VERBAND DER CHEMISCHEN INDUSTRIE e.V.
WIR GESTALTEN ZUKUNFT.

Impacts of classification under the CLP Regulation on other pieces of legislation – on the example of ethanol

Summary position

The classification of substances, mixtures or articles has considerable impacts on other legal fields in EU and national law, as many of these fields resort to the classification and labelling system when it comes to laying down their own specific protection measures. Consequently, tightenings in classification usually result in automatic tightenings also in those legal areas which refer to the above-mentioned classification. Such tightenings can have the shape, for example, of costly retrofitting of plants or marketing restrictions/bans.

The existing automatism gives no consideration to the fact that the classification criteria of the CLP Regulation are based on the intrinsic properties of substances, irrespective of their form/physical state or use. Thus, without a risk assessment the real risk remains ignored for the respective use of a substance. This can lead to unjustifiable requirements in the use of substances/mixtures.

The dossier for ethanol is currently being evaluated according to the Biocidal Products Regulation (EU) No 528/2012 for the use of ethanol as a biocidal active substance. The rapporteur state is Greece. As harmonised classification and labelling is usually pursued for biocidal active substances, the discussion about a harmonised classification of ethanol – as carcinogenic category 1A and toxic for reproduction category 1A – is likely to spring up again at EU level.

Ethanol is used on the industrial scale as a solvent and in many mixtures intended for the general public, e.g. as skin and surface disinfectants in hospitals and private households, in detergent and cleaning products or in cosmetic agents. Where the respective use or range of application is not outside the scope of the CLP Regulation (e.g. in medicines, foods or feeding stuffs) a restriction could apply according to Annex XVII of the REACH Regulation should ethanol be classified as carcinogenic or toxic for reproduction. Except for ethanol-containing foods, it would be no longer permitted to supply ethanol-containing mixtures and articles to members of the general public, and ethanol would need to be substituted in the products – irrespective of whether substitutes with equal benefits are available or not (e.g. in surface disinfection).

It is becoming obvious that the automatic link between classification under the CLP Regulation and connected pieces of legislation does not serve the protection of human health and environment without further risk assessment.

Against this backdrop, industry is calling to examine in detail and on the basis of Articles 36 and 37(1) of the CLP Regulation whether a harmonised classification is necessary for ethanol and whether such harmonised classification would genuinely improve occupational health and safety and the protection of environment and consumers. Otherwise, no harmonised classification should be striven for.

Moreover, for the future it is planned to perform risk assessments for substances of economic relevance as soon as a harmonised classification of a substance is forthcoming. Where adequate risk management is already in place for uses by consumers, for workers or the environment, exemptions need to be established within proportionality, preventing the elimination of entire product groups/productions. Given the wide use of ethanol and the expected negative consequences for consumers and industry (particularly for small and mid-sized enterprises/SMEs) in case of a classification as carcinogenic and toxic for reproduction if swallowed, it should be examined whether a harmonised classification is warranted. Otherwise, there should be no harmonised classification.

Contents

Background

The harmonised and thus legally binding classification of a substance according to the CLP Regulation (for carcinogenic, mutagenic or reproductive toxic substances and for substances causing respiratory sensitisation) has far-reaching consequences for almost all uses of this substance. In the legal provisions on occupational health and safety and on the protection of environment and consumers or in special legislation on biocidal or cosmetic products, usually a classification leads to comprehensive obligations or even to direct use bans, for example, when this is about a carcinogenic, mutagenic or reproductive toxic substance. This happens automatically and without any further examination of whether the use of the substance poses any risks.

At present, a harmonised classification of ethanol as carcinogenic category 1A and toxic for reproduction category 1A is once more under discussion at EU level: against the backdrop of the dossier evaluation for ethanol for use as a biocidal active substance. According to Article 36(2) of the CLP Regulation, substances that are biocidal active

substances in the meaning of the Biocidal Products Regulation 98/8/EC[1] shall normally be subject to harmonised classification and labelling rules. Next, the procedure – inter alia pursuant to Article 37(1) – applies where the competent authority can submit to the European Chemicals Agency (ECHA) a proposal for harmonised classification and labelling.

Greece is the rapporteur Member State for the review of ethanol within the Review Program for biocidal active substances. A first draft for a competent authority report was already submitted; it is currently open for comments by the other Member States. Based on the comments received and on the discussions with the other Member States, Greece can then present a second draft by the meeting of the competent working group of the Biocidal Products Committee (probably in September 2015). It remains to be seen whether a proposal for harmonised classification will come from Greece.

The competent Greek authorities can submit to ECHA a proposal for harmonised classification and labelling according to Article 37(1) of the CLP Regulation, but they are under no obligation to do so.

For harmonised classification all available and good quality data must be resorted to. Therefore, also studies need to be taken into account which are likely to result in a classification of ethanol as carcinogenic and toxic for reproduction. Such a classification of ethanol would have major consequences for almost all uses – not only for the consumer sector but also for industry.

From the toxicological viewpoint a classification as carcinogenic category 1A and toxic for reproduction category 1A would be comprehensible, because for years there have been numerous studies which substantiate the carcinogenic and reproductive toxic effect of ethanol at repeated oral exposure. The studies scrutinised for an assessment of the carcinogenic and reproductive toxic properties of ethanol are largely based on the experiences from the consumption of ethanol as a beverage. The data situation for the oral exposure to ethanol through alcoholic beverages is very good, as compared with other substances. But these data on oral exposure cannot be transferred directly to the scenarios where ethanol is used “only” as a chemical and not as a foodstuff.

