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Recommendations on Public Consultation

during Biocide Active substance Approval of Ethanol

25.02.2025

What is the Biocide public consultation on Ethanol?

Since over 10 years, the evaluation of Ethanol for approval as a biocide is ongoing. The Biocidal Products Committee (BPC) Working Groups have in that context proposed classifying Ethanol as:

- **Carcinogenicity and Reproductive Toxicity Category 1** (1A and 1B still undecided)**;**
- Potential classification on **Mutagenicity** which will still be discussed in an additional Working Group.

As a result, Ethanol is now identified as a **Candidate for Substitution (CfS)** according to Article 10(1) of the Biocidal Products Regulation. ECHA will consequently have to determine if viable substitutes exist before the Biocidal Product Committee Plenary will decide on its approval at the end of 2025.

To inform this decision, ECHA launched **a 60-day public consultation** to collect input from interested stakeholders. This information will be reviewed by authorities before the finalization of a Biocidal Products Committee Opinion, expected to be reached by end of 2025.

By contributing, you can submit information about the safe use of ethanol as a biocide at your location and the critical need for the availability of ethanol as a biocide.

Why your participation matters even if you are not a Biocidal player?

This consultation, although specific to biocidal uses, has far-reaching consequences **across sectors using Ethanol**. A **CMR (Carcinogenic, Mutagenic, or Reprotoxic) Category 1 classification** could as such impact non-biocidal uses of Ethanol.

Additionally, the **harmonized classification process under the CLP Regulation will most likely start in Q2 2025** and will be impacted by the outcome of the biocidal process.

You participation is therefore crucial for **two key objectives**:

1. **Highlighting impacts of a classification**: by explaining the consequences of a CMR classification on your sector, emphasizing the absence of alternatives and socio-economic impacts

2. **National outreach**: where the contributions should additionally service as an advocacy position to engage with EU Institutions and your national authorities.

By contribution as a company or association, you have an opportunity to demonstrate to authorities that Ethanol is crucial to your sector and that viable alternatives do not exist.

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How to participate?

Your input will play a critical role in demonstrating (1) the lack of efficient alternatives and (2) the socio-economic impact of potentially losing Ethanol.

The evaluation of Ethanol and its continued use will heavily rely on the information collected during this consultation. Further official guidance is available on ECHA's website.

Simplified participation steps:

1. **Share your insights on available substitutes and the socio-economic impacts of Ethanol's non-availability;**

2. **Participate in the consultation within the designated 60-day period.**

We advise to have as many contributions as possible from individual players at European and national level.

Important things to remember when drafting your response

- Ensure your submission is visually easy to read and well-laid out on the page.
- You should present scientific and socio-economic data that can help prevent possible unjustified classification of Ethanol.
- In submitting your data, also clearly state why you need Ethanol as Biocidal Product in your Sector.

Only submit objective data in support of your response, avoid to draft a position paper that only makes statements.

What to submit to the public consultation?

- Introduce your sector and provide detail on the type of product that you use, and for which uses/application.
- Submit data related to why you use Ethanol, the performance criteria, function, and benefits of the use of Ethanol in your applications.
- Submit any information related to releases and exposure and worker handling.
- Submit information on alternatives (e.g. their availability and performance).
- If available, submit with your response scientific and/or socio-economic data (this can include studies or testing you may have carried out)
- Highlight standards & specifications needed to be met by your customer's requirements and the importance of Ethanol to reach those standards.
- In your submission, recognize the importance of the Substance Approval and the concerns of the regulators.

Key information should be clearly labelled, and any statements you make should be supported by factual scientific/socio-economic data that can help prevent possible unjustified ban of Ethanol.

