The regulatory future of ethanol in the EU

Simone Bertolini - Senior Consultant, Team Leader Chemicals

Ethanol is one of the most widely used biocidal active substances in the European Union, employed in products intended for hand hygiene, surface treatment, and other disinfectant applications. It is currently under evaluation within the BPR Review Programme for the following Product Types: PT1, PT2, and PT4[1] [2] [3]. Its use is currently allowed due to the transitional regime provided under Article 89 of the BPR, which permits products to remain on the market until a final decision is taken on the active substance it contains.

Despite its long history as a biocide international recommendations[4], ethanol is at the centre of a complex regulatory assessment that could lead to nonapproval for its use as a biocide, or approval with significant restrictions applied. The critical issue is the potential classification of ethanol as a category 1 CMR substance (carcinogenic, mutagenic, or toxic for reproduction) under the CLP Regulation, which would directly influence the approval process of the active substance under the Biocidal Products Regulation (BPR).

Regulatory Framework: BPR and CLP

Biocidal Products Regulation (BPR)

Regulation (EU) No 528/2012 establishes that an active substance must be assessed for efficacy, hazard, and risk, with the final decision by the European Commission on its approval, non-approval, or approval with derogations[5]. The procedure includes:

- Assessment by the Competent Authority of a Member State (eCA),
- Opinion of the Biocidal Products Committee (BPC) of ECHA,
- Decision by the European Commission.

CLP (Classification, Labelling and Packaging)

The CLP Regulation establishes the classification of substances based on their intrinsic hazardous properties[6]. Harmonised classification at the EU level may be proposed by:

- A Member State,
- A manufacturer,
- An importer,
- A downstream user.

The proposal is then evaluated by the Risk Assessment Committee (RAC) of ECHA[5]. Based on the opinion issued by the RAC, the European Commission adopts a delegated act updating Annex VI of the CLP, introducing the new harmonised classification.

The process also includes public consultation phases, during which comments from stakeholders (including industry and trade associations) are collected and considered. Once defined, the new harmonised classification may have implications for other EU legislation. Such potential consequences are assessed separately, in accordance with the requirements and procedures established under the specific regulations concerned.

Current status of ethanol

Approval process as a biocidal active substance

Greece, acting as the evaluating Competent Authority (eCA), submitted to ECHA in March 2024 the updated Assessment Report for ethanol for Product Types PT 1, PT 2 and PT 4. The document analyses hazards, characterises risk, and evaluates the efficacy of the representative products. In September 2024, discussions within the Human Health Working Group of the BPC led to the advancement of a proposal for classification as a category 1 CMR substance[7], based on effects associated with oral intake and the endogenous formation of acetaldehyde, a substance already classified as a CMR. However, the BPC did not reach consensus on the decision regarding ethanol's approval. Consequently, the adoption of the opinion has been postponed to 2026: work will resume during this month, and publication of the BPC opinion is not expected before May 2026[8].

Proposed harmonised classification

To date, ethanol already has a harmonised classification as a highly flammable liquid and vapour[9]. In 2020, Greece notified ECHA of its intention to propose a revision of the harmonised classification, including additional hazard classes[10].

The preliminary proposal includes:

- Flam. Liq. 2, H225 – Highly flammable liquid and vapour
- Eye Irrit. 2, H319 – Causes serious eye irritation
- Repr. 2, H361d – Suspected of damaging the unborn child
- Lact., H362 – May cause harm to breast-fed children
- STOT SE 3, H336 – May cause drowsiness or dizziness
- STOT RE 2, H373 – May cause damage to organs through prolonged or repeated exposure

Formal submission of the proposal is expected by the 31st of December 2026, as new dermal studies on ethanol are currently being generated and are considered necessary to complete the assessment[10].

"Hazard vs risk" discussion

It is considered highly probable that the proposal to classify ethanol as a category 1 CMR substance is mainly based on studies investigating the effects of ethanol when ingested orally. However, for biocidal Product Types 1, 2 and 4, the predominant route of exposure is dermal, which entails a significantly different risk profile compared with oral exposure.