Inhalative and dermal exposure are the relevant exposure routes. The use of ethanol for technical applications (such as a chemical or an ingredient of mixtures, e.g. as an additive, in disinfectants or cosmetics) is limited to these exposures.

In the scope of the CLP Regulation repeated oral exposure can be excluded in the intended use, for example, of consumer products (e.g. cosmetic agents, detergents and cleaning products etc.), for uses in the professional sector (e.g. disinfectants) and for occupational health and safety. Oral exposure can be expected primarily in the use of ethanol in products that fall in the scope of legislation on foodstuffs or medicines but are not subject to the CLP Regulation. Other exposure routes in the industrial sector (e.g. uptake by inhalation) are regulated by limit values (inter alia, limit values for the workplace and emissions).

[1] Repealed by the existing Biocidal Products Regulation (EU) No 528/2012 applicable since 1 September 2013

In Germany, the Permanent Senate Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (MAK Commission) laid down a MAK value[2] of 500 ml/m^3. This value was taken over by the Committee for Hazardous Substances in the Technical Rules for Hazardous Substances (TRGS 900), becoming the applicable occupational exposure limit in Germany. According to the MAK substantiation, the average internal lifetime burden through ethanol at an occupational exposure concentration of 500 mg/m^3 is within the endogenous burden so that workplace exposures of up to 500 ml of ethanol/m^3 do not constitute a noteworthy contribution to the cancer risk. Regarding the teratogenic effect of the alcohol, it is held that the maternal blood ethanol concentration – to which such effects are attributed – is in an order of magnitude which can never be reached through inhalative exposure in the range of the MAK value. Furthermore, it is held that no critical blood concentrations can be reached through dermal uptake.[3]

In the intended use of consumer products no critical blood ethanol concentrations can be reached, either.

No risk assessment is performed for classification under the CLP Regulation. Moreover, under the CLP Regulation the potency of a substance is given no consideration for carcinogenic, mutagenic and reproductive toxic substances (CMR substances) – unlike this is done e.g. for acute toxicity. However, recent scientific publications advocate the taking into account of potency in the classification of carcinogenic and reproductive toxic substances.[4]

But pursuant to Annex I no. 3.6.2.1 of the CLP Regulation it can be warranted to make a classification as carcinogenic based on only one exposure route *"if it can be conclusively proved that no other route of exposure exhibits the hazard."* In consequence, ethanol would need to be classified as carcinogenic only based on the route of oral exposure. As expounded above, within the scope of the chemicals legislation there is no intended oral exposure to ethanol.

This example of a given substance highlights that the risk posed by the use of a substance needs to be examined before automatic legal consequences enter into force under other pieces of legislation: For ethanol the costs, the workload and the use conditions, which would arise automatically from a legal classification as carcinogenic or toxic for reproduction, would obviously be disproportionate to the risk posed by the use of ethanol.

Irrespective of major consequences, a classification of ethanol under the CLP Regulation would not enhance the protection level in the meaning of the legislation on chemicals, occupational health and safety or environmental protection.

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[2] Maximum workplace concentrations

[3] Substantiation of the MAK value for ethanol, published in the series Gesundheitsschädliche Arbeitsstoffe, 26. Lieferung, Ausgabe 1998. DOI: 10.1002/3527600418.mb6417d00, available from http://onlinelibrary.wiley.com/book/10.1002/3527600418

[4] C. Hennes et al., Incorporating potency into EU classification for carcinogenicity and reproductive toxicity, Regulatory Toxicology and Pharmacology, Volume 70(2), November 2014, 457–467

Fields of application for ethanol – An "allround" input

In the year 2012 over 58 million hectolitres (corresponding to ca. 4.5 million tonnes) of ethanol were produced in the European Union, and over 5 million hectolitres were imported. In 2013 the total ethanol consumption in the European Union even exceeded the figures from 2012: over 60 million hectolitres of ethanol were produced and more than 7 million hectolitres were imported. Out of this total, only a relatively small share (ca. 10 %) went into foodstuffs and luxury foods. Somewhat under 1 tenth out of this total was used as solvents in the industrial sector, while over half of the ethanol produced or imported in Europe was used as fuel or fuel additive.[5]

Uses of ethanol in detergents, cleaning and maintenance products for private consumers

Ethanol is used in many detergents and cleaning and maintenance products, for example in

- liquid detergents,
- rinse agents for dishwashers,
- hand dishwashing products,
- household cleaners,
- glass cleaners,
- anti-freeze glass cleaners, defrosting agents,
- shoe care products,
- room scents.

Ethanol concentrations can reach up to 70 % in anti-freeze glass cleaners, defrosting agents and room scents and up to 30 % in glass cleaners, while ethanol concentrations are maximally 10 % in other detergents and cleaning and maintenance products. Detergents and cleaning and maintenance products are usually applied in diluted form (0.5 - 10 %) in water.

In the year 2013, sales achieved with detergents and cleaning and maintenance products for private consumers totalled 4.3 billion euros in Germany.

According to the results of a survey by the German Cosmetic, Toiletry, Perfumery and Detergent Association (IKW), around 21,200 tonnes of alcoholic solvents (mostly ethanol and isopropyl alcohol) were used in 2012. Here, the share of ethanol should amount to ca. 75 % (i.e. roughly 15,000 tonnes per annum). Due to customs regulations, usually denatured ethanol is used which is unsuitable for oral uptake.