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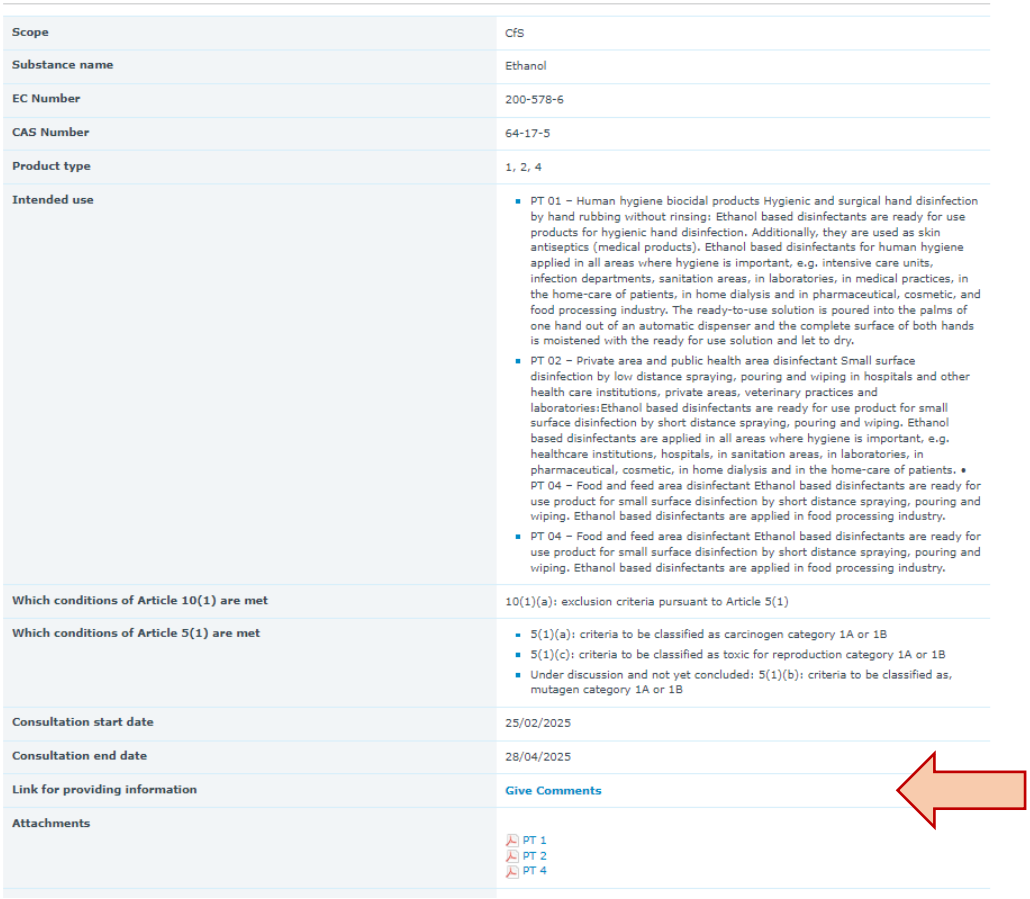
Step by step approach to the Public Consultation

1. **Click on the following link**:
[Consultations on potential candidates for substitution and on derogations conditions - ECHA]

