

**Response to comments document (RCOM)**

on the Annex XV dossier

proposing restrictions on

**Methanol**

**Non-confidential**

**ECHA/RAC/RES-O-0000006324-78-01/F**

ECHA/SEAC/[reference code to be added after the adoption of the SEAC opinion]

**Substance name** **EC Number**  **CAS Number**

**Methanol**  200-659-6 67-56-1

4 December 2015

General Comments and answers to specific information requests

## Specific information requests:

1. According to the restriction report, poisoning cases by incidental ingestion of methanol are more frequent in the northern and central parts of Europe. However, cases of incidental methanol poisoning have been also reported in other parts of Europe. Do you have information on the number of poisoning cases in your country by incidental ingestion of methanol?
2. Could you provide any case reports of methanol poisoning in which methanol dose and health outcome was stated? Full-length published papers on case reports of methanol poisonings as well as unpublished reports of methanol poisoning from Poison Control Centres or other health care institutions would be appreciated.
3. The restriction report proposes a three month transition period for the application of the restriction since its entering into force. Do you have information whether a longer transition period would be required by producers and/or suppliers to adapt to the proposed restriction?
4. Could you provide information on potential substitutes for methanol, especifically on ethanol and isopropanol, regarding their price and market volume (gross turnover)?
5. The proposed restriction is addressed to the supply to the general public of methanol-containing windshield washing fluids and denaturated alcohol. Could you provide information on the market volumes of these two products in the EU?

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| **Ref.** | **Date/type/Org.** | **Comments** |
| **1250** | **Date:** 2015/03/23 15:33  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  Metachem  **Org. country:** Italy  **Company name confidential:** **No** | **General Comments:**  The proposal submitted by Poland not to place on the market methanol for supply to the general public exists in Italy since several years and, consequently, is not creating any new specific reaction. | |
| **Dossier submitter response:**  Thank you for submitting information about national methanol restriction. | |
| **RAC Rapporteurs comments:**  Thank you for this information. | |
| **SEAC Rapporteurs comments:**  Thank you for the comment.  Information was also provided by the Member State REACH Competent Authority. Included in the BD and considered. | |
| **1262** | **Date:** 2015/05/13 16:05  **Type:** BehalfOfAnOrganisation  **Org. type:** European institution  **Org. name:**  REACH Centrum (Methanol REACH Consortium)  **Org. country:** Belgium  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:**  The Methanol REACH Consortium welcomes the opportunity to submit preliminary comments to public consultation on the proposed methanol restriction under REACH.  The proposed restriction aims to tackle a serious issue related to abusers of products containing methanol.  Justification for an EU-wide restriction appears based on an assumption that a significant number of seasonal workers or even migrants between EU countries are abusing alcoholic products containing methanol. However, as the scope of the proposed restriction involves predominantly the misuse or  abuse of methanol and certain products not supported in the REACH registration dossier, the issue appears to be the need for appropriate risk management measures and enforcement to control such products.  The Methanol REACH Consortium has significant reservations with the proposed EU-wide restriction when there are other management and enforcement options available to Member States, such as the addition of bitterants and social programs to tackle this issue. Fortunately, the vast majority of the European population do not seek chemical surrogates to ethanol for consumption. When used as a denaturant in ethanol products, there is evidence that methanol acts as a strong deterrent to the consumption of these ethanol-containing products.  The benefits that methanol and certain methanol-containing products, including its use as a deterrent to product abuse, do not however appear to be addressed in the consultation. Consequently, the Methanol REACH Consortium disagrees with the proposed restriction and is of the opinion that other  risk management measures and appropriate enforcement would be more effective, and is willing to support Member States in finding a suitable solution that does not require an EU-wide restriction. | |
| **Answer to specific info request 1:**  The Methanol REACH Consortium has significant reservation as to the relevance and applicability of using a regional/isolated statistics to extrapolate to the rest of EU. For a few countries considered by the Consortium, the data presented in the Annex XV report does not look to be representative for other parts of EU.  Furthermore, when looking at particular cases, it is important to distinguish whether the product is legally or illegally on the market (bootleg alcohol) and whether any poisoning incidents resulted from a non-intentional misuse (accidental use) or from specific and intended abuse.  Without such distinctions, the consortium does not understand how the requested information can be used to determine whether the restriction would potentially result in lowering of poisoning incidents or possibly even increase cases of poisoning incidents from methanol or other chemicals. | |
| **Answer to specific info request 2:**  Methanol toxicity is well documented and has well known treatment methods.  References published in scientific journals include the annual reports of the American Association of Poison Control Centers’ National Data Poison Data System at http://www.aapcc.org/annual-reports. These include poisoning incident data on the alternatives proposed in the Annex XV report  (ethanol and isopropyl alcohol). For example, the report from 2013:  - Mowry, J.B. et al. (2014) 2013 annual report of the American Association of Poison Control Centers ’ National Poison Data System (NPDS):  31st Annual Report. Clinical Toxicology 52: 1032–1283/  When considering such data, it is important to note that hazard communication and packaging requirements (e.g. child-resistant fastenings) may differ in some countries to those in EU.  With regards to information on methanol on acute oral toxicity in humans including references to specific cases, citations in the Methanol REACH Consortium REACH registration dossier include:  - IPCS/WHO (1997). Methanol, Environmental Health Criteria 196. International Programme on Chemical Safety, World Health Organisation Geneva, 1997.  - Kavet, R. and Nauss, K. M. (1990). The toxicity of inhaled methanol vapors. Critical Reviews in Toxicology 21(1): 21-50.  - Roe, O. (1955). The metabolism and toxicity of methanol. Pharmacol Rev 7: 399-412.  - Dethlefs, R. and Naraqi, S. (1978). Ocular manifestations and complications of acute methyl alcohol intoxication. Med J Australia 2: 483-485.  - Naraqi, S. et al. (1979). An outbreak of acute methyl alcohol intoxication. Aust N Z J Med 9: 65-68.  - Erlanson, P. et al. (1965). Severe methanol intoxication. Acta Med Scand 177: 393-408.  - Becker, C. E. (1983). Methanol poisoning. J Emerg Med 1: 51-56.  - Jacobsen, D. et al. (1990). Effects of 4-methylpyrazole, methanol/ethylene glycol antidote, in healthy humans. J Emerg Med 8: 455-461.  Please note that many incident case reports relate to medical treatments in hospital; treatments may include fomepizole and IV folate, for example. | |
| **Answer to specific info request 3:**  The Methanol REACH Consortium does not see it as appropriate to discuss a transitional period based on the information received, when other risk management measures or appropriate enforcement are likely to be more effective. The Methanol Consortium is willing to support the Member States in finding a suitable solution that does not require an EU wide restriction.  The scope of the restriction proposal mainly involves misuse or abuse of methanol and certain products that are not supported in the REACH registration dossier (e.g. high methanol content windshield wash). From a REACH perspective, the control of such products appears to be an enforcement issue that has not been adequately addressed. | |
| **Answer to specific info request 4:**  Before looking at economic aspects of price and volumes, there is a need/duty to conduct a thorough substitution analysis (ie. technical/ safety performance as well as human health implications).  Absent that analysis, there is no evidence that ethanol and isopropanol would be reasonable substitutes. A forced substitution could result in unconsidered products to be used with potentially unforeseen impact on human health. | |
| **Answer to specific info request 5:**  The Methanol REACH Consortium requests that the wording in the proposed restriction specifies the intended scope of consumer uses and  distinguishes from the excluded professional uses, as stated in the Annex XV report on page 5.  Given the incomplete analysis of substitutes and alternative risk management measures presented in the Annex XV report, the Methanol REACH  Consortium is not in a position to complete a realistic evaluation of the market implications such a restriction would have. | |
| **Dossier submitter response:**  **General Comments:**  The proposed by PL CA for REACH and CLP methanol restriction is namely to eliminate poisonings caused by consumption of methanol contained in high concentrations in winter windshield washing fluids and in denatured alcohol by alcoholics and other person abusing alcohol. These products represent the most common cause of severe methanol poisonings, which in many cases turn fatal. Winter windshield washing fluids containing alcohol and denaturated alcohol, which are available in retail, are consumed as a surrogate of consumable alcohol by some alcoholics. This is encouraged by the difference in price between excisable consumable alcohol and the products in which alcohol is not excisable therefore the price of equivalent quantity of alcohol is considerably lower. Additives to ethanol contained in such products, which make it unpalatable for a great majority of people, do not deter many alcoholics from their consumption. A relatively limited availability of consumable alcohol contributes to using this easealy available surrogate of ethanol in some countries, such as Finland. The restriction of methanol concentration in these products will eliminate incidental methanol poisonings due to consumption of these products.  It was proved in the restriction dossier that restriction is the best risk management option (RMO). Other management options like e.g. addition of bitterants, child resistants fastenings or social programs will not solve the problem.  **Answer to specific info request 1:**  The proposed restriction is namely to eliminate poisonings caused by consumption of methanol contained in high concentrations in winter windshield washing fluids and in denatured alcohol by alcoholics and other person abusing alcohol. These products represent the most common cause of severe methanol poisonings, which in many cases turn fatal. Winter windshield washing fluids containing alcohol and denaturated alcohol, which are available in retail, are consumed as a surrogate of consumable alcohol by some alcoholics. This is encouraged by the difference in price between excisable consumable alcohol and the products in which alcohol is not excisable therefore the price of equivalent quantity of alcohol is considerably lower. In Poland for instance the price of half a litre of the cheapest 40% vodka reaches almost 5 EURO, while the price of 5 litres of the cheapest winter windshield washing fluid containing a similar concentration of ethanol, reaches 2 – 3 EURO. Half a litre of 70% denatured alcohol in Poland costs approx. 1 EURO. Similar price differences also occur in other countries. Additives to ethanol contained in such products, which make it unpalatable for a great majority of people, do not deter many alcoholics from their consumption. A relatively limited availability of consumable alcohol contributes to using this easealy available surrogate of ethanol in some countries, such as Finland. The restriction of methanol concentration in these products will eliminate incidental methanol poisonings due to consumption of these products.  A lot of acute poisonings with methanol from winter windshield washing fluids occur in north and east countries of EU where this kind of products are used by consumers. According to oral information we believe that PL, FI, SE, LT, LV, SL, EE will be positively affected in case of introducing of limitation of methanol in winter windshield washing fluids into force.  Below we included data on the number of poisoning cases related to abuse of methanol since the re-entry into force of the national restriction in Poland.  In February of 2015 Polish CA (Bureau for Chemical Substances) asked all the national Regional Acute Poisoning Centres and Forensic Medicine Centres to provide next data concerning the number of methanol poisonings occurring in the past two years.  Submitted information included time periods which enable a comparison of the data in the time interval when the regulation entered into force the ban of placing on the market for general public products containing methanol with the data concerning period when those provisions did not apply.  In our opinion, such a comparison allows us properly assess the effectiveness of implementing provisions. A total of 14 letters were sent to Forensic Medicine Centres and 12 letters to the Regional Acute Poisoning Centres. We received respectively 9 and 7 replies. Although, submitted information are not the full data concerning the methanol poisonings in Poland, but they can be regarded as a reliable statistical sample, allowing to draw conclusions with regards to effectiveness of the provision.  **CONCLUSIONS**  In January 2014 the placing on the market for general public products containing methanol in the concentration higher than 3,0% by weight was banned by Regulation of Ministry of Economy. Generally it can be concluded that after introducing that ban in Poland the number of poisonings began to fall.  **WINTER PERIOD**  **Data concerning the Regional Poison Centres**  According to data received from the Regional Acute Poisoning Centres in the winter period 2014/2015 there were noted 22 cases of poisoning, while in the winter period 2012/2013 were noted 60 such cases, which indicates almost 3-fold decrease in poisoning one year after implementing the ban.    **Data concerning the Forensic Medicine Centres**  A similar trend was also shown for data obtained from Forensic Medicine Centres.  During the winter 2014/2015 it was confirmed a total of 22 cases of poisoning, while in the period preceding the introduction of the ban in winter 2012/2013 it was recorded 81 cases of poisonings. This is a more than threefold decrease in poisoning.  The following figure illustrates observed decreasing trend:    **SUMMER PERIOD**  **Data concerning the Forensic Medicine Centres**  A similar trend concerning the occurrence of poisonings also remains at summer periods, but then was observed the lower numbers in comparison to winter periods.  Data received from 9 Forensic Medicine Centres confirmed the reduction of the number of poisonings observed in the second and third quarter of 2014 in comparison with the same period in 2013. A few months, after the ban was into force, it was reported 21 cases, while a 1 year earlier there were 50 such cases. The more than two-fold decrease in the number of poisonings is illustrated in the following figure.    **Data concerning the Regional Poison Centres**  The same character also has been observed for data obtained from Regional Poison Centres. While in the summer of 2013 it were reported 39 poisonings, in 2014 there were 19 such poisonings (two times less, as illustrated in the figure below).    **Answer to specific info request 3:**  As was proved in restriction dossier the restriction is the best option for risk management measures. No other EU legislation which may have the potential to reduce the identified risks was identified. Voluntary action by industry is not considered as an effective way of managing the targeted risks in this dossier. In our dossier we propose 3 months transition period taking into account that that all the information about restriction process are publicly available and that the restriction process is long. In our opinion if the restriction is adopted by RAC and SEAC the transition period will be discussed during REACH Committee.  **Answer to specific info request 4:**  A substitution analysis was performed in the dossier. It is technicaly possible to use, in product covered by the restriction, ethanol instead of methanol. It was also proved in the restriction dossier that alternative (ethanol) is safer, has lower impact on human health, than methanol.  **Answer to specific info request 5:**  In the restriction dossier a proposal for an Annex XVII entry is given as follows:“Shall not be placed on the market for supply to the general public”. In our opinion the scope of restriction is clear. It is clearly indicated that professional or industrial uses of methanol or methanol containing products are exempted from the restriction. | |
