Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing restrictions on

Methanol

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

ECHA/SEAC/ RES-O-0000001412-86-100/F

Compiled version prepared by the ECHA Secretariat of RAC's opinion (adopted 4 December 2015) and SEAC's opinion (adopted 11 March 2016)

4 December 2015

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

11 March 2016

RES-O-0000001412-86-100/F

Opinion of the Committee for Risk Assessment

And

Opinion of the Committee for Socio-economic Analysis

on an Annex XV dossier proposing restrictions of the manufacture, placing on the market or use of a substance within the EU

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation and the Committee for Socio-economic Analysis has adopted an opinion in accordance with Article 71 of the REACH Regulation on the proposal for restriction of

Chemical name:	**Methanol**
EC No.:	**EC No 200-659-6**
CAS No.:	**CAS No 67-56-1**

This document presents the opinions adopted by RAC and SEAC. The Background Document (BD), as a supportive document to both RAC and SEAC opinions, gives the detailed ground for the opinion.

PROCESS FOR ADOPTION OF THE OPINIONS

Poland has submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The Annex XV report conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at http://echa.europa.eu/web/guest/restrictions-under-consideration on ***18 March 2015***. Interested parties were invited to submit comments and contributions by ***17 September 2015.***

ADOPTION OF THE OPINION OF RAC

Rapporteur, appointed by RAC: ***Veda Varnai***

Co-rapporteur, appointed by RAC: ***Lina Dunauskiene***

The RAC opinion as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment has been reached in accordance with Article 70 of the REACH Regulation on ***5 December 2015***

The RAC opinion was adopted ***by consensus.***

ADOPTION OF THE OPINION OF SEAC

Rapporteur, appointed by SEAC: ***Robert Csergo***

Co-rapporteur, appointed by SEAC: ***Silvia Grandi***

The draft opinion of SEAC

The draft opinion of SEAC on the suggested restriction has been agreed in accordance with Article 71(1) of the REACH Regulation on ***4 December 2015.***

The draft opinion takes into account the comments of and contributions from the interested parties provided in accordance with Article 69(6) of the REACH Regulation.

The draft opinion was published at ***http://echa.europa.eu/web/guest/restrictions-under-consideration*** on ***9 December 2015***. Interested parties were invited to submit comments on the draft opinion by ***9 February 2016***.

The opinion of SEAC

The opinion of SEAC on the suggested restriction was adopted in accordance with Article 71(1) and (2) of the REACH Regulation on ***11 March 2016.***

The opinion takes into account the comments of interested parties provided in accordance with Article 69(6) and 71(1) of the REACH Regulation.

The opinion of SEAC was adopted ***by a simple majority*** of all members having the right to vote. A joint minority position, including its grounds, is made available in a separate document which has been published at the same time as the opinion.

OPINION

The proposal of the Dossier Submitter:

Methanol CAS No 67-56-1 EC No 200-659-6	Shall not be placed on the market for supply to the general public: – as a constituent of windshield washing fluids (including windshield defrosters) in concentration equal to, or greater than 3.0% by weight, – as an additive to denatured alcohol (*methylated spirit, brennspiritus*) in concentrations equal to, or greater than 3.0% by weight. Member State may maintain any existing and more stringent restrictions for methanol.

THE OPINION OF RAC

RAC has formulated its opinion on the proposed restriction based on information related to the identified risk and to the identified options to reduce the risk as documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. RAC considers that the proposed restriction on methanol is the most appropriate EU wide measure to address the identified risks in terms of the effectiveness in reducing the risks provided that the conditions are modified.

The conditions of the restriction proposed by RAC are:

Substance	**Conditions of the restriction**
Methanol CAS No 67-56-1 EC No 200-659-6	Shall not be placed on the market for or used by the general public: – as a component of windshield washing fluids (including windshield defrosters) in concentration equal to or greater than 0.6% by weight, – as a component[1] of denatured alcohol (*methylated spirit, brennspiritus*) in concentration equal to or greater than 0.6% by weight.

THE OPINION OF SEAC

SEAC has formulated its opinion on the proposed restriction based on information related to socio-economic benefits and costs documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. SEAC considers that the proposed restriction on methanol is the most appropriate EU wide measure to address the identified risks in terms of the proportionality of its socio-economic benefits to its socio-economic costs provided that the scope and conditions are modified.

[1] The term 'constituent' has been proposed by the Forum; indeed, the Guidance on Substance Identification uses the terms constituent for a*ny single species present in a substance that can be characterised by its unique chemical identity* and component for *substance intentionally added to form a mixture*. This has been reflected in the RAC proposal.

The conditions of the restriction proposed by SEAC are:

Substance	Conditions of the restriction
Methanol CAS No 67-56-1 EC No 200-659-6	Shall not be placed on the market for supply to the general public: – as a constituent of windshield washing fluids (including windshield defrosters) in concentration equal to, or greater than 0.6% by weight.

JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

Justification for the opinion of RAC

IDENTIFIED HAZARD AND RISK

The aim of the Dossier Submitter's proposal is to reduce the incidence of severe methanol poisoning following deliberate misuse of windshield washing fluids and denatured alcohol containing methanol by chronic alcoholics and sporadically by non-alcoholics (e.g. binge drinking in adolescents), which are used as a cheap substitute for consumable alcohol. The proposed restriction is also expected to prevent methanol poisoning following accidental ingestion of windshield washing fluids and denatured alcohol, including poisonings in children.

The proposal therefore seeks to limit methanol concentration in windshield washing fluids and denatured alcohol, which are considered to be the principle products that could contain high a percentage of methanol and are recognised as the type of methanol-containing products most frequently linked to methanol poisoning in the general population.

Intentional misuse of substances and mixtures is usually not considered in the exposure estimation process. However, if targeted by the Dossier Submitter in a REACH Restriction, it may be considered in the Annex XV dossier if it relates to known exposure that creates a serious concern for human health or the environment to be addressed at Union level, and there is no other appropriate EU legislation to tackle the problem (see Guidance text below).[2]

RAC concludes that this restriction proposal by presenting the data on severe cases of poisonings following abuse of methanol-containing products in several EU countries fulfils this requirement. It could also be argued that although ingestion of methanol-containing products by alcohol addicts is intentional, it does not have the aim of self-poisoning, but it is a part of clinical feature of addictive behaviour in chronic alcoholism.

Description of and justification for targeting of the information on hazard and exposure

In certain EU countries (e.g. Poland, Finland, Bulgaria) significant numbers of methanol poisoning cases, including those with a lethal outcome (e.g. on average 25 deaths per year for the period from 1995-2012 in Finland) have been reported. When ingestion of adulterated consumable alcohol is excluded, the most common cause of methanol poisoning was ingestion of methanol-containing products available for consumer use. These products are mainly consumed by alcoholics as a surrogate for much more expensive (excisable) consumable alcohol.

There are over 100 methanol-containing products available for consumer use on the EU market, including cleaning agents, solvents, paints, lacquers and/or varnishes, fuels, corrosion inhibitors, biocides, adhesives, glues and binding materials, fragrances, and anti-freeze products. However, the proposed restriction only refers to two types of products, windshield washing fluids and denatured alcohol (*methylated spirit, brennspiritus*), since these two types of products, which can contain methanol in high concentration, represent

[2] According to the Guidance on information requirements and chemical safety assessment (Chapter R.15.2.2. Reasonable worst-case situations), '*the consumer exposure estimation should normally address the intended uses of the products that contain the substances under investigation*.' The Guidance, however, recognizes that '*since consumers may not accurately follow instructions for use of products, an estimation of other reasonably foreseeable uses should be made*', and that '*the difference between other foreseeable uses and abuse can in certain cases be small'*. In such situation, '*the assessor should provide clear argumentation why a certain exposure situation is included'*.

the most common causes of severe methanol poisonings according to available data from the Poison Control/Information Centres in Poland and Finland. The Forum has suggested including windshield defrosters as a sub-group of windscreen washing fluids and this advice has been followed by RAC.

Description of the risk to be addressed by the proposed restriction

Information on hazard(s)

Only data on methanol toxicity in humans are taken into account in this opinion. In this particular case, RAC regards animal data as being of limited use in the assessment of methanol toxicity to humans, due to significant differences in methanol metabolism and susceptibility to methanol toxicity between humans and animals (especially rodents).

In humans, methanol is metabolised to formaldehyde by hepatic alcohol dehydrogenase, which is a saturable rate-limiting process. Formaldehyde is oxidised by aldehyde dehydrogenase to formic acid or formate, depending on the pH, which is then further detoxified by a folate-dependent pathway to carbon dioxide and water. This last reaction step is also of limited capacity which may lead to a disproportionate increase of formic acid/formate in the blood and consequent metabolic acidosis.

Initial symptoms of methanol intoxication often include ataxia, sedation, and disinhibition, and, after a latent period (usually 12 to 24 hours), could be followed by headache, nausea, vomiting, abdominal and muscle pain, dizziness, visual disturbances (blurring, photophobia, constriction of the visible field, changes in colour perception, reduced visual acuity, temporary or permanent blindness), drowsiness, loss of consciousness and death. The principal clinical feature is severe metabolic acidosis of anion-gap type, largely attributed to the formic acid formation.

Based on information on methanol poisoning in humans, the Dossier Submitter (DS) proposed lethality as the point of departure (POD), and chose 0.3 g/kg body weight (bw) as a minimal acute lethal dose of ingested methanol, according to IPCS/WHO (1997).

In the Background Document, an acute oral Derived No-Effect-Level (DNEL) of 0.008 g/kg bw for the general population is described according to calculations performed in the Registrant's Chemical Safety Report for methanol. This was derived from an OEL of 260 mg/m^3 (aimed at protecting workers from acute systemic and local irritation effects of methanol inhalation). This OEL is considered to be, in the majority of cases, also protective from very slight, sub-clinical CNS effects of methanol inhalation, which are reported to start appearing at 270 mg/m^3 (FIOH 2008). However, as mentioned above, the Dossier Submitter based the risk assessment on minimal acute oral lethal dose of 0.3 g/kg bw (quoted in IPCS/WHO 1997 document) without applying an assessment factor.

RAC, however, considers that severe ocular toxicity (including blindness or severely diminished visual acuity) should be considered as a POD as it represents a serious non-lethal adverse effect.

Based on information provided in the Background Document and the data on methanol poisoning cases in humans published in the open literature (Table 1), a minimal methanol oral dose leading to severe ocular toxicity (vision limited to finger-counting at the time of discharge from hospital) was identified to be 0.26 g/kg bw. It originates from a case report of a 34-year-old woman ingesting 50 ml of bootleg whiskey with 35-40% of methanol and <4% of ethanol, described by Bennett et al. (1953). This dose level is related to some degree of uncertainty (issue raised by Methanol REACH Consortium during Public Consultation), since the amount of ingested methanol is stated differently in Table V (pages 450-453 of the article written by Bennett et al. 1953) and in the text of the article. Namely, in the table, the ingested methanol dose is stated as 'MeOH drunk' in ml, ranging from 15–

500 ml. From the article text, however, it could be deduced that values of 'MeOH drunk' shown in Table V do not refer to volume of pure methanol but to the amount of ingested bootleg whiskey (containing 35-40% of methanol). The article text states that 'The smallest amount which produced a fatal result in the outbreak observed by the present authors was three teaspoons (about 15 ml) of 40% methyl alcohol. The highest dose recorded in a survivor was one pint (500 ml) of the same mixture.' The lowest value of 'MeOH drunk' in the table related to lethal outcome was indeed 15 ml, and the highest value in a survivor was 500 ml. RAC, therefore, decided to interpret ingested volume of 50 ml in Table V as an amount of ingested bootleg alcohol and not pure methanol, leading to a methanol dose of 0.26 g/kg bw related to severe ocular effects (taking into the calculation a 40% methanol mixture), instead of 0.66 g/kg bw as calculated by Methanol REACH Consortium (which interpreted 'MeOH drunk' as an amount of pure methanol ingested).