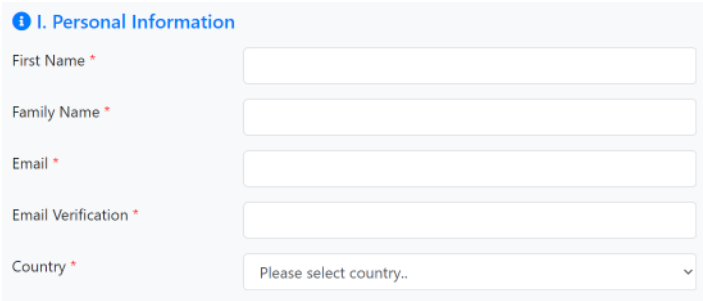
2. **Select "Give Comments"**



Scope	CfS
Substance name	Ethanol
EC Number	200-578-6
CAS Number	64-17-5
Product type	1, 2, 4
Intended use	▪ PT 01 – Human hygiene biocidal products Hygienic and surgical hand disinfection by hand rubbing without rinsing: Ethanol based disinfectants are ready for use products for hygienic hand disinfection. Additionally, they are used as skin antiseptics (medical products). Ethanol based disinfectants for human hygiene applied in all areas where hygiene is important, e.g. intensive care units, infection departments, sanitation areas, in laboratories, in medical practices, in the home-care of patients, in home dialysis and in pharmaceutical, cosmetic, and food processing industry. The ready-to-use solution is poured into the palms of one hand out of an automatic dispenser and the complete surface of both hands is moistened with the ready for use solution and let to dry. ▪ PT 02 – Private area and public health area disinfectant Small surface disinfection by low distance spraying, pouring and wiping in hospitals and other health care institutions, private areas, veterinary practices and laboratories:Ethanol based disinfectants are ready for use product for small surface disinfection by short distance spraying, pouring and wiping. Ethanol based disinfectants are applied in all areas where hygiene is important, e.g. healthcare institutions, hospitals, in sanitation areas, in laboratories, in pharmaceutical, cosmetic, in home dialysis and in the home-care of patients. • PT 04 – Food and feed area disinfectant Ethanol based disinfectants are ready for use product for small surface disinfection by short distance spraying, pouring and wiping. Ethanol based disinfectants are applied in food processing industry. ▪ PT 04 – Food and feed area disinfectant Ethanol based disinfectants are ready for use product for small surface disinfection by short distance spraying, pouring and wiping. Ethanol based disinfectants are applied in food processing industry.
Which conditions of Article 10(1) are met	10(1)(a): exclusion criteria pursuant to Article 5(1)
Which conditions of Article 5(1) are met	▪ 5(1)(a): criteria to be classified as carcinogen category 1A or 1B ▪ 5(1)(c): criteria to be classified as toxic for reproduction category 1A or 1B ▪ Under discussion and not yet concluded: 5(1)(b): criteria to be classified as, mutagen category 1A or 1B
Consultation start date	25/02/2025
Consultation end date	28/04/2025
Link for providing information	**Give Comments**
Attachments	PT 1 PT 2 PT 4

Sections I and II (submitter and organisation information)

I. Personal information – **this information will not be disclosed**



II. Organisation – **you can request this information not to be disclosed**

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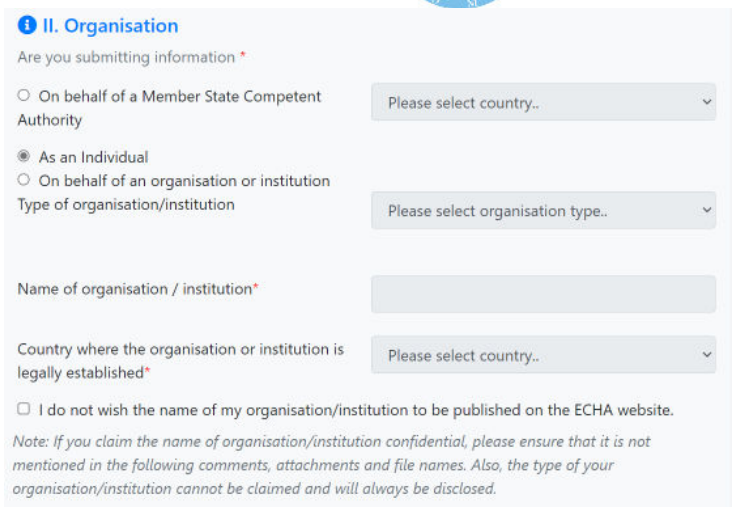
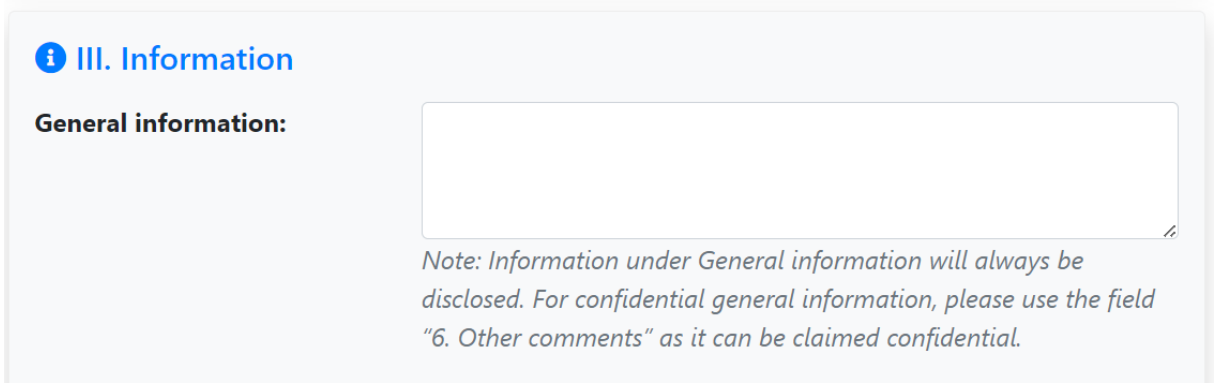


