**Committee for Socio-economic Analysis (SEAC)**

**Response to comments on the SEAC draft**

**Opinion**

**on the Annex XV dossier proposing**

**restriction on**

**Methanol**

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| **Substance name** | **EC number** | **CAS number** |
| **Methanol** | 200-659-6 | 67-56-1 |

**11 March 2016**

Comments on the SEAC draft opinion and specific information requests

## Specific information requests

1. Please provide information on the volumes or type of products of denatured alcohol containing methanol placed on the market for supply to the general public and any relevant socioeconomic information e.g. costs and other impacts of restricting the use of methanol in denatured alcohol.
2. If methanol was to be replaced with i) ethanol, or ii) isopropanol as an anti-freezing component in the windshield washing fluid, what would be the amount needed in order to reach the same (anti-freeze) effect? Are you aware of any special technical or other requirements which would require use of isopropanol instead of ethanol?
3. The draft opinion proposes a 12-months transitional period for the application of the restriction from the date of publication in the OJ (about 12 months after the opinions are finally adopted). Do you have any information on whether this transition period would be enough for the producers/ importers/suppliers to adapt to the proposed restriction?

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| **Ref.** | **Date/Name/Org.** | **Comments** |
| 293 | **Date/Time:** 2016/02/08 13:39  **Type:** Industry or trade association  **Org. type:**  Industry or trade association  **Org. name:**  METHANOL CONSORTIUM  **Org. country:**  Belgium  **Company name confidential: No**  **Attachment:** | **Comments on the SEAC draft opinion:**  The SEAC must take into account findings of a more in-depth socio-economic assessment conducted recently by TNO Triskelion that finds the proposed restriction on methanol to be disproportionate in that resulting costs to society would far outweigh benefits by at least ten times. This socio-economic analysis is herewith submitted as part of the public consultation. Main factors outlined in the analysis focus on:  •Societal Impact: The fundamental difference between the SEAC and TNO Triskelion calculations is that SEAC calculates costs to industry rather than society. However, the restriction will most directly impact the general public and SMEs operating fleet vehicles and other transport services, thus resulting in much higher costs to consumers. In line with ECHA guidance, TNO Triskelion has therefore determined costs to end-users of windshield wash fluid.  •Life Expectancy Factors: With regards to potential benefits of the proposed restriction, the TNO Triskelion estimates avoided costs are between 39 and 112 million Euro per year. These estimates are lower than those of the SEAC, but comparable, with TNO Triskelion accounting for the lower life expectancy of alcohol-dependent people compared to national averages.  •Use of Bitterants: As part of the socio-economic analysis prepared by TNO Triskelion, supported by a technical feasibility assessment from RPA, a risk management option analysis is included for the use of bitterants. Proof of enforceability is already evident from existing legislation in the EU that requires the use of bitterants in denatured alcohol. This is the only risk management option where benefits outweigh costs and can therefore be considered comparable.  In accordance with Article 71(2) of the REACH Regulation, the SEAC must also account for the use of bitterants as a risk management option in its final opinion, as a complete analysis is now available. |
| **Specific information 1:**  see attachment |
| **Specific information 2:**  see attachment |
| **SEAC Rapporteurs response:**  First of all we would like to thank you for submitting these extensive studies (TNO-SEA study and RPA-AoA report) in regard to the restriction proposal on Methanol.  Please find below the SEAC rapporteurs’ assessment of the submitted information.  **1) Health impacts estimation**  *Number of fatalities*  Both the TNO study and the SEAC DO come to a similar conclusion regarding which European countries are at risk (FI, PO, EE, LT, LV, RO, BG, CZ, SK). However, while the SEAC DO considers for health impact calculations only countries where methanol poisoning data were available or reasonable estimates could be provided (FI, PO, RO, BG, CZ, SK), the TNO study also takes into account countries where no poisonings or very limited number of incidents (UK, HU) were reported.  