ECHA
EUROPEAN CHEMICALS AGENCY

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

Instructions & Templates

Version	Changes	Date
Version 1.0	First version.	Mar 25, 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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http://echa.europa.eu/contact

European Chemicals Agency

Mailing address: P.O. Box 400, FI-00121 Helsinki, Finland
Visiting address: Annankatu 10, Helsinki, Finland

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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 a confidential and non-confidential templates).

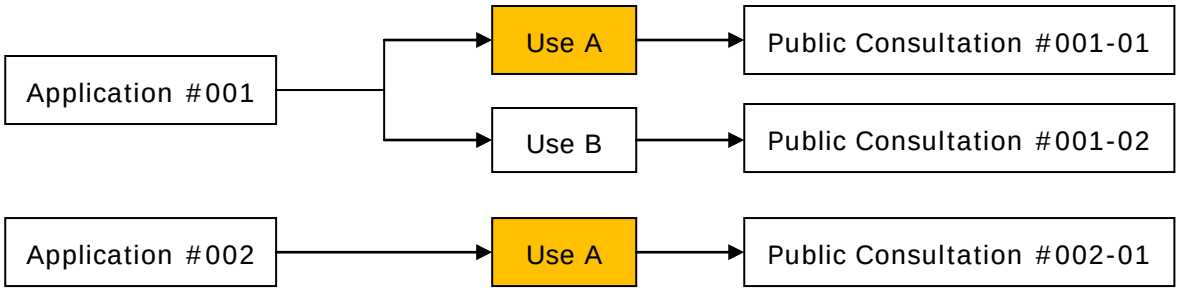
A.2. Purpose of the public consultation on alternatives

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]



A.3. 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.

[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).

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 *templates for third party submission of information on alternatives (confidential and non-confidential)*. Appendix I and II show the templates, which outline the information on alternatives that the Committees will find beneficial for the assessment of Applications for Authorisation. Please follow the templates and provide information on all topics to the extent possible, although all meaningful submissions will be given consideration.

Both the confidential and non-confidential template contain the same report sections. The difference between the two is that in the confidential template interested third parties can include in designated sections confidential information and a justification why the information should be kept confidential. Therefore, submitters may choose to begin by writing their confidential submission using the confidential template. To prepare the non-confidential attachment, the submitter will then need to delete the boxes with confidential information and the justification for why the information should be kept confidential, and then save their work in a separate file marked non-confidential.[2]

Submitting information on alternatives in a non-confidential attachment is important in order to allow ECHA to fully utilize the information provided. Instances where the non-confidential 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 confidential submission only. However, when preparing their final opinion on the granting of an authorisation for the uses applied for, the Committees can refer only to the non-confidential attachment.

The non-confidential submissions will also serve to improve transparency and to enhance the publicly available information on possible alternatives to the Annex XIV substances. The non-confidential submissions 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.

A.4. 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:

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

- ***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.

A.5. 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); and
- the non-confidential 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.