The lowest lethal oral methanol doses reported in the open literature (Table 2) were identified by RAC to be in the range of 0.45 – 0.51 g/kg bw (Bennett et al. 1953, Desai et al. 2013), namely in a similar range as the minimal dose leading to severe ocular toxicity.

Doses below 0.26 g/kg bw leading to severe ocular toxicity and below 0.45 g/kg bw leading to death in humans are published in the open literature, but, in RAC's opinion, these dose levels are too uncertain to be used as a POD[3] (please refer to the Background Document for more detailed clarification).

During Public Consultation several issues were raised regarding relevant no effect levels for lethality and permanent vision impairment following oral methanol exposure in humans.

Based on a literature search and applying PBPK modelling (IndusChemFate v2), the Methanol REACH Consortium proposed a value of 0.40 g methanol/kg bw as a protective level against ocular toxicity without co-exposure to ethanol, and of 0.50 g methanol/kg bw with co-exposure to ethanol or isopropanol. This is taking into account ocular toxicity at ingested methanol dose of 0.66 g/kg bw reported by Bennett et al. (1953); a reported methanol dose of 0.56 g/kg bw as a non-lethal dose that did not result in permanent vision damage in 84 subjects acutely exposed to methanol in a solution containing 5% methanol and 90% ethanol (Martensson et al. 1988); and 0.40 g/kg bw as methanol dose that according to PBPK modelling does not produce high levels of formic acid (related to ocular toxicity).

RAC, however, calculated the minimal oral methanol dose related to severe ocular toxicity as 0.26 g/kg bw, reported by Bennett et al. (1953) (for justification please see text above). RAC does not consider that no-effect studies abolish the relevance of low doses at which methanol toxicity was observed, but rather illustrate the wide variability in susceptibility to methanol toxicity in humans. RAC also points out that the PBPK model used in the Methanol REACH Consortium document is primarily a first tier or screening tool (Jongeneelen and Berge 2011; Jongeneelen and Berge, User manual), that there are uncertainties regarding blood formate levels related to death or permanent eye damage, and that modelling results regarding inter-individual human variability (e.g. gender, body mass, different rate of formate elimination) were not presented. For further clarification please refer to the Background Document.

Conclusion: RAC concluded to consider severe ocular toxicity (significantly reduced visual acuity at 0.26 g/kg bw) as the critical endpoint for further assessment. It was noted that the SCLs for methanol (STOT SE 1; H370: C ≥ 10%; STOT SE 2; H371: 3% ≤ C < 10%) are based on eye toxicity (blindness) in humans.

[3] e.g. description of a poisoning case was not available (Wood and Buller 1904, Ziegler 1921, Duke-Elder 1945); significant contribution of ethanol toxicity cannot be ruled out in lethal outcome following ingestion of 0.08 g/kg bw of methanol described by Bennett et al. (1953); discrepancy in methanol blood concentration and stated amount of ingested methanol of 0.23-0.26 g/kg bw in two lethal cases described by Bennett et al. (1953).

Table 1. Methanol doses related to severe ocular toxicity in human methanol poisoning cases

Reference	**Patient(s)** [N]	**Product**	**Methanol dose**	**Ethanol level in a product**	**Exposure (single, repeated)**
Wood and Buller 1904 (summary not available)	?	wood alcohol	2 teaspoons of methanol (?) (10 ml, **7.9 g**)	?	?
Duke-Elder 1945 (summary not available) **IPCS/WHO 2001** (full document)	?	?	4 ml methanol (**3.2 g**) (?)	?	?
Bennett et al. 1953 (full article)	323 (5 with residual visual disturbances)	adulterated whiskey 35-40% methanol	50 ml bootleg whiskey, "vision limited to finger-counting", 34 yrs F (**16 g** methanol)	<4%	?
Erlanson et al. 1965 (full article)	39 yrs F (63 kg)	100% methanol for technical use (sold as ethanol)	**80 g** (blindness recovered after dialysis)	0 (?)	single (?)
Fujihara et al. 2006 (full article)	37 yrs M	industrial alcohol	100 ml/day, for 4 days, 75% methanol (**59.4 g/day, 238 g total**)	25%	repeated (4 days)
Brahmi et al. 2007 (full article)	16 (16-53 yrs) (1 blind)	cologne (65% methanol), spirits	30 – 1000 ml 65% methanol, blindness 300 ml (**154 g**, 23 yrs M)	?	?
Moschos et al. 2013 (full article)	adult M	70% methanol rubbing solution	one glass, 70% methanol (100-200 ml?, **59.4-119 g**)	?	single
Desai et al. 2013 (full article)	122 (121 M, 20-60 yrs) (32 PVD)	adulterated alcohol	? (range 100-700 ml 6.5% methanol, **up to 36 g**)	40%	?

M – male patient, **F** – female patient; PVD – permanent visual damage, (?) – dose level with high uncertainty due to lack of information

Table 2. Methanol doses related to lethal outcome in human methanol poisoning cases

Reference	Patient(s) [N]	Product	Methanol dose	Ethanol level in a product	Exposure (single, repeated)
Bennett et al. 1953 (full article)	323 (41 died)	bootleg whiskey 35-40% methanol	15 ml 40% bootleg whiskey, 20 yrs F (**4.8 g**, i.e. 0.07 g/kg bw)[†]	<4%	?
			50 ml bootleg whiskey, 41 yrs M and 63 yrs F (**16 g** methanol)[‡]		
			100 ml bootleg whiskey, 49 yrs M (**32 g** methanol)		
Erlanson et al. 1965 (full article)	49 yrs F (55 kg)	100% methanol for technical use	**90 g** (40 g + 50 g 29 h later)	- (?)	repeated (within 29 h)
Gonda et al. 1978 (abstract)	9 (2 died)	?	min. lethal dose 30 ml (**23.8 g**) (?)	?	?
Scrimgeour 1980 (abstract)	372 adult M	sold by a local pharmacy instead of methylated spirit	min. lethal dose 100 ml 82% methanol (**64.9 g**)	- (18% isopropanol)	?
IPCS/WHO 1997 (full document)	?	?	**21-70 g** (0.3-1 g/kg bw)* (?)	?	?
Girault et al. 1999 (full article)	35 yrs F	windshield washing fluid	500 ml 20% methanol (**79 g**)	?	single
Brahmi et al. 2007 (full article)	16 (16-53 yrs) (3 died)	cologne, spirits	30 – 1000 ml 65% methanol, min lethal 1000 ml (**515 g**, 27 yrs M)	?	?
Massoumi et al. 2012 (full article)	51 (children included?) (5 died)	as an ethanol substitute in illicit liquor	<50 ml (**<40 g**)	?	?
Desai et al. 2013 (full article)	122 (121 M, 20-60 yrs) (10 died)	adulterated alcohol	? (range 100-700 ml 6.5% methanol, **up to 36 g**)	40%	?

M – male patient, **F** – female patient; *Articles quoted for the dose range: Erlanson et al. 1965, Gonda et al. 1978, Röe 1955, (?) – dose level with high uncertainty due to lack of information; [†]Significant ethanol toxicity cannot be excluded; [‡]Discrepancy in methanol blood concentration and stated amount of ingested methanol.

Since a dose-response curve and NOAEL could not be established due to the limitations of the database, RAC applied LOAEL to NAEL extrapolation, using an assessment factor (AF) of 3, in line with ECHA Guidance[4] where an assessment factor between 3 and 10 is suggested.

The Methanol REACH Consortium disagreed with the use of this assessment factor (proposing no assessment factors) since it considers that in alcohol abusers, the target population in the proposed restriction, the variability of alcohol dehydrogenases which could affect ethanol and methanol metabolism, is not present, and since from a wide database the lowest values for toxicity have been selected (Methanol REACH Consortium 2015).

RAC points out that well-known variability in methanol metabolism and toxicity in humans is in greater part related to genetic variability in folate metabolism and nutritional folate status (US EPA Toxicological review of methanol (non-cancer), September 2013), than to polymorphism in alcohol dehydrogenase (for further clarification please refer to Background Document).

Nevertheless, according to ECHA Guidance[5] the assessment factor for LOAEL to NAEL extrapolation is defined primarily according to the shape and slope of the dose-response curve and the extent and severity of the effect observed at LOAEL (and not toxicokinetic data). In the case of acute methanol poisoning in humans, the assessment factor is chosen with regard to the fact that dose-response and a 'non-toxic', tolerable dose (NOAEL) could not be established (i.e. although high number of methanol poisoning cases is described in open literature and in the reports from poison control centres, methanol dose is rarely known/stated and the database is rather limited) and severity of the effects - severe ocular toxicity and death (namely, lethal outcome is observed already at a dose level of 0.45 g/kg bw which is rather close to dose related to severe ocular toxicity of 0.26 g/kg bw, chosen as POD).

Conclusion: Using an assessment factor of 3, a **DNEL of 0.088 g/kg bw** is proposed by RAC.

Human health and environmental hazards of alternatives for methanol

The Dossier Submitter identified two alternative substances for methanol in windshield washing fluids (since products with a methanol concentration as low as proposed by the Dossier Submitter and RAC do not possess sufficient anti-freezing function, an adequate substitute for methanol needs to be added), namely ethanol and isopropanol (2-propanol) which are of lower toxicity compared to methanol. RAC recognised that other substances may also be used (e.g. ethylene glycol or propylene glycol in windshield washing fluids and *tert*-butyl alcohol in denatured alcohol) and these are further considered below.

Ethanol has a relatively low acute toxicity by all routes of exposure (Poisindex® Managements database).

Isopropanol also has a relatively low acute toxicity. It is irritating to the eyes, and at very high vapour concentrations also to the upper airways. Prolonged exposure may produce central nervous system depression and narcosis. The harmonised classification of 2-propanol according to the CLP[5] Regulation (1272/2008) includes Eye Irrit. 2 H319; (Causes serious eye irritation), and STOT SE 3; H336 (May cause drowsiness or dizziness). It is not classified for environmental hazards according to the CLP Regulation.

[4] Guidance on information requirements and chemical safety assessment (Chapter R-8:Dose (concentration) - Response characterisation (Version 2.1))

[5] Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

Comparison of acute toxicity of ethanol and isopropanol with acute toxicity of methanol

According to the Poisindex® Managements database, a dose of 1 g/kg absolute ethanol (95% to 99% ethanol) is expected to cause mild to moderate intoxication in most adults, and 5 to 6 g/kg is considered as potentially lethal in non-tolerant adult. A 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, a lethal oral methanol dose in the range as low as 0.45 – 0.51 g/kg bw has been reported (Bennett et al. 1953, Desai et al. 2013). Data from annual reports of the American Association of Poison Control Centers' National Data Poison Data System (NPDS) support the above statements regarding acute toxicity of studied alcohols showing 11 times higher incidence of major outcome and 54 times higher mortality among methanol exposure cases **compared to ethanol** exposure cases, during a 2-year period (Mowry et et al. 2012; Mowry et al. 2013). Incidence of a major outcome was 3.2 times higher and mortality 34 times higher among methanol exposure cases **compared to isopropanol** exposure cases, during the same period. Also, according to the Lithuanian National Health Insurance Fund under the Ministry of Health, data for a 2-year period (2013 and 2014) submitted during Public Consultation (PC) show 27 times higher mortality due to methanol **compared to ethanol** exposure (15% methanol-related mortality *vs.* 0.54% ethanol-related mortality).

