

THE RECLASSIFICATION OF ETHANOL

A.I.S.E. position

3 April 2025

Introducing ethanol, a critical ingredient

Ethanol is an essential and versatile ingredient widely used across various industries, particularly for its disinfecting properties. Key characteristics of ethanol include:

- From bacteria to non-enveloped viruses like polio, ethanol is the most effective substance to fight a broad spectrum of organisms and no comparable alternatives currently exist. During COVID-19, ethanol was the number one ingredient to fight SARS-CoV-2 due to its broad availability and efficacy.
- Ethanol is the most effective and most available disinfectant against healthcare-associated infections (HAIs), which cause 90,000 deaths annually in the EU and cost the region €7 billion per year.
- Ethanol is a vital ingredient in disinfecting products used at home and in hospitals, in the food and pharmaceutical sectors. Disinfection is vital for prevention and control infection.
- Ethanol is safe for the environment: it mainly comes from renewable sources, it is fully biodegradable compared to its alternatives, it leaves no residue on surfaces, it evaporates quickly, and it is generally more sustainable than other options.
- There is no viable alternative to ethanol. No other substance can match ethanol's efficacy in infection control. Alternatives, such as propanol, are less effective and harsher on the skin. There are even no alternatives in the pharmaceutical and food/fragrance sectors for extracting flavours and fragrances and pharmaceutical active substances of natural origin.
- Beyond disinfectants, versatility makes ethanol an important carrier, a solvent and a preservative. Any changes to ethanol's classification under the Biocidal Products Regulation will have wider-reaching effects on non-biocidal products containing ethanol such as surface cleaners, air fresheners, cosmetics, medical devices and medicinal products.

Ethanol-based biocides have been used safely in the healthcare, food, life sciences and hospitality industries for many years. The World Health Organisation (WHO) recommends ethanol-based hand sanitisers as '*the gold standard for hand hygiene in healthcare*' and in March 2020 WHO launched the "Safe Hands Challenge" widely promoting the use of alcohol-based hand sanitisers to fight COVID-19.

Reclassifying ethanol

One substance, two assessments

Ethanol is currently being assessed under the EU Biocidal Products Regulation (BPR), the regulatory framework for products such as surface and hand disinfectants. Specifically, it is progressing through an Active Substance review and authorities have indicated their intention to classify ethanol as toxic to reproduction and carcinogenic.

This classification will affect some categories of biocidal products (PT1, PT2 and PT4) containing ethanol as an active ingredient. It could mean their exclusion from the EU market as soon as [the

end of 2027]. Alternatively, if a derogation is granted, some products may stay on the market under restricted-use conditions.

Ethanol will also be assessed under the Classification, Labelling and Packaging Regulation (CLP), the timing of which is expected to be initiated soon [(Q2 2025)] and could take up to five years to complete. Any changes to ethanol's classification under this Regulation will have wider-reaching effects on non-biocidal products containing ethanol such as cleaners, cosmetics, medical devices and medicinal products.

To avoid unnecessary disruption the CLP process for ethanol should be allowed to be concluded before the ethanol approval under the BPR.

A process with fundamental issues

A.I.S.E believes that the proposed reclassification of ethanol is based on very flawed assumptions: it considers the effects of the substance after oral intake of high doses, in other words utilising data on the adverse effects of (excessive) drinking of alcoholic beverages.

This is not based on the typical uses of ethanol in biocidal products. It also does not take into account mitigation strategies used in industry to provide safe products, such as denaturation of ethanol to prevent drinking of ethanol-containing products. The uptake of ethanol after skin contact or inhalation is negligible and better comparable to the intake of ethanol in non-alcoholic products such as orange juice, where ethanol occurs naturally.

A wide range of unintended consequences

Ethanol's reclassification means a *de facto* ban and would have massive consequences not only on European industry, but also on society as a whole, while not bringing any benefit to human health or the environment. Even with derogations, the availability of ethanol will be severely restricted due to local regulations. Authorities will have to face a host of (unintended) consequences including a change in infection patterns as well as higher costs.

A.I.S.E. position

A.I.S.E. calls on the European authorities to recognise the essential role of ethanol. Ethanol should remain classified based on its real-world, biocidal use, rather than being inaccurately compared to alcohol consumption. Recognising ethanol's essential role in infection control and public health is vital for maintaining effective and safe disinfecting practices.

Specifically, A.I.S.E. calls on ECHA to take realistic exposure routes into consideration. Risk assessments should distinguish between ingestion and dermal/inhalation exposures to avoid unnecessary restrictions and *de facto* bans. It is crucial to consider realistic exposure scenarios to ensure that regulations are based on accurate and relevant data.

Finally, A.I.S.E. calls on the European Commission to fully assess the consequences of reclassifying ethanol on public health, healthcare costs and economic stability. A thorough impact assessment will provide a clear understanding of the potential ramifications and help guide informed decisions.

The European Commission can demonstrate its commitment to simplifying legislation and supporting EU competitiveness by avoiding an unjustified reclassification that does not positively impact EU citizens, while negatively impacting EU industry. Supporting European competitiveness is essential for fostering innovation and economic growth.





About A.I.S.E.

A.I.S.E. represents the detergents and maintenance products industry in Europe. Based in Brussels, A.I.S.E. has been the voice of the industry to EU regulators since 1952. Membership consists of 30 national associations across Europe, 19 corporate members and 23 value chain partners. Through this extensive network, A.I.S.E. represents over 900 companies supplying household and professional cleaning products and services across Europe. Committed to promoting sustainable practices and innovation, A.I.S.E. collaborates closely with European institutions, industry stakeholders, and the public to enhance the sector's environmental protection, consumer safety, and regulatory compliance efforts.

More on www.aise.eu/ethanol

Contact: Nicole Vaini nicole.vaini@aise.eu