| **RAC Rapporteurs comments:**  **RAC Rapporteurs comment #1262-1. Reply to General Comments:**  Justification for an EU-wide restriction includes a possibility of misuse of methanol-containing products in seasonal workers or migrants between EU countries (e.g. in Italy among seasonal workers from the Central Europe’s states), but is primarily based on the fact that, according to information from the restriction proposal and data received during Public Consultation, windshied washer fluids and denatured alcohol caused poisoning among consumers in several EU Member States, including Belgium, Bulgaria, Finland, Germany, Hungary, Italy, Norway, Poland, Sweden and the United Kingdom, with Poland, Finland and Bulgaria as the most severly affected (methanol poisoning has been recorded in other EU countries as well, but poisoning statistics data did not provide source of methanol, or the information was not submitted during PC). In justification for an EU-wide restriction, a severity of the risk, namely death, blindness or other severe sequels of methanol poisoning, was also taken into account, as well as prevention of the market distortion. As explained by the Dossier Submitter, methanol-containing products are widely used in the EU and, given the significantly lower price of methanol compared to the price of alternatives (ethanol or isopropyl alcohol), restrictions limited to certain Member States would create a distortion of the market of methanol-containing products. Please, also see RAC Rapporteurs comment #1264-1. It can also be noted that several EU Member States have intoduced certain legislative measures at national level to reduce the risk of methanol poisoning in the general population, as presented in the restriction proposal and during Public Consultation.  Other management and enforcement options suggested by the Methanol REACH Consortium, such as the addition of bitterants and social programs to tackle this issue, are not considered to be adequate for the target population aimed to be covered with the proposed restriction. Namely, addition of bittering agent to a product is shown not to deter chronic alcoholics from drinking the product (*Toronto Public Health Fact Sheet ‘Non-palatable (toxic) alcohol use’, February 2011; Carnahan RM et al. Acute ethanol intoxication after consumption of hairspray. Pharmacotherapy 2005;25:1646-50; Reid W, Chen L. A Case of hand sanitizer ingestion. Clinical Vignette. Proceedings of UCLA Healthcare 2014; Vol. 18)*; it could also be illustrated by an excerpt from the press describing the case of ingestion of methylated spirits by alcoholics, which occurred in 2010 in New Zealand: “Toxicologist Dr Wayne Temple, director of the National Poisons Centre at Otago University, said methylated spirits used to have methanol added to make it undrinkable. The methanol was toxic and caused blindness, organ damage and death. The methanol was removed in 2007 and replaced with a bitter non-toxic substance that is supposed to make it undrinkable. ‘I'm surprised people are still drinking it with that bittering agent in it because it is one of the strongest you can get,’ he said.” *The Press 2010 Apr. 14, p. A5,* [*Fairfax New Zealand Limited*](http://www.fairfaxmedia.co.nz/)). Despite the fact that social programs in prevention and treatment of chronic alcoholism are already in force in EU countries, abuse of alcoholic beverages and non-consumable alcohol is still an actual public health problem. The rapporteurs want to point out that alcohol abuse is a complex societal and health issue and effective prevention programmes “involve multilevel commitment and have proven difficult to implement in many contexts” (Conrod PJ et al. Effectiveness of a selective, personality-targeted prevention program for adolescent alcohol use and misuse: a cluster randomized controlled trial. JAMA Psychiatry 2013;70:334-42). In addition, expected behavioural changes require time, while in the meantime poisonings (including lethal ones) due to abuse of toxic surrogates for consumable alcohol are expected to occur.  Regarding the benefits of methanol and certain methanol-containing products, including its use as a deterrent to product abuse, RAC considers that adequate alternatives are available and are already in use in EU, including countries with very low winter temperatures (e.g. Norway).  **RAC Rapporteurs comment #1262-2. Reply to comments to specific info request 1:**  Regarding to the Methanol REACH Consortium’s reservation as to the relevance and applicability of using a regional/isolated statistics to extrapolate to the rest of EU, RAC agrees that the benefit of the restriction will be more pronounced in those parts of the EU with colder climate and an habit of drinking strong spirits, but points out that since several EU countries are shown to be affected by methanol-containing products abuse, an EU wide measure is an appropriate approach. This is in line with the above mentioned concern regarding an expected distortion of the market of methanol-containing products (discussed above under Reply to General Comments).  The Methanol REACH Consortium correctly points out that “it is important to distinguish whether the product is legally or illegally on the market (bootleg alcohol) and whether any poisoning incidents resulted from a non-intentional misuse (accidental use) or from specific and intended abuse.” This remark has been already taken into account in the analysis of Poison control centres’ statistical data, in which only poisonings with legal products were considered. Although accidental use and intended abuse is not easy to distinguish in these data, RAC rapporteurs point out that a methanol ban was shown to be efficient in reducing the total number of methanol poisonings in Poland and Finland, indicating prevention of both types of poisonings.  **RAC Rapporteurs comment #1262-3. Reply to comments to specific info request 2:**  The rapporteurs thank the Methanol REACH Consortium for provided information, especially the link to the American Association of Poison Control Centers’ National Data Poison Data System. Unfortunately, in the great majority of cases described in the literature, the methanol dose is not known or not reported, and older references are not available as full articles (or sometimes even as summaries) to the rapporteurs.  **RAC Rapporteurs comment #1262-4. Reply to comments to specific info request 3:**  Please see RAC rapporteurs’ reply to General comments.  **RAC Rapporteurs comment #1262-5. Reply to comments to specific info request 4:**  The toxic profiles of ethanol and of isopropanol (identified as alternatives for methanol) have been described in the restriction proposal. With regard to human health, both alternatives are of lower toxicity compared to methanol.  According to Poisindex® Managements database (Truven Health Analytics Inc. MICROMEDEX® Healthcare Series Vol. 165, 2015), an ethanol dose of 1 g/kg of absolute ethanol (95% to 99% ethanol) is expected to cause mild to moderate intoxication in most adults. Toxic oral dose of isopropanol is about 0.3 – 0.6 g/kg, and the probable oral lethal dose is approximately 3 g/kg bw (although as little as 1.3 g/kg bw was reported as fatal). Ethanol exposure is extremely common, but *per se* rarely results in severe acute morbidity or death. However, ethanol abuse frequently precipitates traumatic injuries and, in chronic abusers, can lead to alcohol dependence (alcoholism) with severe health and social consequences. Severe poisoning cases with isopropanol may include haemorrhagic gastritis, hypotension, respiratory depression, and coma, but lethal outcome is rare and likely secondary to respiratory depression and aspiration.  On the other hand, lethal oral methanol doses in the range of 0.3 – 1 g/kg bw are stated in an IPCS document (*IPCS, ENVIRONMENTAL HEALTH CRITERIA 196, Methanol. WHO, Geneva 1997*) and death has been reported following ingestion of 0.07 g/kg bw of methanol (*Bennett IL Jr et al. Acute methyl alcohol poisoning: a review based on experiences in an outbreak of 323 cases. Medicine (Baltimore). 1953;32:431-63*). Poisindex® Managements database describes exposures to methanol as uncommon events that can result in significant morbidity (including permanent sequelae after severe intoxication such as blindness and basal ganglia necrosis with parkinsonian features) and mortality.  Data from annual reports of the American Association of Poison Control Centers’ National Data Poison Data System (NPDS) support above statements regarding acute toxicity of studied alcohols (*Mowry JB et al. 2012 annual report of the American Association of Poison Control Centers’ National Poison Data System (NPDS): 30th Annual Report. Clin Toxicol 2013;51:949–1229; Mowry JB et al. 2013 annual report of the American Association of Poison Control Centres’ National Poison Data System (NPDS): 31st Annual Report. Clin Toxicol 2014;52:1032–83*).  Namely, two-year (2012 and 2013) poisoning incidence data show 11 times higher incidence of major outcome among methanol exposure cases **compared to ethanol** exposure cases, and 54 times higher methanol-related mortality compared to ethanol-related mortality in reported exposure cases. In NPDS major outcome is defined as: “The patient exhibited signs or symptoms as a result of the exposure that were life-threatening or resulted in significant residual disability or disfigurement (e.g., repeated seizures or status epilepticus, respiratory compromise requiring intubation, ventricular tachycardia with hypotension, cardiac or respiratory arrest, esophageal stricture, and disseminated intravascular coagulation)”. Exposure cases due to consumption of alcoholic beverages are excluded from this analysis since the analysis aimed to evaluate health risks posed by ethanol as an alternative to methanol in products not intended for human consumption. In addition, an availability of consumable alcohol is not expected to be comparable to non-consumable ethanol products. Health effects of chronic abuse of ethanol are not considered here, because prevention of ethanol abuse is not in the scope or proposed restriction. RAC Rapporteurs would like to stress out that they are aware of the problem of chronic alcoholism in Europe. Nevertheless, they consider that methanol restriction is not expected to aggravate this issue, but prevent severe methanol poisonings, including lethal outcomes or cases with irreversible impairments such as blindness or brain damage (please refer to RAC Rapporteurs comment #1264-4 - Reply to General Comment #4). It is considered that approximately 30% of persons with alcohol dependence (alcoholism) stop being alcohol dependant during their lifetime, and even alcoholics with liver cirrhosis might have a favourable prognosis if alcohol cessation is achieved (*Thompson W et al. Alcoholism Follow-up - Prognosis. http://emedicine.medscape.com/article/285913-followup#e3; Vaillant GE. A 60-year follow-up of alcoholic men. Addiction 2003;98:1043-51; Dawson DA et al. Recovery from DSM-IV alcohol dependence: United States, 2001-2002. Addiction 2005;100:281-92*).  Incidence of major outcome was 3.2 times higher and mortality 34 times higher among methanol exposure cases **compared to isopropanol** exposure cases.  According to Lithuanian National Health Insurance Fund under the Ministry of Health, data for 2-year period (2013 and 2014) submitted during PC show 27 times higher mortality due to methanol **compared to ethanol** exposure (15% methanol-related mortality *vs.* 0.54% ethanol-related mortality). There were only 5 recorded cases related to isopropanol exposure, and they were not lethal.  Regarding the technical performance of these alternatives, RAC rapporteurs point out that they are both already in use in the EU, including in countries with very low winter temperatures (e.g. Norway).  **RAC Rapporteurs comment #1262-6. Reply to comments to specific info request 5:**  RAC rapporteurs agree with the Dossier Submitter’s response to this comment. | |
| **SEAC Rapporteurs comments:**  Thank you for the comments.  On general comment: Discussions on RMOs has been taken and proved that restriction is the most appropriated action. Updated BD will fully include this. No direct extrapolation of the Finnish data was undertaken, SEAC made its own calculation and aggregation of data. SEAC rapporteurs have not included in the cost and benefit assessment of the proposed restriction the products illegally placed on the market, however accidental poisonings are included as these products are legally placed on the market and could pose a risk to the population.  On #1: Estimates on EU wide statistics is going to be integrated with a scenario analysis. Updated BD will fully include this.  On #3: See comment in general comment. SEAC intends to propose a transition period of 12-15 months, according to other PC comments and its own assessment.  On #4: Please see DS comments.  On #5: In the restriction dossier the proposal for the Annex XVII entry is given as follows: “Shall not be placed on the market for supply to the general public”. In our opinion the scope of the restriction is clear. | |
| **1264** | **Date:** 2015/05/15 23:20  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  Methanol Institute  **Org. country:** Belgium  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:**  The Methanol Institute (MI) serves as the trade association for the global methanol industry, with an Operations Centre located in Brussels (EU Transparency Register Number: 0846.425.760). MI represents more than three dozen of the world’s leading methanol producers, distributors and technology companies, many of whom are headquartered in EU Member States and have extensive operations across Europe. MI also maintains regional offices in Washington, Singapore and Beijing.  The Methanol Institute welcomes this opportunity to submit preliminary comments for the public consultation on the proposed Annex XV restriction on methanol submitted by the Polish Bureau of Chemical Substances.  Before addressing the questions posed under this public consultation, we first offer several general comments, as well as specific feedback on the dossier itself.  **General Comment #1:**  Annex XV restrictions are meant to apply to EU-wide issues of concern from chemical exposures, and the dossier has failed to provide evidence that exposure to windshield washer fluid and denatured alcohol has led to incidents of methanol poisoning across a large number of EU Member States.  On Page 8, the dossier notes: “The population who faces the risk lives mainly in the northern and central parts of the EU, in countries where people prefer strong alcohols, but those people do not quit their habits coming into other UE Member States and cases of acute poisonings with denatured alcohol containing methanol were noted also in Italy among people from counties in Central Europe.”  The dossier provides a detailed accounting of the unfortunate rise of poisonings from methanol in windshield washing fluid that were experienced in Poland during the period of time when the member state restriction had been superseded. The dossier also describes the situation in Finland which has experienced a number of cases of methanol poisoning from the consumption of windshield wash fluid. Although there is little evidence provided in the dossier to indicate that this consumption is from abusers of alcohol, or simply unintentional exposures. Based on the survey of EU Member State competent authorities included in the dossier’s Annex, the proposers also found incidents of methanol poisonings as follows:  Estonia: In 2006, criminal case with 6 deaths from ingestion of ‘fire ignition liquid.’  Lithuania: A number of cases linked to exposure to windscreen washing fluids and paint removers.  Ireland: A number of cases of methanol poisoning of unknown cause, with many involving children.  United Kingdom: Reported enquiries of exposure to products that may contain methanol.  Bulgaria: A number of cases of methanol exposure from windshield washer fluid and methylated spirit.  Slovenia: One case of a child exposed to model aircraft fuel, and one case of exposure to poorly distilled wine.  Italy: While Page 83 of the dossier cites “Italian partners” reporting poisonings caused by windscreen and denatured alcohol from methanol, and a concern with seasonal workers from the Central Europe’s states, the Questionnaire on Methanol in the Annex does NOT cite any specific data from an Italian competent authority.  Contrary to the conclusion of the dossier proposer, the data indicates that the concern with methanol poisoning from exposure to windshield washer fluid and denatured alcohol is limited to just three EU Member States: Finland, Lithuania, and Bulgaria. While Poland may have documented cases of abusers of alcohol imbibing windshield washer fluid during the period when its member state restriction had lapsed, and there may also be links to abusers of alcohol in Finland, this is clearly NOT an EU-wide problem. Further, there is no evidence in the dossier demonstrating that abusers of alcohol from Central Europe are, due to the free movement across member states, taking their practices of intentionally drinking windshield washer fluid and denatured alcohol across borders to other Member states.  In addition, the proposer has not demonstrated that methanol and methanol-containing products are widely used in all EU member states. The dossier notes that climate conditions vary among member states, and the use of anti-freeze in windshield washer fluid is relevant only to regions where annual temperatures drop below 0oC, which limits applicability to eastern/northern European countries. The “Survey of Methanol (CAS no. 67-56-1)” conducted by the Danish Ministry of the Environment in 2013 does not even cite the use of methanol for windscreen washer fluid or denatured alcohol in its discussion of the use methanol in Denmark and the European Union (See: http://www2.mst.dk/Udgiv/publications/2013/04/978-87-93026-01-8.pdf).  General Comment #2:  An Annex XV restriction is an inappropriate tool to address the misuse of a product. The abuse of alcohol is an endemic problem in many parts of Europe that has enormous costs in human tragedy and monetary impacts. The appropriate responses to concerns that abusers of alcohol may be consuming windshield washer fluid and denatured alcohol are to develop national strategies, increase consumer education, more vigilant enforcement, and targeted use of bitterants.  A European Commission fact sheet on “Alcohol-related harm in Europe” (See: http://ec.europa.eu/health/archive/ph\_determinants/life\_style/alcohol/documents/alcohol\_factsheet\_en.pdf) shows the EU is the heaviest drinking region in the world with 55 million adults in Europe estimated to drink alcohol at harmful levels, and this harmful alcohol consumption is estimated to be responsible for 195,000 deaths per year in the EU due to accidents, liver disease, cancers, etc.  A study by the World Health Organization on “European Status Report on Alcohol and Health, 2010” (See: http://www.euro.who.int/\_\_data/assets/pdf\_file/0004/128065/e94533.pdf), presents the significant societal costs from the abuse of alcohol in Europe. The total tangible cost of alcohol to the European Union for 2003 was estimated to be €125 billion, or the equivalent of 1.3% of GDP. Actual spending on alcohol-related problems accounted for €66 billion, with potential production not realized due to absenteeism, unemployment and premature mortality accounting for €59 billion. Aside from these tangible costs, the intangible costs from pain/suffering, crime, loss of health due to alcohol are estimated at another €152 to €764 billion. While a high proportion of poisonings are related to alcohol, the report notes: “it is not possible to find reliable country data specific to alcohol poisoning.” The report finds that poisonings are more prevalent in European “C-countries” of Belarus, Estonia, Hungary, Kazakhstan, Latvia, Lithuania, Republic of Moldova, the Russian Federation and Ukraine (See table below). Not surprisingly, this list corresponds to those few countries that have been cited by the proposer as reporting incidents of methanol poisoning from abuse of alcohol in windshield washer fluid.  The World Health Organization, with assistance from the Methanol Institute, has issued an information note on “Methanol poisoning outbreaks” finding that: “Outbreaks of methanol poisoning arise from the consumption of adulterated counterfeit or informally-produced spirit drinks. There had been numerous outbreaks in recent years, including in Cambodia, Czech Republic, Ecuador, Estonia, India, Indonesia, Kenya, Libya, Nicaragua, Norway, Pakistan, Turkey and Uganda. The size of these outbreaks has ranged from 20 to over 800 victims, with case fatality rates of over 30% in some instances.” This information note urges countries to put in place a national strategy and legal framework to reduce the harmful use of alcohol, and to use public health campaigns to promote awareness of the dangers of informally-produced and illicit alcohol drinks, which can be targeted towards particular high-risk groups like abusers of alcohol. While the Annex XV proposal does not apply to bootleg alcohol exposures, there are valuable lessons here. Rather than adopting an EU-wide restriction, as recommended by the World Health Organization, EU Member States need to adopt national strategies and conduct targeted public information campaigns. As the proposer’s Methanol Questionnaire in the dossier Annex finds, many member states have no strategy for reducing methanol poisonings.  