The health effects of chronic abuse of ethanol are not considered here, because prevention of ethanol abuse is clearly not in the scope of proposed restriction. RAC is aware of the problem of chronic alcoholism in Europe but considers that the proposed methanol restriction is not expected to aggravate the issue, only prevent severe methanol poisonings, including lethal outcomes or cases with irreversible impairments such as blindness or brain damage.

RAC is aware that lowering methanol concentration in a product is not expected to make that product less attractive for alcohol abusers since methanol will have to be replaced by adequate alternatives, most frequently ethanol and/or isopropanol, which are also substances of abuse (especially ethanol). On the contrary, there is a concern that with an increase in the percentage of ethanol in windshield washing fluids, while eliminating the threat of concurrent methanol poisoning, these products will become more attractive to alcoholics. However, RAC does not consider that this potential increase in windshield washing fluids abuse will add significantly to the number of alcoholics or severity of their ethanol abuse. Namely, methanol-containing products (including windshield washing fluids as the most frequent cause of methanol poisonings in alcoholics according to data from several EU countries) are just a small portion of the total number of products containing non-consumable alcohol which are abused by alcoholics. According to data from annual reports of the American Association of Poison Control Centers' National Data Poison Data System (Mowry et al. 2013, Mowry et al. 2014), 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 and other non-beverage ethanol products 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 windshield washing fluids. Further, abuse of non-beverage alcohol presents only a small part of total alcohol abuse. For example, Estonian data showed that the 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 and Leon 2011). In Finland, a country with rather strict policies regarding consumable alcohol availability, national statistics indicate

that consumption of non-beverage ethanol is below 1% of the total alcohol consumption (Karlsson et al. 2010; Varis and Virtanen 2015) (for further justification please refer to Background Document).

Regarding technical performance of these alternatives (ethanol and isopropanol), RAC points out that they are both already in use in the EU in countries with very low winter temperatures (e.g. Norway).

Other alternatives recognised by RAC:

Propylene glycol (propane-1,2-diol) is not classified according to CLP, either for health or environmental hazards. According to ATSDR it is generally considered to be a safe chemical. The Food and Drug Administration (FDA) has classified propylene glycol as "*generally recognized as safe,*" and is acceptable for use in flavourings, drugs, and cosmetics, and as a direct food additive. According to the World Health Organization, the acceptable dietary intake of propylene glycol is 25 mg of propylene glycol for every kilogram (kg) of body weight. Propylene glycol is able to lower the freezing point of water, and is used, for example, as aircraft de-icing fluid. However, its demand as a substitute for methanol may be affected by its price (which is almost ten times higher than the price of methanol).

Ethylene glycol (ethane-1,2-diol), unlike the alternatives described above, could pose a significant health risk if used as an alternative to methanol. Although classified as Acute Tox. 4*; H302 (Harmful if swallowed), it has been frequently reported as a cause of severe poisonings in humans, including lethal outcomes (Ghannoum et al. 2014, Rogaczewska et al. 2014, Viinamäki et al. 2015). It metabolizes to glycolic and oxalic acid that cause metabolic acidosis and are mainly responsible for its toxic effects. It is more commonly used as an anti-freeze for engines than in windshield fluids (due to its corrosive properties, corrosion inhibitors have to be added to aqueous mixtures), but it could be found in some de-icing fluids for windshields (e.g. according to CICAD 2002, winter windshield washer fluids may contain ethylene glycol at up to 14% by weight). According to the ECHA database of registered chemicals, it is registered for "Use in/as de-icing/anti-icing applications/agents (Consumer use)" as Chemical product category PC 4: Anti-freeze and de-icing products. Its price is slightly higher (<10%) than the price of ethanol.

***Tert*-butyl alcohol** (2-methylpropan-2-ol) is classified according to CLP as Acute Tox. 4* H225 (Harmful if inhaled) and STOT Single Exp. 3; H335 (May cause respiratory irritation). According to INCHEM/IPCS (1987), *tert*-butyl alcohol should be considered as a potential skin and eye irritant. At high concentrations, the vapour can cause narcosis, but there have been no reports of poisoning. *tert*-butyl alcohol (and isopropanol) were recommended by the Indirect Tax Expert Group (Draft Recommendation ITEG/R/2/2014) to be used in partial denaturation of alcohol in the manufacture of certain products (cosmetics, perfumes, hygiene products).

Conclusion: RAC acknowledges the substitutes identified by the Dossier Submitter (ethanol and isopropanol), and has named three other potential substitutes, namely propylene glycol, ethylene glycol and *tert*-butyl alcohol. Alternatives ethanol, isopropanol, propylene glycol and *tert*-butyl alcohol are of lower toxicity compared to methanol. In contrast, ethylene glycol can pose similar risks as methanol.

Information on emissions and exposures

The Dossier Submitter limited the restriction proposal to two types of products, windshield washing fluids and denatured alcohol, since, according to the information obtained from Poison Control/Information Centres in Poland and Finland, these types of products represent the most common causes of severe poisonings with methanol-containing products.

Regarding the maximum amount of windshield washing fluid or denatured alcohol that is likely to be ingested over a 24-hour period, it is evident that up to 2 L of strong (distilled) spirits could be acutely ingested (Glazer & Dross 1993, Zakharov et al. 2014). Nevertheless,

in the light of information contained in the Background Document (data from Polish Poison Control Centre) as well as in the majority of published case reports (Bennett et al. 1953, Scrimgeour 1980, Girault et al. 1999, Brahmi et al. 2007, Desai et al. 2013), RAC supports the Dossier Submitter proposal to consider the amount of 1 L (ingested over 24-hour period) as a realistic worst case scenario for intentional misuse.

RAC also agrees with the Dossier Submitter proposal for one exposure scenario for both windshield washing fluids and denatured alcohol, taking into account difficulties in the estimation of confounding effects of ethanol co-ingestion. It can be assumed that a higher percentage of ethanol in denatured alcohol compared to windshield washing fluid can affect the volume of ingested product (ingested volume of a product could be expected to decrease with an increase in ethanol content), as well as methanol toxicity due to ethanol-methanol interactions. RAC, however, is aware that the data on methanol and ethanol doses in reported cases of methanol poisoning in humans are too limited to allow quantitative assessment of methanol-ethanol interactions (Tables 1 and 2), and information on the pharmacokinetics of methanol in the presence of ethanol is scarce (Coulter et al. 2011; NIH 2007) (for further clarification please refer to Background Document).

Conclusion: RAC agrees with the Dossier Submitter to consider acute (over 24-hour period) ingestion of 1 L of windshield washing fluid or denatured alcohol as a realistic worst case scenario for intentional misuse, and to apply one exposure scenario for both product types.

Characterisation of risk(s)

The Dossier Submitter performed their risk characterisation by calculating a dose of windshield washing fluids or denatured alcohol containing methanol which can result in death to humans, assuming lethal oral dose of methanol in humans of 0.3 g/kg bw (according to IPCS/WHO 1997), 70 kg bw, density of methanol of 0.792 g/ml (at 20 °C), and approximately 1L ingestion of methanol-containing product (as a maximal volume likely to be ingested). Based on these assumptions, the Dossier Submitter calculated that the methanol concentration in a product should be below 3% to prevent lethal poisoning with methanol.

Although for consumers a bw of 60 kg is normally used (according to ECHA Guidance), the Dossier Submitter considered 70 kg bw as more appropriate, based on the assumption that methanol-containing products are consumed mainly by adult men.

As noted above, RAC used a different POD, i.e. severe ocular toxicity instead of death,, which led to a DNEL of 0.088 g/kg bw. Also, 60 kg bw was used, according to ECHA Guidance. Namely, RAC is of the opinion that abuse of methanol-containing products cannot be assigned only to adult men, since female cases were also reported in the literature (Tables 1 and 2), and there is also the potential for abuse of methanol products during binge drinking in adolescents. Other assumptions were the same as proposed by the Dossier Submitter, namely, the density of methanol at 0.792 g/ml (at 20 °C) and ingestion of 1L of methanol-containing product as a realistic worst case scenario for intentional misuse.

Applying the formula:

$$\frac{\text{Consumer bw (60 kg)} \times \text{DNEL (0.088 g/kg bw)}}{\rho_{methanol}\ (0.792\ \text{g/ml}) \times 1000\ \text{ml}} \times 100 = \mathbf{0.67\%}$$

it was calculated that a critical limit of methanol concentration in a product is below 0.67% with RCR of 0.90 when rounded to 0.6%. Therefore, methanol concentration in a product <0.6% could be considered protective against methanol-induced severe ocular toxicity (as well as death).

Namely, if a 60 kg bw person within 24-hour period drinks 1 L of windshield washing fluid or denatured alcohol containing 0.6% of methanol, he/she will ingest 0.079 g/kg bw methanol, leading to an RCR of 0.90 (0.079 g/kg bw / 0.088 g/kg bw).

The population at the highest risk are chronic alcohol addicts who deliberately abuse methanol-containing products as a cheap substitute for consumable alcohol. Non-alcoholics, however, can also be sporadically affected (e.g. binge drinking in adolescents, accidental ingestion).

The registration dossier advises that methanol concentration in liquid mixtures available for consumers should not exceed 2.5%. This limit, however, is intended to protect the general population from inhalation and dermal exposure to methanol in cleaning and de-icing agents, including windshield washing fluids, and is more than four times higher than 0.6% limit proposed by RAC.

Evidence that the existing regulatory risk management instruments are not sufficient

Currently, no general EU-wide restriction of methanol or mixtures containing methanol is in force. Methanol or mixtures containing methanol are not included in Annex XVII (Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles) of REACH Regulation. Furthermore, upon joining the EU, previous national legislation in many Member States was removed with a subsequent rise in numbers of deaths from poisoning (clearly seen e.g. in the Finnish data), however, some national legislation still remains (briefly reviewed below).

In Poland, due to significant numbers of methanol poisonings, the sale to consumers of methanol and mixtures containing methanol in concentrations equal to or higher than 3% (biofuels and fuels for sport motorboats and models are exempted) is restricted since 2014.

In certain other EU countries, namely in Sweden, Denmark, Norway, Lithuania, Germany and Austria, national legislation also restricts the sale of methanol and methanol-containing mixtures to the general public.

In Denmark, according to the Danish Statutory Order No 857 of 05/09/2009, methanol must not be used in engine coolants, in solutions used for preventing the freezing of carburetors or in de-icing fluids, such as washing fluid. Methanol content in products sold to the general public may not exceed 10% in Sweden, Denmark, Norway and Lithuania, and in Germany and Austria permission is needed to purchase products containing methanol at concentrations >10%. These restrictions are part of a national legislation which prohibits the selling of mixtures classified as acute toxic and labelled as "toxic" (T and T+) to the general public.

RAC agrees with the Dossier Submitter that a 10% limit value is clearly not protective enough to prevent severe methanol intoxication. A dose that could induce severely diminished visual acuity (vision reduced to finger-counting) is approximately 200 ml of a product containing 10% of methanol if 0.26 g/kg bw of ingested methanol is regarded as a minimal dose related to severe ocular toxicity in humans. Desai et al. (2013) reported 11% of patients with a lethal outcome and 36% with severe permanent visual damage after ingestion of illicit liquor containing 6.5% volume/volume methanol (in 40% ethanol).