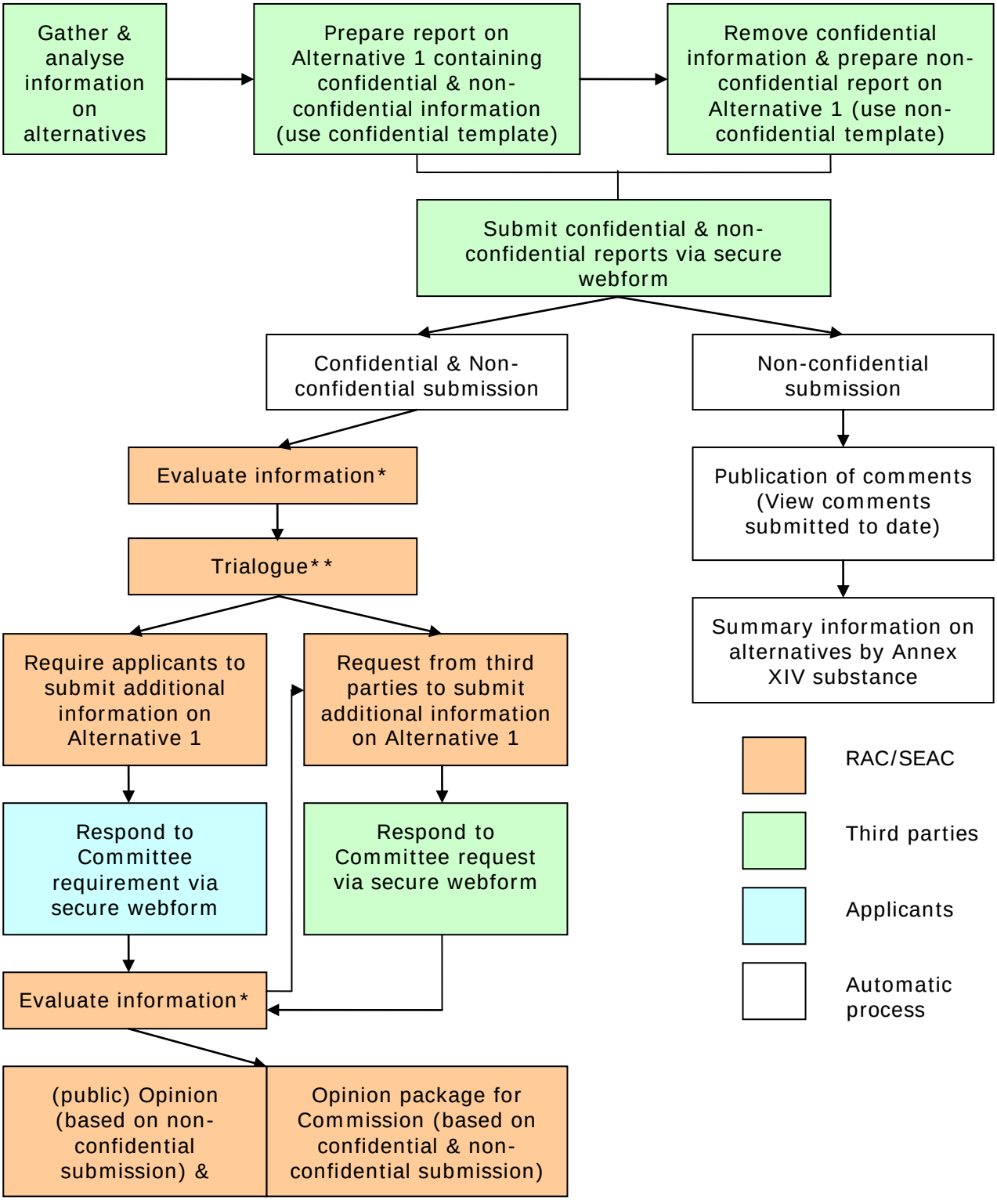
Personal information (first and last name, email address and country of the submitter) and information marked confidential (submitted in the confidential attachment or flagged confidential in the webform fields by clicking the checkboxes) will not be published on our website.

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.

A.6. 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*.

A.7. 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 information during the public consultation on alternatives are asked to provide a justification for confidentiality (in the Template for third party submission of information on alternatives). 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.

A.8. Preparation for 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 B.2 of this document for further details.

