BVMed Bundesverband Medizintechnologie e.V.

BVMed Position

Ethanol: Public consultation on potential candidates for substitution

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Introduction and general information

BVMed represents over 300 industrial and commercial companies as well as suppliers in the medical technology sector. The 20 largest medical device manufacturers worldwide are organised in BVMed.

The crucial role of medical technology in healthcare shows the importance and that medical devices are indispensable on the prevention of health threats in Europe and over the world. The sector ant its products are essential for civil defence and public emergency response, from infection control, wound management, trauma surgery, surgical equipment and many more. Medical technology solutions must be considered humanitarian goods.

As the leading association of the medical device industry in Germany, BVMed comments on the current classification procedure and the call for alternatives to ethanol within PT 1 and PT2 formulation as follows:

Ethanol in the industrial health economy and health care systems

Alcohol-based hygienic disinfectants have long been established as one of the most important measures to prevent and control infections inside and outside of healthcare institutions.

Ethanol plays therefore an important role not only in hand disinfection but also in surface disinfection and in addition to that also in production processes especially within the health care industry. In contrast to other chemicals used for disinfection (isopropanol and hydrogen peroxide), it shows an unbeatable combination of fast, broad-spectrum antimicrobial activity against bacteria and viruses and a favourable exposure profile in various products that is unmatched by available alternatives and has a relatively low hazard potential. Furthermore, the substance is safe and biodegradable.

Ethanol acts specifically and without alternative against non-enveloped viruses such as poliovirus. The prevalence of nosocomial infections has also been reduced through the use of alcohol-based hand sanitisers.

The World Health Organisation (WHO) has therefore classified hand disinfectants containing ethanol as indispensable (1).

Ethanol is readily and quickly available, and any necessary upscaling of production capacity can be achieved quickly, as has been demonstrated during the Covid-19 pandemic. It was shown that infection-chains could be safely and quickly interrupted by disinfection measures. Manufacturers were able to cover the exceptionally high demand for disinfectants during the pandemic mainly through available ethanol.

The data used for the risk assessment and the proposed classification of ethanol as potentially reprotoxic or carcinogenic are based primarily on the (abusive) oral intake of alcoholic beverages.

These data are in no way relevant for the intended use in the field of hygiene, in particular because denatured alcohol is used in these applications. Other exposures (inhalation, dermal) result in low blood levels comparable with endogenous formation or uptake via food.

Even though this consultation and the current classification refers to BPR processes, we would like to refer to the CLP guidances.

They define ‘reasonably foreseeable use’ as, among other things, occupational and non-occupational uses, including reasonably foreseeable accidental exposure, but not misuse.

A CMR classification as class 1 substance would constitute in a de facto ban and has far-reaching consequences for the use of ethanol-containing disinfectants in the whole society not only in the healthcare sector and the health industry.

In particular, it could significantly impair the necessary widespread use of these disinfectants but also the production of lifesaving products like medical devices, IVDs and medicinal products.

In addition to consequences within the worker safety legislation, a classification as reproduction toxic with an effect on/through lactation would result in a work ban for women of childbearing age under German labour law.

It is evident that the automatic linkage of classification according to the BPR or CLP Regulation and the associated regulations without further risk assessment does not serve to protect human health and the environment. Even with derogations, the availability of ethanol will be severely restricted due to local regulations.

We also want to refer to Annex 1 No 3.6.2.1 CLP Regulation which states that the classification as carcinogenic should only be made according to one exposure pathway if it is proven that there is no risk in the other exposure pathways. Accordingly, ethanol would only have to be classified as carcinogenic via the oral exposure pathway. There is no intended oral exposure to ethanol within the scope of substance legislation.

> The classification of ethanol as a CMR substance class 1 in the BPR/CLH process has massive economic and legal impacts and must be stopped immediately.

1. Alternative Identity and Properties

Particularly in its effect against non-enveloped viruses, ethanol is indispensable (1).

Also, the German “Robert Koch Institute” recommends the use of Ethanol as it is more effective against viruses than propyl alcohols (2).

Chlorhexidine digluconate, octenidine hydrochloride, polihexanide, quaternary ammonium compounds, ampholytes, phenol derivatives and triclosan do not enhance the effect of alcoholic disinfectants when added, but depending on the active ingredient, there is a increased hazardous profile and the risk of intolerance or the development of resistance.

The use of polyvinylpyrrolidone (PVP) iodine products is limited by iodine absorption. Aqueous solutions based on chlorinated solvents, PVP iodine or peroxides are not an alternative to alcohol-based hand disinfectants in healthcare facilities due to their lower efficacy, poorer skin tolerance than alcohol-based products, due to their poorer spreading behaviour on the skin and longer

evaporation time, are not an alternative to the use of alcohol-based hand disinfectants in healthcare facilities (3).

Other alternatives would be isopropanol and hydrogen peroxide.