According to CLP, the packaging of a substance or mixture containing methanol should be fitted with child-resistant fastenings if methanol is present in a concentration ≥3%. However, this measure is not expected to be efficient in adults.

Conclusion: RAC considers a 0.6% methanol concentration in the two proposed types of methanol-containing products to be protective against methanol-induced severe ocular toxicity and death. The calculation is based on consumer severe ocular toxicity as the POD

leading to a DNEL of 0.088 g/kg bw, assuming a body weight of 60 kg and 1L ingestion of methanol-containing product in 24 hours as a realistic worst case scenario for intentional misuse.

In addition, RAC concludes that described regulatory risk management instruments at national level are not sufficient to control the risks of intentional misuse.

JUSTIFICATION THAT ACTION IS REQUIRED ON AN EU WIDE BASIS

Justification for the opinion of RAC

Methanol-containing products caused poisoning among consumers (mostly alcohol addicts drinking winter windshield washing fluids and denatured alcohol as a surrogate for consumable alcohol) in several EU Member States, including Belgium, Bulgaria, Finland, Germany, Norway, Poland and the United Kingdom, with Poland, Finland and Bulgaria as the most severely affected (methanol poisoning has been recorded in other EU countries as well, but poisoning statistics data did not provide the source of the methanol, or the information was not submitted during PC). In Finland, for example, approximately 25 methanol-related deaths per year were recorded during the period 1996-2012, mostly caused by ingestion of windshield washing fluids.

In justification of an EU-wide restriction, the severity of the risk, namely death, severe ocular toxicity or other severe sequels to methanol poisoning, was also taken into account, as well as prevention of market distortion. The Dossier Submitter points out that methanol-containing products are widely used in all EU Member States and, given the significantly lower price of methanol compared to the price of alternatives (ethanol or isopropanol), restrictions limited to certain Member States would create a distortion of the market of methanol containing products.

It is also noted that several EU Member States have introduced certain legislative measures at national level to reduce the risk of methanol poisoning in general population, as presented in previous section.

Conclusion: RAC agrees with the Dossier Submitter that action is needed on an EU-wide basis, also taking into account severity of the risk, namely death, severe ocular toxicity or other severe sequels of methanol poisoning.

Justification for the opinion of SEAC

The risk targeted by the Dossier Submitter is the acute poisonings (with a high rate of fatal cases) occurring to alcoholics drinking methanol-containing windshield washing fluids, particularly those used in winter (hereafter winter windshield washing fluids), and denaturated alcohol (methylated spirit), as a substitute for consumable alcohol.

Winter windshield washing fluids are broadly used in the EU due to their anti-freeze properties, as in most of the countries there are at least some regions where winter temperatures may regularly fall below zero centigrade.

The population affected is mainly located in the central and northern parts of the European Union (EU), however, cases have also been observed elsewhere in Europe. Sixteen EU Member States have reported methanol poisoning cases. Out of the sixteen Member States, there are seven countries where poisoning cases due to ingestion of windshield washing fluids have been reported (information submitted in the restriction dossier and via the Public Consultation). At least in two countries, fatal cases have occurred. The number of countries with poisoning cases may well be higher, as the reporting is not carried out systematically in all EU countries. For example, SEAC received new information during the public consultation that methanol poisoning cases have been reported including infants and adults drinking the

product accidentally, mainly after the product was decanted into non labelled bottles without child resistant fastenings.

In Figure 1:

- red represents the countries where deaths due to methanol poisoning from windshield washing fluid have been reported;
- orange represents the countries which have experienced cases of poisonings occasionally in the past 10 years due to ingestion of windshield washing fluids;
- yellow represents the countries where there have been significant methanol poisoning(s) in the past years, but no clear evidence that those were caused by windshield washing fluid;
- purple represents the countries where some sporadic methanol poisoning have happened in the past years but data could not be verified, so a concrete link to windshield washing fluids could not be assumed by SEAC;
- green represents the countries where no methanol poisoning have happened in the past years;
- blue represents the countries where data could not be collected.

Figure 1: Information available on fatalities due to methanol poisoning from windshield washing fluids in the EU Member States.

A number of Member States have, or had, national legislation related to the proposed restriction. National legislation restricting the sale of methanol to the general public has been enacted in, for example, Sweden, Denmark, Norway, Lithuania, Germany and Austria.

In Denmark, according to the Danish Statutory Order No 857 of 05/09/2009, methanol must not be used in engine coolants, in solutions used for preventing the freezing of carburettors or in de-icing fluids, such as windshield washing fluid. Methanol content in products sold to the general public may not exceed 10% in Sweden, Denmark, Norway and Lithuania. In Germany (and Austria) national regulation (ordinance) controls the placing on market of substances and mixtures (labelled with T, T+, O and F+ and also covers those labelled with CMR Cat. 3) and a permission is needed to purchase products containing methanol at concentrations >10%, setting rules for both the seller and the buyer. These restrictions are part of national legislations which prohibit the selling of mixtures classified as acutely toxic to the general public.

When joining the EU, national legislation in some Member States (e.g. Finland) had to be repealed and, following this, a rise in the number of deaths from methanol poisoning was observed.

Based on the observed data, national legislation seems to have been effective in some countries in reducing poisoning cases from methanol in winter windshield washing fluids. There is no specific study available, however, that has unequivocally demonstrated any causal link. Therefore, SEAC cannot endorse or dismiss a causal link between the two events (no scientific study is available demonstrating the connection), although the data available appear to suggest it (see benefits section of the opinion and Section D of the Background Document).

The Dossier Submitter has indicated that, except for the Danish ban of methanol in engine coolants, solutions used for preventing the freezing of carburetors, or in deicing fluids, the remaining national legislations have to be repealed after 1st of June 2015 when the Classification, Labelling and Packaging Regulation 1272/2008 (CLP) started to be used for classification of mixtures (methanol is classified as Acute Tox. 3 and STOT SE 1 according to CLP). The repeal of several national legislations due to the aforementioned CLP Regulation may also broaden the number of countries affected.

In Poland, due to significant numbers of methanol poisonings, the sale to consumers of methanol and mixtures containing methanol in concentrations equal to or higher than 3% (biofuels and fuels for sport motorboats and models are exempted) has been restricted since 2014. This national restriction will remain until the current restriction proposal has been considered.

The justification for addressing the risk on a Union-wide basis also results from the need to avoid the risk of creating unequal market conditions. If no Union-wide measure is adopted, Member States may adopt their own individual national legislations on the issue as now seems to be the case. This would result in different forms of national legislations and with a potential distortion of the internal market which is against the principle of free circulation for goods throughout the European Union. A Union-wide legislation would ensure a 'level playing field' among all producers of windshield washing fluids.

Conclusion:

SEAC notes that, based on the information currently available, human health risks due to methanol in winter windshield washing fluids are present in a number of Member States: two Member States have reported a large number of fatalities and other five Member States have experienced cases of poisonings occasionally in the past 10 years. Furthermore, the risk could be even more widespread, as many countries do not systematically report methanol poisonings and their respective causes. Based on this and on RAC's assessment of the risk posed by winter windshield washing fluids, SEAC is of the view that health risks from winter windshield washing fluids may arise in number of Member States.

Currently the Background Document refers only generally to the use of methanol in denatured alcohol. There is no specific information when it comes to the identified hazard

and risk of denatured alcohol nor that justification of that action is required on a Union-wide basis in regards to denaturated alcohol. As such SEAC cannot evaluate the socio-economic impacts of the inclusion of the denaturated alcohol into the scope.

Having diverging national legislation (e.g. differing concentration limits) across the Member States will potentially distort the internal market, and is not in line with the principle of harmonisation of the internal market in chemicals. A number of Member States have seen it necessary earlier and might again need to introduce such legislation, as the existing legislation has been repealed.

Based on the widespread risks to human health and the possible internal market distortions, SEAC concludes that EU-wide action is justified.

JUSTIFICATION THAT THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU WIDE MEASURE

Justification for the opinion of RAC

Previous restrictions of methanol in Finland and Poland, regulated at national level, have proven to be effective in the reduction of the number of methanol poisonings in these countries. Nevertheless, as stated above, no general EU-wide restriction of methanol or mixtures containing methanol is currently in force. Legislative measures at national level in certain EU countries refer to methanol limits significantly above the limit proposed by RAC in this opinion (3% or 10% *vs.* 0.6%, respectively).

Besides REACH Annex XVII restriction proposal for methanol described in the Background Document, the Dossier Submitter did not identify any other EU legislation with the potential to reduce the identified risks.

Other management and enforcement options suggested during Public Consultation, such as the addition of bittering agents and social programs to tackle the issue of methanol-containing products abuse, are not considered to be adequate for the target population aimed to be covered with the proposed restriction (please refer to the Background Document for detailed justification).

During RAC consultation, minimum unit pricing for methanol was also suggested to be considered. However, information that would enable the evaluation of the effectiveness of this measure was not provided either by the Dossier Submitter or during Public Consultation, so minimum unit pricing for methanol was not further evaluated by RAC (it should be also noted that this measure is not in the remit of REACH).

Conclusion: RAC agrees with the Dossier Submitter that restriction of methanol is the most appropriate EU-wide measure.

Justification for the opinion of SEAC

Deliberate abuse is usually not considered in the exposure estimation process under REACH. However, if there is no other EU legislation in place to tackle the problem and if it is targeted by the Dossier Submitter in a restriction proposal, it may be considered in an Annex XV dossier under REACH. This is the case when deliberate abuse relates to a known or reasonably foreseeable exposure and creates concern for human health or the environment to be addressed at Union level (See Guidance text below[6]). RAC has concluded

[6] According to the Guidance on information requirements and chemical safety assessment (Chapter R.15.2.2. Reasonable worst-case situations), '*the consumer exposure estimation should normally address the intended uses of the products that contain the substances under investigation.*' The Guidance, however, recognizes that '*since consumers may not accurately follow instructions for use of products, an estimation of*

that this restriction proposal, by presenting the data on severe cases of poisonings following abuse of methanol-containing products in several EU countries, fulfils the requirements to be dealt under REACH. SEAC takes into account the opinion of RAC. In addition to deliberate abuse of methanol-containing windshield washing fluids, on several occasions, methanol in windscreen washing fluid has been accidentally consumed; this restriction may also help to prevent such cases.

The question is, therefore, whether, REACH is the most appropriate EU framework to control the risk rather than whether it is possible under REACH to regulate this matter.

RAC considers a 0.6% methanol concentration in the winter windshield washing fluid products to be protective against methanol-induced blindness and death.

According to RAC, the limit value (2.5%) in the Chemical Safety Report of the registrants of methanol is intended to protect the general population only from inhalatory exposure.

Winter windshield washing fluid

The Dossier Submitter has conducted a thorough data collection for the years 2010-2013 regarding the sources of methanol poisonings for the Polish region of "Silesian Agglomeration" (See Background Document Table D.1-5) and received data on methanol poisonings due to winter windshield washing fluid from Finland for the period 1993-2013 (See Background Document Table D.1-6). According to these data, the number of fatalities caused by methanol poisoning rose significantly after national legislation restricting the supply of methanol and/or methanol-containing mixtures was lifted in Finland (1994) and Poland (2010).