It is nevertheless important to emphasise that classification decisions under the CLP Regulation must be based solely on the intrinsic hazard of the substance, and not on the risk associated with specific uses as a disinfectant. Therefore, considerations related to the relevant exposure route for biocidal products do not directly affect the classification process, but they become central in the risk assessments carried out under the framework of the Biocidal Products Regulation (BPR).

Regulatory consequences of a CMR 1A or 1B classification

Effect on the BPR

Ethanol, if classified as a category 1A or 1B CMR substance, would meet the exclusion criteria set out under the BPR, particularly those related to carcinogenicity and reproductive toxicity. According to Article 5(1) of the BPR, substances that meet at least one exclusion criterion cannot be approved for use in biocidal products[5].

However, Article 5(2) of the BPR allows for the possibility of granting approval by derogation if at least one of the following conditions is demonstrated:

- **Negligible risk:** exposure to the active substance, under the worst realistic conditions of use, results in negligible risk to humans, animals, or the environment.
- **Essential use:** the active substance is essential to prevent or control a serious danger to human health, animal health, or the environment.
- **Disproportionate socio-economic impact:** non-approval would have a disproportionate negative impact on society compared to the potential risks associated.

If ethanol were approved despite a CMR 1A or 1B classification, it would automatically become a candidate for substitution (Article 10 BPR), with significant consequences for the market of ethanol based biocidal products[5].

Practical implications of approval by derogation of ethanol as an active substance

- Ethanol may be approved as an active substance only for an initial period not exceeding five years (Art. 4(1) BPR).
- The authorisation of a biocidal product containing ethanol as an active substance may be granted for a period not exceeding five years, and renewal may also be granted for a period not exceeding five years (Art. 23(6) BPR).
- Biocidal products containing ethanol as an active substance must undergo a comparative assessment at the time of authorisation (Art. 23(1) BPR) and will be authorised only if no better alternatives exist (Art. 23(3) BPR).
- The use of biocidal products containing ethanol as an active substance will be subject to appropriate risk mitigation measures, ensuring that exposure of humans, animals, and the environment is minimised (Art. 5(2) BPR).
- Ethanol based biocidal products may not be made available on the market for use by the general public (Art. 19(4) BPR)[5].

Obligation for reclassification and re-labelling (CLP)

A CMR 1A/1B classification entails:

- Updating SDS and labelling and packaging in accordance with CLP (new hazard statements and precautionary statements).
- Mandatory adjustments for all actors in the supply chain (manufacturers, importers, formulators, distributors).

Effect on other legislation

Although the assessment of ethanol as a CMR substance originates within the biocides regulatory framework, a harmonised CLP classification as CMR 1A or 1B would have horizontal effects, meaning it would apply across all sectors using ethanol as a substance or as an ingredient in mixtures. Below are examples of impacted sectors:

- **REACH:** Classification as a CMR category 1 would make ethanol eligible for identification as a Substance of Very High Concern (SVHC)under REACH[11]. Once identified as an SVHC, the substance may be placed on the Candidate List according to Article 59 of REACH. Inclusion in the Candidate List immediately triggers a series of obligations for suppliers throughout the supply chain. Furthermore, classification as a category 1 CMR would result in a ban on placing on the market for supply to the general public CMR 1A/1B substances (and mixtures above specific concentration limits), according to entries 28–30 of Annex XVII, with derogations/exemptions and periodic updates via Commission acts.
- **Cosmetics:** The use of substances classified as CMR 1A or 1B under Regulation (EC) No 1272/2008 is prohibited in cosmetic products[12]. However, derogations are possible.
- **"Carcinogens, Mutagens and Reprotoxic Substances" Directive (CMRD):** The reclassification of ethanol as CMR 1A/1B would automatically bring the substance under the scope of Directive 2004/37/EC, which regulates the protection of workers exposed to CMR substances. This would entail stricter obligations for employers, including strengthened risk assessments, substitution of the substance where technically feasible, and reduction of exposure to the lowest achievable level. Closed processes or advanced technical measures would also become necessary, along with mandatory health surveillance for exposed workers[13].