Regarding a substitution of ethanol in all cleaning products, it should be taken into account that ethanol has different functions in detergents and cleaning and maintenance products, depending on the field of application; for example as

[5] Exchange of views on the Ethyl Alcohol market, Preparation 2012 Balance sheet, 418th meeting of the management committee for the common organization of agricultural markets; Ethyl alcohol balance EU-27 2013, EU Official Journal C 358/5 of 10.10.2014

- soil release agent,
- viscosity regulator,
- storage stabiliser,
- wetting agent,
- foam regulator,
- or anti-freeze / defrosting agent.

Given the versatility of ethanol for different uses and application purposes, in many fields only complex solutions would enable a substitution. Such solutions could be realised only with considerable development work at high cost.

Moreover, it can be assumed that in most cases the toxicological properties of the substituting substances are examined less intensively than those of ethanol. In individual instances, substitution might be possible e.g. by isopropyl alcohol, resulting in less favourable product properties (e.g. odour).

In Germany, detergents and cleaning and maintenance products are subject, inter alia, to the Food, Feed and Commodities Code (LFGB) where §30 bans the production, treatment or placing on the market of consumer goods which, due to their material composition, can damage health in their intended or foreseeable use.

An oral uptake of detergents or cleaning and maintenance products is neither an intended nor a foreseeable use but constitutes misuse. It is worth noting that the reports by the Federal Institute for Risk Assessment (BfR) and the poison information centres do not allow the conclusion that detergents or cleaning and maintenance products are misused by drinking them because of their ethanol content.

Use of ethanol in professional cleaning and disinfection

Ethanol is used in numerous products for professional cleaning and disinfection. The advantages of ethanol are excellent effectiveness (particularly its antiviral effect) and high volatility. Ethanol evaporates in application and, unlike other active ingredients; it does not remain on the skin or on surfaces as an unwanted residue.

Because of stringent and strictly controlled customs regulations, usually denatured ethanol is used which is unsuitable for human consumption (oral uptake).

Major fields of application:

1. Skin and hand disinfectants

Skin and hand disinfectants consist of ethanol or mixtures of ethanol with propanol as active ingredients. They are indispensable for maintaining hygiene in hospitals and medical practices, in food service and processing industries, and in the pharmaceutical industry. These products/active ingredients are the best way to prevent nosocomial (hospital acquired) infections and to control multi-resistant germs, to avoid germ trans-

mission in the food chain, and for product protection. Only thorough and regular hand hygiene can effectively interrupt transmission paths.

The German market for hand disinfectants is worth ca. 80 million euros. All virucidal products are based on ethanol. Here, other known disinfectants have a reduced efficacy spectrum.

2. Ethanol in ready-for-use disinfectant products

Ready-for-use ethanol products of high alcohol content are the products of choice for the targeted, needs-oriented disinfection of small areas in the health sector, in large-scale kitchens, in food treatment and processing and in the pharmaceutical industry. These disinfectants are applied via hand spray bottles or impregnated tissue systems. Here, too, the products are ethanol-based; their residue behaviour and fast application are peerless as compared with other active ingredients. Also for these reasons, ethanol-containing products are preferred in the implementation of HACCP concepts.[6] This market is worth roughly 50 million euros in Germany.

3. Use of ethanol in glass cleaners

All ready-for-use glass cleaners for the cleaning of glass mirrors and sensitive surfaces are mostly based on ethanol as active ingredient. Partly, mixtures of ethanol with other alcohols (e.g. propanol) are used too. The absence from residues and the easy applicability of ethanol-based products cannot be equalled with other inputs. Sales of ca. 20 million euros are achieved in Germany with this product group.

Use of ethanol in cosmetic products

Ethanol is an important constituent in the formulations of many different cosmetic products, e.g. skin creams, facial tonics, deodorants, perfumes, sunscreens, oral care products, nail varnishes, mascara and lipsticks. In the year 2013, cosmetic product sales in Germany totalled 12.9 billion euros. The use concentrations are up to 95 % in perfumes, hairsprays, deodorant sprays etc., up to 30 % in sunscreens, skin care products and lipsticks, and up to 10 % in many other product categories.

Cosmetic products are closely observed by consumers and the media, and all scientific findings are taken note of critically. A classification as carcinogenic or toxic for reproduction might have highly negative consequences in the public discussion. This would pose a threat especially to natural cosmetics, because also this sector frequently works with ethanol or ethanolic extracts. There is no substitute for ethanol in the fragrance and perfume industry.

Use of ethanol in printing inks and varnishes

The German and European printing ink industry uses ethanol mainly in printing inks and varnishes for food packaging where ethanol is among the most important basic

[6] Hazard Analysis and Critical Control Points concept

solvents. The relevant printing inks and varnishes are printed on plastic films mostly in so-called gravure and flexo printing. Food packaging obtained in this manner accounts for most types of standard commercial food packaging.

Ethanol emitted during the printing process is regulated by the German (European) immission (emission) protection provisions. Residual contents in printed packaging are strictly limited; they are subject to food law rules. The limit values laid down by ethanol experts for food packaging are by several orders of magnitude higher than they would ever be detectable in foodstuffs in practice. Because of stringent and strictly controlled customs regulations, denatured ethanol is used in this sector without any exception. Consequently, it is unsuitable for human consumption (oral uptake). In total, ca. 25,000 - 30,000 tonnes of ethanol are channelled into this use in Germany alone; at European level this totals up roughly to at least 60,000 tonnes of ethanol. Converted into product volumes of ethanol-based printing inks and varnishes, this results in ca. 50,000 tonnes of printing inks in Germany and ca. 120,000 tonnes at European level. Sales achieved with these printing inks amount to ca. 200 million euros in Germany and ca. 400 million euros in Europe.