In 2012, the Methanol Institute formed a Bootleg Alcohol Prevention Subcommittee under our Product Stewardship Committee to address concerns around methanol poisoning from illegal counterfeit spirits and poorly distilled “local” spirits. In addition to our work with the WHO cited above, we are working with an NGO in Indonesia to combat methanol poisonings in local communities and by tourists (a particular problem in Bali) by providing training for local first responders and hospital staff to recognize and effectively treat cases of methanol poisoning from bootleg alcohols, and have launched consumer education campaigns to warn against the dangers of bootleg alcohol. We are now seeing documented cases where these education efforts have saved lives.  The production of windshield washer fluid and denatured alcohol is a specialized segment of the methanol distribution chain with mixture bottling companies that can be easily identified in those few markets in the EU utilizing methanol for these applications. As such, the addition of bitterants to windshield washer fluids and denatured alcohol such as Bitrex (See: http://www.bitrex.com/) , which is the brand name of the most bitter substance known to man, would be an extremely effective and low cost alternative to an Annex XV restriction. As this web site notes: “An extremely low cost solution, it can be added to most compatible products for less than a penny, yet research has shown that consumers are willing to pay up to 15% more for a product containing Bitrex.” Not only would the addition of Bitrex to windscreen washer fluid and denatured alcohol prevent consumption by abusers of alcohol, it would also prevent children from being poisoned by accidental ingestion and would reduce poisonings by suicide. The proposer’s dossier failed to identify the use of bitterants as a potential alternative management risk option.  Another potential option is to control access to these products through licensed sales, particularly in those few countries that appear to be impacted by the abuse of alcohol in windshield washer fluid and denatured alcohol. Any enforcement of such controls by the appropriate Member State authoritative body would likely be a significant deterrent to the misuse of these products.  General Comment #3:  The proposed restriction to no more than 3% methanol by weight in windshield washer fluid and denatured alcohol is based on assumptions that can be challenged, and is inconsistent with existing restrictions of 10% in several EU Member States. If an Annex XV restriction is deemed to be an appropriate step, we would encourage revising the proposal to the 10% by weight level now in force in several member states.  Page 68 of the dossier notes: “If windshield washing fluids contain about 30% w/w of methanol, the dose which can result in death of person (adult, 70 kilograms) is only 90 ml. These calculation clearly shows that there is a need to introduce restriction which reduce the concentration of methanol in products available for consumers… For windshield washing fluids containing methanol in concentration of 3.0% w/w, lethal dose is approximately, according to Table B 10-1, 900 ml…there is little likelihood that the windshield fluid is drunk in a single dose of 900 ml.”  The proposer here has offered an assumption that abusers of alcohol would not consume more than 900 ml of windshield washer fluid or denatured alcohol in a single dose, although no further justification is offered to support his assumption. Table B. 10-1 also shows that the consumption of 265 ml of windshield wash fluid with 10% w/w methanol would result in the same level of exposure. One can equally assume that this is more likely a “single dose” exposure from the consumption of windshield washer fluid or denatured alcohol would be less than 265 ml, which would support a restriction at the 10% by weight level.  Further, this level is consistent with existing restrictions in a number of EU Member States (Denmark, Sweden, Norway, Lithuania, Germany and Austria). The dossier notes that these Member State 10% restrictions will have to be repelled in June 1, 2015 when the CLP Regulation will be used for classification of mixtures. These restrictions are part of national restrictions prohibiting the selling of mixtures classified as acute toxic and labelled as “toxic” to the general public. If there is support for restricting the volume of methanol in these two product applications, we would therefore strongly encourage the RAC and SEAC to consider modifying the proposed Annex XV restriction to a limit of no more than 10% by weight which would be consistent with current national restrictions in several EU Member States.  General Comment #4:  The restriction of methanol in windshield washer fluid and denatured alcohol could have unintended consequences that must be considered by the RAC and SEAC.  As the dossier notes, currently there is no validated risk assessment for ethanol at the European level (Page 70), and that Finland found windshield wash products containing 20 to 100% ethanol. By substituting methanol with ethanol in windshield waster fluid and denatured alcohol, it can well be anticipated that the volume of alcohol in the mixture will be increased, and with unknown risks. Further, one can expect that abusers of alcohol would be much more likely to consumer these products once they became aware of the levels of ethanol alcohol available. This would only exacerbate concerns for the epidemic level of alcohol abuse in many parts of Europe.  In June 2010, the UK Health Protection Agency warned that failure to add windscreen wash to a vehicle’s windscreen wiper water could account for around 20 percent of cases of Legionnaires ’ disease, in a report published in the European Journal of Epidemiology. Adding windshield wash mitigates the transmission of Legionella bacteria to drivers and passengers that can cause pneumonia. (See: http://phys.org/news195847365.html). Therefore, a restriction on the use of methanol in windshield washer fluids could lead to an increase in cases of Legionnaires ’ disease.  European Commission Regulation (EU) No. 1008/2010 concerning the type-approval of requirements for windscreen wiper and washer systems for the general safety of motor vehicles establishes a testing protocol for automobile manufacturers requiring that the windscreen washer system shall be filled and fully primed with low-temperature windscreen washer fluid consisting of a 50% solution of methanol that must be placed in an ambient temperature of -18 to 30C. Given these design criteria, a solution of just 3% methanol is unlikely to provide adequate protection against icing, and could lead to increased highway accidents and fatalities.  Specific Comments:  Page 9: The dossier notes that “Methanol is not yet identified as a SVHC” and “Methanol is not yet classified as CMR.” We find these to be prejudicial statements without warrant which should be removed from the dossier.  Page 11: The molecular formula for methanol is cited as CH4O, which is not correct. The correct molecular formula for methanol is CH3OH.  Page 13: The dossier quotes the Methanol Institute in finding that total world-wide methanol use exceeds 90 million tons. This too is incorrect. For 2014, actual global methanol demand was 65 million metric tons.  Page 15 (and Page 61): The dossier cites a previous Italian proposed classification of methanol for reproductive toxicity. However, on 17 September 2014 the Committee on Risk Assessment issued its opinion rejecting the Italian proposal noting:  “Methanol is used in a variety of industrial applications, in waste water treatment, and as a fuel.  Other uses include the production of formaldehyde, acetic acid, chloromethanes, methyl methacrylate, methylamines, dimethyl terephthalate, and as a solvent or antifreeze in paint strippers, aerosol spray paints, wall paints, carburettor cleaners, and car windshield washer fluids.  The substance currently has a harmonised classification in Annex VI to the CLP Regulation as a flammable liquid, as a substance causing specific target organ toxicity after single exposure and as toxic if swallowed, inhaled or in contact with skin.  The dossier submitter, Italy, proposed to classify methanol as a substance which may damage the unborn child (Repr. 1B; H360D). RAC disagreed with the proposal to classify methanol for developmental toxicity, instead concluding that classification for this hazard class is not warranted, based on the available data.”  Therefore, these references to the Italian classification proposal must be removed from the dossier. | |
| **Answer to specific info request 1:**  It appears from a detailed Internet search that little data on methanol poisonings is available for poison control centers across EU Member States. The Questionnaire on Methanol included in the Annex to the dossier clearly shows a lack of statistical data from poison control centers in the responding EU Member States, and the dossier itself notes that information about accidents/incidents from consumer exposure from poison control centers is not available at this time. The WHO report cited above also finds that it is not possible to find reliable country-specific data on alcohol poisonings.  The most comprehensive documentation of incidents reported to poison control centers is found in the annual reports of the American Association of Poison Control Centers, with the most recent published report covering reported incidents to US poison control centers for the year 2013 (See: https://aapcc.s3.amazonaws.com/pdfs/annual\_reports/2013\_NPDS\_Annual\_Report.pdf). The report features a series of tables on the demographic profile of single substance cases, including a subset for “Automotive Products: Methanol (Dry Gas, Windshield Washing Solutions, etc) (Table 22A, P. 1213). The report cites 1,072 single exposure cases for this subcategory, with 341 from children and 737 from adults. To put this into context, as much as 200 million gallons of methanol for windshield washer fluid is used annually in the US automotive fleet of 246 million passenger cars. Of the total exposures, the vast majority – 969 – were from unintentional exposure, with 90 intentional exposures. Unintentional exposures include environmental, occupational, therapeutic error, misuse, food poisoning, and unknown. Intentional exposures can include suspected suicide, abuse and unknown. The number of patients treated in health care facilities was 392, and one case resulted in death.  Ethanol is cited in the dossier as a potential replacement for methanol in windshield washer fluids and denatured alcohol. This report also finds the over 50,000 mentions of reports of ethanol poisoning from beverages, with nearly 8,000 documented cases, resulting in 79 deaths. Another 3,700 cases of ethanol poisoning (non-beverage) were reported. The AAPCC 2013 Annual Report also documents 2,400 cases of poisoning from isopropanol, another potential methanol substitute.  While not called out in the AAPCC report, there is an alarming increase in the number of ethanol poisonings from household products accessed by teenagers as an alternative to controlled spirits. From the internet, children can find detailed instructions for distilling ethanol from hand sanitizers, which can contain 60-95% ethanol. Other products being abused include mouthwash and breath fresheners that can contain 5-25% ethanol, as well as perfumes/colognes containing 50-99% ethanol. These may be much more widely used sources of alcohol abuse and poisonings than from exposure to windshield washer fluid and denatured alcohol.  One of the primary measures suggested by the proposer for gauging the effectiveness of the proposed restriction if it were to be adopted was to track the number of incidents of methanol poisoning from exposure to windshield washer fluid and denatured alcohol as reported to EU Member State poison control centers. Since that information is not collected in any useful manner today, it is unlikely that this will be a viable option for monitorability. | |
| **Answer to specific info request 2:**  The AAPCC 2013 Annual Report cited above includes an abstract (P. 1262) describing the single 2013 US fatality from methanol poisoning from exposure to windshield washer fluid. The abstract notes that the patient was a 17-year old girl who police found had conducted an internet search on methanol poisoning, found empty bottles of windshield washer fluid in the patient’s home, and ruled the manner of death as suicide. A simple internet search for “methanol poisoning reports” finds any number of specific case studies. | |
| **Answer to specific info request 3:**  A three-month transition period for the application of the proposed restriction could be very problematic for producers and/or suppliers depending on the timing of when the proposed restriction enters into force. The use of methanol as the active ingredient in windscreen washer fluid is very much a seasonal demand with higher volumes used during winter months. As such, any transition period spaning the winter season, nominally October-March, could be disruptive and difficult to administer. | |
| **Answer to specific info request 4:**  Page 72 of the dossier finds: “Regardless whether methanol or ethanol is applied, the product can be used in the same temperature range… An analysis of windshield washer fluids on the Polish market indicates that in the case of a 5 litre pack, replacing methanol with ethanol will result in approx. doubling the product price… It is important to underline that methanol is one of the substance of lower cost among organic products.” Further, Page 94 notes: “Despite the higher cost of ethanol mixtures it can be expected that demand for the alternative mixtures would be identical as for mixtures of methanol”  These are potentially dangerous assumptions that could result in higher numbers of highway fatalities. As the dossier notes, a greater volume of ethanol is required to provide the same effective product temperature range as methanol, and that ethanol costs are 2.5 times higher than methanol. Even a doubling of the cost of windshield washer fluid would provide a significant disincentive for using any windshield washer fluid and would encourage consumers to dilute windshield washer fluid to the point where it is no longer effective as a deicer. | |
| **Answer to specific info request 5:**  The dossier notes that surveys of windscreen washer fluid in Poland and Finland have found methanol concentrations of up to 60-70% by volume. This is clearly an excessive level that is not consistent with global best practices. Material Safety Data Sheets show the typical volume of methanol contained in windshield washer fluid based on the temperatures at which the products are designed to maintain the fluid mixture in a liquid state for the effective application on windscreens. One US manufacturer – PEAK – provides MSDS listings that are consistent with industry practices and show methanol volume content for the following range of windshield wash fluids (See: http://www.peakhd.com/msds/):  -30°F/-34°C – 35% methanol  -20°F/-28°C – 33% methanol  -0°F/-17°C – 23% methanol  +20°F/-6°C – 7-9% methanol  Even with methanol content in windshield washer fluid ranging up to 35% by volume for consumer use in the United States, there is no evidence that this product is being misused by abusers of alcohol. | |
| **Dossier submitter response:**  General Comment #1:  The proposed restriction is namely to eliminate poisonings caused by consumption of methanol contained in high concentrations in winter windshield washing fluids and in denatured alcohol by alcoholics and other person abusing alcohol. These products represent the most common cause of severe methanol poisonings, which in many cases turn fatal. Winter windshield washing fluids containing alcohol and denaturated alcohol, which are available in retail, are consumed as a surrogate of consumable alcohol by some alcoholics. This is encouraged by the difference in price between excisable consumable alcohol and the products in which alcohol is not excisable therefore the price of equivalent quantity of alcohol is considerably lower. In Poland for instance the price of half a litre of the cheapest 40% vodka reaches almost 5 EURO, while the price of 5 litres of the cheapest winter windshield washing fluid containing a similar concentration of ethanol, reaches 2 – 3 EURO. Half a litre of 70% denatured alcohol in Poland costs approx. 1 EURO. Similar price differences also occur in other countries. Additives to ethanol contained in such products, which make it unpalatable for a great majority of people, do not deter many alcoholics from their consumption. A relatively limited availability of consumable alcohol contributes to using this easealy available surrogate of ethanol in some countries, such as Finland. The restriction of methanol concentration in these products will eliminate incidental methanol poisonings due to consumption of these products.  A lot of acute poisonings with methanol from winter windshield washing fluids occur in north and east countries of EU where this kind of products are used by consumers. According to oral information we believe that PL, FI, SE, LT, LV, SL, EE will be positively affected in case of introducing of limitation of methanol in winter windshield washing fluids into force.  The change in classification of mixtures containing methanol introduced by CLP Regulation since June 1, 2015 may cause some incidents of methanol poisonings also in countries where severe poisonings were not noted so far.  However it should be underlined that there are countries in European Union where winter windshield washing fluids are not used because of average yearly temperature. It is true that for such countries (for example CY, EL, ES, IE, MT, PT) there will be no benefit but also such countries will not have additional costs. We can assume that for such countries benefit/cost for “windshield washing fluids restriction” is zero.  For denaturated alcohol we can assume that such poisonings can occur in all Member States. Such assumption can be based on the following information:   * denaturated alcohol is widely used across the EU as a cleaning agent or as a fuel for touristic cooking appliances, * till the 1st of June 2015 a number of countries, namely Scandinavian countries (apart from Finland) and at least Germany, Austria and Lithuania will still have in place national legislation restricting the sale to general public substances and mixtures classified as toxic or very toxic, according to directive 67/548/EEC and directive 1999/45/EC. This legislation restricts concentration of methanol in products intended for general public to 10% (T, R39/23/24/25). However this legislation will have to be repelled from June 1, 2015, when the CLP Regulation is used for classification of mixtures. Even if these national legislation is rearranged to fit CLP and the restriction will cover mixtures of category 1 – 3 considering the acute toxicity, mixtures containing methanol will be classified as Acute Tox. 3, H301/311/331 when the concentration of methanol will be equal or higher than 30%. Denaturated alcohol with so high concentration of methanol when drunk even in small quantities - the lethal oral dose of mixture containing methanol in concentration 30% w/w for 70 kg person is equal to 88 ml - cause severe poisonings with the high rate of fatal cases, * in countries in which there is no above mentioned restriction the concentration of methanol in denaturated alcohol is usually very high (for example about 40% w/w in product Denaturat P9 (trade name) available on Polish market – based on the information found in section 3.2 of SDS). According to calculation performed by the dossier submitter if the concentration of methanol in mixture is equal to 40% w/w, the lethal oral dose of such mixture for 70 kg person is equal to, approximately, 66 ml.   