Market impact

Possible effects for industry

- Reduced availability of ethanol-based disinfectants in retail
- Increase in costs and regulatory burdens for manufacturers and importers
- Need for reformulation and repositioning of product lines
- Potential competitive advantage for alternative authorised substances not subject to exclusion criteria
- Restrictions in workplace settings, especially for vulnerable groups
- Strategic uncertainty throughout the entire supply chain

Potential future scenarios

Scenario 1 – Approval and adoption of the CMR classification
The BPC considers the CMR classification proposed within the Working Group. Possible outcome:

- Approval only under derogation according to Art. 5(2)
- Products authorisable for professional use only
- Strong impact on the consumer market

Scenario 2 – Alignment with the OSOA principle (One-Substance-One-Assessment)
The BPC and the Commission await the RAC opinion under CLP, acknowledging the absence of risks associated with biocidal use. Possible outcome:

- Approval of ethanol without CMR classification
- Market continuity under standard conditions

Alternative scenario (not yet regulated)
Creation of two separate entries in the ECHA registers:

- Ethanol (pure, intended for human consumption) → with CMR classification
- Ethanol (not intended for human consumption) → without CMR classification

However, a dual entry based on use is incompatible with the CLP, because classification is hazard based and linked to the identity of the substance (not to its uses). Therefore, this proposal would require legislative amendments and is currently not applicable. Nevertheless, it could emerge as a potential solution in critical situations.

Conclusions

The future of ethanol will depend on the combined outcome of the BPR process and any potential harmonised CLP classification; technical work is ongoing and, according to sector agendas and communications, the key milestones are expected in 2026. If a CMR 1A/1B classification is confirmed, the exclusion criteria would apply, with approval granted only by derogation (maximum 5 years) and likely limitations on uses by the general public during product authorisation. In parallel, "horizontal" effects would materialise: a ban on supply to the general public under REACH Annex XVII, stringent rules/possible derogations in cosmetics (Art. 15), and strengthened obligations under the CMRD for the protection of workers.

Appendix I – Regulatory update as of 26 February 26th 2026

On the 24th of February 2026, the European Chemicals Agency (ECHA) published a significant update regarding the approval process of ethanol as a biocidal active substance[13]. In the February 2026 meeting, the Biocidal Products Committee (BPC) adopted its opinion for the approval of ethanol for the following Product Types:

- **PT 1 – Human hygiene products** (e.g. hand disinfectants)
- **PT 2 – Disinfectants and algaecides not intended for direct application to humans or animals**
- **PT 4 – Food and feed area disinfectants**

The Committee concluded that the safe use of ethanol has been demonstrated for all repre-sentative uses in these PTs.

Status of classification as a CMR substance

Despite the approval, the BPC did not reach any conclusion regarding the carcinogenic or reprotoxic properties of ethanol. As a result, no new hazard classification has been proposed. According to the BPC, the absence of a clear conclusion stems from:

- Insufficient data on dermal exposure, which represents the primary exposure route for biocides;
- Inhalation studies that do not comply with required methodological standards;
- Most CMR evidence derives from the voluntary oral consumption of alcoholic beverages, considered unsuitable as a scientific basis for a regulatory decision in the context of biocides;
- New exposure studies are underway, but waiting for their results would delay the approval process excessively.

Next steps

Now that the BPC has adopted its opinion:

- ECHA will transmit the opinion to the European Commission, which will prepare a draft implementing regulation for the approval or non-approval of ethanol.
- The draft will be submitted to a vote by Member States in the Standing Committee on Biocidal Products of the European Commission.
- If approved, the Commission will formally adopt the decision, making it legally binding.

