Public consultation on alternatives

Seminar on Applications for Authorisation

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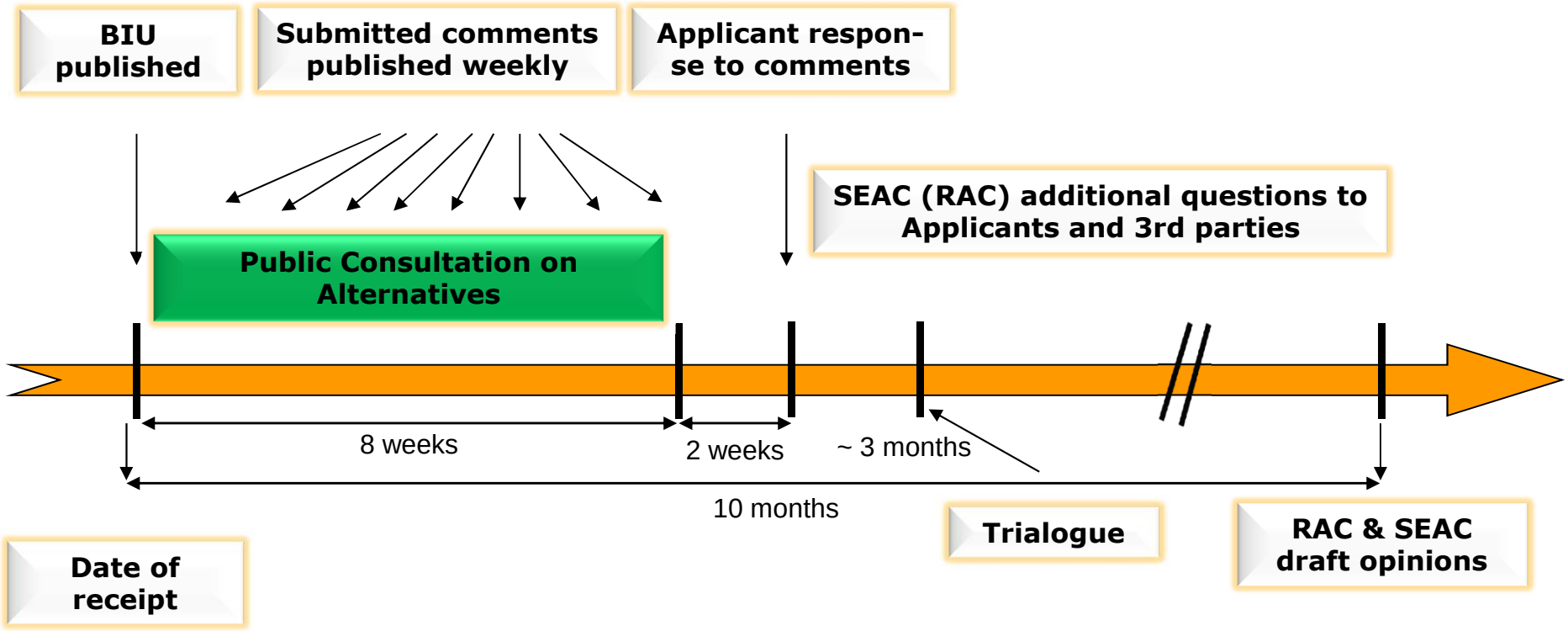
Outline

- Why do we need a Public Consultation on alternatives?
- How does it work?
- What information on alternatives is requested?
- How is the submitted information evaluated?
- How to ensure a meaningful and efficient Public Consultation on Alternatives?

Purpose and objectives

- To gather information on alternatives: Art. 64.2
- To establish a process that ensures:
  - Relevant and meaningful information on alternatives is gathered
  - Public engagement in the regulatory process
    - Transparency/Good administrative practices
    - All available information on alternatives is taken into account in the decision for granting an authorisation

Process overview



Process

- Start of the Public Consultation:
  - upon receipt of application (i.e., fee paid by the applicant)
  - publication of the Broad information on uses package on ECHA's website:

http://www.echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/applications-for-authorisation

Applications for authorisation

The placing on the market and use of Substances of Very High Concern included in the Authorisation List requires an authorisation. A manufacturer, an importer or a downstream user can apply for an authorisation. Applications for authorisation are submitted to ECHA. At the end of the authorisation process, which includes a public consultation and the development of opinions by ECHA's Committees on Risk Assessment and Socio-economic Analysis, the European Commission decides on the granting or refusing of authorisations.