According to the Dossier Submitter, several other Member States may face a similar increase in methanol poisonings after national legislations are lifted due to the entering into force of the CLP Regulation (See Background Document section A.3.1). SEAC partially agrees with the Dossier Submitter's argument but considers that the intentional consumption of winter windshield washing fluids will depend on several factors like individual preference of alcohol drinking.

Currently no general EU-wide restriction of methanol or mixtures containing methanol is in force, and no other EU legislation that may have the potential to reduce the targeted risk has been identified:

- Methanol or mixtures containing methanol are not included in Annex XVII of the REACH Regulation.
- Methanol is not identified as a Substance of Very High Concern since it doesn't fulfill the criteria of Article 57 of REACH Regulation.
- Methanol is not classified as Carcinogenic, Mutagenic or Reproductively toxic (CMR) and currently no consumer restriction of methanol under article 68(2) of REACH can be proposed[7].
- Voluntary action by industry is not considered an effective way of managing the targeted risk in this dossier as, according to a survey performed in Finland, the majority of producers/formulators of winter windshield washing fluids seems to be Small and Medium Size Enterprises (SME) which results in a scattered market, lacking an anchor entity capable of leading the process of moving from methanol to

other reasonably *foreseeable uses should be made*', and that '*the difference between other foreseeable uses and abuse can in certain cases be small*'. In such situation, '*the assessor should provide clear argumentation why a certain exposure situation is included*'.

[7] RAC considered a proposal that methanol be classified as reproductively toxic but agreed no classification for this endpoint: http://echa.europa.eu/opinions-of-the-committee-for-risk-assessment-on-proposals-for-harmonised-classification-and-labelling/-/substance-rev/4106/term?_viewsubstances_WAR_echarevsubstanceportlet_SEARCH_CRITERIA_NAME=methanol&_viewsubstances_WAR_echarevsubstanceportlet_SEARCH_CRITERIA_EC_NUMBER=200-659-6

alternatives

RAC concludes that the current regulatory risk management instruments are not sufficient to control the risks. Several other initiatives were proposed as possible risk management measures during the SEAC plenaries and in the Public Consultation. However, with the exception of adding bittering agents (see page 14), adequate information to assess these measures has not been submitted, so SEAC cannot assess it.

SEAC considers the suggested restriction, with the condition of a modification of scope, to be the most appropriate EU wide measure.

Denatured alcohol

Currently the Background Document does not contain specific information related to the use of methanol in denatured alcohol. RAC acknowledges that the same exposure scenario could be used for winter windshield washing fluid as for denaturated alcohol. However, based on the lack of socio-economic data (no information was included in the Annex XV report nor submitted in the public consultation) and the fact that methanol is already regulated in legislation where methanol is added to ethanol to avoid the payment of duties[8], SEAC is not able to evaluate the socio-economic impacts of the inclusion of denatured alcohol in the scope of the restriction. However, the Commission still could take note of the assessment of RAC and consider if any action is necessary under the legislation mentioned above.

Other products

SEAC is aware that other methanol-containing products are available on the market. However, the Dossier Submitter has not proposed to include them in the scope, and the Annex XV restriction dossier does not provide information on these other potential methanol-containing products, thus, no extension of the scope can be justified; such information was also not submitted in the Public Consultation.

Conclusion:

Due to lack of information regarding costs and benefits concerning the restriction of methanol in denaturated alcohol, SEAC does not support the inclusion of the denaturated alcohol into the scope.

SEAC agrees with the Dossier Submitter that a restriction is an appropriate EU-wide measure for addressing the risks to human health from winter windshield washing fluids, however, SEAC cannot exclude that other measures or initiatives may be equally or more effective.

Effectiveness in reducing the identified risks

Justification for the opinion of RAC

Based on positive experience with national restrictions of methanol in Poland, and previously in Finland, the Dossier Submitter expects that an EU-wide methanol restriction will be effective in reducing the identified risks, namely severe methanol poisonings in consumers abusing methanol in windshield washing fluids and denatured alcohol as a cheap substitute for alcoholic beverages.

Poison Control Centres' statistics in Poland showed that the total number of poisonings with methanol was almost seven times lower during the period in which a ≤3% methanol restriction was in place (2001-2010) compared to the period without restriction (2011-

[8] This refers to any duties according to Directive 2008/118/EC and 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 and Commission implementing Regulation (EU) No 162/2013.

2013). The number of fatal poisonings was eight times lower during the period with the restriction compared to time period without restriction[9]. New data for Poland, collected after the restriction was re-introduced (in January 2014), also shows a decrease in total number of methanol poisonings, although to a lesser degree, 2.7 times (230 cases in the winter 2012/2013 and the summer 2013 *vs.* 84 cases in the winter 2014/2015 and summer 2014). In Finland, data from the Poison Information Centre indicates eleven times lower incidence of fatal poisonings during a nine-year period in which a total ban of selling methanol-containing products to the general population was in place, compared to the 18-year period after this ban was lifted (according to data presented in the Background Document and Malinen 2003).

Conclusion: RAC agrees with the Dossier Submitter opinion on the expected effectiveness of the proposed restriction.

Justification for the opinion of SEAC

Proportionality to the risks

The Dossier Submitter did not perform a full cost-benefit analysis (CBA) due to a lack of information (see Background Document Part F). The approach undertaken was to present a partial quantification and monetisation of costs and benefits only for windshield washing fluids using the data provided by Finland. As such, the Dossier Submitter acknowledges that, the information available in the Background Document only depicts the situation in Finland and their validity to represent the situation at EU level is unclear (Background Document part F.7.).

SEAC has used some parts of this partial quantification and monetisation of costs and benefits presented by the DS to make its own assessment, which is presented below. As SEAC does not support the inclusion of denaturated alcohol into the scope of the restriction, the possible costs or benefits due to a restriction proposal covering also denaturated alcohol were not assessed.

Costs

Summary of Dossier Submitter's proposal:

The main cost element identified by the Dossier Submitter is the substitution cost for methanol with ethanol and isopropanol.

According to the Background Document "methanol is a better solvent and a more cost-efficient anti-freezing component than the substitutes (ethanol or isopropanol). In order to achieve technical applicability as an anti-freezing component in -20 °C temperature, the proportion of alternatives needed in the product was stated to be higher, contributing to a 20 - 50% increase in costs" due to both the higher price and larger volumes needed (Background Document part F.2.). It is assumed that to achieve similar performance the amount of ethanol needed to replace 1 tonne of methanol is 1.3 tonnes, and the amount of isopropanol needed to replace 1 tonne of methanol is 1.5 tonnes (Background Document part F.7). The Dossier Submitter argues that the "price of ethanol is from 2 to 3-fold greater than the market price of methanol. The price of the other alternatives is even higher. Depending on the content of ethanol in the winter windshield washing fluids, the price of final products increases respectively. The increased cost of the alternatives will be included in the price of the final product and will be passed on the consumers. Despite the higher cost of ethanol containing winter windshield washing fluids it can be expected that demand for the alternative winter windshield washing fluids would be largely similar as for winter windshield washing fluids with methanol" (Background Document p. 94). A study submitted

[9] The data for fatal poisonings are available for only one year with the restriction (2010) and three years without restriction (2011-2013)

in the public consultation on the SEAC Draft Opinion stated as well that "This increase would be largely transferred to the consumer, since it is expected that demand for winter wind shield washing fluids (wwf) would not change.".[10]

To calculate the substitution costs, the Dossier Submitter has considered the expected price increase of the alternatives used to formulate windshield washing fluid, based on the Finnish data available for methanol placed on the market in windshield washing fluids. "...the amount of methanol placed on the market in windshield washing fluids varied between 904 tonnes and 2 559 tonnes (mean 1 502 tonnes, median 1 346 tonnes) during the period of 2004-2011" (see Background Document, section C). Based on the data presented above, the Dossier Submitter calculated three different scenarios for yearly substitution costs (cost element of the partial CBA provided by DS, representing the costs only for the Finnish market) as follows (Background Document Table F.7-1.):

- lower estimate: €420 540
- central estimate: €1 399 721
- higher estimate: €4 043 447

Besides the cost of substitution, the Dossier Submitter lists also some other potential sources of cost related to the restriction e.g. the possibility of closures of some of the businesses operating in the windshield washing fluid sector and some costs related to the proposed indicators for monitorability.

The Finnish Competent Authority (CA) performed a survey regarding the businesses that are placing windshield washing fluids on the market and reported all of them to be Small and Medium Enterprises (SME's). According to the survey a ban on methanol in windshield washing fluid will bring severe difficulties for the SMEs whose product portfolio is largely based on windshield washing fluids. According to the survey (Table F.2-1 in the Background Document) the assumed response to a ban indicates that 20% of the businesses surveyed could face closing down their windshield washing fluid activities. However, it is noted that the estimate is highly uncertain as the response rate to the survey (11 responses) was far too low to allow an accurate estimation and to use it in the cost calculation. Due to highly uncertain validity of the survey the costs related to the closing of businesses or parts of businesses where not monetised and not taken into account in the CBA.

The costs related to potential business closures and the monitoring indicators were not taken into account in the partial CBA.

Conclusion:

SEAC agrees with the Dossier Submitter's approach in presenting the substitution costs, i.e. the volume times the price difference between methanol and the alternatives taking into account the higher volume of alternatives needed to have the same effect. Furthermore, SEAC agrees that the substitution costs can largely be transferred to consumers, as the quantity of winter windshield washing fluids demanded is likely to be unaffected by such a price increase.

Even if prices are significantly higher after the restriction, in order to reduce their cost, consumers cannot dilute the product (to make it go further) as this would result in a lower concentration than indicated by the producer to fulfill its purpose as winter windshield washing fluid and deicer (potentially leading to road accidents). This could cause extensive damage to the windshield washing system of the car.

Other potential cost elements (possible closure of some business, possible capital

[10] RPA (2016): Analysis of Alternatives in context of the proposed Restriction of Methanol, report for Methanol Consortium, January 2016, London, Norfolk, UK

expenditure) could not be quantified due to lack of data. However, given the stable demand for the antifreeze component, potential business closures are expected to be (partially) compensated by other companies expanding their supply, and the resulting change may be largely distributional.

As discussed before, due to a lack of available data, the partial CBA presented in the BD reflects only the socio-economic costs and benefits of the Finnish situation. An extrapolation of the data to an EU wide level is not straight forward and thus it was not carried out in the BD. To reach a conclusion on the proportionality of the proposal, SEAC has therefore decided to evaluate the information presented in the dossier, the Public Consultation and other sources and propose how it can be aggregated to reflect the situation in the EU as a whole.

As mentioned earlier, SEAC notes there is no data available in the Background Document, and no additional information was received during either public consultations, and thus SEAC cannot conclude on the likely magnitude of the costs of a restriction of methanol in denaturated alcohol.

Key elements underpinning the SEAC conclusion

SEAC agrees with the Dossier Submitter that the main cost component of the restriction is the substitution cost. The capital expenditures and working capital costs are not likely to contribute to the overall costs and will not be assessed further.

Table 3 Relative prices of methanol and potential alternatives.