Section III: Comments

III. Information on the relevant Product Types

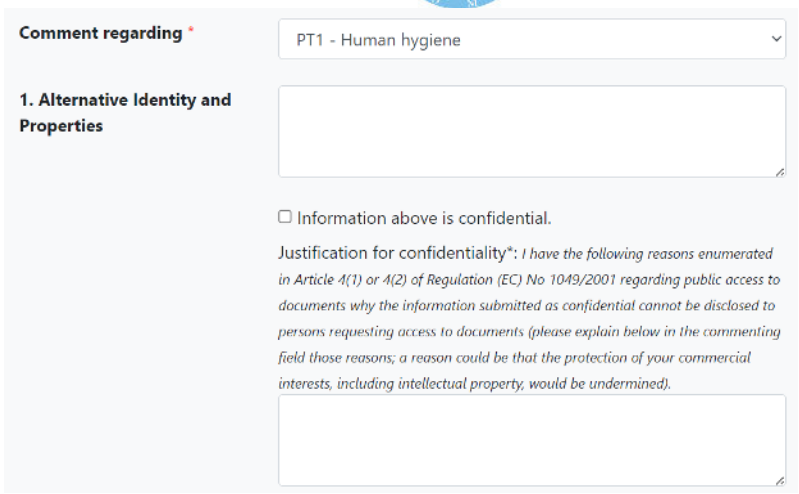
This section is for detailed feedback on Ethanol, including technical, economic, and risk-related information. **Clear, specific, and personalized contributions are essential for a comprehensive evaluation.**

Stakeholders are encouraged to be as detailed and comprehensive as possible in their explanations, **especially when discussing the limited alternatives to Ethanol and its essentiality**. This includes providing both technical and economic arguments to illustrate the limitations of these alternatives.



A. Information on the Availability of suitable alternatives

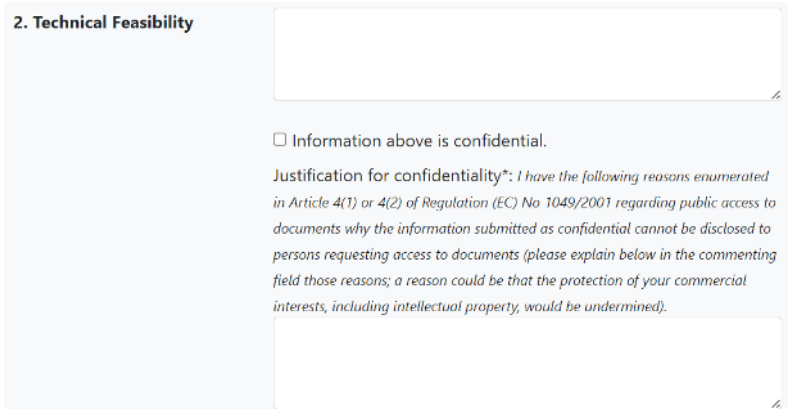
1. Alternative identity and properties



Describe here why there are no suitable Alternatives for Ethanol, based on: e.g.

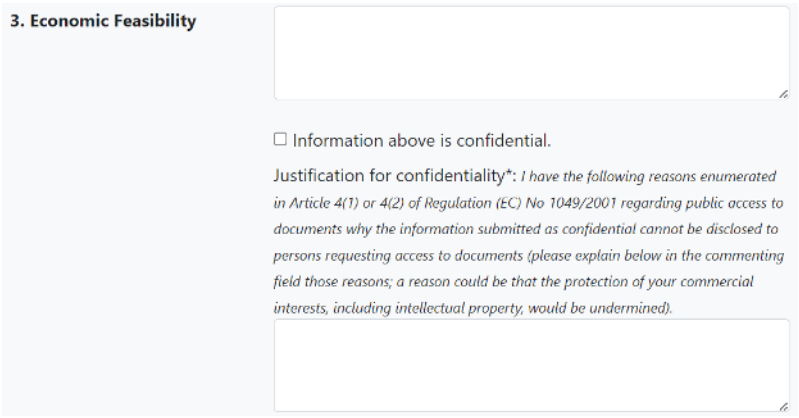
- Effectiveness against target organisms,
- Exposure,
- Amount needed
- Hazards of Alternatives
- Measures necessary to protect humans, animals and the environment,