Without any restriction of concentration of methanol in some mixtures available for consumers, it must be expected that the number of new incidences of poisoning caused by ingestion of winter windshield washing fluids and denaturated alcohol containing high concentration of methanol in some EU Member States will remain at the level seen today (for example 24 fatalities caused by winter windshield washing fluids every year in Finland). The change in classification of mixtures since June 1, 2015 may exaggerate the problem.  General Comment #2:  The proposed restriction is namely to eliminate poisonings caused by consumption of methanol contained in high concentrations in winter windshield washing fluids and in denatured alcohol by alcoholics and other person abusing alcohol. These products represent the most common cause of severe methanol poisonings, which in many cases turn fatal. Winter windshield washing fluids containing alcohol and denaturated alcohol, which are available in retail, are consumed as a surrogate of consumable alcohol by some alcoholics. The restriction of methanol concentration in these products will eliminate incidental methanol poisonings due to consumption of these products.  The restriction will not eliminate suicidal methanol poisonings, however it may partly limit their number.  The restriction will not eliminate nor most likely reduce the number of potential poisonings with fake consumable alcohol with added methanol and legally placed on the market.  It is not the aim of the restriction to solve the problem of abuse of alcohol which exist in many parts of Europe.  Existing legislation concerning methanol, namely the child resistant fastening, did not prevent the high number of severe poisonings with methanol in countries where the concentration of methanol in products available to general public was not restricted.  Also the addition of bitterants to windshield washer fluids and denatured alcohol such as Bitrex, which make it unpalatable for a great majority of people, do not deter many alcoholics from their consumption.  General Comment #3:  For calculation of doses of windshield washing fluids or denaturated alcohol containg methanol which can result in death to humans, the following assumptions were taken into account:  - lethal oral doses of methanol in humans by oral route: 0.3 g/kg bw (due to the well documented in the literature (Tephly T.R., 1991) lethal oral doses of methanol in humans),  - body weight: 70 kg person (it is assumed that methanol in windshield washing fluids or denaturated alcohol is drunk mainly by man and that’s why in our calculation we used a value of body weight of 70 kg instead of 60 kg recommended for consumers in Guidance published by ECHA). It is believed that 70 kg is more appropriate value for adult man.  - density of methanol at 20°C: 0.792 g/ml  Taking into account these information the lethal oral dose for a 70 kg person was calculated: 26.5 ml. This value was used to calculate the lethal oral dose of windshield washing fluids (denaturated alcohol) containing different concentrations of methanol. The calculations are summarized in the table below.  The lethal oral dose of windshield washer fluids/windshield defrosters (denaturated alcohol) depends on concentrations of methanol.   |  |  | | --- | --- | | Concentration of methanol in windshield washer fluid/windshield defrosters (denaturated alcohol) (% w/w) | The lethal oral dose of windshield washing fluids/windshield defrosters (denaturated alcohol) (ml) | | 0,5 | 5303 | | 1 | 2651 | | 1,5 | 1767 | | 2 | 1325 | | 2,5 | 1060 | | 3 | 883 | | 4 | 662 | | 5 | 530 | | 6 | 441 | | 7 | 378 | | 8 | 331 | | 9 | 294 | | 10 | 265 | | 11 | 241 | | 12 | 220 | | 13 | 203 | | 14 | 189 | | 15 | 176 | | 16 | 165 | | 17 | 155 | | 18 | 147 | | 19 | 139 | | 20 | 132 | | 21 | 126 | | 22 | 120 | | 23 | 115 | | 24 | 110 | | 25 | 106 | | 30 | 88 | | 35 | 75 | | 40 | 66 | | 45 | 58 | | 50 | 53 | | 55 | 48 | | 60 | 44 | | 65 | 40 | | 70 | 37 |   The evaluation, performed by dossier submitter on the basis of lethal oral doses of methanol in humans, indicates a risk for the human health if consumer swallowing windshield washing fluids or denaturated alcohol containing high doses of methanol. If windshield washing fluids or denaturated alcohol contain about 30% w/w of methanol, the dose which can result in death of person (adult, 70 kilograms) is only 90 ml. These calculation clearly shows that there is a need to introduce restriction which reduce the concentration of methanol in products available for consumers. It was proposed to establish maximum concentration of methanol in mixtures available for general public at level of 3.0% w/w. For windshield washing fluids (denaturated alcohol) containing methanol in concentration of 3.0 % w/w, lethal oral dose is approximetaly 900 ml. There is little likelihood of drinking such high doses of windshield washing fluids/windshield defrosters or denaturated alcohol.  The assumption that there is likelihood of drinking 900 ml of windshield washing fluids (denaturated alcohol) was based on the information from Poison Centres (Table below) – expert opinion. From the Table it can be concluded that one person can ingestion up to 1000 ml of windshield washing fluid (denaturated alcohol) - worst case scenario. Generally it is difficult to establish the amount of methanol which has been drunk. In some cases in which the source of methanol was identified - as windshield washing fluids - the maximum value: 1000 ml of windshield washing fluid is mentioned.  Table. Report of methanol toxicity – data obtained from Poison Centres.   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | |  | Data | Sex | Age | Methanol  (the level of methanol in blood) | Source of methanol | Death/poisonings | | 1 | 02.01.11 | W | 54 | **1.35‰** | windshield washing fluids | death | | 2 | 20.05.11 | M | 39 | **3.2‰** | not identified | death | | 3 | 23.05.11 | M | 39 | **0.6‰**  ethanol 2.55‰ | not identified | poisonings | | 4 | 21.06.11 | M | 55 | **1.85‰** | not identified | death | | 5 | 11.07.11 | W | 44 | **0.6‰**  ethanol 0.57‰ | not identified | poisonings | | 6 | 16.10.11 | M | 38 | **0.68‰** | windshield washing fluids (suicide attempt) | death | | 7 | 31.10.11 | M | 55 | **2.35‰** | **0.5 l** windshield washing fluids | poisonings **blindness** | | 8 | 01.11.11 | M | 38 | **2.6‰** | windshield washing fluids | poisonings | | 9 | 12.11.11 | M | 64 | **0,25‰** | windshield washing fluids | poisonings **blindness** | | 10 | 16.11.11 | M | 59 | **3.7‰** | not identified | death | | 11 | 07.12.11 | M | 72 | **1.35‰** | windshield washing fluids | poisonings | | 12 | 08.12.11 | M | 51 | **4.98‰** | not identified | poisonings | | 13 | 16.12.11 | K | 47 | **5.5‰** | not identified | death | | 14 | 17.12.11 | M | 58 | **3.8‰** | not identified | death | | 15 | 18.12.11 | M | 63 | **4.96‰** | **1 l**  windshield washing fluids | death | | 16 | 19.12.11 | M | 57 | **7.2‰** | Windshield washing fluids | death | | 17 | 20.12.11 | M | 66 | **2.0‰** | not identified | death | | 18 | 26.12.11 | M | 41 | **0.17‰** | not identified | poisonings | | 19 | 04.02.12 | M | 52 | **0.63‰** | **0.75l**  windshield washing fluids | poisonings blindness | | 20 | 06.03.12 | M | 37 | **5.18‰** | **1l**  windshield washing fluids (suicide attempt) | poisonings |   General Comment #4:  We can not agree with the statement that substitution of methanol by ethanol in windshield washing fluids will cause epidemic level of alcohol abuse in many parts of Europe.  Below you will find the information about windshield washing fluids available on Polish market containing methanol. Usually the concentartion of ethanol in such product is up to 30%.   |  |  |  |  | | --- | --- | --- | --- | |  | Ingredients | Concentration % | Crystallization temperature (°C) | | Winter windshield washer fluids No 1 | **Ethanol** | 20-30 | -20 | | Methanol | < 3.0 | | Isopropanol | <0.5 | | Winter windshield washer fluids No 2 | **Ethanol** | < 30 | -22 | | Methanol | < 2.7 | | Ethylene glycol | < 1 | | Methanol | < 20 | | Isopropanol | < 5 | | Winter windshield washer fluids No 3 | **Ethanol** | 15 - 20 | -20 | | Methanol | 3 - 10 | | Ethylene glycol | < 2 |   We can also an not agree with the statement that: “Given these design criteria, a solution of just 3% methanol is unlikely to provide adequate protection against icing, and could lead to increased highway accidents and fatalities” – as it was proved in the dossier there are alternatives of methanol which can be used in windshield washing fluids (for example ethanol). The windshield washing fluids which contains ethanol can be used during winter period.  Specific Comments:  Page 9: The dossier notes that “Methanol is not yet identified as a SVHC” and “Methanol is not yet classified as CMR.” We find these to be prejudicial statements without warrant which should be removed from the dossier.  We will include in the dossier the following information: “Methanol is not classified as CMR.”  Page 11: The molecular formula for methanol will be corrected.  Page 13: The dossier quotes the Methanol Institute in finding that total world-wide methanol use exceeds 90 million tons. This too is incorrect. For 2014, actual global methanol demand was 65 million metric tons. – the information will be corrected.  Page 15 (and Page 61): The dossier cites a previous Italian proposed classification of methanol for reproductive toxicity. However, on 17 September 2014 the Committee on Risk Assessment issued its opinion rejecting the Italian proposal – when we prepared the restriction dossier the Italian proposal of reclassification of methanol was still under discussion. We will include in the dossier information about RAC conclusion on Italian proposal of reclassification of methanol.  **Answer to specific info request 1:**  Thank you for sending us a link to the annual reports of the American Association of Poison Control Centers.  **Answer to specific info request 3:**  Transition period: in our dossier we propose 3 months transition period taking into account that that all the information about restriction process are publicly available and that the restriction process is long. In our opinion if the restriction is adopted by RAC and SEAC the transition period will be discussed during REACH Committee.  **Answer to specific info request 4:**  We can not agree with the statement: “These are potentially dangerous assumptions that could result in higher numbers of highway fatalities. As the dossier notes, a greater volume of ethanol is required to provide the same effective product temperature range as methanol, and that ethanol costs are 2.5 times higher than methanol. Even a doubling of the cost of windshield washer fluid would provide a significant disincentive for using any windshield washer fluid and would encourage consumers to dilute windshield washer fluid to the point where it is no longer effective as a deicer.”  The cost of windshield washer fluids containing ethanol is of course higher than cost of windshield washer fluids containing methanol but we have not noticed in Poland tendency during drivers to dilute windshield washer fluid.  **Answer to specific info request 5:**  Our survey was based on the information which can be found in Safety Data Sheet of windshield washer fluids. We agree that in SDS manufacturers can include the information about the of range components. Even if we take into account the data which was sent by Methanol Institute and we assume that methanol concentration in windshield washer fluids is about 35%, according to Table B.10-1 the lethal oral dose of such product is equal to 75 ml. | |
| **RAC Rapporteurs comments:**  **RAC Rapporteurs comment #1264-1. Reply to General Comment #1:**  In line with ECHA Guidance on Annex XV for restrictions, Chapter “*Limits – when should an Annex XV dossier not be prepared?*” it is stated that “when the risk is relevant in just one Member State, there is no basis for it to be addressed on a Community wide basis”. In the case of this restriction proposal, however, severe methanol poisonings (including lethal outcome) related to ingestion of windshield washing fluids (WWF) or denatured alcohol, have been reported in several EU member states from different European regions, including Belgium, Bulgaria, Finland, Germany, Hungary, Italy, Norway, Poland, Sweden and the United Kingdom, with Poland, Finland and Bulgaria as the most severly affected according to information from the restriction proposal and data received during Public Consultation (methanol poisoning has been recorded in other EU countries as well (e.g. Estonia, Lithuania, Romania) but poisoning statistics data did not provide the source of methanol or the information was not submitted during PC).  Furthermore, measures to reduce the risk posed by methanol-containing products have been introduced in several EU Member States in a form of legislative at a national level, such as permission to purchase products containing methanol in the concentration above 10% (in Austria, Germany, Lithuania and Sweden) or above 3% (in Poland), restriction of the sale to general public of products with more than 10% of methanol (in Denmark and Norway, as a part of a national legislation that restricts the sale to the general public of substances and mixtures classified as toxic or very toxic according to directives 67/548/EEC and 1999/45/EC), and (in Denmark) a ban of methanol use in deicing fluids (washing fluids; except for water-methanol mix solutions used in aircrafts) and in engine coolants or solutions used for preventing the freezing of carburetors (except for water-methanol solutions used in aircrafts).  In justification for an EU-wide restriction, a severity of the risk, namely death, blindness or other severe sequels of methanol poisoning, was also taken into account, as well as prevention of the market distortion. As explained by the Dossier Submitter, methanol containing products are widely used in the EU (e.g. methanol in WWF in concentration above 0.1% is used in at least 10 EU member states, according to information from the restriction proposal and data received during Public Consultation) and, given the significantly lower price of methanol compared to the price of alternatives (ethanol or isopropyl alcohol), restrictions limited to certain Member States would create a distortion of the market of methanol-containing products.  **RAC Rapporteurs comment #1264-2. Reply to General Comment #2:**  RAC rapporteurs acknowledge the valuable assistance of the Methanol Institute to the World Health Organization (WHO) and NGO (in Indonesia) in primary and secondary preventive actions regarding methanol poisoning with illegal alcohol (bootleg spirits). Nevertheless, they would like to point out that public health campaigns to promote awareness of the dangers of methanol are not expected to be effective for the main target population of proposed restriction, namely alcoholics. Alcoholism, recognised as a disease (F10 Alcohol related disorders; F10.1 Alcohol abuse; by ICD-10), is defined as an addiction to ethanol, where addiction is defined by WHO as “repeated use of a psychoactive substance or substances, to the extent that the user (referred to as an addict) is periodically or chronically intoxicated, shows a compulsion to take the preferred substance (or substances), has great difficulty in voluntarily ceasing or modifying substance use, and exhibits determination to obtain psychoactive substances by almost any means”. Chronic alcoholics can ingest even toxic alcohols, although being aware of their toxicity, if consumable alcohol is not available to them: “Desperate alcoholics have intentionally substituted methanol-containing substances for ethanol, even knowing that it may have harmful effects” (from *Kruse JA. Methanol poisoning. Intensive Care Med 1992;18:391-7*).  The Dossier Submitter took into consideration the use of bitterants in the restriction proposal (Restriction proposal, page 9: “Additives to ethanol contained in such products, which make it unpalatable for a great majority of people, do not deter many alcoholics from their consumption”). As previously discussed in the second paragraph of RAC Rapporteurs comment #1262-1, an addition of bittering agent to a product is shown not to deter chronic alcoholics from drinking the product.  Regarding another RMO proposed by the Methanol Institute, i.e. licensed sales in order to prevent selling WWF and denatured alcohol to alcoholics, RAC rapporteurs consider this measure as very problematic, both from ethical and practical aspects.  **RAC Rapporteurs comment #1264-3. Reply to General Comment #3:**  Cases of methanol poisoning with more than one litre ingestion are reported in the literature. For example, acute ingestion of 1.9 L of WWF was reported by Glazer and Dross (*Glazer M, Dross P. Necrosis of the putamen caused by methanol intoxication: MR findings. AJR Am J Roentgenol 1993;160:1105-6.1993*) and 1.5 L of adulterated alcohol ingestion is reported by Zakharov (*Zakharov S et al. Czech mass methanol outbreak 2012: epidemiology, challenges and clinical features. Clin Toxicol (Phila) 2014;52:1013-24*). In a 17-year old female case of methanol poisoning described by Mowry et al., “multiple empty bottles of windshield wiper fluid containing methanol were found at the patient’s home and car” (*Mowry JB et al. 2013 Annual Report of the American Association of Poison Control Centers’ National Poison Data System (NPDS): 31st Annual Report. Clin Toxicol 2014;52:1032–83*).  Also, regarding safety issue of 10% methanol product, poisonings with 6.5% methanol mixture (in adulterated alcohol with 40% ethanol), followed by death and blindness, have been reported in the literature (*Desai T. Methanol poisoning: predictors of visual outcomes. JAMA Ophthalmol 2013;131:358-64*).  **RAC Rapporteurs comment #1264-4. Reply to General Comment #4:**  Although a risk assessment of ethanol has not been performed at EU level, it is recognised that it is of markedly lower acute toxicity compared to methanol. For detailed comparison please refer to RAC Rapporteurs comment #1262-5 - Reply to comments to specific info request 4.  It is possible that with increased percentage of ethanol in WWF, while eliminating threat of concurrent methanol poisoning, these products will become more attractive to alcoholics. RAC Rapporteurs, however, do not consider that this potential increase in WWF abuse will add significantly to the number of alcoholics or severity of ethanol abuse. Namely, methanol-containing WWF are just a small portion of products containing non-consumable alcohol which are abused by alcoholics. Just to illustrate this opinion, data from annual reports of the American Association of Poison Control Centers’ National Data Poison Data System (NPDS) were analysed in order to compare the number of cases of intentional exposure to non-consumable ethanol (hand sanitizers, mouthwash containing ethanol, ethanol-based rubbing alcohol, cleaning agents excluding automotive products, other non-beverage ethanol products) with the number of cases of intentional exposure to methanol-containing automotive products, including WWF, for the most recent available two-year period (2012 and 2013; *Mowry JB et al. Clin Toxicol 2013;51:949–1229, Mowry JB et al. Clin Toxicol 2014;52:1032–83*). The number of cases of **intentional exposure to products containing non-consumable ethanol (without methanol or other toxic alcohol) was 27 times higher compared to the number of cases of intentional exposure to methanol-containing automotive products, including WWF**.  