B. INSTRUCTIONS

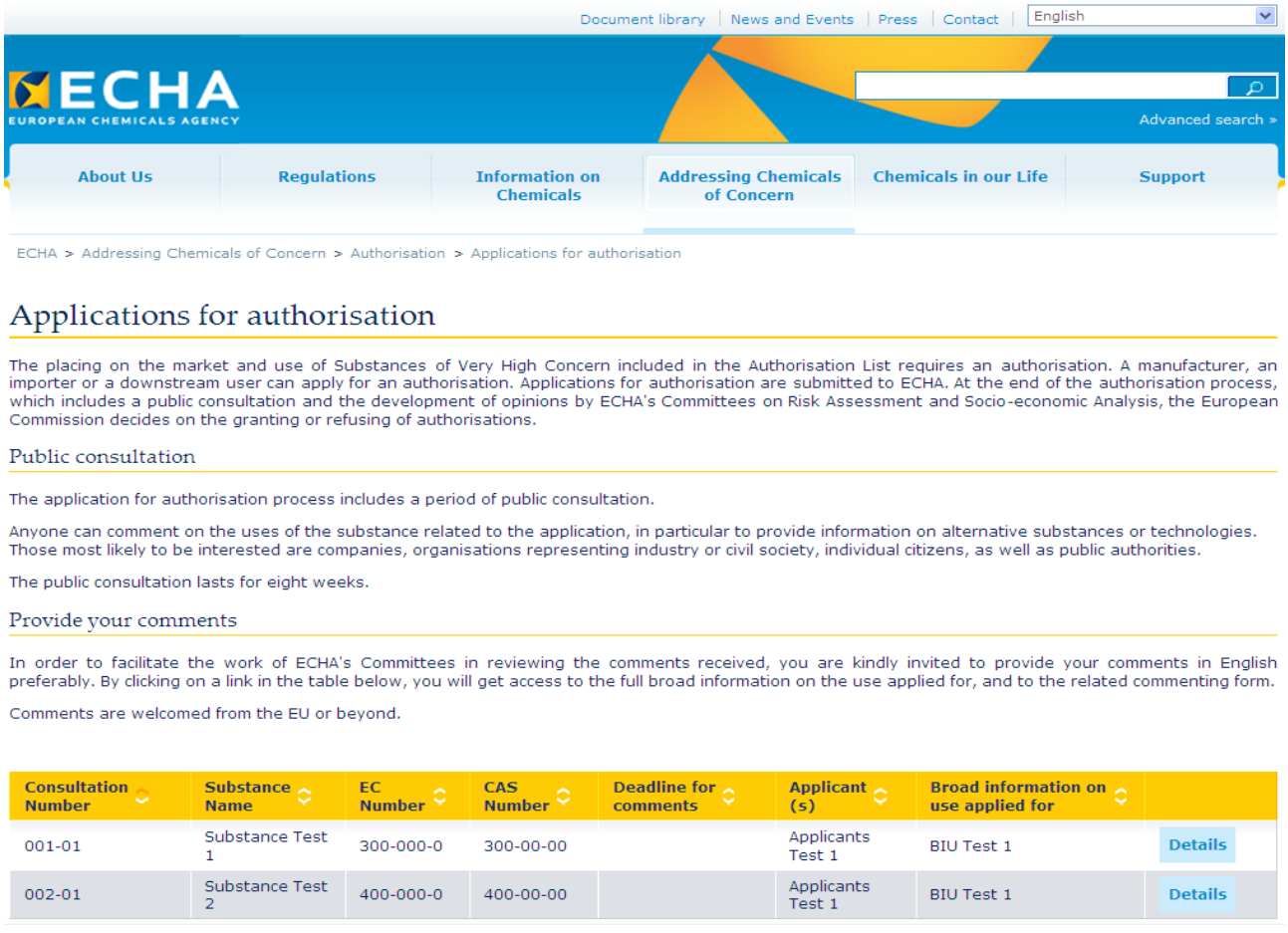
To submit information on alternatives follow the steps described below:

B.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.