Substance	Price according to BD €/t [11]	Price $/t – July 2015[12]	Price €/t[13]– July 2015	Price difference of alternatives vs. Methanol (€/t, %)	
Methanol	390 (May 2013)	435	391	NA	NA
Ethanol	921 (June 2008)	1 048	941	550	241%
Isopropanol	995 (June 2008)	1 508	1 355	964	347%
Propylene glycol	No data in the Background Document	4 218	3 789	3 398	969%
Ethylene glycol	No data in the Background Document	1 125	1 011	620	259%
tert-butyl alcohol	No data in the Background Document	1 557	1 399	1 008	358%

As seen in Table 1, the price of the alternatives to methanol is at least 2.5 - 3.5 times higher than methanol, except for Propylene glycol. Propylene glycol, ethylene glycol and tert-butyl alcohol were included in the table, as they were discussed in RACs draft opinion, however they are considered to be less likely as potential alternatives than ethanol and isopropanol.

The Public Consultation has indicated that when using ethanol or isopropanol instead of methanol, the necessary quantities to achieve similar performance might be higher than indicated in the BD, while the Dossier Submitter claims in its proposal that the estimates are an overestimation. SEAC has taken note of the different estimates and considers the amounts of 1.3 for ethanol and 1.5 for isopropanol are reliable and thus will use those values in the analysis.

[11] Background Document: Table C.2.4-2. The cost of methanol and some alternatives to methanol. For Methanol, Ethanol and Isopropanol.

[12] http://www.molbase.com/en/index.html

[13] Exchange rate: http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm; 1 USD is equal to 0.898230485943 €

Depending on the alternatives used and the content of the alternative in the winter windshield washing fluid, the price of final products will increase accordingly.

SEAC in its own analysis describes the methanol market in the EU (prices and volumes) in windshield washing fluids, using aggregated country data.

The approach is to compare the benefits from reducing methanol poisonings in the most affected countries based on data availability and information from the PC (Finland (robust data), Poland (circumstantial data), the three Baltic States and some EU Member States (assumptions)), versus the costs of substituting methanol in winter windshield washing fluid in the whole EU. The volume estimation of methanol to be substituted for the EU as a whole is based on use data from Finland and rough aggregation assumptions of use indicators, e.g. number of vehicles and monthly temperature.

The indicators chosen for establishing the quantity of methanol used in windshield washing fluids in the EU, were:

1. Average winter (monthly) temperatures for each Member State (data received from the dossier submitter during the consultation phase and data collected by rapporteurs);
2. The population in each Member State (data collected from Eurostat);
3. Gross domestic product(GDP) per capita in purchasing power standards (PPS[14]) for each Member State (data collected from Eurostat);
4. Vehicles per capita for each Member State (data collected from Eurostat);
5. The Finnish data of methanol volumes used in windshield washing fluids (data from the Public Consultation and the Background Document part D).

Based on the collected data, SEAC prepared a rough aggregation (presented below) using the Finnish data for methanol used in windshield washing fluids to calculate the mean value (1 472 tonnes per year) and the standard deviation (457 tonnes per year) of methanol used in windshield washing fluid in Finland for the period of 2002-2013 (Annex 1 -Table 4). The mean value differs from the mean presented by the Dossier Submitter (1 502 tonnes per year), due to the fact that the Dossier Submitter performed the analysis for the period 2004-2011. SEAC uses its own calculations (time period 2002-2013) in subsequent elements of its evaluation.

The aggregation to the EU level was calculated in the following steps:

a. Using the average methanol use in winter windshield washing fluids in Finland (1 472 tonnes) as the fixed variable, the, overall average of EU-28 consumption of methanol in windshield washing fluid (kg) per person in the EU, was calculated:

   1 472 000 kg (methanol use in winter windshield washing fluids in FIN) / Population of Finland / PPS (110) of Finland * PPS(100) of EU-28, yielding in a consumption of 0.24 kg/person (EU-28) of methanol in windshield washing fluid.

b. The Finnish vehicles per capita (approx. 0.55 vehicles per capita in Finland (VCF)) was chosen to be the second fixed indicator for further calculations.

c. Using the above figures (0.24 kg/person of methanol in windshield washing fluid and approx. 0.55 vehicles per capita in Finland) and the following additional indicators (population, GDP per capita in PPS, vehicles/capita for each MS), the total simulated methanol market volumes in windshield washing fluid were calculated for each

[14] PPS = purchasing power standard

Member State and for the EU-28:

0.24 kg Methanol per person x Population of each Member State / PPS EU x PPS Country / VCF x VC (vehicles in capita in the country).

d. Monthly average temperatures (November-March) have been used to narrow down the uncertainties of comparing any Member State data with the Finnish data. Where the average monthly temperatures are above four centigrade, it is assumed that there is no need for an anti-freezing component, as summer versions of windshield washing fluids or plain water may be used instead. As a result, the amount of winter windshield washing fluids (containing methanol) used in those months was assumed to be zero in the calculation. The aggregation resulted in an estimation of 56 458 tonnes of methanol on the EU market that potentially needs to be substituted due to the restriction proposal.

   One respondent to the public consultation on the SEAC Draft Opinion proposed an estimation of 125 million liters of methanol, i.e. around 99 215 tonnes, instead of 56 458 tonnes. However, this new estimate is based on a number of far reaching assumptions and overestimates of the total volume of methanol used. For example, the submitted study assumes that all cars in the EU will use windshield washing fluid with methanol content at least once every day of the year (365 days a year). In addition, the number of cars used in the calculation is not clear; both 279 million cars and 264 million cars are used without explaining the difference. Moreover, the calculations regarding the amount of windshield washing fluid used per car per year and the methanol content of the products in different countries are questionable.

In the partial CBA carried out by the Dossier Submitter, the costs are presented in a manner that implicitly assumes that there will be a total shift from methanol to ethanol and/or isopropanol. The Background Document offers two references to support this (Background Document section F.7). SEAC will therefore use the same assumption. The Dossier Submitter assumes that ethanol will replace 70% of the current volume of methanol and isopropanol 30%, but no justification is provided. The distribution between the two alternatives is highly dependent on the business decision of each actor involved in the winter windshield washing fluids sector as well as on the consumers making the purchase. Everything else being equal, it is more likely that companies will make a shift towards ethanol as it is available, technically feasible and clearly cheaper.

As mentioned above, to achieve similar performance as methanol, there is a need for 1.3 tonnes of ethanol or 1.5 tonnes of isopropanol. Based on the aggregated EU-wide market volumes for methanol in windshield washing fluid of 56 000 tonnes, SEAC estimated the quantity of substitutes of methanol to be either 73 000 tonnes of ethanol or 85 000 tonnes of isopropanol (or any other distribution combination between the two alternatives). A sensitivity analysis was performed based on the standard deviation of the Finnish methanol market and using the same aggregation as described on page 12; the results for the EU-wide market volumes for methanol in windshield washing fluids can be seen in Annex 1-Table 5. The central volume estimate would yield a monetary value of the substitution cost of around €40.4 million (all ethanol as the cheapest alternative) at a 2015 price level. SEAC also calculated a monetary impact for a case where all actors would move to isopropanol. This alternative yields a monetary value of the substitution cost of around €81.6 million. With the given data constraints SEAC will use the monetary value of €40.4 million for the proportionality assessment. SEAC acknowledges the underlying uncertainties of the estimates and the highly unlikely possibility that all actors would move to isopropanol with the corresponding monetary value.

During the public consultation on the SEAC Draft Opinion, one respondent's SEA study used consumer level price differences (GDP/ca adjusted to different countries) between the methanol free and methanol-containing products to estimate the cost of a potential restriction. The 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.

In Annex 1-Table 4, the central estimate (mean) for the methanol used in windshield washing fluid in Finland is 1 472 tonnes. Using the standard deviation of 457 tonnes, SEAC has performed a sensitivity analysis on the volume of the methanol used in windshield washing fluid in Finland and EU-wide.

Conclusion:

SEAC considers that the potential methanol use volumes within the EU can be best described based on the presented aggregation and use volumes of methanol in winter windshield washing fluids in Finland. SEAC acknowledges that the approach does not offer a definitive volume and the accuracy of the resulting estimate cannot be assessed. However, this is seen as an acceptable way forward, as no robust EU wide information of the methanol used in winter windshield washing fluids was provided by the DS or via the public consultation.

Therefore in the cost calculations SEAC uses the methanol in winter windshield washing fluid volumes as calculated above multiplied with the price difference of methanol and the alternatives. The resulted monetary values are then to be transformed into fatalities to indicate the number of cases in a break even approach and thus demonstrate proportionality.

Furthermore, SEAC notes that RAC has established a safe value of 0.6% by weight. The estimated impacts are not changed as in the Annex XV report already considered the impacts of the full phase out of methanol in windshield washing fluids.

SEAC takes note of possible additional costs such as loss of jobs and businesses as identified by the Dossier Submitter. However, as mentioned earlier, assuming the need for winter windshield washing fluids (with antifreeze) does not change, these costs are believed to be mostly distributional - some companies will cease trading, whereas other companies will take over their market share in the future.

Although the Dossier Submitter argued that the monitoring will probably be "costly" (Background Document - page 90), an estimation of these costs was not undertaken. SEAC could not verify this statement but considers that the possible associated costs are at least 3 orders of magnitude lower than the monetised costs and do not as such affect the proportionality. Due to the difficulties of confirming and estimating these potential cost elements, and if in fact they are relevant to include at all, the monitoring costs have not been included in the proportionality analysis.

Comments in the Public Consultation suggested that the Dossier Submitter should have also assessed another, apparently less costly, measure namely introducing bitterants to the windshield washing fluids. One substance proposed is Bitrex[15] (a brand name), claimed to be one of the bitterest substance known to man. The producer claims that adding Bitrex to a product is "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". According to the Public Consultation comments, this could considerably lower the cost of reducing the risks, as compared to the proposed restriction. However, a separate complete Risk management Option (RMO) proposal regarding bitterant additives was not performed by the Dossier Submitter, nor was submitted in the Public Consultation. As such SEAC could not express a view on the

[15] http://www.bitrex.com

associated costs and benefits of the risk reduction capacity of such an RMO. SEAC notes that RAC has concluded that adding bitterant additives is not an effective solution for chronic alcohol dependents. Based on information from RAC, adding bitterant agent to a product has been shown not to deter chronic alcoholics from drinking the product.[16] One of the studies submitted during public consultation on the SEAC Draft Opinion concludes that although bitterants could be effective against accidental consumption, there is "a lack of evidence for action against intentional consumption"[17], and that effectiveness of a bitterant under the conditions of intentional consumption is worth further evaluation (e.g. effective concentration, type of bitterant). This fits well with the conclusions of RAC regarding the ineffectiveness of bitterants in deterring alcohol dependent people. As the authors of this report stated, 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.

Benefits

Summary of Dossier Submitter's proposal:

The main benefit element identified by the Dossier Submitter consists of the avoided fatalities due to methanol poisonings after drinking windshield washing fluid as a substitute of consumable alcohol.

Based on the available statistical data, the Dossier Submitter argues that a restriction of methanol in windshield washing fluids and in denaturated alcohol could lead to a decrease of 22.91 deaths per year[18]. This decrease comes from the data collected in Finland in the period 1986-2011. When a regulation on methanol was in force (1986-1994) there were recorded 22 deaths, on average 2.44 per year. After the lift of the ban, in the period 1995-2011, there were 431 recorded deaths with an average of 25.35 deaths per year. According to data collected in the Stakeholder Consultation carried out during the dossier preparation "almost all poisonings in Finland were caused by consumption of windshield washing fluids".