RAC Rapporteurs are aware that this statistics is limited due to the fact that 1) it does not show total exposure to ethanol and methanol containing products, but only cases of exposure reported to Poison Control Centres (with a notion that due to significantly higher toxicity of methanol, exposure to methanol-containing products is expected to be more frequent compared to cases of exposure to products containing non-consumable ethanol), 2) it includes both abuse and suicidal attempts in category ‘Unintentional exposure’. Nevertheless, the Rapporteurs consider that these numbers put into perspective a ratio of methanol-containing WWF abuse and abuse of products containing non-consumable ethanol. In addition, abuse of non-beverage ethanol presents only a small part of total alcohol abuse. For example, Estonian data showed that age-standardized prevalence rate of non-beverage alcohol drinking was 1.4% among respondents who reported drinking at least once in their lifetime and were alcohol consumers at the time of the study (*Pärna K, Leon DA. Surrogate alcohol drinking in Estonia. Alcohol Clin Exp Res 2011;35:1454-7*). Even in Finland, a country with rather strict policies regarding consumable alcohol availability, national statistics indicates that consumption of non-beverage ethanol is below 1% of the total alcohol consumption (*Karlsson T et al. A new alcohol environment. Trends in alcohol consumption, harms and policy: Finland 1990 – 2010, Research report. Nordic Studies on Alcohol and Drugs 2010, Vol 27:497-513; Varis T, Virtanen S. Alcoholic beverage consumption 2014. National Institute for Health and Welfare: Official Statistics of Finland 14/2015*). The Rapporteurs are, therefore, of the opinion that methanol restriction is not expected to have a marked effect on alcoholism as a public health issue, and, taking into account the acute toxicity of methanol, priority should be given to prevention of further lethal poisonings and severe non-lethal poisonings with permanent, debilitating sequels due to methanol-containing products abuse.  Concern regarding increased risk of Legionnaire’s diseases related to failure to add windscreen wash to a vehicle’s windscreen wiper water was raised by case control study conducted in England and Wales (*Wallensten A et al. Windscreen wiper fluid without added screenwash in motor vehicles: a newly identified risk factor for Legionnaires' disease. Eur J Epidemiol 2010;25:661-5*). The authors, however, did not relate the risk with the absence of use of methanol, but considered plausible that lack of biocidal agents in a screenwash allows growth of *Legionella spp.* bacteria (“The finding that not adding screenwash to the water used as windscreen wiper fluid poses a risk is biologically plausible; it is likely that *Legionella* bacteria would grow in the stagnant water of the windscreen wiper fluid reservoir, which is intermittently sprayed onto the windscreen, creating an aerosol. Some of the aerosol may be sucked into the passenger compartment through the ventilation intake. It is also plausible that screenwashes, as they usually contain biocidal agents like propranolol, inhibit the growth of Legionella”). In that respect, any alternative to methanol that possesses adequate biocidal activity is appropriate, including ethanol and isopropanol (another name is 2-propanol, probably misspelled as ‘propranolol’ by the authors of above mentioned study) (*Barah F. Non-antibiotic biocides: An updated review. In: Microbial pathogens and strategies for combating them: science, technology and education. Editor: Méndez-Vilas A. Formatex Research Center, 2013*).  RAC Rapporteurs agree with the Dossier Submitter that WWF containing proposed alternatives for methanol (ethanol and isopropanol) can be efficiently used during winter period. For example, WWF with methanol concentration below 0.01% are used in the wintertime in Norway.  RAC agrees with the Dossier Submitter regarding proposed changes in the Background Document on pages 9, 11, 13 and 15.  **RAC Rapporteurs comment #1264-5. Reply to answer to specific info request 1:**  Regarding comparison of acute toxicity of methanol, ethanol and isopropanol and abuse of ethanol in relation to the scope of proposed restriction please refer to RAC Rapporteurs comment #1262-5 (Reply to comments to specific info request 4).  Usefulness of Poison Control Centres in EU Member States as monitoring option has been questioned by RAC since reporting of poisoning cases is not obligatory in all EU countries. However, RAC agrees with the DS and the Forum that the proposed restriction is enforceable through inspections, and that due to the relevance of methanol as an impurity in alcohol based food products and in the denaturation of technical alcohol based products, various analytical methods exist for the determination of methanol in ethanol (e.g. EN 15721).  **RAC Rapporteurs comment #1264-6. Reply to answer to specific info request 2:**  RAC Rapporteurs thank the Methanol Institute for the valuable information on annual reports of the American Association of Poison Control Centers’ National Data Poison Data System (NPDS).  **RAC Rapporteurs comment #1264-7. Reply to answer to specific info request 3:**  RAC Rapporteurs recognises the problems related to 3-month transition period during winter season, taking also into account comment from MS Finland (twelve month transition period for products already in stock).  **RAC Rapporteurs comment #1264-8. Reply to answer to specific info request 4:**  RAC Rapporteurs agree with the Dossier Submitter that increased cost of windshield washer fluids containing ethanol is not expected to increase the number of fatalities related to road accidents due to reduced use or excessive dilution of WWF. According to the Dossier Submitter, Poland, as a country with an experience with methanol ban in WWF, did not notice these problems. Also, RAC Rapporteurs are not aware of this problem in Norway in which WWF with methanol concentration below 0.01% are used during winter. In addition, road accidents statistics for Finland does not show significant differences in the number of fatal accidents and the number of injured between the periods with and without methanol ban in WWF, including data for car accidents only (*Katila A, Keskinen E. Road accidents in Finland. IATSS RESEARCH 2003;27:88-90*).  **RAC Rapporteurs comment #1264-8. Reply to answer to specific info request 5:**  RAC Rapporteurs thank the Methanol Institute for information on methanol content in WWF. Unfortunately, in published cases of methanol poisonings with WWF, percentage of methanol is rarely stated. Nevertheless, it is shown that ingestion of 6.5% methanol mixture (in adulterated alcohol with 40% ethanol), can lead to death and blindness (*Desai T. Methanol poisoning: predictors of visual outcomes. JAMA Ophthalmol 2013;131:358-64*). | |
| **SEAC Rapporteurs comments:**  Thank you for all your comments.  On general comment #1: SEAC notes that based on the information currently available in the dossier the human health risks are present in potentially 10 Member States. Please consult the corresponding RAC’s responses for the detailed responses.  On general comment #2: Please see RAC’s responses.  On general comment #3: Please see RAC’s responses.  On general comment #4: The current proposal refers on methanol in windshield washing fluids.  Specific comments: Please see BD responses.  #1: Thank you for your contribution.  #2: Thank you for your contribution.  #3: Seasonality of production is an element that could be further investigation and included in the opinion development. See comment in general comment. SEAC intends to propose a transition period of 12-15 months, according to other PC comments and own assessment.  #4: SEAC shares to a point that dilution is an element that could pose a risk. However not enough information are given to support the statement.  #5: Please see RAC’s responses. | |
| **1265** | **Date:** 2015/05/18 16:07  **Type:** MemberState  **MS name:** Norway  **Country:** Norway  **Company name confidential:** **No** | **General Comments:**  We support the introduction of stricter restrictions on methanol in windshield washing fluids and in denatured alcohol. It is important to avoid that alcoholics are poisoned when misusing these products.  According to the Norwegian product register, very few windshield washing fluids on the Norwegian market contain methanol, and the methanol concentration in these is well below 0.01 % by weight. These products are used in the wintertime. | |
| **Answer to specific info request 1:**  According to the Norwegian Institute for public health, during the period 2002-2004 bootleg spirit containing ca. 20 % methanol was distributed and drunk several places in Norway. In total 51 persons were hospitalized, ten of these died. Additionally, eight persons were found dead from methanol poisoning in their homes during the same period. In the period 2007-2008 four persons died after suspected ingestion of denatured (methylated) spirit.  The table below gives information on the numbers of contacts that the Norwegian Poison Information Centre from people of all ages who had ingested windshield washing fluids.  Year 2010 2011 2012 2013 2014 Sum:  No. contacts 35 55 40 53 41 224 | |
| **Answer to specific info request 2:**  Slørdal L, Skogholt A, Aarstad K, Ellingsen C L, Brekke M B and Haugen O A (2010). Metanolforgiftningene i 2007–08 (The methanol poisonings in 2007-08), http://tidsskriftet.no/article/1939173/ (the report is written in Norwegian) | |
| **Answer to specific info request 3:**  (we do not have any information on this) | |
| **Answer to specific info request 4:**  The windshield washing fluids sold in Norway normally contain ethanol, 2-propanol and 4-metyl-2-pentanon. We do not have data on their price and market volumes. | |
| **Answer to specific info request 5:**  There is minimal use of methanol in windshield washing fluids in Norway. Information from the Norwegian product register indicate that the total sale of windshield washing fluids in Norway in 2013 was 16 600 metric tons. Less than 0.001% of this amount (16 tons) was products that contained methanol. The methanol concentration in those few products was well below 0.01% by weight.  We do not have data or information on denatured alcohol. | |
| **Dossier submitter response:**  Thank you for supporting our proposal. | |
| **RAC Rapporteurs comments:**  Thank you for supporting restriction proposal and for the valuable information. | |
| **SEAC Rapporteurs comments:**  Thank you for the comments. | |
| **1267** | **Date:** 2015/05/19 14:52  **Type:** MemberState  **MS name:** Finland  **Country:** Finland  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:**  General comments  Scope  In our opinion the restriction proposal should discuss how the Commission Implementing Regulation (EU) No 162/2013 on 21 February 2013 amending the Annex to Regulation (EC) No 3199/93 on the mutual recognition of procedure for the complete denaturing of alcohol for the purposes of exemption from excise duty is related to the proposal to include methanol as an additive to denaturated alcohol in the scope of the restriction. According to the Regulation methanol is allowed to be used in denaturing of alcohol but it is not used in all Member States e.g. Finland for that purpose.  We also notice that no precise data is submitted supporting the proposal to restrict methanol as an additive to denaturated alcohol.  Lowering the concentration limit  We would like to propose lowering the concentration limit from 3 % to 0.1 %. Please see Attachment 1 for justification.  DNEL  In our opinion DNEL is not needed in this restriction proposal. If included the scientific background of the DNEL value (8 mg/kg bw/day) should be clarified (e.g. toxic effects and assessment factors).  Alternatives  There is a lot of data on the hazard properties of alternatives in the Annex XV Restriction report. A more detailed comparison between methanol and the alternatives in relation to hazard, suitability for the purpose, technical applicability etc. would be beneficial.  SEA  It seems that the dossier includes assessment of costs caused by the restriction mostly under uncertainty estimation (section F7). The dossier could merit from further discussion on the costs and benefits and how they compare with each other, along with an estimation of the generalizability of the Finnish information to the entire EU area or, if possible, even some kind of cost and benefit estimation over the entire EU area. It would also be good to include in the dossier a full description of assumptions underlying the cost calculations.  It has been voiced by Finnish operators that a restriction setting a limit of 3 % for methanol in windscreen washing fluids would mean that using methanol in the windscreen washing fluids would most likely be terminated because the concentration would be too low to fulfill the purpose of the product. Therefore it would seem that the costs associated with restricting the methanol concentration to 0.1 % would be identical to those associated with restricting methanol concentration to 3 %. (The cost assessment performed in the dossier actually assumes complete substitution.)  If however products containing 0.1-3 % of methanol would stay on the market, the benefits of the restriction in terms of lower mortality could be lower than what is estimated in the dossier, because more fatal cases might remain. Also the benefit associated with avoided incidents of loss/impairment of vision could be somewhat lower because effects on vision might still take place (this benefit was not quantified in the dossier but is still existent).  Editorial  The unit in Table B.10-2. seems to be incorrect in the column 'Exposure'. In our understanding it should be 'g in solution'. Also in Table B.10-3. the unit in the column 'Exposure' should be mg/kg bw/day. | |
| **Answer to specific info request 1:**  - an update to Table D.1-6. :  In year 2013 the number of fatalities caused by methanol poisoning in Finland was seven (Ojanperä I. 2015, Department of Forensic Medicine, University of Helsinki). The deaths in the Table have been verified by forensic analyses. Almost all poisonings were caused by consumption of windscreen washing fluids. | |
| **Answer to specific info request 3:**  In our opinion a twelve month transition period is needed for products already in stock. | |
| **Answer to specific info request 4:**  - an update to the Table C.1-2. and to the text following the Table:  Table C.1-2 Tonnage placed on the market in Finland in windscreen washing fluids from year 2002 to 2014 (Finnish Chemical Products Register 2015)  Methanol Ethanol Isopropanol  2002 1326 3474 4323  2003 1565 4061 4106  2004 904 5606 3043  2005 1334 4743 1995  2006 1745 5061 2811  2007 1358 5095 2617  2008 1127 5952 1927  2009 1246 6594 2892  2010 1748 6353 1187  2011 2559 7707 1746  2012 935 4382 702  2013 1819 6465 920  2014 1422 4621 736  In 2012-2014, according to the Finnish Chemical Products Register, there were windscreen washing fluids on the Finnish market as follows:  - methanol containing:  2012: 44 products (39 contained methanol from 23 to 70 %)  2013: 35 products  2014: 38 products  - ethanol containing:  2012: 92 products (83 contained ethanol from 20 to 100 %)  2013: 114  2014: 134  - isopropanol containing:  2012: 67 products (35 products contained isopropanol from 20 to 100 %)  2013: 76  2014: 80. | |
| **Dossier submitter response:**  Thank you for your comments.  Concentration limit: according to our knowledge RAC proposed lower concentration limit – 0.1%/  DNEL:  In restriction dossier for methanol prepared by PL CA it is proposed to established 3% limit value for methanol in windshield washing fluids and denaturated alcohol. The calculation, performed by dossier submitter on the basis of lethal oral doses of methanol in humans, indicates a risk for the human health if consumer swallowing windshield washing fluids/denaturated alcohol containing high doses of methanol. If windshield washing fluids/denaturated alcohol contain about 30% w/w of methanol, the dose which can result in death of person (adult, 70 kilograms) is only 90 ml. Based on:  - dossier submitter previous experience (in Poland till 1 June of 2010 the placing on the market for general public mixtures containing methanol in the concentration higher than 3.0% by weight was banned by Regulation of Ministry of Economy),  - specific concentration limit specified for methanol in Table 3.2 in Annex VI to CLP (mixtures which contains methanol in concentration lower than 3.0% are not classified for acute toxicity),  it is propose to establish maximum concentration of methanol in mixtures available for general public at level of 3.0% w/w. For windshield washing fluids/denaturated alcohol containing methanol in concentration of 3.0 % w/w, lethal oral dose is approximately, according to Table B.10-1, 900 ml. There is little likelihood of drinking such high doses of windshield washing fluids or denaturated alcohol (According to the information obtained from Poison Centres – expert opinion - it can be concluded that one person can ingestion up to 1000 ml of windshield washing fluid/denaturated alcohol - worst case scenario. In some cases in which the source of methanol was identified - as windshield washing fluids - the maximum value: 1000 ml of windshield washing fluid is mentioned).    The proposed maximum concentration limit of methanol in mixtures available to consumers (windshield washing fluids and denaturated alcohol) - 3% - is also confirmed by the performed risk characterisation in which DNEL value presented in the methanol registration dossier has been applied. In accordance with Annex I to REACH Regulation the risk to people may be adequately controlled, if during the stages of existence of substances which are outcomes of the manufacture or identified uses the levels of exposure do not exceed appropriate DNEL values. In accordance with Table B.10-2 and Table B.10-3, with methanol concentration in fluids (windshield washing fluids/denaturated alcohol) reaching approximately 2.7% the calculated exposure value exceeds DNEL value - thus it may be stated that the risk is not adequately controlled. This value is close to the value of 3.0% calculated based on the lethal methanol dose to human population per os (0.3 g/kg bw), which is cited in the literature, and on the assumption that there is little likelihood that the windshield fluid is drunk in a single dose of 900 ml.  According to our knowledge RAC is proposed to lower the concentration limit of methanol in the products covered by the restriction. RAC proposes the following concentration limit: 0.1%.  Alternatives:  In our opinion there is enough information in the dossier about alternatives. Alternatives are available and technically feasible.    SEA  We can not agree wit the statement: “It has been voiced by Finnish operators that a restriction setting a limit of 3 % for methanol in windscreen washing fluids would mean that using methanol in the windscreen washing fluids would most likely be terminated because the concentration would be too low to fulfill the purpose of the product.” In Poland there are lot of windshield washing fluids on the market which contains almost 3% of methanol. See some examples in Table below:   |  |  |  |  | | --- | --- | --- | --- | |  | Ingredients | Concentration % | Crystallization temperature (°C) | | Winter windshield washer fluids No 1 | Ethanol | 20-30 | -20 | | **Methanol** | **< 3.0** | | Isopropanol | <0.5 | | Winter windshield washer fluids No 2 | Ethanol | < 30 | -22 | | Methanol | < 2.7 | | Ethylene glycol | < 1 | | **Methanol** | **< 20** | | Isopropanol | < 5 | | Methanol | 3 - 10 | | Ethylene glycol | < 2 |     In our opinion the restriction proposed by us – up to 3% of methanol – is very good risk management option. On pages 5/6 you can find the information about data on the number of poisoning cases related to abuse of methanol since the re-entry into force of the national restriction in Poland.  