2. Technical feasibility



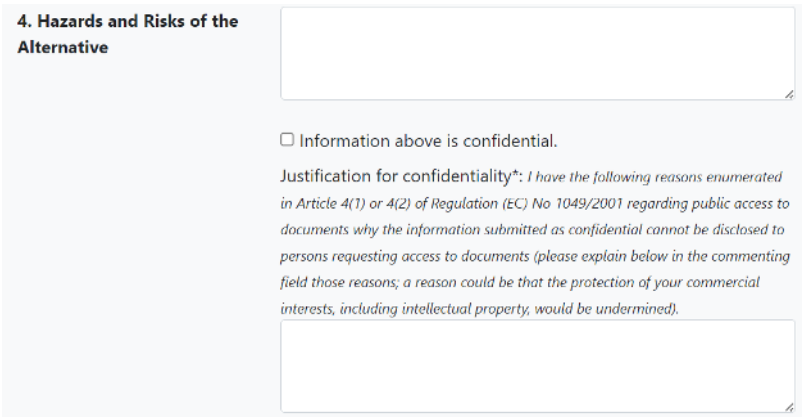
Show that the alternative you propose can fulfil the function of the potential candidate for substitution. Describe the precise functions or tasks performed by the alternative for the use(s) in question. Include a description and outcome of the process and, where relevant, under what process conditions the function must be performed. If possible, discuss any adaptations or changes in the technology, process, procedure, device, modification of end product or other solutions necessary to replace the potential candidate for substitution for the specified use(s) (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. Submission of information in the consultation on potential candidates for substitution under the Biocidal Products Regulation. If possible, include any other benefits (corporate image, compliance legislation, worker safety, relation with community, etc.) and obstacles or difficulties identified or expected in relation to replacing the potential candidate for substitution for the specified use(s). If possible, 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



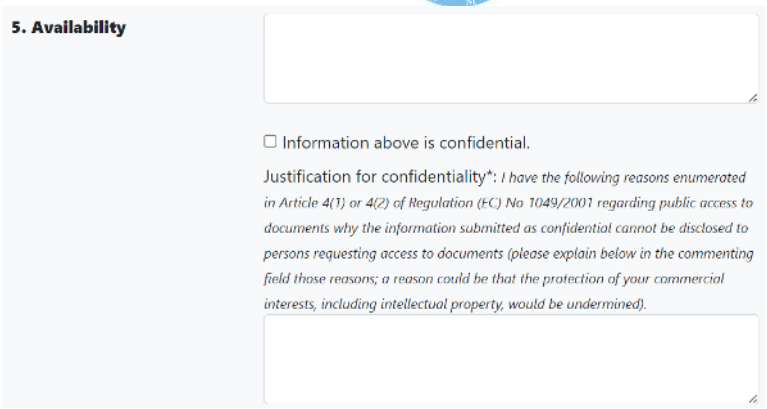
If possible, estimate the direct and indirect costs and revenues associated with the transitioning to the alternative. Detail the methodology, the sources of data and its quality and reliability, the assumptions and uncertainties in the analysis and their impact on the conclusions of the assessment. Clearly set out the boundaries of the assessment and show the reasoning for the setting of these boundaries.

4. Hazards and risks of the alternative



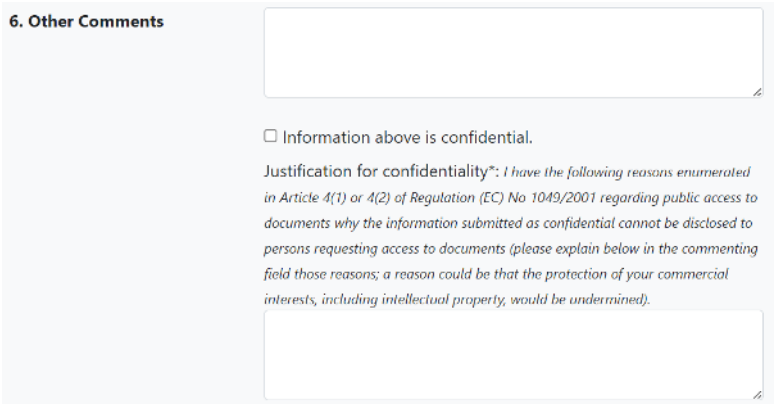
Describe the risks to human health and the environment associated with the use of the alternative for which you are providing comments. Discuss whether the transfer to the alternative would result in reduced overall risks to human health and the environment. In the risk assessment of the alternative, consider any 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. Support your analysis with information on research and development activities, if appropriate. Describe the methodology of comparing the risks of potential candidate for substitution 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



