

German Social Insurance
European Representation
50 Rue d'Arlon
1000 Brussels
Belgium

Phone: +32 2 282 05-50
info@dsv-europa.de
www.dsv-europa.de
Transparency Register ID:
917393784-81



Deutsche Sozialversicherung
Europavertretung | DSV

Opinion from German Social Insurance issued on 26 August 2025

on the planned reclassification of ethanol



I. Preliminary remark

Ethanol is a central working substance and is widely used as a disinfectant, preservative, solvent and cleaning agent as well as in fuels. It can enter the human body through the skin, mucous membranes, respiratory tract, or orally. Currently, two procedures concerning ethanol are underway within the framework of European chemicals legislation in order to examine possible hazards for human health and the environment. Both procedures are significant for occupational health and safety protection of employees.

The European Chemicals Agency (ECHA) is conducting a re-evaluation of ethanol under the Biocidal Products Regulation (BPR). The background is a legislative amendment from 2012, according to which all biocidal active substances that entered the European market before 2013 must be re-examined for hazards – including ethanol. In the course of this re-evaluation, it will be examined whether ethanol meets the criteria to be classified as potentially carcinogenic (C), mutagenic (M), or toxic to reproduction (R) – i.e., as a so-called CMR substance – including effects on/through lactation. On the basis of the ECHA opinion, the European Commission will subsequently implement the re-evaluation of ethanol legally in a delegated act.

Parallel to this re-evaluation under biocidal law, a revision of the harmonised classification and labelling of ethanol under the CLP Regulation (Regulation on Classification, Labelling and Packaging of Substances and Mixtures) is also planned. The procedure serves to ensure uniform risk management standards in the European Union (EU) and to simplify hazard communication.

The German Social Insurance (DSV) generally supports any re-evaluation of chemical substances with regard to possible risks to human health and the environment. However, it strongly emphasises that the use of ethanol in various industrial processes and as a biocidal active substance in disinfectants remains indispensable. Classification as a CMR substance without considering the actual route of exposure may have adverse effects on the working world, healthcare provision, and the economy. The DSV therefore advocates, in advance of the reclassification, for proportionate, scientifically differentiated, and practical solutions in order to avoid possible undesirable legal consequences.



II. Opinion

1 _ Biocidal Products Regulation

Ethanol-based disinfectants are indispensable in hospitals, care and other medical facilities, as they effectively protect patients and employees from infections. At present, there are no suitable alternatives that offer comparable efficacy and availability to ethanol. The DSV therefore advocates recognising the high importance of ethanol as a biocidal active substance and calls on the European Commission to continue to allow the unrestricted use of disinfectants.

Ethanol is characterised by its broad antimicrobial efficacy, rapid action, and good skin compatibility. A blanket hazard classification of ethanol as a CMR substance and the associated restriction of use, ignoring the actual route of exposure, would therefore have far-reaching and inappropriate consequences for infection control, patient safety, and the occupational health and safety of employees in healthcare and beyond.

Depending on the category of classification, the use of disinfectants would only be permitted in exceptional cases, such as to combat serious health threats in the event of a pandemic. Routine daily use in medical and care facilities, especially for hand and surface disinfection, would be severely restricted. Such restrictions would therefore contradict the established use of ethanol in disinfectants, the absorption of which via skin and respiratory tract is scientifically well studied and can generally be safely controlled with existing limit values. The studies used for the reclassification of ethanol as a CMR substance, however, refer exclusively to the harmful properties of this substance when ingested orally, not to the almost exclusively occupational exposure via skin and/or respiratory tract.

Ethanol is also used in food-related areas, for example, for disinfecting work surfaces and equipment – primarily because it leaves no harmful residues and, by evaporating quickly, inhibits the growth of microorganisms. When used properly, activities involving ethanol-containing disinfectants are harmless from an occupational safety perspective. In addition, ethanol is denatured in most areas of application, which rules out misuse as drinking alcohol and thus oral intake.



2 _ CLP Regulation

The planned revision of the harmonised classification and labelling of ethanol as a CMR substance – particularly as carcinogenic or toxic to reproduction – would also have profound and potentially disproportionate impacts on numerous industries as well as on the occupational health and safety of employees in those sectors.

Ethanol is an indispensable working substance in a wide range of industrial and commercial applications, from the chemical and pharmaceutical industries to food and cosmetics production, laboratory applications, disinfection, and medical technology. From the DSV's point of view, a blanket classification of ethanol as a CMR substance, without taking into account the real routes of exposure and scientific risk assessments, would not only jeopardise proven production processes but also call into question established safety standards. The DSV therefore calls on the European Commission, in the revision of the harmonised classification and labelling of ethanol, to ensure that safe workflows are not impaired by disproportionate requirements.

Protective measures are already in place in companies today that effectively protect employees – for example, in paint, varnish, and adhesive manufacturing, cleaning, plastics and rubber processing, or food production – from the absorption of ethanol through skin and respiratory tract. Protection against exposure after a classification as a CMR substance would in principle require measures – such as the use of ethanol in closed systems, maintaining exposure registers, or mandatory occupational medical surveillance – whose practical implementation, however, is only possible to a limited extent and in many cases hardly feasible.

Adjustments to the current regulations regarding reproductive toxicity in connection with the classification of ethanol on/through lactation would also have far-reaching consequences. In this case, pregnant or breastfeeding employees could not carry out activities with ethanol-containing products – even if exposure in daily work is reduced to a negligible level by protective measures. This would in fact lead to employment bans and, in the opinion of the DSV, is not a sensible approach.

3 _ Need for legal impact assessment

An impact assessment is required for initiatives of the European Commission that have significant economic, ecological, or social effects. This also applies to implementing and delegated acts. In order to find practical solutions, all relevant factors – from actual exposure to societal and economic impacts – must be taken into

account. The DSV therefore calls on the European Commission to incorporate its considerations and concerns into the impact assessment for the amendment of the BPR and CLP Regulation.

A blanket CMR classification of ethanol in the BPR and CLP Regulation would disregard the practical realities of many industries. A well-founded and comprehensive evaluation of all the impacts mentioned by the DSV is therefore essential to ensure that the use of ethanol remains possible in areas where it is indispensable for infection prevention and production technology.

As an approach, differentiation of classification according to the field of application should be considered – for example, through separate evaluation of denatured and non-denatured ethanol. In addition, targeted exemptions should be examined, taking into account the relevant risk of health hazards. In this way, substances could be excluded where, due to the existing exposure pathway, no health risk exists in the workplace.

About us

The German Federal Pension Insurance (DRV Bund), the German Social Accident Insurance (DGUV), the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband), the national associations for statutory health and long-term care insurance funds at the federal level and the Social Insurance for Agriculture, Forestry and Horticulture (SVLFG) have joined forces to form the "German Social Insurance - Working Group Europe" (Deutsche Sozialversicherung Arbeitsgemeinschaft Europa e. V.) with a view to their common European policy interests. The association represents the interests of its members vis-à-vis the bodies of the European Union (EU) as well as other European institutions and advises the relevant stakeholders in the context of current legislative projects and initiatives. As part of the statutory insurance system in Germany, health and long-term care insurance with 75 million insured persons, pension insurance with 57 million insured persons and accident insurance with more than 70 million insured persons in 5.2 million member companies offer effective protection against the consequences of major risks of life.