In practice, already the discussion about potential carcinogenic, mutagenic or reproductive toxic properties of a substance used in consumer products triggers rejection in customers.

This impacts in particular the printing inks and varnishes used in food packaging production. Using carcinogenic or reproductive toxic substances in food packaging would be unthinkable for reasons of customer acceptance, and such a classification of ethanol would mean the immediate end for the use of ethanol in printing inks for food packaging – without ethanol posing a real risk for consumers.

Use of ethanol in food production

Ethanol is a constituent of many foodstuffs, typically of alcohol-containing products (e.g. beer, wine and spirits, alcoholic chocolates). Furthermore, ethanol in low quantities is a constituent of ingredients in processed foods. Through fermentation or fermentative processes, low concentration ethanol also forms naturally in various “non-alcoholic” foodstuffs (e.g. in ripe fruits and juices up to 1 % ethanol, in kefir up to 1 % ethanol, in sourdough bread up to 0.3 % ethanol).

Ethanol is used deliberately as an ingredient or an auxiliary substance in food production. Fields of application:

- Ingredient for foodstuffs (e.g. liqueurs) and food preparations,
- raw material in the production of table vinegar,
- ingredient or raw material in the production of food flavouring agents (mainly as a carrier and an extraction solvent, starting material or technical auxiliary substance),
- solvent and extractant for botanical extracts, food additives and functional raw materials for the food sector,

- crystallisation aid, precipitation agent and use for wash steps in production processes for inputs for the food sector.

In pure form or as a constituent, ethanol is also used for cleaning and/or disinfection purposes and for technical purposes in food production:

- In pure form for the cleaning of cutting/slicing machines and to remove protein residues after equipment and machinery cleaning,
- disinfection of equipment and machinery, particularly for the (fast) disinfection of surfaces in food contact,
- disinfection connected with the filling of processed products,
- hand hygiene, staff hygiene.

At EU level, Directive 2009/32/EC permits ethanol as an extraction solvent for all uses in the production of foodstuffs and food ingredients. According to Regulation (EC) No 889/2008, ethanol is the only permitted solvent for foods from organic production. Depending on the company, volumes of up to several thousands of tonnes of ethanol are used annually as a carrier and an extractant for the production of flavouring agents and extracts from botanical starting materials. Flavouring agents can largely consist of ethanol.

To date, ethanol can be used in the food sector without any regulatory restriction. This explains the very wide application and use of ethanol so that the question of alternatives did not come up any earlier. Given its high volatility, ethanol also enables intermediate disinfection without rinsing; this avoids residual water in the production process. Without ethanol for disinfection, certain hygiene concepts for the food sector (especially against mould) would become impossible to implement. As other biocidal active ingredients (QAV, chlorine-containing substances) are no longer available, ethanol-containing cleaners and disinfectants are among the few remaining alternatives for the cleaning of machinery and equipment in the production of baby foods and organic foodstuffs. Ethanol in concentrations of 50-100% is used for disinfection purposes in dairies. Because of its special properties (high efficacy against germs, free from water, fast evaporation without residues), there are no comparable alternatives.

According to the CLP Regulation, only end products for final consumers would not fall under the classification and the labelling requirement for ethanol as carcinogenic and toxic for reproduction. This would mean that many foodstuffs and their ingredients can be manufactured no longer or only under the strictest conditions in the European Union. This gives rise to fears of food production relocating to non-EU Member States, with an enormous economic damage for the European food industry. Moreover, the non-availability of ethanol-containing cleaners and disinfectants would put at stake food hygiene. This is likely to result in an increase in microbial risks, with negative impacts on food safety.

Use of ethanol as a fuel additive

In Germany, the minimum share according to §37a of the German Federal Immission

Control Act (Bundes-Immissionsschutzgesetz/BImSchG; act on the prevention of harmful effects on the environment caused by air pollution, noise, vibration and similar phenomena) of biofuels in the total quantity of petrol and diesel placed on the market by the mineral oil industry shall be 6.25 % in each year. In the field of Otto fuels only ethanol is available in sufficient quantities to meet this requirement. Consequently, in 2013 over 1.2 million tonnes of ethanol were added to Otto fuels and placed on the market. The provisions of the existing act prescribe a changeover to the greenhouse gas share from 2015.

Ethanol as a process solvent and in analytics

Ethanol is used as a process solvent in many large-scale industrial processes, e.g. in the production of medicines, liquid crystals, colorants, staining solutions and test kits for rapid analysis. Here, ethanol is preferable to other solvents: Ethanol can be removed easily from the finished product after the relevant production steps, and residues do not pose any risk to consumers.

Ethanol is used in analytics e.g. as a simulant to assess the migration from plastic food contact materials.

Migration can be determined in real foodstuffs in contact with the commodity in the intended use or, for the sake of simplicity, in food simulants. Usually, simulant solvents serve for this purpose. The standard migration conditions for plastics are laid down in Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food.

Use of ethanol in in-vitro diagnostics (IVDs) / Medical devices

Ethanol is an important solvent in the manufacture of in-vitro diagnostics and a major component of many of these products. IVDs include reagents and test strips. These are used for the medical laboratory examination of samples taken from the body and thus constitute an essential basis for the targeted therapy of diseases.