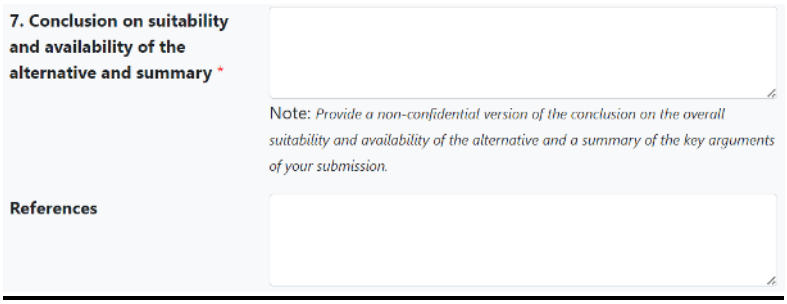
For suitable alternatives, discuss whether they are available (in the required quantity) without undue delay. Include information on the data sources and their reliability. 6. Conclusion on suitability and availability of the alternative Conclude on the overall suitability and availability of the alternative for the potential candidate for substitution for which you are submitting this information.

6. Other comments *If you selected "Other" in the PT-Use combination selection field above, please provide here a detailed description of the PT-Use(s)*



7. Conclusion on suitability and availability of the alternative and summary

Provide a non-confidential version of the conclusion on the overall suitability and availability of the alternative and a summary of the key arguments of your submission.



Section IV: Add Attachments

Ethanol REACH together with the Downstream User Associations provide a Position Paper on the Sector Specific Impact of CMR Classification. The Downstream User

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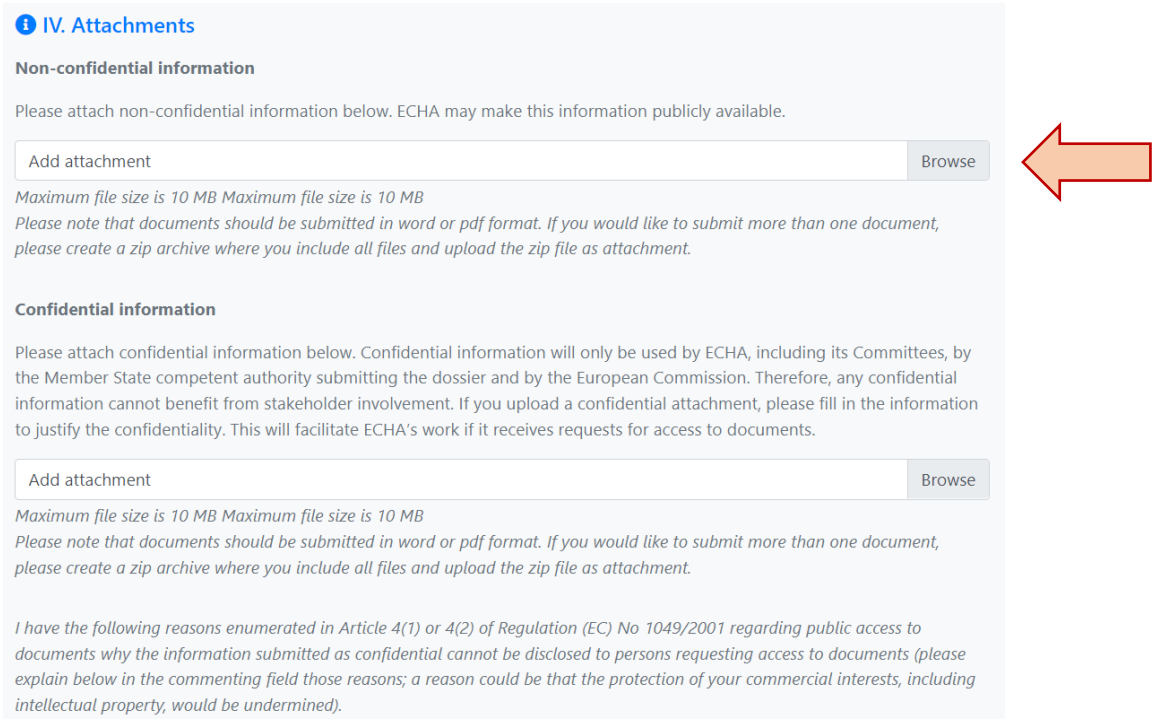
Associations also provide Sector Specific Position Papers and Information. You can MODIFY the text to your specific Use and Upload a separate document.