The following assessment was made to determine the possible benefits of the restriction (benefit element of the partial CBA provided by DS, representing the benefits only for the Finland-See Background Document page 95):

- The typical subject of methanol poisoning is a 50 year old male with a drinking problem (Background Document assumption)
- Male life expectancy in Finland 78 years (data: Background Document)
- 28 years per death to be lost
- Number of lost life years = 28 years x 22.91 deaths =641.48 life years/year
- Value of life year lost (VOLY) = €70 172 (2013 price level) (data: ECHA Guidance on Socio-Economic Analysis – Restrictions, actual value should be 82 598 at a discount rate of 4%, 2013 price level)
- Monetised benefits of the restriction (counting only for windshield washing fluids and for Finland) = 641.48 x €70 172 = €45 million

[16] Toronto Public Health Fact Sheet 'Non-palatable (toxic) alcohol use', February 2011 and Carnahan RM et al. 2014

[17] RPA (2016): Analysis of Alternatives in context of the proposed Restriction of Methanol, report for Methanol Consortium, January 2016, London, Norfolk, UK

[18] Lampinen et al. 2013

The Dossier Submitter has performed a sensitivity analysis[19], the variable being the number of years lost due to death attributed to methanol poisoning from windshield washing fluids. For the lower estimate it was assumed that 10 years per death will be lost resulting in €16 million of benefits (10 years x 22.91 death x €70 172). For the central estimate, the baseline value of €45 million is used while for the higher estimate, the variable used is the value of a life year (€157 446: ECHA Guidance on Socio-Economic Analysis – Restrictions, €125 200 -2003 value[20]). In addition the Dossier Submitter also gave an estimate of benefits based on Value of Statistical life.

Conclusion*:*

SEAC agrees that the benefits estimation can be based on the number of fatalities (avoided) in the Members States that are likely to be affected.

As mentioned earlier in general terms, SEAC notes there is no specific data available in the Background Document regarding the benefits of a restriction of the methanol content in denaturated alcohol.

Key elements underpinning the SEAC conclusion:

According to information provided in section B, methanol has a harmonised classification and is classified in hazard classes for human health. The worst effects of methanol poisoning are irreversible disturbance of vision (blindness) and death (See Background Document F.1.1 Human health impacts).

RAC has assessed the substitutes identified in the Background Document and other additional substitutes identified (see RAC opinion). RAC has concluded that the risks of acute death from the alternatives are lower than from methanol, and in the case of ethanol, similar to those from any ethanol-based consumable alcohol/hard liquor.

Methanol, ethanol and isopropanol are not classified for environmental hazards. Both ethanol and methanol have similar physical properties. Since ethanol is the cheapest available alternative on the market, SEAC agrees that ethanol is likely to be the main alternative for methanol.

Due to lack of available data, the Dossier Submitter was not able to quantify potential benefits in order to perform a detailed quantitative cost-benefit analysis. The presented partial CBA by the Dossier Submitter applies only to Finland and a direct extrapolation of the data to an EU-wide level is not straightforward.

SEAC agreed that if no new information was received (from the PC, or the dossier submitter), only benefits related to windshield washing fluids would be considered.

SEAC mostly agrees with the approach taken by the Dossier Submitter to evaluate the benefits of the proposed restriction, but has developed the benefit estimates further in its own calculations.

In the case of Finland SEAC calculated the mean value (24 fatalities per year) and the standard deviation (11 fatalities per year) for the period of 1995-2013. Given the 24 fatalities and on average two deaths per year with a prior national legislation, the reduction capacity is **22 fatalities per year** for Finland. The mean differs from the mean presented by the Dossier Submitter (25 fatalities per year), due to differing periods of analysis (Annex 1-Table 6).

[19] Background Document: Table F.7-2. Estimates of benefits under different parameter values using the WTP approach in Finland.

[20] Actual value should be 185 327 at a discount rate of 4%, 2013 price level, resulting in €101m of benefits (28 years x 22.91 death x €157 446).

SEAC extended the benefits to cover also the possible magnitude of fatalities in Poland. According to data in the BD there were registered 83[21] confirmed methanol poisoning with 51 fatal poisonings (61% death rate) in the Silesian Agglomeration from 2010 to 2013 (1st and 2nd quarter) after the national ban on methanol in Poland was lifted. For 26 of the 83 poisonings the source was identified as methanol in winter windshield washing fluids. 10 of the poisonings were caused by contamination of consumable alcohol with methanol from the Czech Republic, which SEAC agrees to be outliers/non-representative, as the possibility of re-occurrence or representativeness for the rest of Poland is very low. As such from the 83 cases 10 were deducted, leading to a conclusion that 70% (=51/73) of the cases were fatal and 36% (=26/73) of the cases were caused by methanol in winter windshield washing fluids.

The Silesian Agglomeration corresponds to around 1/6 of the population of Poland, and assuming that the area was representative for Poland during the period 2010 – 2013, the total number of methanol poisonings in Poland would be:

- up to 438 (= 73*6) cases of methanol poisoning
- around 306 (= 438*70%/100) fatal methanol poisoning
- 156 (= 438*36%/100) cases due to of confirmed methanol poisoning in winter windshield washing fluids
- 109 (= 306*36%/100/3.5 years) fatal methanol poisoning in winter windshield washing fluids, with the average of **31 fatalities per year (extrapolation of the known fatalities in the Silesian Agglomeration)**

In the benefits assessment the above number of fatalities will be used for Poland.

Besides the above assumptions, there were 42 cases of poisoning with methanol (Silesian Agglomeration) due to unknown sources. According to the DS[22] 63% of the poisonings in which the source of methanol was identified are due to winter windshield washing fluids.

The DS assumes that 70% of these cases where the source could not be established are caused by products containing methanol legally sold to consumers (the remaining 30% are not to be assessed in anyway as those are due to illegal activities). SEAC could not verify the DS assumptions made in regards of the cases where the source of poisoning was unknown, however SEAC could not argue different as there was no data available. SEAC considers that even so it is worth assessing it as the potential upper limit of the cases in Poland. The detailed additional calculation regarding the number of methanol poisonings with methanol in windshield washing fluids is described in the Annex 1.

SEAC is of the view that the calculation of benefits should cover all the possible affected countries (the initial approach with a very conservative estimate was based only on the data gathered from Finland). The Public Consultation suggested the area of main concern to be the Member States around the Baltic Sea (e.g. Finland, Poland, Estonia, Latvia and Lithuania), although there is clear evidence that other Member States are also affected. Even if it appears largely a problem for the central-eastern and Baltic area of the European Union, the above countries make out about 20% of the EU Member States and around 10% of the EU population. After assessing the available data, SEAC considers that a number of countries, i.e. the Czech Republic, Slovakia, Romania and Bulgaria, with similar low (or very low) winter temperatures, similar cultural habits and/or similar drinking habits ("pattern of drinking score[23]) could also be affected, leading to one third of the Member States affected involving around 18% of the total EU population.

21 BD Section D

22 Idem

23 WHO, European status report on alcohol and health 2010

In order to calculate the number of plausible fatalities in each of the Baltic countries and the four Central-Eastern European (CEE) countries identified above, SEAC will use the number of fatalities per tonnes of methanol calculated for Poland and will multiply it for the volume of methanol calculated for each of the countries. Based on the Polish data indicating one fatality per 0.215 tonnes of methanol, SEAC has calculated the impact for the other Member States:

- for the Baltic countries (EE, LT, LV), the central estimate of fatalities would be around **4 fatalities per year;**
- for the CEE countries (CZ, SK, RO, BG) the central estimate of fatalities would be around **25 fatalities per year.**

Conclusion:

SEAC estimates that 82 deaths (central estimate, Finland: 22, Poland: 31, Baltic: 4, CEE: 25) may be avoided EU-wide (Annex 1-Table 7) per year.

The number of fatalities avoided, as calculated above, is the main figure for describing the benefits of the proposed restriction. In order to monetise the benefits, SEAC used the Value of a Statistical Life (VSL). The detailed methodology used and the corresponding calculations can be seen in Annex 1.

As a result, the monetized value of the central estimate of 82 fatalities avoided would be between €209-323 million using Value of Statistical Life (lower bound to represent the monetary value of the fatalities observed in Finland and Poland, the upper bound includes the assumed fatalities from the Baltic and the mentioned CEE states as well). (Annex 1-Table 10)[24]

SEAC acknowledges the existence of several other benefits besides the fatalities avoided, as for instance, those resulting from the avoidance of costs such as vision impairment, medical care and treatment of poisoned people, loss of potential productivity and premature death. The TNO-SEA study submitted in the SEAC Draft Opinion public consultation undertook a research on the potential cost of (chronic) visual impairment. Based on a research on available studies the SEA reports that there is a ratio of 0.667 fatal cases, total cases and visual impairment cases (i.e. for one fatal case there is approximately 0.7 cases of visual impairment). For the fatalities calculated in the submitted study (87 fatalities) the authors calculate a monetary value of 17.5 million Euro for the costs for medical and non-medical care and loss of healthy life years due to visual impairment as a result of methanol poisoning). SEAC finds the estimates reliable, however it will not include the cost of visual impairment in the monetised socio-economic assessment although it would strengthen even more the benefits/cost ratio of the proposed restriction.

Although some of these aforementioned "other" benefits could yield a significant additional monetary value, the Dossier Submitter could not readily present an estimate of them and SEAC could not assess them. Therefore, they are not taken into account in the quantitative analysis although they clearly increase the amount of benefits.

Proportionality

As concluded in the subchapter on Costs, the monetary value of the substitution cost is

[24] SEAC also calculated the monetised (central estimate) value based on observed fatalities alone. For this calculation it used the documented fatalities due to methanol in windshield washing fluids based on the cases recorded in Finland, 86.7 million Euro (22 fatalities/year), and in the Silesian Agglomeration, Poland, 20.4 million Euro (5 fatalities/year), a total aggregate being 107.4 million Euro (27 fatalities/year).
Taken the Silesian data to be representative for the whole Poland, the value for Poland would be 122.2 million Euro (i.e. 31 avoided fatalities/year) and the aggregate would amount to 209 million Euros.

estimated to be €40.4 million. These monetary costs translate into 10 fatalities/year using the Value of Statistical Life approach (Annex 1 -Table 9). In order to reach the break-even, the proposed restriction would need to yield at least the same size benefits (as avoided deaths).

As already stated, the number of avoided fatalities based on the scenario described above yielded benefits of €323 million. These monetary benefits are based on the central estimate of 82 fatalities avoided due to the proposed restriction.

The comparison shows that the current benefits based on central "fatalities avoided" estimates would yield the benefits of €323million to cover the estimated costs of €40.4 million. If presented in annual fatalities, the avoided 82 fatalities cover the estimated 10 fatalities. SEAC concludes that the estimated benefits cover the costs and notes that based on the described analysis the proposed restriction is proportional.

Key elements underpinning the SEAC conclusion:

Costs were calculated based on the simulated volumes of methanol in winter windshield washing fluids on the EU market and multiplied with the cost difference of the alternatives (lower end-all actors move to ethanol, upper end-all actors move to isopropanol). Then these cost estimates were converted into number of fatalities using the VSL estimate (ECHA Guidance €1.7 million-3.6 million) and WHO figures (€ 2.0-5.9 million).

The results should be read taking into account all the uncertainties that where presented in the opinion regarding the costs as well the benefits.

This analysis of the proportionality of the proposal, due to lack of data, did not take into account any other health benefits (vision impairment, cost of hospitalisation etc.), and for that matter the benefits are underestimated. On the cost side, potential business closures and monitoring costs are not included, and therefore the costs may be underestimated.

As previously mentioned, the available information did not allow a clear cut cost-benefit assessment of the proposed restriction. Some items, both on the costs and on the benefits side, could not been monetised even though they could have significant monetary values.