For the estimation of fatal cases due to ingestion of methanol-containing windshield washing fluids in the different countries, the TNO study makes a number of assumptions which defer from those taken ahead in the SEAC DO. For example, in the case of Finland and Poland the TNO study assumes that a realistic estimate would be to reduce the average number of fatalities reported by half. In the rapporteurs view, however, the number of fatalities reported by the DS for Poland and Finland is reliable and therefore should be taken forward as a “realistic estimate” of the number of fatal cases in these countries (and not as a “high estimate” as defined in the TNO study). Other assumptions made in the TNO study for the Baltic countries (EE, LT, LV) and for the so called “medium risk countries” are considered acceptable.  In spite of the different approach taken, the total number of fatalities calculated in the TNO report (87 fatal cases) is in the same order of magnitude as the total number of fatal cases calculated in the SEAC DO (82 fatal cases).  In any case, the Scientific Committees of ECHA can take any observed data only as a minimum. There are countries, which have not reported anything and in many countries the reporting is partial, therefore SEAC Rapporteurs consider the figures to be an underestimate for the EU and that the real number of fatalities will most likely be higher than the figures calculated suggest.  *Unit cost of mortality*  The ECHA Guidance on Socio-Economic Analysis-Restrictions recommends using the VSL (Value of Statistical Life) when calculating unit costs for mortality, and this is the approach agreed by SEAC and taken in the SEAC DO. The TNO report applies the value of YLL (Years of Life Lost) derived from the VSL, and adjusts further the VSL based on the GDP/ca for each European country.  The Guidance suggests that “if you are considering using any of the unit costs used in this section (i.e. VSL), it is recommended to check if these values have been “superseded” by more recent studies". In line with the Guidance, the SEAC DO uses a recent WHO study (2011) where the value of the VSL is around 3.9 Million Euro in 2015 price level. According to the TNO assessment, the cost of one life lost (based on YLL) is around 1.2 Million Euro (65 000 Euros/YLL x 18 YLL). This figure is further adjusted with the GDP/ca resulting in different VSL per European country; the highest VSL is for Finland (1.4 Million Euros) and the lowest for Bulgaria (0.2 Million Euros). The approach of adjusting for the GDP/ca is not considered acceptable and is not taken into consideration in the final SEAC Opinion.  *Costs of visual impairment*  According to the TNO study, there are approximately 0.7 cases of visual impairment for each fatal case due to methanol poisoning. Considering the 87 fatalities calculated in the study, the authors calculate a monetary value of 17.5 Million Euro for the costs of medical and non-medical care and the loss of healthy life years due to visual impairment as a result of methanol poisoning. The SEAC rapporteurs find these estimates reliable but will not include the cost of visual impairment in the assessment, although it would strengthen even more the benefits/cost ratio of the proposed restriction.  **2) Cost of substitution**  The TNO study estimates that 125 Million litres of methanol are used in windshield washing fluids in the EU (approximately 99 000 tonnes of methanol). In order to arrive to this figure, the study assumes that the volume of windshield washing fluid used per car per year is the same all over Europe, and although the authors acknowledge that this is "probably not correct" they do not apply any adjustment factor to the calculations. The study also assumes that all cars in the EU will use windshield washing fluid at least once per day, 365 days per year. This leads to a clear overestimation of the total volume of windshield washing fluids in use in the EU. (The total number of cars used in the calculation is not clear, different figures are used in the report; 279 Million cars on page 14, 264 Million cars on page 8). Additionally the assumptions made in the study regarding the methanol content of windshield washing fluids in the different European countries have no backing substantiated evidence.  Thus, SEAC considers that the amount of methanol presented in the DO (56 000 tonnes) is better justified and will use it in its assessment.  The TNO study uses the price difference between a methanol free windshield washing fluid and one that contains methanol in different concentration levels to calculate the market value of the windshield washing fluid business if a restriction would be in place. It assumes that in the "as is situation" the yearly windshield washing fluid business is 30.2 billion Euro and due to the restriction it would increase to 32 billion Euro (pages 90-92). This assessment is highly unreliable as it considers the retail value of the product as an additional cost for society rather than the cost difference of alternatives needed to replace methanol. The use of retail value does not account for the fact that the price of a product is made of different elements (raw materials, manufacturing costs, market place, competition, market condition, brand, quality of product, etc.) and is not appropriate to use in this case. The extra cost for the society of this restriction is only the value resulting from multiplying the increase in price by the amount of alternative and not the other cost elements.  **3) Use of bitterants**  The TNO evaluation of the effectiveness of bitterants as a deterrant to the drinking of methanol-containing windshield washing fluids describes significant uncertainties regarding its effectiveness. Denatonium benzoate is the most readily available bitterant, with reportedly low toxicity. As the report states, information on the effectiveness of bitterants is very limited, and “pertinent scientific data indicating the effectiveness of bitterants (i.e. denatonium benzoate) to prevent abuse of products containing methanol by alcohol dependent people is lacking”. Also, there are no available data which could indicate to what extent experimental studies on denatonium benzoate effectiveness performed in non-alcoholic individuals could be extrapolated to alcohol dependent people; it is thus difficult to predict how many alcohol dependent people compared to non-alcohol dependent people will be deterred by the same concentration of bitterant in a product.  From reports in the available literature, it can be concluded that adding bittering agent to a product does not deter chronic alcohol dependent people from drinking such products in an effective manner. Chronic alcoholism is a disease with both psychological and physical dependence on ethanol, and an urge for alcohol consumption in an alcoholic seems to be able to override aversive taste of a product (e.g. Reid and Chen 2014; Jones et al. 1989). Also, it is recognised that sensitivity to bitter taste varies substantially in the human population (up to 16-fold inter-individual variation in threshold perception was found for denatonium benzoate), which is largely explained by genetic variability of taste receptors (Roudnitzky et al. 2011). It seems that sensitivity to bitter taste is also inversely associated with alcohol intake, i.e. that individuals with enhanced perception of bitter taste have less frequent alcoholic intake compared to individuals with less sensitive perception of bitterness (Duffy et al. 2004), and an association between genetic variation in a bitter taste receptor gene and the consumption of alcohol was observed has been reported (Dotson et al. 2012).  To what degree an increasing amount of denatonium benzoate (10 ppm, 20 ppm, 50 ppm or more) could influence its effectiveness in alcohol dependent people is also unclear. In the above report, 20 ppm of denatonium benzoate in a methanol product was used for risk calculation (In such a risk assessment, it would be prudent to use the ‘high estimates’, i.e. “assuming that alcohol dependent people are less responsive to the deterring effects of bitterants”).  With a lack of actual data in alcohol dependent people, and being aware of apparently different behaviour of alcohol dependent people and non-alcohol dependent people with respect to consumption of drinks with aversive taste, the uncertainties in estimating the risk such as presented in the TNO study (pages 60-63) are high.  The conclusion of the RPA report, that although bitterants could be effective against accidental consumption, there is “a lack of evidence for action against intentional consumption”, and that effectiveness of a bitterant under the conditions of intentional consumption is worth further evaluation (e.g. effective concentration, type of bitterant) fits well with the conclusions of RAC regarding the ineffectiveness of bitterants in deterring alcohol dependent people. |
| 294 | **Date/Time:** 2016/02/08 21:05  **Type:** Industry or trade association  **Org. type:**  Industry or trade association  **Org. name:**  Methanol Institute  **Org. country:**  Belgium  **Company name confidential: No**  **Attachment:** | **Comments on the SEAC draft opinion:**  Please find attached the Methanol Institute's comments on the draft opinion of the Committee for Socio-economic Analysis (SEAC) concerning a proposal to restrict methanol.  8 February 2016  The Methanol Institute shares many concerns on surrogate alcohol use and the methanol poisonings reported in the SEAC draft opinion.  Making consumer windshield wash fluid safe for consumption as a surrogate alcohol could, however, have major unintended long-term repercussions across the EU. Based on experience in Finland in the 1960s with household windshield wash, such a regulatory approach can increase surrogate alcohol consumption by making surrogate alcohol more readily accessible and attractable to the public (Nordlund & Osterberg, 20101).  Social media forums on surrogate alcohol are filled with anecdotal examples of how warnings of methanol toxicity have a deterrent effect on illegal consumption of ethanol containing products.  