CONCLUSION

A classification of ethanol as carcinogenic and toxic for reproduction cannot enhance the health protection of consumers. Quite the contrary, such classification would lead to a considerable loss in health protection e.g. in the field of disinfection. Moreover, many everyday products for end consumers and in the professional sector would be no longer available.

A substitution of ethanol, which is possible only in some individual cases, would result in a situation where the only solvent obtained from renewable resources (ethanol received from fermentation or agricultural raw materials) would have to be substituted by petrochemical solvents.

Automatic legal consequences of classification – on the example of ethanol

CHEMICALS LEGISLATION

A number of rules in the chemicals legislation are linked with classifications according to the CLP Regulation, e.g. the providing of safety data sheets to recipients or chemical safety reports with exposure scenarios under REACH. The classification of substances is also a decisive criterion in decisions for restrictions and authorisation requirements within the REACH Regulation.

REACH restriction

Commission regulations under REACH restrict the manufacture, placing on the market and use of substances which pose an unacceptable risk to human health or the environment. After the inclusion of CMR substances in Annex VI to the CLP Regulation, the Commission regularly imposes use restrictions for these substances in consumer products. Entries 28 to 30 in REACH Annex XVII govern the restriction of substances classified as carcinogenic, mutagenic or toxic for reproduction in consumer products (categories 1A and 1B). As soon as a substance is included by way of Commission regulation in one of the tables appertaining to these entries, this substance can be no longer used in uses for final consumers or placed on the market if a certain concentration limit is exceeded. This concentration limit can be either laid down – as a substance-specific concentration limit – within the harmonised classification according to the CLP Regulation, or it is generically 0.1 % for substances classified as carcinogenic cat. 1A or 1B and 0.3 % for substances classified as toxic for reproduction cat. 1A or 1B. The concentration limit usually reflects the value where no risk needs to be expected.

In practice, this means that consumer products like detergents and cleaning and maintenance products would be subject, inter alia, to the ban of sale to the general public according to the REACH Regulation (EC) No 1907/2006, Annex XVII, nos. 28 and 30 if a substance-specific limit value (to be determined for ethanol) was exceeded of if the generic limit value for ethanol was equalled/exceeded.

Consequences for manufacturers would be work- and cost-intensive reformulations and the loss of an ingredient which offers excellent biodegradability and can be obtained from renewables – without taking into account that the use of ethanol in detergents and cleaning and maintenance products primarily involves dermal exposure but no relevant oral exposure.

Such a use ban would also impact skin and hand disinfectants as well as surface disinfectants for private households.

Recent scientific studies clearly show that regular or multiple disinfection with ethanol causes no relevant dermal ethanol absorption in users.[7] No carcinogenic or reproduc-

[7] Reinhold Andreas Lang et al., Transdermal absorption of ethanol- and 1-propanol-containing hand disinfectants, Langenbeck's Archives of Surgery, vol. 396, issue 7, pp. 1055-1060

tive toxic properties need to be expected in dermal exposure scenarios, which would have to be resorted to for assessing the risk potential of ethanol. Within the “Screening Information Data Set” the OECD concluded in October 2004 that no well-substantiated evidence was found for risks at the workplace or through the use of ethanol in consumer products.

Instead, a classification of ethanol as carcinogenic and toxic for reproduction without any differentiation of exposure routes would have far-reaching negative effects on maintaining the medically necessary hygiene standards in private and public health and in industry (foodstuffs, pharma industry). Hand disinfection is globally accepted as the most efficient strategy against the spreading of bacterial or viral diseases, particularly against multi-resistant microorganisms. The World Health Organization (WHO) explicitly recommends an ethanol-based formulation of 80 % by volume for regular hand disinfection. In Germany, the Federal Institute for Drugs and Medical Devices (BfArM) granted several standard approvals for ethanol-based hand disinfectants. Available studies show that alcohol-based hand disinfection, as it is common practice in the health sector, is much better tolerated by the human skin than the also used soap-based cleaning products.

A classification as carcinogenic and toxic for reproduction if swallowed and the resulting use ban in consumer products would cause a gradual worsening of the public hygiene standard. This should be seen in a negative light, also in respect of the model role of European health care systems for newly industrialised countries. The worldwide hand hygiene campaigns initiated by the industrial nations are almost invariably based on ethanol hand disinfection; these campaigns would be reduced to absurdity.

REACH authorisation

After undergoing a multistage procedure, substances classified as carcinogenic or toxic for reproduction cat. 1A or 1B can be subjected to an authorisation requirement. After expiry of a transitional period (“sunset date”) then the use of such substances only remains possible if the impacted company has filed a costly application for the authorisation of the relevant use(s). Moreover, authorisations are reviewed and can be withdrawn so that the authorisation costs need to be incurred repeatedly and companies have no adequate protection of investments.

In practice, already the inclusion of a substance in the candidate list of substances for authorisation triggers reactions among customers: Especially consumer goods manufacturers do not want to use such substances in the production chain, not even where the substances are no longer present in the final products.

OCCUPATIONAL HEALTH AND SAFETY

As regards occupational health and safety, there would be massive impacts on activities involving ethanol.

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work (Chemical Agents Directive, CAD)

Alongside the obligations arising from the physico-chemical properties of ethanol, a classification as carcinogenic or toxic for reproduction cat. 1A would also generate additional obligations for employers.

For each activity involving ethanol (a widely used laboratory and process chemical), the risk would need to be newly determined, assessed and documented (Article 4).