DO NOT UPLOAD THE ASSOCIATION POSITION PAPER AS SUCH BUT RATHER YOUR OWN INDIVIDUAL CONTRIBUTION FOCUSING EITHER ON ETHANOL BIOCIDAL USES OR ON THE IMPACT OF THE CLASSIFICATION ON BROADER ETHANOL APPLICATIONS (COSMETICS AND PERSONAL CARE, FRAGRANCES, AUTOMOTIVE SECTOR, FOOD PRODUCTION, PHARMA, …)



Guidance on the content of the contribution

In view of preparing the content of your input, we would advise you to look at the following elements:

1. Product Overview

Ethanol is a widely used biocidal active substance with broad-spectrum efficacy, particularly in disinfectants and antiseptics. Its key advantages include:

- Proven **virucidal, bactericidal, fungicidal, and tuberculocidal** activity.
- **High efficacy against non-enveloped viruses**, which is critical for infection control.
- **No residues on surfaces**, making it safe for food contact applications.
- **Rapid evaporation**, ensuring convenient use in healthcare and public settings.
- **Well-documented safety profile** with minimal risks when used appropriately.

2. Efficacy & Testing

- Ethanol is one of the few substances **fully virucidal and efficient** against non-enveloped viruses such as noroviruses and polioviruses.
- Supported by **WHO recommendations** and studies (e.g., Kramer et al., 2022) that highlight its superior disinfection properties.
- **Long shelf life of formulated products**, ensuring stability and usability over time.

3. Safety Considerations

- No toxicologically relevant **residues** or persistent environmental contamination.
- No reported cases of **skin sensitization** under normal use.
- Compared to alternatives, **lower risk of accidental poisoning** due to rapid evaporation.
- **No tainting of food and odorless**, making it suitable for food-related applications.

4. Regulatory Considerations

- Ethanol is under assessment for potential classification as **carcinogenic and/or toxic to reproduction**. However:
  - There is **no conclusive evidence** of carcinogenicity from real-world exposure levels.
  - Toxicological evaluations should differentiate **ingestion vs. topical and inhalation exposure**.
  - Any classification must consider **risk-based assessment** rather than hazard-only classification.

5. Risks of Substitution

If ethanol is substituted or restricted, the following risks must be considered:

- **Lack of equally effective alternatives**:
  - No substitute biocidal active substance offers **equal virucidal efficacy against non-enveloped viruses**.
  - Other active substances have **higher toxicity profiles or leave residues**.
- **Supply chain vulnerabilities**:
  - Alternative substances are significantly **more expensive and less available**.
  - Scaling up production for substitutes would require **massive investments in new facilities, technologies, and regulatory approvals**, facing resistance from authorities and NGOs.
- **Potential public health risks**:
  - Reduced availability of effective disinfectants could increase **infection rates in healthcare, food processing, and public hygiene**.
  - Increased use of **weaker disinfectants** may lead to **higher microbial resistance**.

6. Market & Supply Chain Impact

- Ethanol production is well-established with **stable supply chains**.
- Alternative biocides face **higher production costs, lower availability, and logistical challenges**.
- Regulatory decisions should account for **economic feasibility and continuity of supply** to prevent market disruptions.

7. Strategic Positioning for Consultation

- Emphasize ethanol's **indispensability in public health**.
- Highlight **scientific evidence** supporting its safety and efficacy.
- Provide a **balanced perspective** on regulatory concerns while advocating for **risk-based decision-making**.

- Engage stakeholders in industry, healthcare, and regulatory bodies to ensure an **informed discussion**.

Should you have any questions on the public consultation or need further technical information, please do not hesitate to contact us: XXXXX@

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ANNEX: ECHA Guidance and Instructions for further information

- Further Information on the Approval of Active Substances: https://echa.europa.eu/de/regulations/biocidal-products-regulation/approval-of-active-substances
- Further Information on the Candidates for Substitution https://echa.europa.eu/de/current-candidates-for-substitution-and-derogations-conditions.
- More Information on the Submission of Information during the Public Consultation:https://echa.europa.eu/documents/10162/1027022/bpr_cons_instructions_en.pdf/3dae5912-c62c-4965-b9ff-3ee26731b6c9
- Instructions for comments on CfS and derogations
- Submission of information in the consultation on potential candidates for substitution under the Biocidal Products Regulation
- Guidance on the preparation of socio-economic analysis as part of an application for authorisation