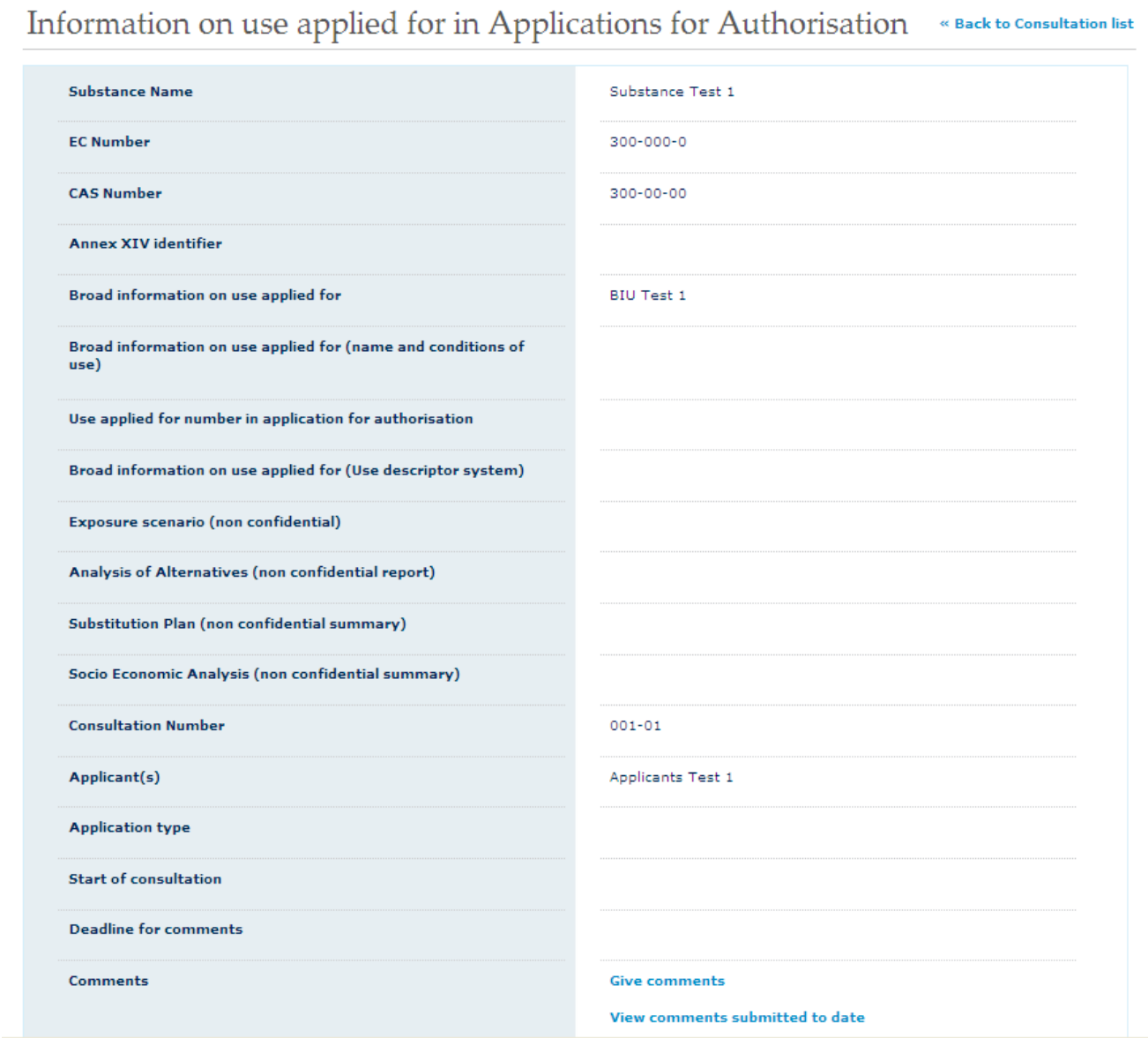
B.2. Click on Details in the last column of the Consultation table to view detailed **Information on use applied for in Applications for Authorisation**.



[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).

B.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 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**.



Information on use applied for in Applications for Authorisation « Back to Consultation list

Substance Name	Substance Test 1
EC Number	300-000-0
CAS Number	300-00-00
Annex XIV identifier	
Broad information on use applied for	BIU Test 1
Broad information on use applied for (name and conditions of use)	
Use applied for number in application for authorisation	
Broad information on use applied for (Use descriptor system)	
Exposure scenario (non confidential)	
Analysis of Alternatives (non confidential report)	
Substitution Plan (non confidential summary)	
Socio Economic Analysis (non confidential summary)	
Consultation Number	001-01
Applicant(s)	Applicants Test 1
Application type	
Start of consultation	
Deadline for comments	
Comments	Give comments View comments submitted to date

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).

Public consultation on alternatives for Applications for authorisation: Comments submitted to date

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	Substance Test 1
EC Number	300-000-0
CAS Number	300-00-0
Annex XIV identifier	
Broad information on use applied for (title)	BIU Test 1
Use applied for number in application for authorisation	
Consultation number	001-01
Applicant name(s)	test 2 test 2
Consultation period	01/02/2012 - 01/03/2012

Comments

Organisation information	Alternative:					Classification and Labelling	Attachments
	Type	Generic name	EC Number	Cas Number	Description of tech		
Affiliation: individual **Type/ Role in sup chain:** **Name of org/company:** **Country:** Finland	Substance (in a mixture), other	Substance test 1	100-000-0	100-00-0		**According to GHS:** C&L information test 1	AfA Comments test 1.doc

B.4. After clicking on **Give comments** from the **Information on use applied for in Applications for Authorisation** web page (see step B.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 confidential and non-confidential attachment.

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 Public consultation on alternatives for Applications for Authorisation: Comments submitted to date.