Practicality, including implementability, manageability and enforceability

Justification for the opinion of RAC

Implementability and manageability

The Dossier Submitter presented two alternatives for methanol in windshield washing fluids and denatured alcohol, ethanol and isopropanol, which are adequate and available, safer than methanol, and already in use. The implementation of the proposed restriction (by switching to alternative substances) is clear and understandable to all actors involved.

RAC agrees that the proposed restriction is implementable and manageable.

Enforceability

RAC agrees with the Dossier Submitter and the Forum that the proposed restriction is enforceable through inspections, which may be done at the formulators' sites and in the retail sector as well.

The Forum expressed concern that the wording stated in the original proposal regarding methanol "as an additive to denatured alcohol" could be interpreted that denatured alcohol based on technical alcohol with no intentionally added methanol above the proposed methanol limit is not restricted, i.e. the supplier might claim that all methanol above 0.6% is not an additive but an impurity in technical alcohol. Therefore the Forum suggested considering the wording "*as a constituent of denatured alcohol*" instead of "*as an additive to denatured alcohol*". RAC agrees with the Forum, and suggests using the term 'component' instead of 'constituent' proposed by the Forum (justification is given on page 1 of the Opinion).

Justification for the opinion of SEAC

Based on the available information (Background Document), SEAC considers that practicality including enforceability should not create a particular problem.

As restricting the addition of methanol to winter windshield washing fluids seems to be technically feasible, the actors should be capable to comply with the restriction proposal. Given the fact that analytical methods to measure methanol concentration in these mixtures are already available, this restriction is also expected to be manageable for the enforcement authorities.

For enforcement purposes, it is recommended that the restriction contains a restriction limit so that enforcement authorities can set up an efficient supervision mechanism. The proposed restriction limit by RAC is 0.6% by weight, of methanol in these mixtures. Reliable analytical methods to detect the proposed restriction limit of methanol are available (method of determining of methanol in windshield washing fluids (including windshield defrosters) is based on direct analysis of such fluids by gas chromatography with flame ionization detection (GC-FID). The restriction will be enforceable.

The transitional period of 3 months has been challenged in the Public Consultation. SEAC is of the view that more time is needed for industry to comply with the restriction. SEAC considers that if a restriction will be adopted then the transitional period should allow industry to comply, however, at the most covering one winter period. Therefore, SEAC proposes a transition period of 12 months. The proposed period will allow interested parties (producers, distributors, wholesalers etc.) to sell off their products in 2016-2017. The transitional period would allow to adapt to new business operational conditions, and the restriction to probably be in force for the 2017-2018 winter period. SEAC concludes that the proposed restriction can be considered implementable, enforceable and manageable.

Monitorability

Justification for the opinion of RAC

RAC agrees with the Dossier Submitter and the Forum 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 aqueous solutions of methanol and ethanol (e.g. EN 15721).

Justification for the opinion of SEAC

According to the Dossier Submitter the evolution of the following indicators may provide an estimation of the effect of the restriction in reducing the exposure:

1. number of accidents occurring to consumers as a result of ingestion of methanol;
2. percentage of mixtures, available for general public, which have a methanol concentration above 0.6 % w/w;
3. number of mixtures, available for general public, which have a methanol concentration above 0.6 % w/w.

Indicator number 1 can be provided by collecting information about accidents/incidents occurring to consumers as a result of exposure to methanol-containing products from poison control centers. However, as RAC already pointed out, there is no legal obligation in all Member States to collect such data.

It is also highlighted in the Background Document that indicators number 2 and number 3 will probably be costly; however, SEAC does not know the magnitude of it. According to the Dossier Submitter, "Indicators will be chosen according to the resources that can be allocated to the monitoring of this measure". SEAC argues that this could lead to a gap in assessing the benefits if one or more Member States are not able to allocate funds to follow up on the restriction outcome.

It should be highlighted that not every product (windshield washing fluids (including windshield defrosters)) available on the market must be controlled. If the proposed restriction is included in Annex XVII of the REACH Regulation, the company placing on the market windshield washing fluid with methanol concentration higher than 0.6% may be subject to enforcement.

According to information received from the Polish enforcement authorities, the cost of analysing one sample of methanol in a mixture containing methanol (for example in a windshield washing fluid) is approximately €20.

BASIS FOR THE OPINION

The Background Document, provided as a supportive document, gives the detailed grounds for the opinion.

Basis for the opinion of RAC

The main changes introduced in the restriction as suggested in this opinion compared to the restrictions proposed in the Annex XV restriction dossier submitted by Poland are:

1) In line with the Forum advice, the scope of the restriction proposal is changed in a way that windshield defrosters are added as a subtype of windshield washing fluids (for the justification supporting this change see BacD chapter A.1.2);
2) A DNEL value of 0.088 g/kg bw (based on minimal oral methanol dose leading to severe ocular toxicity, i.e. 0.26 g/kg bw with AF of 3) is proposed for the risk assessment (instead of 0.008 g/kg derived from an inhalatory OEL or the minimal acute oral lethal dose of 0.3 g/kg bw). Instead of 70 kg body weight used by the Dossier Submitter, 60 kg body weight was used in the calculation, as recommended in ECHA Guidance. Thus, the methanol limit value for windshield washing fluids and denatured alcohol is lowered from the value proposed by the Dossier Submitter of ≥3% to **≥0.6%;**
3) Other alternatives not mentioned in the Background Document, but recognised by RAC, are discussed.

Basis for the opinion of SEAC

The main changes introduced in the restriction as suggested in this opinion compared to the restriction proposed in the Annex XV restriction dossier submitted by Poland are the Background Document and information submitted in the Public Consultation.

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Annex 1 - List of Tables

Table 4 - Amount of Methanol (t/year) used in windshield washing fluids in Finland 2002-2013

Year	Methanol market in windshield washing fluid t/year
2002	1 326
2003	1 565
2004	904
2005	1 334
2006	1 745
2007	1 358
2008	1 127
2009	1 246
2010	1 748
2011	2 559
2012	935
2013	1 819
Mean	**1 472**
Median	**1 346**
Standard deviation	**457**

Table 5 - The central estimate of 56k tonnes of methanol to be replaced with ethanol and isopropanol on the EU market was tested with an upper and lower estimate. The sensitivity analyses was performed based on the standard deviation of the Finnish methanol market and following the same aggregation as described on page 12.

	Methanol (t)	Ethanol (t)	Isopropanol (t)
Lower estimate	38 936	50 616	58 404
Central estimate	*56 458*	*73 395*	*84 687*
Higher estimate	73 980	96 174	110 970

Table 6 - Number of fatalities per year due to methanol poisoning in Finland

Year	Fatalities/year
1995	8
1996	15
1997	18
1998	29
1999	33
2000	46
2001	30
2002	25
2003	43
2004	26
2005	30
2006	12
2007	28
2008	15
2009	30
2010	24

Year	Fatalities/year
2011	19
2012	11
2013	7
Mean	**24**
Median	25
Standard deviation	**10.96**

The total number of methanol poisonings from methanol in windshield washing fluids in Poland is (2010-2013):

- additional 108 cases due to methanol poisoning in winter windshield washing fluids ((42 cases*63%*70%) out of the 73 cases of methanol poisoning =18 cases in the Silesian Agglomeration * 6(Silesian Agglomeration=1/6 of Poland population))
- additional 75 fatal methanol poisoning in winter windshield washing fluids ((18 cases/73 cases)*306 fatal poisoning with methanol in Poland)) = around 21 cases per year.

Table 7 and 8 reflects the numbers for Poland (31 fatal cases) without the potential additional fatalities (which are due to the unknown source).

Table 7 - Total number of fatalities avoided. In the sensitivity analysis central estimate for Finland was tested with a SD-11 according to Table 2. In the case of Poland as no better proxy could be used the same SD-11 was used. In the case of the Baltic and CEE region the Polish preference rate was used (See page 17)

	Population	Tonnes of methanol in wwf	Fatalities low estimate	Fatalities central estimate	Fatalities high estimate
Finland	5 471 753	1 472	11	22	33
Poland	38 005 614	8 649	20	31	42
Baltic (EE,LT,LV)-Polish preference rate	6 220 629	801	2	4	5
CEE (CZ,SK,RO,BG)-Polish preference rate	43 023 230	5 386	16	25	34
Total	**92 721 226**	**14 312**	**49**	**82**	**114**

Table 8 - If the Finnish data of one fatality per 0.067 tonnes of methanol is used (instead of the Polish indicator), the fatalities in Poland, the Baltic countries and the CEE countries end up being three times higher.

	Population	Tonnes of methanol in wwf	Fatalities low estimate	Fatalities central estimate	Fatalities high estimate
Finland	5 471 753	1 472	11	22	33
Poland-Finnish preference rate	38 005 614	6 653	50	99	149
Baltic (EE,LT,LV)-Finnish preference rate	6 220 629	801	6	12	18
CEE (CZ,SK,RO,BG)-Finnish preference rate	43 023 230	5 386	40	80	121
Total	**92 721 226**	**14 312**	**107**	**214**	**321**

SEAC has conducted a benefits estimation based on the values from Table 4 and the Value of Statistical Life (VSL). Some recently available data from the World Health Organization (WHO)[25] was used for the calculation of population weighted average of the country specific VSL estimates. According to their findings, the average values for the EU28 (VSL in €, 2011) are the following:

	base value	minimum	maximum
average EU28	3 370 891	1 685 446	5 056 337

Using the above data and compound rate of 4% recommended by the ECHA Guidance on Socio-Economic Analysis, the base value in 2015 prices will be €3 943 466, the minimum value will be €1 980 946 and the maximum value will be €5 942 837 for the EU-28.[26]

In the sensitivity analysis, estimates derived from the ECHA Guidance on Socio-Economic Analysis will also be used, as follows: lower estimate €1 684 286, higher estimate €3 615 131.[27]

Table 9 - Total number of fatalities needed to offset the costs based on VSL

	Lower estimate		Central estimate		Higher estimate	
Cost Euro	*27 839 055*	*56 301 082*	*40 367327*	*81 637 979*	*52 895 599*	*106 974 875*
	VSL = 1 980 946 Euro		VSL = 3 943 466		VSL = 5 942 837	
Number of fatalities	14	28	10	21	9	18
	VSL = 1 684 286		-	-	VSL = 3 615 131	
Number of fatalities	17	33	-	-	15	30

Table 10 - Estimation of benefits based on VSL

		Lower estimate	Central estimate	Higher estimate
		1 980 946	*3 943 466*	*5 942 837*
Fatalities	*49*	97 066 357	193 229 819	291 199 014
	82	162 437 577	**323 364 187**	487 312 636
	114	225 827 852	449 555 089	677 483 421
		1 684 286		*3 615 131*
	49	82 530 009		177 141 407
	82	138 111 443		296 440 721
	114	192 008 592		412 124 905

[25] http://www.heatwalkingcycling.org/index.php?pg=requirements&act=vsl&PHPSESSID=q3jkco40bnm8aj7poon2v765o5

[26] ECHA Guidance on Socio-Economic Analysis – Restrictions: FV(0.04;4;0;3370891)= 3 943 466; FV(0.04;4;0;1693321)= 1 980 946; FV(0.04;4;0;5079962)= 5 942 837

[27] ECHA Guidance on Socio-Economic Analysis – Restrictions: FV(0.04;12;0;1052000)= 3 615 131, FV(0.04;12;0;-2258000)= 3 615 131