useful information about the hazards and risks of the Annex XIV substance and the alternative you are proposing: http://echa.europa.eu/information-on-chemicals/.

Discuss whether the transfer to the alternative would result in reduced overall risks to human health and the environment. In the risk assessment of the alternative, consider not only the risks in relation to the hazards that were the basis for placing the Annex XIV substance on the Candidate list but also other relevant risks and effects associated with the alternative. These may also be related to other aspects affecting the overall hazard/risk reduction capacity of the transfer to the alternative, such as changes in energy or raw material consumption, recyclability, climate impact, or physical conditions.

Support your analysis with information on research and development activities. Describe the methodology of comparing the risks of the Annex XIV substance and the alternative. Document the data sources used, their quality and reliability, the assumptions made, the uncertainties in the analysis and their impact on the conclusions of the assessment.]

5. AVAILABILITY

(You may find the following guidance useful for this section: Chapter 3.10 of the Guidance on the preparation of an application for authorisation)

[For suitable alternatives, discuss whether they are available (in the required quantity) without undue delay (taking into account the sunset date of the Annex XIV substance). Relate your discussion to the information included in the webpage: Information on use applied for in Applications for Authorisation, at a minimum to the section "Availability" in the public version of the applicant's Analysis of Alternatives.

Include information on your data sources and their reliability.]

6. CONCLUSION ON SUITABILITY AND AVAILABILITY OF THE ALTERNATIVE

(You may find the following guidance useful for this section: Chapter 3.10 and 3.11 of the Guidance on the preparation of an application for authorisation)

[Conclude on the overall suitability and availability of the alternative for the substance and use(s) combinations (i.e., public consultations) you are submitting this information.]

7. OTHER COMMENTS

[Include other information you may have on the alternative.]

REFERENCES

[Ensure that the information you provide is well-referenced throughout the document. Include a list of references here.]

APPENDICES

[Include other information that you consider relevant for the Analysis of Alternatives, e.g., list of data sources, data collection approach, organisations consulted, methodologies and tools used, summary of assumptions, etc.]

ANNEX – JUSTIFICATIONS FOR CONFIDENTIALITY CLAIMS[10]

[Include your justifications for confidentiality for each blanking that you have carried out in the "public version" of your third party submission of information on alternatives[11]. 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. 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 your third party submission of information on alternatives:

[…]

Page 3

Alternative X

[…]

- *Technical feasibility*

The alternative was tested during four years in our factory of Villecity. The tested mixture called [Blank #2] was supplied by [Blank #3] in drums of [Blank #4] litres. The detailed results of the tests carried out are presented in Table 4.2:

[10] This annex will not be made publicly available. Please include this annex only in the "*complete version*" attachment, if you submit one.

[11] The justification will help ECHA when processing Access to Documents Requests under Regulation 1049/2001.

Table 4.2 Results of Alternative X technical feasibility

Blank #5

[redacted]

[…]

Table of justification for confidentiality in the Annex of the "complete version" of your third party submission of information on alternatives:

Blanked out item reference	***Page number***	***Justification for confidentiality***
Blank #1	*2*	*[insert here your justification]*
Blank #2	*3*	*[insert here your justification]*
Blank #3	*3*	*[insert here your justification]*
…	*…*	*…*