The following template can be used to organise in an attachment the confidential and non-confidential information on alternative you wish to present:
- Template for third party submission of information on alternatives (confidential)
- Template for third party submission of information on alternatives (non-confidential)

I agree with the Terms and Conditions of this webform.

Compulsory fields are marked with an asterisk (*).

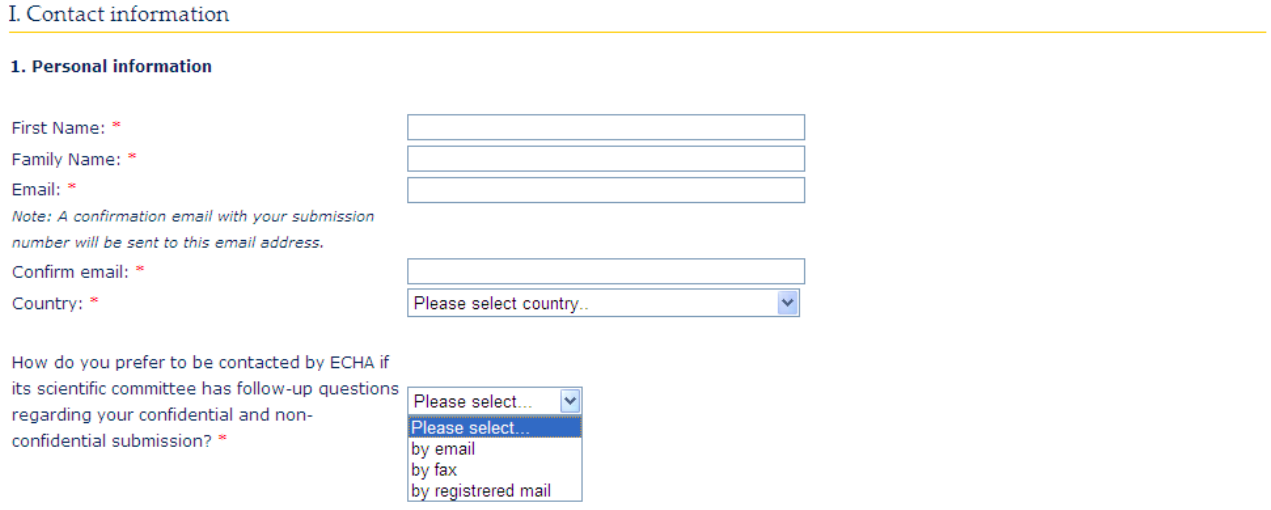
Fill out the secure **webform** by following the steps described below. Fields marked by "*" are mandatory:

B.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..

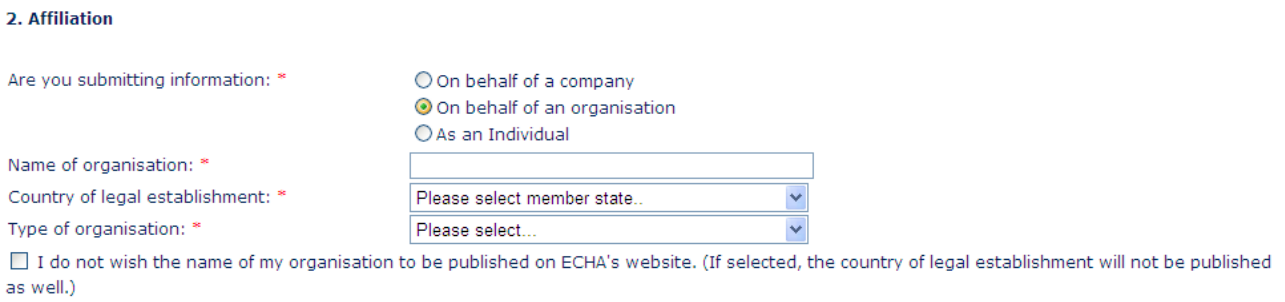
How do you prefer to be contacted by ECHA if its scientific committee has follow-up questions regarding your confidential and non-confidential submission? *

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.



B.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 *Templates for third party submission of information on alternatives (confidential and non-confidential)*.

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

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

replace or remove the need for the Annex XIV substance for the use applied for by the applicant.