According to Articles 5 and 6 of the Directive, general and specific protection and prevention measures for hazardous chemical agents at work, including physico-chemical risks, would need to be taken into account. Arrangements would have to be made to deal with accidents, incidents and emergencies (Article 7), and workers would need to be informed about the measures and their activity involving a hazardous chemical agent.

In practice, this means the following for the companies:

- New risk assessments and possibly also analyses if substitution is suitable (checks for substitutions) would need to be performed for all processes using ethanol.
- All protection measures (technical, organisational, personal) for the concerned processes would need to be reviewed and adapted if necessary.
- All operating instructions and the list of hazardous chemical agents would have to be updated.
- Internal labelling, e. g. on containers and pipes, would need to be reviewed and adapted if necessary.
- It would have to be examined whether use restrictions might apply for the concerned processes.

Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (CMD)

The Carcinogens and Mutagens Directive puts employers under the obligation to reduce the use of carcinogens at the workplace and to replace the substance or the process as far as is possible. Employers also need to document their efforts and submit the findings to the relevant authorities. In detail, this means the following:

- Prevention of worker exposure by way of suitable measures or reduction to the lowest level as is technically possible,
- replacing the substance or the process if technically possible, or

- use of the substance in closed systems if technically possible.
- Employers need to take measures against unforeseen exposure, e.g. due to an accident.
- Workers need to be trained specifically and regularly in the handling of carcinogenic substances.
- Health surveillance for workers is necessary prior to first exposure and at regular intervals thereafter.
- Employers need to take special measures for access control to the working area where carcinogenic substances are used.

Furthermore, employers need to take the following general measures to protect workers:

- Limitation of the quantities of a carcinogen or mutagen at the place of work;
- keeping as low as possible the number of workers exposed or likely to be exposed;
- design of work processes and engineering control measures so as to avoid or minimise the release of carcinogens or mutagens into the place of work;
- evacuation of carcinogens or mutagens at source, local extraction system or general ventilation, all such methods to be appropriate and compatible with the need to protect public health and the environment;
- use of existing appropriate procedures for the measurement of carcinogens or mutagens, in particular for the early detection of abnormal exposures resulting from an unforeseeable event or an accident;
- application of suitable working procedures and methods;
- collective protection measures and/or, where exposure cannot be avoided by other means, individual protection measures;
- hygiene measures, in particular regular cleaning of floors, walls and other surfaces;
- information for workers;
- demarcation of risk areas and use of adequate warning and safety signs including ‘no smoking’ signs in areas where workers are exposed or are likely to be exposed to carcinogens or mutagens;
- drawing up plans to deal with emergencies likely to result in abnormally high exposure;
- means for safe storage, handling and transportation, in particular by using sealed and clearly and visibly labelled containers;
- means for safe collection, storage and disposal of waste by workers, including the use of sealed and clearly and visibly labelled containers.

In particular the putting into place of special extraction systems and measuring facilities

is very cost-intensive and without any evident benefit for the safety of workers from exposure to ethanol – a substance which is not carcinogenic in inhalative or dermal exposure.

Demarcation of the workplace, where ethanol is to be used, as a risk area and displaying “adequate” warning and safety signs seems grotesque: ethanol is a solvent for which – unlike for other solvents – safe use can be ensured easily, and during working hours an exposure causing a cancer disease could be brought about only by way of misuse.

Directive 92/85/EEC on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding

Pregnant and breastfeeding workers in the meaning of Directive 92/85/EEC may under no circumstances be obliged to perform duties where the assessment has revealed a risk of exposure, which would jeopardize safety or health, to carcinogenic or mutagenic agents.

Consequently, pregnant workers in the food service industry could only work with alcoholic beverages if exposure can be excluded. Otherwise, such activities would need to be performed by their colleagues.

The impacts of tighter occupational health and safety (OHS) rules concern many sectors:

According to the German Federal Statistical Office, in July 2014 around 20,000 persons were working in the industry producing detergents and cleaning and maintenance products. An estimate by the German Cosmetic, Toiletry, Perfumery and Detergent Association (IKW) shows that out of this total roughly 10 % (2,000 persons in production and product development) are handling denatured ethanol, as is used for detergents and cleaning and maintenance products.

Roughly 45,000 persons are working in the production of cosmetic agents. Pursuant to an IKW estimate, out of this total ca. 40 % (18,000 persons in production and product development) are handling denatured or undenatured ethanol, as is used for cosmetic products; most of these workers are women.

Additionally to workers employed directly in the cosmetics industry, over 450,000 persons (e.g. in skilled trades like hairdresser’s shops, beauty or nail salons or in specialist retail trade or distribution) are economically impacted by the provisions for cosmetic products.

No accidents with oral uptake of ethanol are known in the above sectors. Here, an oral uptake of ethanol would mean misuse which, from our viewpoint, cannot be influenced by tighter OHS rules. Moreover, denatured ethanol is frequently used in technical applications. Substances of unpleasant flavour or odour are deliberately chosen as denaturants so that the misuse of ethanol through oral uptake can be largely excluded.

As inhalative or dermal uptake routes have no role for mutagenic or reprotoxic effects, the question arises who would be protected by a classification of ethanol as carcinogenic or mutagenic.

The OHS rules apply in the production of food and feedstuffs and human and veterinary medicines, too, irrespective of these products being exempted from the provisions of the chemicals legislation like e.g. the REACH and CLP Regulations.