Below you will find the alternative analysis of cost and benefits of implementation of methanol restriction:  Costs and benefits of implementation of proposed restriction can be analyse separately for windshield washing fluids and for denaturated alcohol.  For windshield washing fluids the countries in which such fluids are used were identified. There are countries in European Union where such fluids are not used because of average yearly temperature. For such countries, if the restriction is adopted, there is no benefit but also such countries will not have additional costs. We can assume that for such countries benefit/cost for “windshield washing fluids restriction” is zero.  In the Table below the average temperature in January in member states countries is presented.  Table: The average temperature in member states countries in January.   |  |  | | --- | --- | | Country | Average temperature in January [◦C] | | AT | -15 ÷ -1 | | BE | -10 ÷ 0 | | BG | -6 ÷ -3 | | HR | -6 ÷ 8 | | CY | approximately 6 | | CZ | -3 ÷ -1 | | DK | -6 ÷ 0,5 | | EE | approximately -9 | | FI | -12 ÷ -2 | | FR | -7 ÷ 0 | | EL | 9 ÷ 17 | | ES | approximately 5 | | NL | -1 ÷ 6 | | IE | 2 ÷ 10 | | LT | -8 ÷ -2 | | LU | -1 ÷ 2 | | LV | -8 ÷ 5 | | MT | 10 ÷ 16 | | DE | -10 ÷ -2 | | PL | -10 ÷ -1 | | PT | approximately 12 | | RO | approximately -5 | | SK | approximately -6 | | SI | -3 ÷ 0 | | SE | -10 ÷ -1 | | HU | -4 ÷ -1 | | UK | -5 ÷ 0 | | IT | -6 ÷ -1 |   Based on the above mentioned table we can assume that for the following countries:  - CY  - EL  - ES  - IE  - MT  - PT  benefit/cost for “windshield washing fluids restriction” is zero.  The cost and benefit for “windshield washing fluids restriction” can be calculated based on Finish data. The analysis is presented below.  Tonnage of methanol and ethanol placed on the market in Finland in windscreen washing fluids from year 2002 to 2012 (Finnish Chemical Products Register 2013) and number of fatalities caused by methanol poisoning in Finland is presented below.  Table: Tonnage placed on the market in Finland in windscreen washing fluids and the number of fatalities caused by methanol poisonings in Finland in the years 2002-2013.   |  |  |  |  | | --- | --- | --- | --- | |  | Methanol | Ethanol | fatalities | | 2002 | 1326 | 3474 | 25 | | 2003 | 1565 | 4061 | 43 | | 2004 | 904 | 5606 | 26 | | 2005 | 1334 | 4743 | 30 | | 2006 | 1745 | 5061 | 12 | | 2007 | 1358 | 5095 | 28 | | 2008 | 1127 | 5952 | 15 | | 2009 | 1246 | 6594 | 30 | | 2010 | 1748 | 6353 | 24 | | 2011 | 2559 | 7707 | 19 | | 2012 | 935 | 4382 | 11 | | **Average** | **1440** | **5366** | **24** |   Price difference: 531 **€/ton (between ethanol and methanol)**  Based on above mentioned information, the cost of restriction in Finland (only for poisonings caused by windshield washing fluids, because the methanol content in denaturated alcohol is restricted in Finland. Other causes for methanol poisonings are extremely rare in Finland):  1440 x 531 = 764640  VSL (**Value of a Statistical Life**) = 1 000 000 **€**  **benefit/cost:** 24000000/764640 **=31.3**  For denaturated alcohol we can assume that such poisonings can occur in all Member States. Such assumption can be based on the following information:   * denaturated alcohol is widely used across the EU as a cleaning agent or as a fuel for touristic cooking appliances, * till the 1st of June 2015 a number of countries, namely Scandinavian countries (apart of Finland) and at least Germany, Austria and Lithuania still have in place national legislation restricting the sale to general public substances and mixtures classified as toxic or very toxic, according to directive 67/548/EEC and directive 1999/45/EC. This legislation restricts the concentration of methanol in products intended for general public to 10% (T, R39/23/24/25). However this legislation will have to be repelled in June 1, 2015, when the CLP Regulation will be used for classification of mixtures. Even if these national legislation is rearranged to fit CLP and the restriction will cover mixtures of category 1 – 3 considering the acute toxicity, mixtures containing methanol will be classified as Acute Tox. 3, H301/311/331 when the concentration of methanol will be equal or higher than 30%. Denaturated alcohol with so high concentration of methanol when drunk even in small quantities - the lethal oral dose of mixture containing methanol in concentration 30% w/w for 70 kg person is equal to 88 ml - cause severe poisonings with the high rate of fatal cases, * in countries in which there is no above mentioned restriction the concentration of methanol in denaturated alcohol is usually very high (for example about 40% w/w in product Denaturat P9 – based on the information found in SDS). According to the calculation performed by dossier submitter if the concentration of methanol in mixture is equal to 40% w/w, the lethal oral dose of such mixture for 70 kg person is equal to, approximately, 66 ml.   In Poland a detailed analysis of methanol poisonings was performed based on the information submitted by the Head of the Regional Acute Poisoning Centre with the Clinical Toxicology Department of the Occupational Medicine and Environmental Health Institute in Sosnowiec. It covered methanol poisoning cases in the voivodships of Opolskie and Śląskie, and bordering territories of Małopolskie Voivodship, hereinafter referred to as “Silesian Agglomeration”. Territory from which the data on the poisonings were collected has the population of approx. 6 million inhabitants (almost one sixth of Poland’s population), which enabled to accept the data as a statistical sample, representative for Poland. In 2013 denaturated alcohol containing methanol was identified as a source of poisonings of two people in “Silesian Agglomeration”. It can be assumed that in 2013 danaturated alcohol containing methanol caused 12 fatalities in Poland.  Yearly cost in Poland in time when no restriction for denaturated alcohol containing methanol was in force:  VSL (Value of a Statistical Life) = 1 000 000 €  cost: 12 000 000 €  Table B.10-2 and B.10-3: appropriate units in these Tables in column Exposure will be added.  Transition period: in our dossier we propose 3 months transition period taking into account that that all the information about restriction process are publicly available and that the restriction process is long. In our opinion if the restriction is adopted by RAC and SEAC the transition period will be discussed during REACH Committee.  We will update Table C.1-2 taking into account data delivered during Public Consultation.  We will update Table D.1-6 taking into account data delivered during Public Consultation. | |
| **RAC Rapporteurs comments:**  Please see SEAC rapporteurs comments related to the proposal to include methanol as an additive in denaturated alcohol in the scope of the restriction proposal.  Thank you for the valuable comments and support for 0.1% methanol concentration limit, with justification.  Instead of using acute oral DNEL for methanol of 0.008 g/kg bw for general population, taken from the Chemical Safety Report, and derived from an OEL of 260 mg/m3 (aimed to protect workers from acute systemic and local irritative effects of methanol inhalation, and also considered protective from very slight, sub-clinical CNS effects of methanol inhalation), RAC proposes to use a DNEL based on a minimal oral methanol dose leading to death (0.08 g/kg bw).  A more detailed comparison between methanol and the alternatives in relation to hazard will be added in RAC Draft Opinion document. | |
| **SEAC Rapporteurs comments:**  Thank you for your comments.  General Comments: Regarding the scope of the restriction proposal, SEAC rapporteurs have proposed to reduce it to methanol-containing windshield washing fluids since no socio-economic data are available for the use of methanol as an additive in denaturated alcohol. For the concentration level and hazard to human health please see DS and RAC’s responses. SEAC rapporteurs have proposed an aggregation of cost on the whole EU and aggregation of the benefits in the MS where concrete data was available or could have been simulated with a level of confidence.  #1: Thank you for the updated information.  #3: SEAC intends to propose a transition period of 12-15 months, according to other PC comments and own assessment.  #4: Thank you for the updated information. | |
| **1399** | **Date:** 2015/07/02 09:56  **Type:** MemberState  **MS name:** Lithuania  **Country:** Lithuania  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:** | |
| **Answer to specific info request 1:**  Please see attached file | |
| **Dossier submitter response:**  Thank you very much for submitting the information about methanol poisoning cases in Lithuania. We will include this information in updated restriction dossier. | |
| **RAC Rapporteurs comments:**  Thank you for the valuable information. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. | |
| **1400** | **Date:** 2015/07/03 13:31  **Type:** MemberState  **MS name:** Norway  **Country:** Norway  **Company name confidential:** **No** | **General Comments:**  MSCA Question 1:  Is there any national legislation in your country that restricts the marketing and/or supply to the general public of methanol-containing products? If so, could you provide information on the products covered and content level of methanol concerned? Is this methanol content limit based on any risk assessment of the substance?  Yes. It is prohibited to import or sell methanol containing products for private use according to the Norwegian product regulations, § 5-1. Cfr. the unofficial English version of the regulations on our webpages: http://www.miljodirektoratet.no/en/Legislation1/Regulations/Product-Regulations/Chapter-5/  MSCA Question 2:  In case you have national legislation in place to restrict the marketing and/or supply to the general public of methanol-containing products, does this national legislation relate to the classification and labelling of the methanol-containing products? If so, how will the change in the classification criteria according to the CLP Regulation affect the application of the restriction? Please specify which products - and related content level of methanol - will be restricted under your national legislation after 1 June 2015, i.e. after the end of the transition period for the application of the classification criteria to mixtures according to CLP.  Cfr. Reply to question 1. | |
| **Dossier submitter response:**  Thank you for the information about national restriction concerning marketing and/or supply to the general public of methanol and methanol-containing products. | |
| **RAC Rapporteurs comments:**  Thank you for the valuable information. | |
| **SEAC Rapporteurs comments:**  Thank you for the comments. | |
| **1401** | **Date:** 2015/08/03 15:33  **Type:** MemberState  **MS name:** Germany  **Country:** Germany  **Company name confidential:** **No** | **General Comments:**  [This general comment concerns the additional questions asked to MSCAs in May by ECHA on behalf of the Polish CA]  MSCA Question 1:  Is there any national legislation in your country that restricts the marketing and/or supply to the general public of methanol-containing products? If so, could you provide information on the products covered and content level of methanol concerned? Is this methanol content limit based on any risk assessment of the substance?  MSCA Question 2:  In case you have national legislation in place to restrict the marketing and/or supply to the general public of methanol-containing products, does this national legislation relate to the classification and labelling of the methanol-containing products? If so, how will the change in the classification criteria according to the CLP Regulation affect the application of the restriction? Please specify which products - and related content level of methanol - will be restricted under your national legislation after 1 June 2015, i.e. after the end of the transition period for the application of the classification criteria to mixtures according to CLP.  Both questions will be adressed in one answer:  In Germany the „Chemikalien Verbotsverordnungs“ (ChemVerbotVO) is a national regulation (ordinance) which controls the placing on market of substances and mixtures. Limitations exist for certain types of chemicals in their possibility to be sold to the general public.  The regulation sets rules for both the seller and the buyer.  The seller has to be qualified (either through a specific certified course or through being a pharmacist), be at least 18 years old and be 'responsible' (responsible is defined in German law). Additionally, methanol and methanol containing products (with an exemption for the use in fuel cells) may not be placed in selling-automats or any other kind of self-service system. In the praxis this means that such products are kept locked away from customers.  When selling, you have to be either certain that the product is used in a permitted manner or the seller has to inform the buyer about the specific risks of the substance, on how to use the substance safely and on the behaviour in case of an emergency.  The buyer of such products has to be at least 18 years old.  Additionally, the buyer has to show his ID and information like bought amount, name and address of the buyer, date of the exchange have to be documented and the documents need to be kept for at least five years.  The ChemVerbotsVO covers substances and mixtures labelled with T, T+, O and F+ and also covers those labelled with CMR Cat. 3 according to the Dangerous Substances Directive – therefore, methanol is affected by the above-mentioned restrictions. An adaption of the ChemVerbotsVO to the CLP criteria is currently underway. | |
| **Dossier submitter response:**  Thank you for the information about national restriction concerning marketing and/or supply to the general public of methanol and methanol-containing products. | |
| **RAC Rapporteurs comments:**  Thank you for the valuable information. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. | |
| **1413** | **Date:** 2015/08/31 15:34  **Type:** BehalfOfAnOrganisation  **Org. type:** Other contributor  **Org. name:**  Methanol REACH Consortium  **Org. country:** Belgium  **Company name confidential:** **No** | **General Comments:**  Following the preliminary comments already submitted to the public consultation,the Methanol REACH Consortium has commissioned a Socio-Economic Analysis (SEA) on Methanol, in relation to the proposed restriction by Poland. The phase 1 report (with the preliminary findings of the SEA and literature review) is expected for submission by September 18th (end of Public Consultation).  Below are key points relating to initial findings of the SEA and literature review:  1/ The proposed restriction is also on denatured alcohol and it is not clear what exactly is meant by ‘supply to the general public of denatured alcohol’. Some innovative and environmental fuels could potentially be seen as ‘denatured alcohol’ or as ‘supply of denatured alcohol to the general public’, e.g. ethanol fuels and fuel cells.   Unless the scope of the restriction is clearly defined, the development and use of such fuels could potentially be impacted, with a possibly very significant and negative impact to EU industry including hindering innovation and sustainability in the area of fuel developments and fuels that can meet new regulatory standards (e.g. requirements for vessels).  2/ The Annex XV report supports the proposed EU-wide restriction by refering to a number of methanol poisoning incidents in a (small) number of EU Member States. However, in all cases except for Poland, the causes of the methanol poisoning incidents are not indicated; these could be causes other than the misuse of consumer products, e.g. bootleg alcohol intentionally extended with methanol (as in the Czech bootleg alcohol case in 2012). Furthermore, data presented for Finland do not show a relation between the number and volume of methanol containing products compared to the increase in methanol poisoning cases: after an apparent increase in methanol poisoning incidents up to the year 2000 the number of methanol poisoning cases tends to decrease, while the number of products containing methanol continues to increase.   The relation between the misuse of the products that are proposed to be restricted and the problem that is intended to be solved is not clearly shown or otherwise demonstrated in the Annex XV report. The Annex XV report therefore does not justify that the mentioned products are the cause of a EU wide problem that needs to be tackled by a restriction.  3/ In response to a WHO survey, as published in 2009 under the EU Alcohol Strategy (http://ec.europa.eu/health/alcohol/policy/country\_profiles/), a majority EU Member States (Austria, Croatia, Cyprus, Finland, France, Hungary, Ireland, Italy, Lithuania, Malta, Netherlands, Poland, Portugal, Romania, Slovenia, Spain, Sweden) indicated that there is not a significant issue with surrogate alcohol use in their country. Several other countries mentioned that there was no information on such abuse (Denmark, Greece, Luxembourg). Poland also mentioned no issue with surrogate alcohol abuse at that time.   Since misuse of surrogate alcohol consumer products does not appear to be a EU wide issue, there is no justification for a EU wide restriction. In the Annex XV dossier, a justification is given for migrant workers, and yet the characterisation of surrogate alcohol abusers would generally exclude migrant workers.  4/ According to a 2006 survey in Estonia published by Lang et al. in Alcohol and Alcoholism Vol. 41, surrogate alcohol users seek high ethanol containing products and do not (intentionally) use products with methanol. Studies from Russia and Belarus also show the preference of high ethanol containing surrogate alcohols among alcohol dependent people (e.g. .  Where there is an issue with health risks from misuse of consumer products for surrogate alcohol, this is for high ethanol containing products. Setting a very low methanol percentage is therefore not necessary in the restriction. Instead a restriction could be considered at 3%w/w, such as for in Poland, or 10%,w/w such as in other countries (e.g. Austria, Denmark, Germany and Lithuania). Instead of a restriction, requiring a bitterant to be added in methanol formulation could also be a suitable risk management option in order to facilitate abusers identifying (by taste) and therefore avoiding methanol containing products.  5/ There is a rather hazardous drinking pattern in the Northern and North-Eastern Member States of the EU, combined with a preference for strong drinks. A large percentage of alcohol in these Member States is unrecorded (illegal). Statistics show that this leads to a large number of alcohol (i.e. ethanol) poisonings, many more than in the other EU Member States, even if the total amount of reported alcohol consumed is not much more. Also, the total rate of accidental poisoning deaths is clearly higher in these Member States than in the rest of the EU. The number of ethanol poisoning cases is much higher than the relatively limited number methanol poisoning in the same Member States.   The methanol poisoning cases reported are mostly a by-effect of a general pattern of alcohol abuse, combined with a relatively high incidence of not drinking legal alcohol (partly caused by culture and partly by lack of affordability of legal alcohol). The major issue of hazardous alcohol use patterns leads to a much higher number of deaths and to a much higher negative socio-economic impact than any misuse of consumer products containing methanol. A EU-wide restriction of methanol containing consumer products can only have a relatively minor effect on this mainly Northern and North-Eastern European problem and is therefore not justified.  