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:*

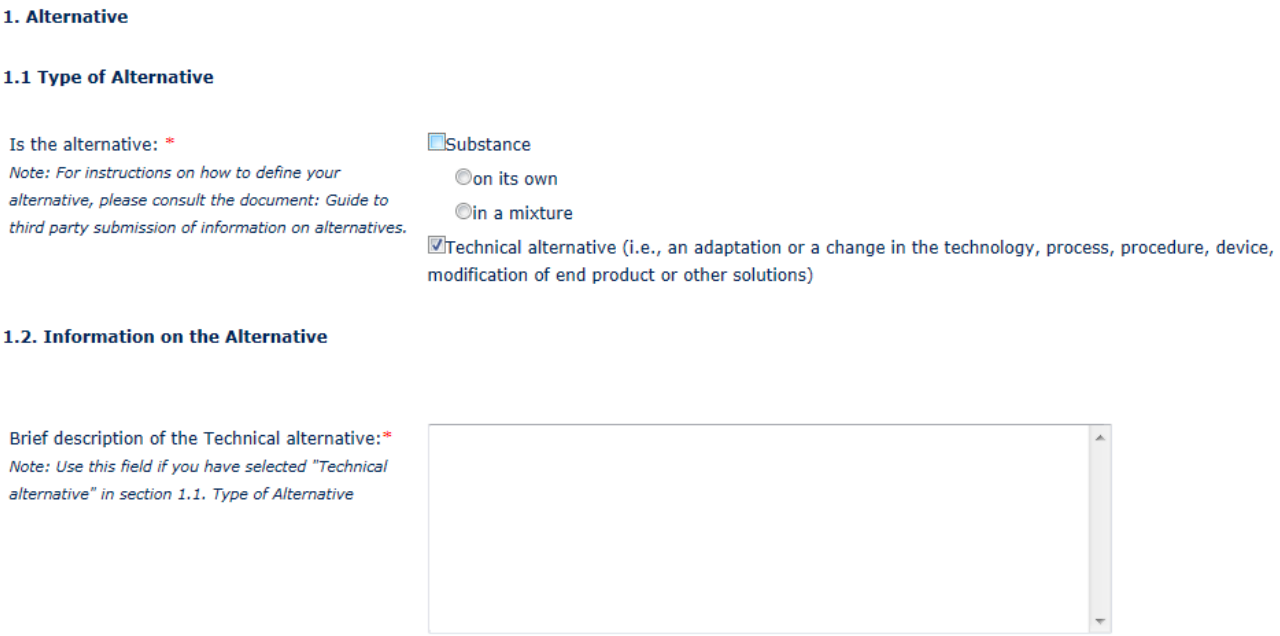
- ( ) Classification, Labelling and Packaging (CLP) Regulation
- ( ) Globally Harmonised System (GHS)
- ( ) Dangerous Preparations Directive (DPD)

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.)

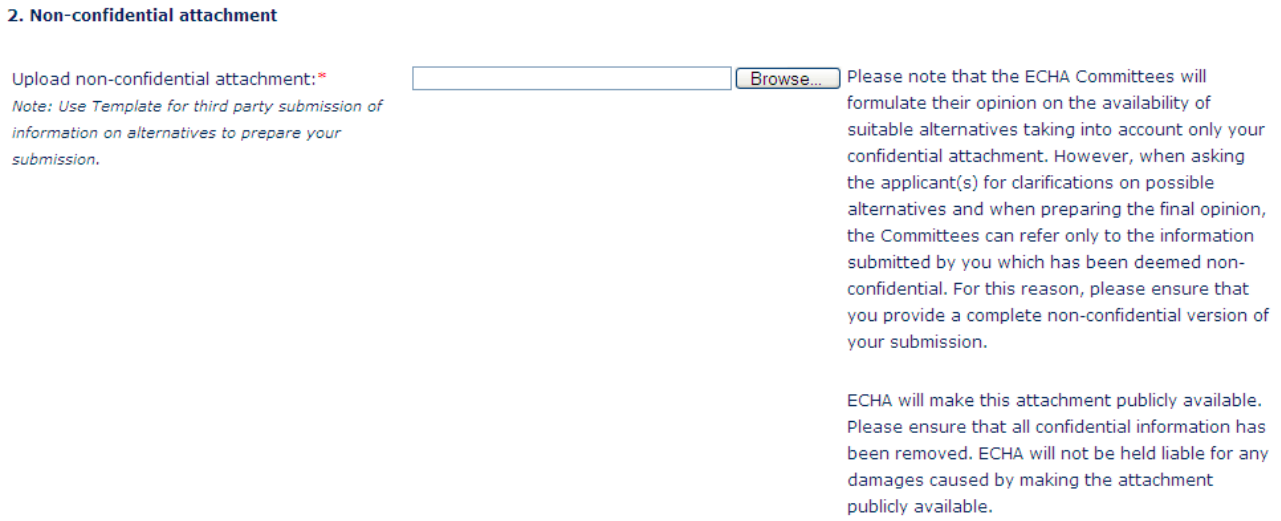
c) Technical alternative: provide a **Brief description of the Technical alternative** (non-confidential), which briefly outlines the adaptations or changes in the technology, process, procedure, device, modification of end product or other solutions necessary to replace or remove the need for the Annex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