ENVIRONMENTAL LAW

Waste legislation

Under European legislation, the classification of waste is oriented to the EU chemicals law. The properties of waste which render it hazardous (formerly H-criteria, now HP-criteria) were adapted to the GHS system in late 2014. The H-criteria and the HP-criteria, respectively, determine from when the hazardous waste property is given. The basis for waste classification is created in the Waste Framework Directive (2008/98/EU) and in the European List of Waste.

The classification of waste as hazardous makes matters more complicated in several ways. For example, the control of waste – including the "waste bureaucracy" – is becoming much more exacting. Greater efforts become necessary to obtain permits for establishments. Requirements to waste disposal are rising, and so do the requirements in occupational health and safety.

SPECIAL LEGAL PROVISIONS

Biocidal Products Regulation (EU) No 528/2012 (BPR)

Active substances classified as carcinogenic or toxic for reproduction cat. 1A or 1B fall under the exclusion criteria according to Article 5 BPR. This means that such active substances are only approved if one of the following conditions is met:

- The risk to humans, animals or the environment is negligible under realistic worst case conditions of use.
- It is shown by evidence that the active substance is essential.
- Not approving the active substance would have a disproportionate negative impact on society.

A CMR classification would have far-reaching consequences under the biocidal products legislation:

for the approval of active substances:

- According to Article 4 BPR, an approval of ethanol as a biocidal active substance can be granted only for an initial period of 5 years (compared with 10 years otherwise); a renewal of the approval becomes necessary after that. For applicants, a renewal means a duplication of work and costs.

- In particular, this impacts disinfectants for skin, hands, medical instruments and surfaces in health care and veterinary hygiene.

for the approval of biocidal products:

- According to Article 19 BPR, biocidal products classified as carcinogenic or toxic for reproduction cat. 1A or 1B shall not be authorised for making available on the market for use by the general public. This would be the case already where a concentration of 0.1 % is exceeded in the biocidal product.
- According to Article 42 BPR, a Union authorisation – which enables the placing on the market and use in the entire European Union – cannot be granted for products that contain active substances falling under the exclusion criteria of Article 5 BPR. This means that a manufacturer who wants to place his biocidal product on the market in several EU Member States, needs to apply for one national authorisation and then for mutual recognition on every other Member State. This brings enormous workloads and costs.

Cosmetics Regulation

Cosmetic products are governed by the Cosmetics Regulation (EC) No 1223/2009. Pursuant to this piece of legislation, cosmetic products made available on the market shall be safe for human health when used under normal or reasonably foreseeable conditions of use. The safety of each individual product is assessed within the safety assessment. This is required for all cosmetic products and includes, inter alia, an examination of exposure. Also at comparatively high use concentrations of ethanol in some cosmetic products, exposure of consumers is usually very low.

Even in mouth care products, a relevant uptake of ethanol through cosmetics is very low; no uptake needs to be expected for all other products. In Germany, reports by the Federal Institute for Risk Assessment (BfR) or the poison information centres do not enable the conclusion that there is a misuse of cosmetic products by drinking them because of their ethanol content.

For the use of ethanol in cosmetic products, a possible classification of ethanol as carcinogenic or toxic for reproduction would result in a ban of this important ingredient – because of the direct link between the cosmetics and chemicals legislations, as regards CMR substances in cosmetics. This substance could not be used any longer at short notice, even though a non-availability of ethanol would not benefit in any way the health of workers or consumers. In principle, the cosmetics legislation provides for the possibility of using ethanol again after evaluation by the Scientific Committee on Consumer Safety (SCCS), but this would require a wide range of activities with an uncertain outcome. According to Article 15(2) of the Cosmetics Regulation (EC) No 1223/2009, the following items of information need to be submitted for an assessment of a CMR 1A or 1B substance under the cosmetics legislation (i.e. use is possible in exceptional cases at the following – rather narrow – conditions):

- Food safety requirements are complied with.
- An analysis has been performed of whether suitable alternative substances are available. Authorisation is possible if there are no such suitable alternative substances.
- Only one particular use with a known exposure is authorised.
- The substance must have been evaluated and found “safe” by the SCCS. Here, exposure to other sources is taken into consideration too. Re-evaluation by the SCCS every five years.

Legal provisions on motor fuels

According to Directive 2009/28/EC on the promotion of the use of energy from renewable sources and Directive 98/70/EC relating to the quality of petrol and diesel fuels, 10 % of the energy content of all fuels need to be replaced by renewable energy and 6 % of greenhouse gas emissions need to be cut by 2020.

In Germany, 672,028 tonnes of ethanol for the fuel sector were produced in the year 2013, and 1,206,255 tonnes were consumed. The major use of ethanol in Germany is admixing with petrol for the grades E5 and E10, followed by use as the petrol additive ETBE.

For the foreseeable future, only ethanol will be available in sufficient volumes as a substitute for vehicles with Otto engine.

Legal provisions on in vitro diagnostic (IVD)/medical devices

EU Directive 89/79/EC on in vitro diagnostic medical devices regulates their authorisation on the European market. Consequently, medical devices and thus also IVDs are subject to strict regulation; they need to bear the CE marking in proof of conformity. This ensures a high level of safety and quality for IVDs. Relevant legal provisions include not only general requirements to the safety of use and the suitability for the intended purpose; there are also special parts on design and production as regards the chemical and physical properties of IVDs.