Public consultation

The application for authorisation process includes a period of public consultation.

Anyone can comment on the uses of the substance related to the application, in particular to provide information on alternative substances or technologies. Those most likely to be interested are companies, organisations representing industry or civil society, individual citizens, as well as public authorities.

The public consultation lasts for eight weeks.

Provide your comments

In order to facilitate the work of ECHA's Committees in reviewing the comments received, you are kindly invited to provide your comments in English preferably. By clicking on a link in the table below, you will get access to the full broad information on the use applied for, and to the related commenting form.

Comments are welcomed from the EU or beyond.

Consultation Number	Substance Name	EC Number	CAS Number	Deadline for comments	Applicant (s)	Broad information on use applied for	
001-01	Substance Test 1	300-000-0	300-00-00		Applicants Test 1	BIU Test 1	Details
002-01	Substance Test 2	400-000-0	400-00-00		Applicants Test 1	BIU Test 1	Details

Information on use applied for in Applications for Authorisation

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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

Finalised by ECHA based on applicant's proposal

Published as provided by the applicant. Applicant's responsibility to ensure no confidential info is included

8 weeks of Public Consultation on Alternatives

Submitted comments published weekly on website

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

New comments added weekly

Comments

Organisation information	Alternative:					C&L and GHS / DSD DPD	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)	Substance test 1	100-000-0	100-00-0		**According to GHS:** C&L information test 1	AfA Comments test 1.doc

Requested information on alternatives during Public Consultation

- Substance/mixture identification and/or description of technology/process
- Properties
- Classification & labelling information
- Technical feasibility
- Economic feasibility
- Risks
- Availability

Evaluation of submitted information

- Committee on Risk Assessment (RAC) and Committee for Socio-Economic Analysis (SEAC)
  - Assess submissions (together with the application) based on:
    - Relevance for the uses applied for
    - Quality and clarity
    - Completeness of the analysis: technical feasibility, economic and risk information
  - Trialogue:
    - How relevant are the public consultation submissions to the uses applied for?
  - Clarifying questions to:
    - applicants (Art. 64.3): tight deadlines!
    - public consultation submitters

Meaningful and efficient consultation

- Challenges:
  - The information is submitted on voluntary basis with short timelines
  - Public consultation submissions are prepared in the absence of complete information

- Addressing the challenges:
  - ECHA:
    - sets process and content of BIU package
  - Applicant:
    - prepares BIU package – starting point for the Public Consultation

BIU package: key to meaningful consultation

- Illustrate your case in the BIU package:
  - Brief wording of the BIU and use descriptors
  - Public version of the Exposure Scenario
  - Analysis of Alternatives report (non-confidential)
  - Summary of the Substitution Plan (non-confidential)
  - Summary of the Socio-Economic Analysis (non-confidential)

Objective:

Communicate well your case to the public to maximise relevant submissions from 3rd parties & to limit the number of follow up questions from SEAC/RAC

BIU package: key to meaningful consultation

- Consider the trade off between releasing information (as part of the BIU package) and having to respond to irrelevant information submitted during the Consultation
  - Can you communicate your case using publicly available information (e.g., using ranges, industrial averages, patent information, etc.)?
- Anticipate what can be submitted during the Public Consultation
  - Screen publicly available information on alternatives
  - "Test drive" your BIU package to determine what alternatives may come up based on your public submission only

Conclusion

- Public Consultation: collecting information on alternatives for the use applied for
- BIU package: key to meaningful and efficient consultation on alternatives
- Possibility for applicant to provide counterarguments but with tight deadlines
  - Responses to submissions within 2 weeks of close of consultation
  - Trialogue
  - Responses to RAC/SEAC written questions

Thank You!