2. Non-confidential attachment

Prepare detailed information about the alternative using the Template for third party submission of information on alternatives (non-confidential). Save your work in an

unprotected[5] Word (or pdf or rtf) file.[6] Upload your non-confidential attachment. ECHA will make this attachment publicly available without undue delay on our website. Please ensure that all confidential information has been removed. ECHA will not be held liable for any damages caused by making the attachment publicly available.

Please note that the ECHA Committees will formulate their opinion on the availability of suitable alternatives taking into account only your confidential attachment. 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 complete non-confidential version of your submission.



Both the confidential and non-confidential template contain the same report sections. The difference between the two is that in the confidential template you can include in designated sections confidential information and a justification why the information should be kept confidential. Therefore, you may choose to begin by writing your confidential submission using the confidential Template for third party submission of information on alternatives. To prepare the non-confidential version of your document, you will then need to delete the boxes with confidential information and the justification for why the information should be kept confidential, and then save your work in a separate file marked non-confidential.

3. Confidential attachment

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

Please note that the Committees will formulate their opinion by taking into account only the information in the confidential attachment. Therefore, ensure that your confidential attachment

[5] Please enable printing and copying of text.
[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.

contains your entire submission (consisting of the confidential and non-confidential information) with the confidential information clearly marked as shown in the template.

Please note that if an access to documents request pursuant to Regulation (EC) No 1049/2001 on public access to documents is received regarding this information, in order to define its position ECHA will have to perform first an assessment of the content of this information. Therefore, you are invited to indicate any reason for which disclosure of this information should be denied (in the justification section in the confidential Template for third party submission of information on alternatives). Please note that access to documents can only be denied if one of the exceptions set out in Article 4 of the Regulation (EC) No 1049/2001 on public access to documents applies.

4. 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)

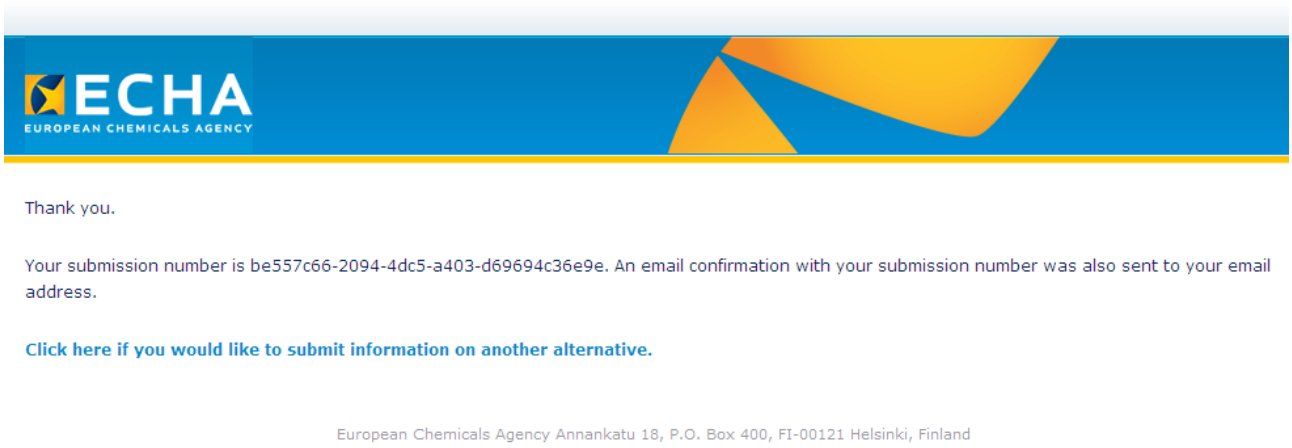
B.5. Submit your information to ECHA

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.