Additionally, research supporting methanol as a deterrent to surrogate alcohol abuse shows:  -Methanol-containing products are not usually selected by surrogate alcohol users (e.g. Lang et al., 20062)  -Methanol is not usually found as a major component of surrogate alcohols (e.g. Solodun et al., 20113; Lachenmeier et al., 20094)  -Methanol’s inebriating effects differ substantially from ethanol and other alcohols, where the effects have been described as a “disappointment” to alcoholics (e.g. Bryson, 19965)  -Symptoms associated with methanol toxicity, such as temporary blindness, numbness and severe headaches, are considered by alcohol abusers as ‘poor’ or ‘bad’ surrogate alcohol (e.g. Bobrova, 20126)  -As toxic substances in an ethanol-containing product can deter consumption, the potential benefits of adding an intentionally toxic substance to a product containing ethanol may outweigh the risk of poisoning (e.g. Carnahan et al. 20057)  Encouraging surrogate alcohol use across the EU is therefore a greater threat than the current isolated cases of methanol poisoning from surrogate alcohol use. This is particularly the case because there is no evidence of methanol poisonings from windshield wash fluid in many EU countries even though windshield wash fluid containing methanol is available in those markets.  To limit the potential for abuse of windshield wash fluid, the SEAC draft opinion currently considers that bitterants are ineffective. This position is inconsistent with the European Commission’s recommendation that a bitterant is a key component in denatured alcohol to prevent illegal consumption and use.  From information provided in the RAC Background Document, there is clear evidence of the effectiveness of bitterants, dependent on:  1)Type of bitterant  2)Concentration of bitterant  3)Individual differences of bitterant  So, it is therefore evident that the scientific references cited by the SEAC have a very limited practical relevance to evaluating the proper use of bittering agents in windshield wash fluid:  -Toronto Public Health Fact Sheet ‘Non-palatable (toxic) alcohol use’ (2011) defines ‘non-palatable’ as any denatured alcohol, such as Chinese cooking wine or methyl alcohol, even without any bittering agent. As this reference has no relevance to effectiveness of bitterants, the RAC and SEAC must have misunderstood ‘non-palatable’ as inferring ethanol product that contains a bitterant, when actually it is a synonym for denatured alcohol.  -Carnahan et al. 20057 include a description of a single (chronic alcoholic) patient consumption of a denatured alcohol formulation containing 0.1 % tert-butyl alcohol, 6 ppm denatonium benzoate bitterant and ethanol. This level of denatonium benzoate is well below the levels usually recommended by industry or set by regulatory authorities for a concentrated ethanol solution.  -Reid & Chen 20148 report on a case of intentional abuse of a hand sanitizer. However the level of the denatonium benzoate bitterant in the product is not specified and the formulation contains a flavouring at above 1000 ppm, which is not used in windshield wash fluid.  In conclusion, it is not possible for the SEAC to conclude that the proposed restriction is proportionate or justifiable without evaluating the consequences of removing deterrents of consumption of windshield wash fluid as a surrogate alcohol.  References: (1) Addiction, Vol. 95, S551-S564, 2000; (2) Alcohol & Alcoholism, Vol. 41, 446-450, 2006; (3) Interdisciplinary Toxicology, Vol. 4, 198-205, 2011; (4) Alcohol & Alcoholism, Vol. 44, 93-102, 2009; (5) Comprehensive Reviews in Toxicology: For Emergency Clinicians. Chapter 38. CRC Press, 1996; (6) Doctoral Thesis. University College London, 2012; (7) Pharmaco-therapy, Vol. 25, 1646-1650, 2005; (8) Proceedings of UCLA Healthcare, Vol. 18, 2014.  \* \* \*  The Methanol Institute serves as the trade association for the global methanol industry.  The Methanol Institute is registered in the European Commission’s Transparency Registry as:  0846.425.760 |
| **SEAC Rapporteurs response:**  The SEAC Rapporteurs thank you for the submitted comments.    The SEAC Rapporteurs consider that there is sufficient evidence of methanol poisonings from windshield washing fluids in a number of European countries, as presented in the SEAC DO. Additionally, an SEA submitted during the public consultation estimated a similar number of fatalities (82 in the DO, 87 in the SEA) and identified the same Member States as the ones affected. The SEAC Rapporteurs consider that, given the lack of systematic reporting of methanol poisoning cases, the real number of fatalities will most likely be higher than the figures calculated. Moreover a number of Member States presently have or have had measures addressing the availability of/access to methanol (e.g. Sweden, Germany) suggesting there is a potential risk/problem in those countries too.  Regarding the effectiveness of bitterants, please see the response to the previous comment. |