There is no oral uptake of ethanol in the use of IVDs, but a classification as carcinogenic and/or toxic for reproduction would have strong negative consequences, for the following reason: Both users and the competent monitoring and regulatory agencies are highly critically observing the classification of IVDs under the dangerous substances legislation, and they are increasingly calling for less dangerous substitute substances.

Legal provisions on human and veterinary medicinal products and food and feeding stuff

The use of ethanol as a constituent of food and feeding stuffs or human and veterinary medicinal products does not fall in the scope of the REACH and CLP Regulations.

Therefore, it is exempted from classification and labelling under CLP and from the legal consequences ensuing from a restriction under the REACH Regulation.

However, the production of food and feeding stuffs and human and veterinary medicinal products is subject to the existing legislations on occupational health and safety and environmental protection and would be fully impacted by the earlier described tighter rules, in case of a classification of ethanol as carcinogenic and toxic for reproduction.

In particular, small and micro-enterprises enterprises in food production (such as distilleries and breweries) cannot implement the requirements for the handling of carcinogenic substances in their production processes. It is worth noting that these requirements are intended for the safe handling of dangerous substances like e.g. benzene. The usual tasting steps would be no longer permitted either.

As a result, many small and micro-enterprises (e.g. in the production of spirits) would be forced to give up operations, because a changeover would be impossible due to the arising costs or because of special features of the production process.

Evaluation of the situation

A harmonised classification of ethanol as carcinogenic and toxic for reproduction category A (H350: May cause cancer if swallowed; H360Df: May damage fertility or the unborn child if swallowed) – referring to oral uptake and according to the criteria of the CLP Regulation – would be based solely on intrinsic properties without risk assessment. Such classification would be formally correct. But the ensuing legal consequences for connected pieces of legislation, which are largely linked to the harmonised classification by an automatism, would be out of proportion to the real risk for human health or the environment.

Already today, repeated oral exposure of workers to ethanol is nearly excluded under the existing provisions for occupational health and safety. Misuse of ethanol cannot be fully prevented by any legal rules, irrespective of their level of detail. Dermal or inhalative exposure is below critical ethanol concentrations.

The only exposure route where a “repeated oral exposure to ethanol” can be assumed is the use of ethanol as a (luxury) food which (almost) everyone can consume at one’s own discretion – because this does not fall in the scope of the chemicals legislation. Irrespective of this, the manufacturers of ethanol-containing foodstuffs would be impacted by the consequences of classification and labelling to the OHS provisions and environmental protection rules.

Regarding the environment, ethanol is a solvent with many advantages, because it is readily biodegradable.

An examination of the intrinsic properties of ethanol clearly shows that substances can have dangerous properties (e.g. their oral uptake may cause cancer) while their use – where oral uptake is excluded – poses no risk.

It becomes evident that the automatic link between classification under the CLP Regu-

lation and connected pieces of legislation without further risk assessment does not contribute to enhancing the protection of human health and the environment. In the relevant legal fields this link results in obligations like e.g. a substitution requirement which employers or manufacturers of consumer products need to fulfil, also if they have no suitable substitutes available. This increases the risk of substances with less well-examined properties being used.

In the chemical industry, massive problems are caused mainly by the legal consequences of harmonised classification in connected legislations – whereas manufacturers of food and feedstuffs, food packaging or consumer-related products (e.g. cosmetics, cleaning agents or disinfectants) are impacted themselves by harmonised classification and labelling. Even if the connected pieces of legislation were adapted and exemptions for ethanol were introduced, the labelling requirement would still persist. Obviously, a consumer product labelled as carcinogenic could not be sold and would adversely affect the image of the manufacturer.

A classification of ethanol as carcinogenic and toxic for reproduction is highly likely to have a very negative influence on maintaining the mandatory standard of hygiene in the health sector where especially the risks of spreading multi-resistant micro-organisms need to be given consideration. The hygiene standard would be at risk in animal keeping too. Here, it is worth noting that the hygiene standard needs to be improved to enable a reduced use of antibiotics in animal keeping, as is pursued for political reasons.

European provisions on occupational health and safety, protection of the environment and consumer protection should aim to expose humans and environment to the lowest risk possible. It is essential to carry out a risk assessment for this purpose. Examining the intrinsic substance properties without examining exposure cannot replace a full risk assessment.

The classification is taken as the assessment basis for the above-described rules, without adding risk-related assessment parameters. This leads to factually unjustified legal consequences for the use of ethanol.

We are calling for the following:

Classification decisions should not lead to a non-availability of well-established, safely used substances or to disproportionate requirements in occupational health and safety and environmental protection.

Instead of automatic legal consequences, industry is calling for an examination of exposure and for a risk assessment to be first made for the uses at issue. Where adequate risk management is already in place for consumers, workers or environment, tighter rules should not apply automatically in connected legislations. Options permitting deviations from the “standard legal consequences” (e.g. exemptions from certain obligations) should be incorporated in all the relevant legal provisions. Industry should be involved in examinations of the legal consequences of classification decisions. For substances of economic relevance with risk management in place, classification deci-

sions should be suspended until a time the connected pieces of legislation have been adapted.

In view of the negative impacts of a possible classification of ethanol (as carcinogenic and toxic for reproduction) for the manufacturers of foods and consumer-related products, it should be examined in detail on the basis of Articles 36 and 37(1) of the CLP Regulation whether a harmonised classification is necessary for ethanol and whether such classification would really bring improvements in occupational health and safety, protection of the environment or consumer protection. If this is not the case, no harmonised classification should be pursued for ethanol.