B.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 I:

TEMPLATE

for third party submission of information on alternatives for

Applications for Authorisation

CONFIDENTIAL

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

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DECLARATION

We, [Submitter's name], claim the information in this annex confidential. 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]

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.]

Confidential information:
[Insert confidential information here.]

Justification for confidentiality:
[Insert here. For guidance on how to formulate your justification, see this document, Section A.7. Justification for confidentiality.]

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.]

Confidential information:
[Insert confidential information here.]

Justification for confidentiality:
[Insert here. For guidance on how to formulate your justification, see this document, Section A.7.Justification for confidentiality.]

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 Section 4.3.Economic feasibility in the applicant's Analysis of Alternatives report (non-confidential) and the non-confidential summary of the 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.]

Confidential information:
[Insert confidential information here.]

Justification for confidentiality:
[Insert here. For guidance on how to formulate your justification, see this document, Section A.7.Justification for confidentiality.]

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 4.4. Reduction of overall risk due to transition to the alternative in the applicant's Analysis of Alternatives report (non-confidential). 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.]

Confidential information:
[Insert confidential information here.]

Justification for confidentiality:
[Insert here. For guidance on how to formulate your justification, see this document, Section A.7. Justification for confidentiality.]

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 Section 4.5.Availability in the applicant's Analysis of Alternatives report (non-confidential).

Include information on your data sources and their reliability.]

Confidential information:
[Insert confidential information here.]

Justification for confidentiality:
[Insert here. For guidance on how to formulate your justification, see this document, Section A.7.Justification for confidentiality.]

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.]

Confidential information:
[Insert confidential information here.]

Justification for confidentiality:
[Insert here. For guidance on how to formulate your justification, see this document, Section A.7.Justification for confidentiality.]

7. OTHER COMMENTS

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

Confidential information:
[Insert confidential information here.]

Justification for confidentiality:
[Insert here. For guidance on how to formulate your justification, see this document, Section A.7.Justification for confidentiality.]

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.]

Confidential information:
[Insert confidential information here.]

Justification for confidentiality:
[Insert here. For guidance on how to formulate your justification, see this document, Section A.7. Justification for confidentiality.]

APPENDIX II:

TEMPLATE

For third party submission of information on alternatives for

Applications for Authorisation

NON-CONFIDENTIAL

Legal name of submitter(s): *[Insert the legal name(s) of submitter(s) unless you have asked your name not to be published in the webform by clicking the box "I do not wish the name of my company/organisation to be published on ECHA's website."]*

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Instructions:

Both the confidential and non-confidential template contain the same report sections. The difference between the two is that in the confidential template you can include in the designated sections confidential information and a justification why the information should be kept confidential. Therefore, you may choose to begin by writing your confidential submission using the confidential Template for third party submission of information on alternatives. To prepare the non-confidential version of your document, you will then need to delete the boxes with confidential information and the justification for why the information should be kept confidential, and then save your work in a separate file marked non-confidential.

Please provide information on the following topics if possible.

1. ALTERNATIVE ID AND PROPERTIES

(For guidance on what to provide in this section, please refer to the same section in the confidential attachment.)

2. TECHNICAL FEASIBILITY

(For guidance on what to provide in this section, please refer to the same section in the confidential attachment.)

3. ECONOMIC FEASIBILITY

(For guidance on what to provide in this section, please refer to the same section in the confidential attachment.)

4. HAZARD AND RISKS OF THE ALTERNATIVE

(For guidance on what to provide in this section, please refer to the same section in the confidential attachment.)

5. AVAILABILITY

(For guidance on what to provide in this section, please refer to the same section in the confidential attachment.)

6. CONCLUSION ON SUITABILITY AND AVAILABILITY OF THE ALTERNATIVE

(For guidance on what to provide in this section, please refer to the same section in the confidential attachment.)

7. OTHER COMMENTS

(For guidance on what to provide in this section, please refer to the same section in the confidential attachment.)

REFERENCES

(For guidance on what to provide in this section, please refer to the same section in the confidential attachment.)

APPENDICES

(For guidance on what to provide in this section, please refer to the same section in the confidential attachment.)