| 295 | **Date/Time:** 2016/02/09 13:44  **MS name:**  Sweden  **Country:**  Sweden  **Company name confidential: No** | **Comments on the SEAC draft opinion:**  1.The Swedish Chemicals Agency supports the restriction of methanol in windshield washing fluids.  2.The Swedish Chemicals Agency thinks that the exclusion of denaturated alcohol from the scope is questionable.  SEAC argues that there is not enough available information on hazard and risk of methanol exposure via denaturated alcohol to justify a restriction. There are however indications in the draft opinion and in the BD that an inclusion of denaturated alcohol in the restriction could be proportional, and the Swedish Chemicals Agency thinks that this should have been investigated by the DS and/or by SEAC.  For windshield washing fluids, the benefits are estimated to be 8 times larger than costs (draft opinion p.19). The estimated benefits only include avoided fatalities, but not the costs of expected adverse health effects, such as vision impairment. Assuming that the substitution costs for methanol in denaturated alcohol is of similar magnitude to those of methanol in windshield washing fluids, relatively few cases of methanol poisoning caused by denaturated alcohol are required to conclude that an inclusion of denaturated alcohol in the scope of the restriction is proportional.  In Silesia (draft opinion p.17), only 26 out of 73 identified methanol poisonings over 3,5 years were caused by windshield washing fluids, while the remaining two thirds of the reported cases had unspecified causes. In the BD (p.122), it is mentioned that there were two reported cases of methanol poisoning caused by denaturated alcohol in Silesia in one year (2013). As a comparison, the identified cases over 3.5 years for windshield washing fluids were 7.4 cases/year, or less than four times the number of identified cases of poisoning caused by denaturated alcohol.  Even though we should be careful to draw conclusions from these small data samples, it indicates that a restriction of methanol in denaturated alcohol could be proportional, especially when taking the relatively high share of unspecified causes among methanol poisoning cases (nearly two thirds in Silesia) into account.  The Swedish Chemicals Agency is concerned by SEACs proposal to exclude denaturated alcohol from the scope of the restriction. The existing information in the BD and the draft opinion indicate that denaturated alcohol is a cause of methanol poisoning among consumers, and that proportionality of a restriction of methanol in denaturated alcohol cannot be dismissed. |
| **SEAC Rapporteurs response:**  The SEAC Rapporteurs thank you for the submitted comments.  SEAC assessed the available information in the Annex XV report and concluded there is no socio-economic data available to evaluate the socio-economic impacts of restricting the content of methanol in denaturated alcohol. During the Public Consultations, both on the Annex XV report and on the SEAC DO, no additional information has been received regarding the costs of restricting methanol in denaturated alcohol. Therefore, and due to the lack of information, the SEAC rapporteurs cannot support the inclusion of denaturated alcohol in the scope of the present restriction. |
| 296 | **Date/Time:** 2016/02/09 16:14  **Country:**  Bulgaria  **Company name confidential: No** | **Comments on the SEAC draft opinion:**  Methanol should be restricted as an anti-freezing component in the windshield washing fluid because there are proofs of the toxicity even of small quantities of methanol on the organism following inhalation, oral or percutaneous exposure. In Bulgaria there are reported cases of suffocation in the cabin of cars caused by methanol containing windshield fluids. Also there are cases of headaches, nausea, low concentration of the driver also caused by such type of windshield washing fluids. This creates a potential risk of accidents on the road. А lot of people are exposed, in many cases without knowing, to the effect of the substance, including small children and pregnant women. These fluids are easily accessible from the market and people under 18 years could buy them and consume then instead of spirit drink for which could lead to severe consequences even death. There are also such cases reported in Bulgaria almost every year. It is important that there is a Bulgarian Ordinance №35/1995 which banned the use of methanol in liquid household chemicals. According to all above we consider that if there is an alternative substance with the same anti-freezing effect it should be used instead of methanol in the windshield washing fluids. |
| **Specific information 1:**  We do not have such information. |
| **Specific information 2:**  According to the freezing point of the substances the water solution of approx. 40 vol % methanol or 50 vol % ethanol or 70 vol % isopropyl alcohol will freeze at -30°C. |
| **Specific information 3:**  No. |
| **SEAC Rapporteurs response:**  The SEAC Rapporteurs thank you for the submitted comments. |