6/ Methanol can be used as part of a liquid that also contains a high level of ethanol, as in denatured alcohol. Both substances (and some other alcohols) depend on alcohol dehydrogenases in metabolism, and ethanol has a clearly higher affinity to these enzymes than methanol. That is why ethanol is used as an antidote in methanol poisoning. There are also toxicokinetic data showing that a relatively high level of methanol in blood in combination with a high original ethanol concentration does not lead to the same effects as a similar methanol level alone. Furthermore, if the ethanol/methanol ratio in a product is around 90/5 or higher, acute effects of ethanol can be expected at the same or lower volume of product than acute effects of methanol. Therefore several cases of high ethanol ingestion together with some methanol ingestion may be registered as methanol poisoning, based on relatively high methanol concentrations in blood, while they are actually ethanol poisoning cases.   A restriction of methanol content in denatured alcohol to much below 10%w/w is unlikely to have serious impact on the risks for two reasons: 1) the effects of methanol will not occur, due to the preferential metabolism of ethanol and 2) if an amount of methanol would be ingested that could lead to serious effects, the ethanol ingestion alone would already lead to serious toxic effects itself, so the methanol restriction will not help.  7/ In the substitution of methanol in de-icer windshield wash fluid, the relative ability to depress freezing point of the mixture must be considered. If the ability to depress the freezing point is much lower and/or the cost of the substitute is significantly higher, then there is a potential for less effective windshield washing fluid or reduced use of windshield wash due to relatively higher price. Furthermore, several alternatives may already be contained in formulations of methanol containing windshield wash (including ethanol) which have a competitive metabolism with methanol, thereby reducing potential for toxicity of methanol following combined exposure.   The consequences of substitution requires detailed analysis which is currently underway.  Preliminary conclusion  A EU-wide restriction of methanol in denatured alcohol and windshield wash fluids is not justified and could possibly lead to an increase surrogate and bootleg alcohol consumption and ultimately poisoning risks from non-methanol containing surrogate and bootleg alcohol use.  There is evidence to suggest that methanol does act as a deterrent to abuse of consumer products containing ethanol, at least by some abusers or potential abusers. Adding a bitterant may be a more effective preventative measure than a restriction of methanol, when not only considering the biological deterrent from the unpleasant taste, but as from an economic perspective and as a method for abusers to identify (and therefore avoid) methanol containing products. | |
| **Dossier submitter response:**  **General Comments:**  1.  After submitting the restriction proposal to ECHA, we included in the proposal following information concerning denatured alcohol:  **“Denatured alcohol**, also called "methylated spirits" or "spiritus", is [ethanol](http://en.wikipedia.org/wiki/Ethanol) that has additives to make it [poisonous](http://en.wikipedia.org/wiki/Poisonous), extremely bad tasting, foul smelling or [nauseating](http://en.wikipedia.org/wiki/Emetic), to discourage recreational consumption. In some cases it is also dyed ethanol alcohol.  Denatured alcohol is used as a [solvent](http://en.wikipedia.org/wiki/Solvent) and as fuel for alcohol burners and camping stoves. Because of the diversity of industrial uses for denatured alcohol, hundreds of additives and denaturing methods have been used.  The main additive has traditionally been [methanol](http://en.wikipedia.org/wiki/Methanol) (in concentration 10%), giving rise to the term "methylated spirits". Due to the fact that sometimes denatured alcohol was consumed by alcoholics, the addition of methanol to denaturated alcohol was stopped in order to completely prevent the use of denatured alcohol as a substitute of alcoholic beverage. Another reason for this decision was to prevent accidental poisoning, which can happen because the denatured alcohol is used in households. Other typical additives include [isopropyl alcohol](http://en.wikipedia.org/wiki/Isopropyl_alcohol), [acetone](http://en.wikipedia.org/wiki/Acetone), [methyl ethyl ketone](http://en.wikipedia.org/wiki/Methyl_ethyl_ketone), [methyl isobutyl ketone](http://en.wikipedia.org/wiki/Methyl_isobutyl_ketone), and denatonium.  [Denaturing](http://en.wikipedia.org/wiki/Denaturation_(food)) alcohol does not [chemically](http://en.wikipedia.org/wiki/Chemical_structure) alter the ethanol molecule. Rather, the ethanol is [mixed with other chemicals](http://en.wikipedia.org/wiki/Adulterant) to form an undrinkable solution.  After adding of methanol to the ethanol alcohol (as pure substance or water mixture) the product becomes a mixture. Manufacturers of such mixtures slightly change the trade name for example instead of “Denaturat” they use the name “Denaturat P9” and what is important the product being a mixture can be legally sold to all users including individual ones. It is difficult to distinguish between denatured alcohol and “denatured alcohol” with methanol regarding its physical properties. It is only possible with analytical analyze.”  2.  The number of fatalities caused by methanol poisoning rose significantly after Finland joined the European Union in 1994, and following abolition of the ban on selling products containing methanol to the general population – such ban was previously in force. It is worth emphasising that in the course of the next 6 years after the ban had been abolished, the number of fatal poisonings was growing significantly. Almost all the poisonings were caused by consumption of windscreen washing fluids. It must be also mentioned that the methanol content in denaturated alcohol in Finland is restricted.  3.; 5.  The aim of proposed restriction is namely to eliminate poisonings caused by consumption of methanol contained in high concentrations in winter windshield washing fluids and in denatured alcohol by alcoholics and other person abusing alcohol. It is not the aim of the proposed restriction to solve problems of alcoholism.  4.  Thank you for sending the information about publication which contains the information about survey performed in Estonia on alcohol and alcoholism.  In our opinion addition of bitterant to methanol mixtures is not enough risk management option. Additives added to such products, which make it unpalatable for a great majority of people, do not deter many alcoholics from their consumption.  6.  We are aware that for the products proposed to be restricted (windshield washing fluids and denaturated alcohol) there is usually combined exposure to methanol and ethanol. Ethanol to some extend protects against acute poisonings with methanol. It is very difficult to established, based on the medical history – the amount of methanol and ethanol in mixtures covered by restriction (the ratio methanol/ethanol).  Ethanol is also used as a first measure in curing acute poisonings with methanol but it could be added that protective effect of ethanol during drinking mixture of methanol-ethanol is different than during first measure. The clinical goal of ethanol therapy is to achieve a therapeutic serum ethanol level of between 100 and approximately 150 mg/dl.  7.  As was shown in restriction dossier the alternatives to methanol in windshield washing fluids are available. Alternatives can performed the same function as methanol in windshield washing fluids available for consumers. | |
| **RAC Rapporteurs comments:**  **RAC Rapporteurs comment #14143-1, Answer to Key points 2 and 3:**  For answers to comments on justification for the restriction at EU wide basis, please refer to RAC Rapporteurs comment #1262-1 (Reply to General Comments) and comment #1264-1 (Reply to General Comment #1).  The comparison of time trends between fatal methanol poisoning cases, volume of methanol and ethanol in WWF and number of products containing methanol for Finland (time period 2002-2013) are shown on Figure 1 [data originate from the restriction proposal, including presentation from Tukes, from MS Finland comment sent during PC, and from Marquart H, Mense M, Mulder E. Preliminary socio-economic analysis of proposed restriction on methanol. TNO Triskelion, September 2015, in which mortality data from Lapatto-Reiniluoto and Ikäheimo (2012) were stated].    **Figure 1**. Time trends for fatal methanol poisoning cases, volume of methanol and ethanol in WWF and number of products containing methanol in Finland, from 2002-2013  WWF = windshield washing fluid; N = number  It can be observed that the incidence of fatal methanol poisoning shows a clear falling trend although the volume of methanol in WWF products remained the same or slightly increased over the studied time period while the volume of ethanol in WWF and the number of methanol-containing WWF showed a clear increase. Increased number of methanol-containing WWFs without parallel increase in methanol volume in WWF, but simultaneously increased presence of ethanol volume in WWF could indicate an increase in the number of products with higher percentage of ethanol and lower percentage of methanol, as well as an increase in ethanol-based WWF. Indeed, a trend of increase in the number of WWF containing ethanol (in concentration of 20-100% of a product) is observed for the period 2012-2014, according to data provided by MS Finland during PC (92 products in 2012, 114 in 2013 and 134 in 2014). All of that could be, hypothetically, related to decreasing number of fatal methanol poisoning.  **RAC Rapporteurs comment #14143-2, Answer to Key point 4:**  Regarding effectiveness of adding a bitterant to methanol-containing product as an alternative risk management option, please refer to RAC Rapporteurs comment #1262-1 (Reply to General Comments).  **RAC Rapporteurs comment #14143-3, Answer to Key point 5:**  RAC Rapporteurs agree with the Dossier Submitter that the aim of restriction is to prevent severe, including fatal, methanol poisonings. Prevention of alcohol abuse and dependence, although important, is not within the scope or proposed restriction. Please, also refer to RAC Rapporteurs comments #1262-5 (Reply to comments to specific info request 4) and comment #1264-4 (Reply to General Comment #4).  **RAC Rapporteurs comment #14143-4, Answer to Key point 6:**  It is proposed by Methanol REACH Consortium that due to interaction of methanol and ethanol, products with high ethanol to methanol ratio (e.g. 95% ethanol/5% methanol) should not pose a health risk to humans (e.g. *Martensson E et al. Clinical and metabolic features of ethanol-methanol poisoning in chronic alcoholics. Lancet 1988;1(8581):327-8*), and that some ethanol poisonings with these types of products could be misdiagnosed as methanol poisonings. RAC Rapporteurs are, however, aware of severe methanol poisonings with mixtures with high ethanol content, occurring in Norway (*Hovda KE et al. Anion and osmolal gaps in the diagnosis of methanol poisoning: clinical study in 28 patients. Intensive Care Med 2004;30:1842-6*) and in New Zealand (*Meyer RJ et al. Methanol poisoning. N Z Med J 2000;113:11-3*). In described cases, laboratory findings, pathognomonic for methanol poisoning, were observed, including metabolic acidosis, anion gap, high blood methanol and formic acid, and patients were treated with ethanol or fomepizol. Poisoned patients described by Hovda et al. (2004) ingested illegal spirits with approximately 80% of ethanol and 20% of methanol, while patients described by Meyer et al. (2000) (majority of them having a history of alcohol abuse), ingested methylated spirits containing 5% methanol and 70-90% ethanol (*Lachenmeier DW et al. Surrogate alcohol: what do we know and where do we go? Alcohol Clin Exp Res 2007;31:1613-24*). It is interesting that a problem of methanol poisoning due to abuse of methylated spirits (alcohol denatured by methanol) in New Zealand existed even after permitted limit of methanol was lowered from 5% to 2%: “The Committee notes that adverse health effects are continuing to occur as a result of the deliberate ingestion of methylated spirits, albeit to a lesser degree since the reduction of the allowable methanol concentration in methylated spirits from 5% to 2% in 1999.” (*Environmental Risk Management Authority (ERMA) New Zealand Decision: Application HRC05002, December 2006*). During 3-year period (2002-2005), 27 poisonings were recorded, including 3 fatal cases, which in June 2007 led to complete ban of methanol in denatured alcohol sold to the general public (details of these poisonings are not available to RAC Rapporteurs).  In EU, Indirect Tax Expert Group (ITEG) recommended to abandon the use of methanol as a denaturant in the sector of cosmetics, perfumes and personal hygiene, due to concern for methanol-related health risks posed by abuse of these products (Draft Recommendation ITEG/R/2/2014 - Exemption from Excise Duties. Cosmetics, perfumes and personal hygiene products. Use of methanol as an alcohol denaturant). This non-binding recommendation has been adopted following discussions on 31 October 2014 in the ITEG (22 Member States were in favour, 1 against and 5 abstained).  It is well known that ethanol acts as antidote for methanol poisoning due to its significantly higher affinity for alcohol dehydrogenase compared to methanol’s. However, RAC Rapporteurs agree with the Dossier Submitter that although ethanol is also used as a first measure in acute methanol poisonings, its protective effect during drinking mixture of methanol-ethanol is different from therapeutic application. Co-ingestion of methanol and ethanol inhibits methanol metabolism to formic acid as long as ethanol is present at certain concentration in the blood (above 0.2 g/kg; *Haffner HT et al. The kinetics of methanol elimination in alcoholics and the influence of ethanol. Forensic Sci Int 1997;89:129-36*). Since only 3-5% of an ingested methanol dose is excreted unchanged by the kidneys, and up to 12% of unchanged methanol is excreted via the lungs, and elimination rate is 8.5 mg/dL/hr in the absence of ethanol (which is significantly lower if compared to average elimination rate of ethanol of 15 to 20 mg/dL/hr in non-alcoholic adults, and 30 to 40 mg/dL/hr in alcoholics; Poisindex® Managements database), methanol concentration in blood begins to noticeably decrease only when ethanol concentration falls below critical value of 0.2 g/kg, due to metabolic change to toxic formic acid. It was observed that ethanol co-ingestion delayed the onset of symptoms beyond 24 hours, to even 72 hours (*Barceloux DG et al. American Academy of Clinical Toxicology practice guidelines on the treatment of methanol poisoning. J Toxicol Clin Toxicol 2002;40:415-46*). This is the reason why ethanol therapy in severe cases has to be maintained during several days, and haemodialysis is recommended to speed up methanol elimination from the body. Also, it is recommended that if it is not possible to measure methanol blood concentrations and to perform haemodialysis, ethanol therapy should be continued for a minimum of 9 days (Poisindex® Managements database). Due to high inter-individual variability in metabolism and susceptibility to toxic effects of both ethanol and methanol (e.g. patient with ethanol blood concentration of 1510 mg/dL survived, although ethanol level at 400 mg/dL is considered as potentially lethal, and fatal outcome was observed already at 250 mg/dL; Poisindex® Managements database), as well as variable and often not well defined circumstances of exposure, it is not feasible to predict which dose of co-ingested ethanol will be protective against methanol toxicity, including severe outcomes, such as death or blindness. Namely, assessment of the outcome of methanol-ethanol interaction in poisoning cases with ethanol co-ingestion could be especially problematic in alcoholics: “One could postulate that the present ethanol/methanol mixture would give a better outcome or prognosis, as an antidote was also ingested (e.g. patients 49 and 51). However, this delayed the onset of symptoms and made it difficult to relate these to the intake of the liquor. Many of the patients were alcoholics and interpreted the symptoms of methanol poisoning as alcohol withdrawal. Therefore many drank more ethanol or smuggled spirit and thereby treated themselves.” (*Hovda KE et al. Anion and osmolal gaps in the diagnosis of methanol poisoning: clinical study in 28 patients. Intensive Care Med 2004;30:1842-6*).  In the light of these reports, the risk of methanol poisoning due to ingestion of mixtures with high ethanol to methanol ratio cannot be excluded.  **RAC Rapporteurs comment #14143-5, Answer to Key point 7:**  Regarding Methanol REACH Consortium concern about methanol alternatives in WWF in terms of effectiveness and reduced use due to higher price of the products, please refer to RAC Rapporteurs comment #1264-8 (Reply to answer to specific info request 4). | |
| **SEAC Rapporteurs comments:**  #1: SEAC has proposed a modification of the scope of the restriction due to the lack of data regarding the use of methanol in denaturated alcohol supplied to the general public.  #2: This issue has been addressed in SEAC discussion. SEAC notes that based on the information currently available in the dossier and from the Public Consultation, the human health risks are present in a significant number of Member States.  #3: Please see RAC’s comment.  #4: Please see RAC’s comment.  #5: SEAC rapporteurs does not share the view that unrecorded necessarily means illegal alcohol nor with the statement “The methanol poisoning cases reported are mostly a by-effect of a general pattern of alcohol abuse, combined with a relatively high incidence of not drinking legal alcohol (partly caused by culture and partly by lack of affordability of legal alcohol)” No clear evidence has been submitted to support the statement. The Northern and Central-Eastern part of Europe represent almost 20% of the EU population, so the effects cannot considered as minor.  #7 For the alternatives please see BD responses, for the issue regarding bitterants please consult RAC’s responses. | |
| **1421** | **Date:** 2015/09/15 16:42  **Type:** MemberState  **MS name:** Lithuania  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:** | |
| **Answer to specific info request 4:**  Please see attached some information on poisonings with methanol and its possible substitutes. | |
| **Dossier submitter response:**  Thank you very much for submitting the information about methanol and possible substitutes of methanol poisoning cases in Lithuania. We will include this information in updated restriction dossier. | |
| **RAC Rapporteurs comments:**  Thank you for the valuable information. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. | |
| **1422** | **Date:** 2015/09/16 11:04  **Type:** MemberState  **MS name:** Sweden  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:**  Sweden wants to thank Poland for preparing this dossier.  Our comments are compiled in a word file where comments are given to the five questions. The data presented in our answers are provided by the Swedish Poison Information Centre and The Swedish Product Register. The word file is attached under the section IV Non-confidential attachment. | |