All potential substitutes show a significantly higher hazardous profile and jeopardise the necessary compliance in hygiene within the healthcare sector since ethanol-based disinfectants show a very high level of acceptance among healthcare professionals.

2. Technical Feasibility

From a procedural perspective every replacement of disinfectants needs to be tested according to the state of the art (pharmacopoe and standards) to ensure the efficacy.

The implementation of replacements includes rationales for substitution, efficacy validation, protocol and procedure adjustments as well as staff training and lasts at least 6-9 months.

In case of non-biocidal uses of ethanol additional sectoral legislation (e.g. for medical devices, IVD or medicinal products) has to be taken into account.

3. Economic Feasibility

Compared to possible substitutes the economic advantages of Ethanol are given as available, scalable and cheap.

Especially the Covid-19 pandemic showed the fast upscale possibilities in case of urgent need for disinfectants.

The market for hand disinfectants in Germany is already at a three-digit million level. All relevant virucidal products are ethanol-based, while the spectrum of other common disinfectants is limited. (4).

Substitution with more expensive but less effective substances would place an unnecessary financial burden on the healthcare system, which is already under severe strain in many European countries, even though the risk potential of ethanol in these applications does not correspond to oral abuse and would lead to an increased infection potential.

The implementation of necessary infection control measures can help to reduce additional burden on the healthcare system and the economy caused by preventable infections. Hand disinfectants and surface disinfectants are risk-minimising biocides, medical devices and technologies. When used continuously, they can help to prevent infections (5). According to the Robert Koch Institute, approximately 600,000 nosocomial infections in Germany lead to up to 20,000 deaths every year (6). The length of hospital stays increases due to an infection. This leads to additional costs for the healthcare system. A cost-benefit analysis concludes that a variety of ‘Infection Protection and Control (IPC)’ programmes are cost-effective (7). These programmes also include hand hygiene, for which the relevant hand disinfectants are required (8). The results show how essential it is to maintain and strengthen preventive measures against nosocomial infections. These include hand disinfectants and surface disinfectants. A classification as required in this procedure would endanger the protection against (nosocomial) infections to an unimaginable extent.

Disinfectants are often placed on the market as dual use products under the BPR and the medical device regulation (MDR; Reg 2017/745). A change in the main active ingredient requires extensive and resource-intensive testing and approval

processes under both regulations. To place a medical device on the market the development and approval process lasts at least 7 years.

Additional to the approval processes also indirect expenses within the use and application have to be considered e.g. employee training, disinfection protocols and SOPs and the modification of inventory management systems.

4. Hazards and Risks of the Alternative

Possible alternatives of Ethanol show different hazards and risks depending on the specific substance.

The profiles of in the section 1 mentioned substances are well known within the European Chemical Agency and therefore we want to highlight only a few arguments:

Isopropanol shows a comparable hazard and risk profile to Ethanol. Besides the chemical properties also the higher skin dryness caused by isopropanol has to be considered.

The hazardous profile of other alternatives like hydrogen peroxide is significant different and show characteristics like corrosion, possible eye and skin damage.

5. Availability

Possible alternatives are available in principle, but scaling the production volume is not possible in the short or medium term.

Strict planning rules and limit thresholds for industrial plants have always been part of everyday life for the chemical industry. Especially for chemicals such as hydrogen peroxide, authorisation procedures for plants are necessary due to the potential risk.

Isopropanol has a petrochemical origin and considerable environmental drawbacks due to the energy intensive production must be taken into account.

6. Other comments

Within classification processes, substance authorisations and product approvals the regulatory complexity must be considered.

A possible classification of Ethanol as CMR 1A/1B have a huge impact on other legislations. Among other product legislations its mainly the MDR (especially Annex 1, section 10.4.1), but also occupational safety law and maternity protection law.

Especially in the women dominated field of health care this would lead to restrictions in the use of the chemical for example by women of childbearing age or breastfeeding women.

We therefore urge for a proper impact assessment within BPR and CLP processes to avoid dramatic consequences.

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

Ethanol is recommended for hygienic uses by the WHO and the German RKI and is safely used for over 75 year worldwide even Islamic countries (9) (10). Since 2005, hand sanitiser dispensers have been installed in numerous healthcare facilities in Saudi Arabia (11). Ahmed et al. (2006) report that alcohol has long been a component of household cleaners and other materials for public use by Muslims. Since 2003, the use of alcohol-based hand sanitizers has been permitted in hospitals of the Saudi Arabian National Guard (SANG-HA) (12).

The planned classification of Ethanol is mainly based on data from the - abusive - oral intake of alcoholic beverages.

This hazard-based classification does not reflect use and exposure in hygienic applications and would have a huge impact to the healthcare system.

BVMed therefore urgently request that the planned classification be stopped immediately and for only exposure-relevant data to be included within the assessment.

This would avoid serious consequences for the industrial health sector, which would severely restrict or even ban the availability and use of ethanol as the main or auxiliary active ingredient in products such as hand disinfectants, surface disinfectants and in various production and hygiene processes.

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