Market Implications

- If ethanol is approved, biocidal products containing the substance will have to be authorised under the BPR, either through national authorisation or European Union authorisation.
- If it is not approved, products containing ethanol will have to be withdrawn from the EU market within the applicable transitional periods.

Implications for the harmonised classification intention submitted by Greece under the CLP Regulation

The opinion adopted by the Biocidal Products Committee (BPC) significantly changes the regulatory context surrounding Greece's intention to submit a revision of the harmonised classification of ethanol under CLP.

Possible future scenarios regarding the proposed revision of the classification

Scenario 1 – Submission of a revision limited to non-CMR endpoints

According to official ECHA documentation, the Greek intention includes several endpoints beyond CMR:

- Eye Irrit. 2, H319
- STOT SE 3, H336
- STOT RE 2, H373
- Lact. H362

Greece could deliberately withdraw the CMR hypothesis and submit a reduced harmonised classification proposal, thus preserving the objective of updating the classification without entering into a highly controversial endpoint. Ethanol could therefore receive an expanded but non-CMR harmonised classification, with moderate market impact and no severe restrictions.

Scenario 2 – Submission of a revision including a "soft" CMR proposal (Repr. 2)

The current Greek intention includes a classification as Repr. 2. After the latest BPC opinion (24 February 2026), which does not support any CMR classification, Greece could continue to support the Repr. 2 classification—scientifically easier to justify—and refrain from proposing 1A/1B classifications. As a consequence, a Repr. 2 classification would impose additional labelling obligations but would not automatically trigger BPR exclusion or broad restrictions.

Scenario 3 – Withdrawal of the intention

The lack of scientific support from the BPC for a CMR classification could lead Greece to withdraw its intention. However, withdrawal would also exclude any possible reclassification for non-CMR hazard classes. Should this scenario occur, the regulatory impact would be minimal.

Bibliography

[1] «Stato regolatorio dell'etanolo per PT1,» [Online]. Available: https://echa.europa.eu/it/information-on-chemicals/biocidal-active-substances/-/disas/factsheet/1303/PT01

[2] «Stato regolatorio dell'etanolo per PT2,» [Online]. Available: https://echa.europa.eu/it/information-on-chemicals/biocidal-active-substances/-/disas/factsheet/1303/PT02

[3] «Stato regolatorio dell'etanolo per PT4,» [Online]. Available: https://echa.europa.eu/it/information-on-chemicals/biocidal-active-substances/-/disas/factsheet/1303/PT04

[4] REGULATION (EU) No 528/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 May 2012 concerning the making available on the market and use of biocidal products, 2012.

[5] ECHA, Introductory Guidance on the CLP Regulation, Version 4.0 a cura di, ECHA, 2025.

[6] «Human Health WG-III-2024,» in Minutes of Human Health WG-III-2024, 2024.

[7] ECHA/NR/25/40, ECHA's opinion on ethanol postponed to 2026.

[8] E. CHEM, «ECHA CHEM,» [Online]. Available: https://chem.echa.europa.eu/100.000.526/harmonised/336617?searchText=ethanol. [Consultato il giorno 23 02 2026]

[9] «Registry of CLH intentions until outcome - Ethanol,» [Online]. Available: https://echa.europa.eu/it/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e1852d3d63

[10] ECHA, Guidance on the preparation of an Annex XV dossier for the identification of substances of very high concern, 2.1 a cura di, 2018.

[11] REGOLAMENTO (CE) n. 1223/2009 DEL PARLAMENTO EUROPEO E DEL CONSIGLIO, 2009.

[12] Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens, mutagens or reprotoxic substances at work.

[13] ECHA/NR/26/09, ECHA's Biocides Committee supports approval of ethanol in disinfectants.

Contact us

Simone Bertolini
simone.bertolini@bpt.eurofinseu.com

information@bpt.eurofinseu.com