| **Dossier submitter response:**  Thank you for providing us information about number of telephone questions on product containing methanol and questions on intoxication due to intake of products containing methanol received by Swedish Poison Information Centre.  Thank you also for submitting us information from case reports of methanol poisonings. | |
| **RAC Rapporteurs comments:**  Thank you for the valuable information. | |
| **SEAC Rapporteurs comments:**  Thank you for providing us information about number of telephone questions on product containing methanol and questions on intoxication due to intake of products containing methanol received by Swedish Poison Information Centre.  Thank you also for submitting us information from case reports of methanol poisonings. | |
| **1423** | **Date:** 2015/09/16 16:02  **Type:** MemberState  **MS name:** Denmark  **Company name confidential:** **No** | **General Comments:**  In Denmark, the use of methanol has been banned since 1964 for use in engine coolants and carburettor anti-freezing liquids. The ban has since then been expanded to also comprise windshield washing fuels, and has been transferred to the Danish Statutory Order No. 857 of 05/09/2009, which is still in force. Obviously, alternatives to methanol are available. The original ban from 1964 was introduced as a consequence of a number of deaths after intake of carburetor anti-freezing liquids. Although carburetor anti-freezing liquids are only used in older cars, a market still exists for these cars.  The ban has been effective and we do not experience poisoning cases due to intake of windshield washing fuels containing methanol (as such products are not allowed on the market). We would, therefore, suggest that the restriction should fully ban the use of methanol for production of windshield washing fuels. If a more lenient restriction is opted for, we strongly support the option proposed by Poland that Member States should be allowed to maintain existing and more stringent restrictions of methanol in windshield washing fuels.  Finally, we would like to draw your attention to a recent Danish survey from 2013 on methanol, which includes information on uses and regulation of methanol in Denmark. See link: http://www2.mst.dk/Udgiv/publications/2013/04/978-87-93026-01-8.pdf | |
| **Dossier submitter response:**  Thank you for the information about Danish legislation concerning the use of methanol.  Thank you also for supporting our option that Member States may maintain any existing and more stringent restrictions for methanol. | |
| **RAC Rapporteurs comments:**  Thank you for the valuable information and for supporting restriction of methanol in WWF.  Regarding the option which would allow certain MS restrictions more stringent than the restriction set at EU level, RAC was informed by the Commission that this is not foreseen by the present EU legislation. | |
| **SEAC Rapporteurs comments:**  Thank you for the comments. | |
| **1424** | **Date:** 2015/09/17 19:36  **Type:** BehalfOfAnOrganisation  **Org. type:** Other contributor  **Org. name:**  ReachCentrum  **Org. country:** Belgium  **Company name confidential:** **No**  **Attachment confidential:** **Yes**    **Privacy comment:** Some information contained in the attached documents should be kept confidential since they could be linked to intellectual pro*p*erty rights.  Confidential attachment  *Removed* | **General Comments:**  The Methanol REACH Consortium hereby submits a preliminary socio-economic analysis conducted by TNO Triskelion, which is relevant to the RAC and in particular the SEAC.  In addition, a review on the acute toxicity of methanol is submitted for attention of the RAC. | |
| **Dossier submitter response:**  *Removed (confidential attachment)*  **\*Denatured alcohol**, also called "methylated spirits" or "spiritus", is [ethanol](http://en.wikipedia.org/wiki/Ethanol) that has additives to make it [poisonous](http://en.wikipedia.org/wiki/Poisonous), extremely bad tasting, foul smelling or [nauseating](http://en.wikipedia.org/wiki/Emetic), to discourage recreational consumption. In some cases it is also dyed ethanol alcohol.  Denatured alcohol is used as a [solvent](http://en.wikipedia.org/wiki/Solvent) and as fuel for alcohol burners and camping stoves. Because of the diversity of industrial uses for denatured alcohol, hundreds of additives and denaturing methods have been used.  Legal additives include, but are not limited to, methanol, isopropyl alcohol, acetone, methyl ethyl ketone, methyl isobutyl ketone, and denatonium.  The main additive has traditionally been [methanol](http://en.wikipedia.org/wiki/Methanol) (in concentration 10%), giving rise to the term "methylated spirits". Due to the fact that sometimes denatured alcohol was consumed by alcoholics, the addition of methanol to denatured alcohol was stopped in many countries in order to prevent the use of denatured alcohol as a substitute of alcoholic beverage. The price of denatured alcohol (without high excise tax) is much lower than the price of consumable alcohol. Another reason for this decision was to prevent accidental poisoning, which can happen because the denatured alcohol is used in households.  Nowadays the use of methanol as denaturant in denatured alcohol is not particularly common in the EU. According to Regulation (EU) No 162/2013 of 21 February 2013, amending the Annex to Regulation (EC) No 3199/93 on the mutual recognition of procedures for the complete denaturing of alcohol for the purposes of exemption from excise duty, the denaturing procedure employed in all EU member states is as follows.  Per hectoliter of absolute ethanol:  - 3 liters isopropyl alcohol (IPA),  - 3 liters methyl ethyl ketone (MEK),  - 1 gram denatonium benzoate.  However, additional denaturing procedures are employed in specific member states. Countries using methanol as denaturant are Ireland, Greece, Malta (wood nafta), the Netherlands and the United Kingdom. For example additional denaturing procedures employed in Netherlands required per hectolitre of absolute ethanol:  Five litres of a mixture consisting of:  — 60 % by volume of methanol,  — 20 % by volume of acetone,  — 11 % by volume of fusel oil (a concentrate of by-products of alcohol distillation),  — 8 % by volume of water,  — 0,5 % by volume of methyl ethyl ketone (MEK),  — 0,5 % by volume of formalin (a watery solution of 37 % by weight of formaldehyde).  After adding of methanol to the denatured alcohol (as pure substance or water mixture) the product becomes a mixture. Manufacturers of such mixtures slightly change the trade name for example instead of “Denaturat” they use the name “Denaturat P9” and what is important the product being a mixture can be legally sold to all users including individual ones. It is difficult to distinguish between denatured alcohol and “denatured alcohol” with methanol regarding its physical properties. It is only possible with analytical analyze.  5. Effectiveness of bitterant: we cannot agree with the suggestion included in the document that addition of bitterant to the products covered by the restriction is the most effectiveness risk management option. Additives of bitterant to the products covered by the restriction, which normally make the products unpalatable for a great majority of people, do not deter many alcoholics from their consumption. | |
| **RAC Rapporteurs comments:**  RAC Rapporteurs thank Methanol REACH Consortium for detailed and clearly presented report on “Points of Departure for Acute Methanol Toxicity by Ingestion” and “Preliminary socio-economic analysis of proposed restriction on methanol”, which both contain valuable information to further clarify certain important points in the methanol restriction proposal.  **Cited toxic doses (minimum doses for lethality and permanent vision impairment)**  From the available open literature, RAC recognised the lowest ingested methanol dose inducing blindness of 4 mL, reported by Duke-Elder WS in Textbook of Ophtalmology, Vol III. St. Louis, CV, Mosby Co, 1945. This old ophthalmology textbook is not available to RAC Rapporteurs, but according to statement from Methanol REACH Consortium Technical Committee, Duke-Elder only provides a reference to Ziegler (*Ziegler SL. The ocular menace of wood alcohol poisoning. British Journal of Opthalmology 1921;5:365-73*), who “also does not provide any case studies or references to support the assertion that a single teaspoon of methanol can cause blindness”. Ziegler (1921) article is available to RAC Rapporteurs, and on page 370 it is stated: “If taken pure, a single teaspoonful has been known to cause blindness, and an ounce to cause death” (teaspoon usually corresponds to 5 mL), without reference to case study or literature data. The uncertainty related to this dose level due to the lack of information was also raised during RAC consultation.  On the other hand, case report with minimum lethal ingested dose of methanol of three teaspoons (approximately 15 mL) of adulterated whiskey containing 40% of methanol (4.8 g) has been described in the article written by Bennett IL Jr et al. (1953), which is available to RAC Rapporteurs (*Bennett et al. Acute methyl alcohol poisoning: a review based on experiences in an outbreak of 323 cases. Medicine (Baltimore). 1953;32:431-63*). However, lethal outcome in this patient (20 years old female, case 17 in Bennett’s report) is by Methanol REACH Consortium considered as a result of ethanol poisoning that was misdiagnosed as methanol poisoning, due to high blood ethanol level (340 mg/dL), while no methanol was detected. In general, blood ethanol levels in the range of 300-400 mg/dL are related to severe level of intoxication (hypothermia, hypoglycaemia, poor muscle control, poor recall, seizures), and levels above 400 mg/dL are considered as potentially lethal (ethanol levels related to intoxication can vary widely, depending on an individual's tolerance to ethanol) (Poisindex® Managements database). This patient was not hypothermic, but showed pathognomonic signs of methanol poisoning: visual disturbances (“snowstorm” vision), retinal oedema and hyperaemia of optical discs. Absence of detectable methanol in blood does not exclude methanol poisoning, since there was a 12-hour latent period before the symptoms occurred, during which methanol was metabolised to formic acid (formic acid was not measured). Ethanol ingestion that led to high blood ethanol level could occur several hours after methanol ingestion, when formic acid was already formed, and could be a contributing factor to methanol toxicity (e.g. contributing to acidosis and CNS depression). RAC Rapporteurs have no reliable information available that amount of ingested methanol presents non-accurate anamnestic information. Also, they point out that this patient, as all but one patient from described group, did not receive antidote treatment (ethanol), since it was not standard treatment protocol at that time.  **Modelling of blood methanol and formate levels**  PBPK model presented in Methanol REACH Consortium document is an interesting approach, but it should be pointed out that by the authors of the model it is “aimed to have an accuracy within an order of magnitude. The model is regarded as a first tier tool or screening tool” (*Jongeneelen FJ, Berge WF. PBTK-model IndusChemFate, version 2.00 - User manual 2; Jongeneelen FJ, Berge WF. A generic, cross-chemical predictive PBTK model with multiple entry routes running as application in MS Excel; design of the model and comparison of predictions with experimental results. Ann Occup Hyg 2011;55(8):841-64*). It would be, therefore, interesting to see the range of results when different human types are entered in the model (e.g. normal man versus obese woman).  The authors of Methanol REACH Consortium document pointed out that the model could not take into account co-exposure with ethanol, does not include certain sub-populations, and that there is uncertainty with blood formate levels related to death or permanent eye damage. RAC Rapporteurs would also like to add that there are large inter-individual differences regarding the elimination of both methanol and formate in humans, due to genetic differences (e.g. polymorphism in methylene tetrahydrofolate reductase that reduces folate activity and subsequently metabolism of formic acid), gender, folate deficiency (e.g. in persons with gastrointestinal disorders, inadequate diets, alcoholism, pernicious anaemia, in smokers, or in those taking folic acid antagonist medications such as some antiepileptic drugs), and presence of a disease (e.g. decreased kidney function, alcoholism) (*Hovda KE, Urdal P, Jacobsen D. Increased serum formate in the diagnosis of methanol poisoning. J Anal Toxicol 2005;29:586-8; US EPA. Toxicological review of methanol (noncancer), September 2013*). It is proposed that long formate half-life can include slow formate metabolism (due to low hepatic folate stores or to genetic deficiencies in formate-metabolizing enzymes), slow formate excretion due to kidney disease (renal tubular acidosis or non-oliguric renal failure) or genetic deficiencies in the renal formate transporters (*Hovda KE et al. Extremely slow formate elimination in severe methanol poisoning: a fatal case report. Clin Toxicol (Phila) 2007;45(5):516-21*).  Another approach is described by Kavet and Nauss (*Kavet R, Nauss KM. The toxicity of inhaled methanol vapors. Crit Rev Toxicol 1990;21(1):21-50*), using Michaelis-Menten kinetics to very roughly estimate the concentration (or dose) of methanol that puts the folate pathway into saturation. Based on data on non-human primates to estimate the maximum rates of formate oxidation and methanol metabolism, the authors estimated that in a person with 60% body water, a dose of 210 mg/kg bw methanol would saturate the folate pathway (12.6 g for 60 kg person) and lead to toxic effects. However, taking into account marked differences in formate elimination (although the half-life of serum formate in most cases is reported to be 2.5–5 hours, half-lifes of formate longer than 12.5 hours are also possible, according to *Hovda KE et al. Methanol and formate kinetics during treatment with fomepizole. Clin Toxicol (Phila) 2005;43(4):221-7; Hovda KE et al. Extremely slow formate elimination in severe methanol poisoning: a fatal case report. Clin Toxicol (Phila) 2007;45(5):516-21*), inter-individual differences could significantly influence this estimation.  **No effect levels (for lethality and permanent vision impairment)**  No-effect studies are valuable since they can give better impression about methanol exposure and related health effects. However, in line with general issues with described approach stated by the authors themselves, they do not abolish the relevance of low doses at which methanol toxicity was observed. Rather, they better illustrate wide variability in susceptibility to methanol toxicity in humans.  According to EU Regulation (EC) No 110/2008, in certain beverages (Fruit marc spirit) the maximum methanol content allowed is 1,500 grams per hectolitre of 100% vol. alcohol, i.e. 1.9%. The reason why these beverages are not related to reports of methanol poisonings in epidemiological literature (and there are reports of poisonings with surrogate alcohol with similar percentages of methanol) could be due to the fact that these beverages are more expensive than surrogate alcohol and therefore not drunk in such a high quantity that could lead to toxic effects of methanol.  **Assessment Factors and Risk Characterisation**  According to ECHA Guidance on information requirements and chemical safety assessment (Chapter R-8:Dose (concentration) - Response characterisation (Version 2.1)), derivation of DNEL is based on NOAEL or LOAEL dose observed in human population.  Since LOAEL value in the case of methanol toxicity was found for rather relevant exposure conditions and is based on an adequate route of exposure, the assessment factor is needed only for extrapolation from LOAEL to NOAEL (especially regarding the severity of effect – death or blindness – observed at LOAEL level). In line with ECHA Guidance where an assessment factor between 3 and 10 is defined, factor 3 is chosen.  RAC Rapporteurs would like to add at this point that although targeted population consists mainly of adult alcohol dependant persons, alcohol abuse in adolescents and elderly cannot be excluded. Also, it has been recognized that the main source of variability in susceptibility to methanol toxicity in humans, beside ethanol co-ingestion, are the factors related to folate metabolism, namely polymorphism in methylene tetrahydrofolate reductase and folate deficiency (discussed in the previous section), which could be present in the target population as well. Also, there is another recognised uncertainty which is supposed to be covered by the proposed assessment factor of 3, namely the volume of methanol-containing product that could be ingested by alcoholics. RAC has used the value of 1 L, in line with the Dossier Submitter proposal, but is aware that higher volumes have been reported in the literature (up to almost 2 L of strong spirit could be acutely ingested according to reports of Glazer & Dross 1993 and Zakharov et al. 2014) and stated during Public Consultation (MS Finland).  Regarding methanol-ethanol interaction please refer to RAC Rapporteurs comment #14143-4 (Answer to Key point 6)  Ethanol and isopropanol, as proposed alternatives for methanol, expected to be present in considerable amount in winter WWF, are known to be abused by alcoholics. There is a concern that unpleasant side effects of methanol ingestion, such as headache, abdominal pain, and nausea, will not deter alcoholics from abuse, bearing in mind that both the risk of severe methanol toxicity and the presence of bitterants did not prevent abuse in this population group (also please refer to RAC Rapporteurs comment #1262-1 - Reply to General Comments).  **In conclusion**, RAC Rapporteurs are of the opinion that the minimal lethal oral dose adequately reported in available literature is 4.8 g (0.08 g/kg/bw for 60 kg person) described by Bennett et al. (1953). They also point out that PBPK model used in Methanol REACH Consortium document is primarily aimed as a first tier tool or screening tool, since expected accuracy is within an order of magnitude. Also, modelling results including inter-individual human variability (e.g. gender, body mass, different rate of formate elimination) were not presented. Omission of assessment factors is not considered justified by the RAC Rapporteurs, primarily due to well-known variability in methanol metabolism and toxicity in humans which is in greater part related to genetic variability in folate metabolism and nutritional folate status, than to polymorphism in alcohol dehydrogenase. They also do not consider that no-effect studies abolish the relevance of low doses at which methanol toxicity was observed, but rather illustrate wide variability in susceptibility to methanol toxicity in humans. | |
| **SEAC Rapporteurs comments:**  *Removed (on confidential attachment)* | |
| **1426** | **Date:** 2015/09/18 15:46  **Type:** MemberState  **MS name:** Belgium  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:** | |
| **Answer to specific info request 1:**  Please find Belgian MSCA comment on Poison Center data on Methanol in attached file. | |
| **Answer to specific info request 2:**  Please find Belgian MSCA comment on Poison Center data on Methanol in attached file. | |
| **Dossier submitter response:**  Thank you for sending us information from Belgian Poison Centres about incidents caused by methanol and product containing methanol. | |
| **RAC Rapporteurs comments:**  Thank you for the valuable information. | |
| **SEAC Rapporteurs comments:**  Thank you for the comments. | |