

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing restrictions on

Methanol

Draft

4 December 2015

(Draft)

4 December 2015

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 Socio-economic Analysis (SEAC) has adopted an opinion in accordance with Article 71 of the REACH Regulation on the proposal for restriction of

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

This document presents the opinion adopted by SEAC. The Background Document (BD) provides support to both RAC and SEAC opinions, giving the detailed ground for the opinions.

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 **18 September 2015**.

ADOPTION OF THE OPINION OF SEAC

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 2015**.

THE OPINION OF SEAC

The proposal of the Dossier Submitter:

<p>Methanol</p> <p>CAS No 67-56-1</p> <p>EC No 200-659-6</p>	<p>Shall not be placed on the market for supply to the general public:</p> <ul style="list-style-type: none"> – as a constituent of windshield washing fluids in concentration equal to, or greater than 3.0% by weight, – as an additive to denaturated alcohol (<i>methylated spirit, brennspritus</i>) in concentrations equal to, or greater than 3.0% by weight. <p>Member State may maintain any existing and more stringent restrictions for methanol.</p>
--	---

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.

The conditions of the restriction proposed by SEAC are:

<p>Methanol</p> <p>CAS No 67-56-1</p> <p>EC No 200-659-6</p>	<p>Shall not be placed on the market for supply to or used by the general public:</p> <ul style="list-style-type: none"> – 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 SEAC

JUSTIFICATION THAT ACTION IS REQUIRED ON AN EU WIDE BASIS

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 denatured alcohol. As such SEAC cannot evaluate the socio-economic impacts of the inclusion of the denatured 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

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 below¹). RAC has concluded 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 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

¹ 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'.

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 proposed².
- 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 SME enterprises which results in a scattered market, lacking an anchor entity capable of leading the process of moving from methanol to 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 denatured 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 duties³, 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 denatured alcohol, SEAC does not support the inclusion of the denatured alcohol into the scope.

² 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

³ 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.

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.

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).

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 were 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 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 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 1 Relative prices of methanol and potential alternatives.

Substance	Price according to BD €/t ⁴	Price \$/t – July 2015 ⁵	Price €/t ⁶ –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.

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.

⁴ Background Document: Table C.2.4-2. The cost of methanol and some alternatives to methanol. For Methanol, Ethanol and Isopropanol.

⁵ <http://www.molbase.com/en/index.html>

⁶ Exchange rate: http://ec.europa.eu/budget/contracts_grants/info_contracts/infoeuro/infoeuro_en.cfm; 1 USD is equal to 0.898230485943 €

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 (PPS⁷) 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 2-Table 2). 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:

$1\,472\,000\text{ kg (methanol use in winter windshield washing fluids in FIN) / Population of Finland / PPS (110) of Finland * PPS(100) of EU-28}$, 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 Member State and for the EU-28:

$0.24\text{ kg Methanol per person} \times \text{Population of each Member State} / \text{PPS EU} \times \text{PPS Country} / \text{VCF} \times \text{VC (vehicles in capita in the country)}$.

- 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

⁷ PPS = purchasing power standard

methanol on the EU market that potentially needs to be substituted due to the restriction proposal.

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 2-Table 3.

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.

In Annex 2-Table 2, 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 Bitrex⁸ (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 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 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.⁹

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 year¹⁰. 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”.

⁸ <http://www.bitrex.com>

⁹ Toronto Public Health Fact Sheet ‘Non-palatable (toxic) alcohol use’, February 2011 and Carnahan RM et al. 2014

¹⁰ Lampinen et al. 2013

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

The Dossier Submitter has performed a sensitivity analysis¹¹, 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 value¹²). 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.

¹¹ Background Document: Table F.7-2. Estimates of benefits under different parameter values using the WTP approach in Finland.

¹² 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).

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 2-Table 4).

SEAC extended the benefits to cover also the possible magnitude of fatalities in Poland. According to data in the BD there were registered 83¹³ 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 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 DS¹⁴ 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

¹³ BD Section D

¹⁴ Idem

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 2.

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 score¹⁵) could also be affected, leading to one third of the Member States affected involving around 18% of the total EU population.

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 2-Table 5) 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 2.

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 2-Table 8)

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.

¹⁵ WHO, European status report on alcohol and health 2010

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 estimated to be €40.4 million. These monetary costs translate into 10 fatalities/year using the Value of Statistical Life approach (Annex 2-Table 7). 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 were 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 be monetised even though they could have significant monetary values.

Practicality. incl. enforceability

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

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 opinions.

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.

References not included in the Background Document

- Alcohol-related harm in Europe-Key data; European Commission, Health&Consumer Protection Directorate-General, Factsheet; 2006
- <http://bankrate.com/calculators/retirement/life-age-expectancy-calculator.aspx>
- Carnahan RM et al. Acute ethanol intoxication after consumption of hairspray. *Pharmacotherapy* 2005; 25:1646-50; Reid W, Chen L. A Case of hand sanitizer ingestion. *Clinical Vignette. Proceedings of UCLA Healthcare* 2014; Vol. 18
- Dawson DA, Grant BF, Stinson FS, Chou PS, Huang B, Ruan WJ. Recovery from DSM-IV alcohol dependence: United States, 2001-2002. *Addiction* 2005; 100(3):281-92.
- http://ec.europa.eu/health/archive/ph_determinants/life_style/alcohol/documents/alcohol_factsheet_en.pdf
- http://ec.europa.eu/taxation_customs/taxation/excise_duties/alcoholic_beverages/not_human/index_en.htm
- <http://emedicine.medscape.com/article/285913-followup#e3>
- https://en.wikipedia.org/wiki/Human_body_weight#By_country; Special Eurobarometer 246 / Wave 64.3 – TNS Opinion & Social
- https://en.wikipedia.org/wiki/Template:Average_height_around_the_world; Special Eurobarometer 246 / Wave 64.3 – TNS Opinion & Social
- <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31992L0083:en:HTML>
- <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:009:0012:0030:EN:PDF>
- <http://www.heatwalkingcycling.org/index.php?pg=requirements&act=vsl&PHPSESSID=q3jkco40bnm8aj7poon2v765o5>
- Methanol Poisonings, Information Note; WHO; 2014
- James B. Mowry, Daniel A. Spyker, Louis R. Cantilena Jr., Naya McMillan, Marsha Ford; 2013 Annual Report of the American Association of Poison Control Centers' National
- John U., Rumpf H-J., Bischof G., Hapke U., Hanke M., Meyer C., 2013. Excess mortality of alcohol dependent individuals after 14 years and mortality predictors based on treatment participation and severity of alcohol dependence. *Alcohol Clin Exp Res*; Vol **, No *, 2012: pp 1-8
- <http://www.molbase.com/en/index.html>
- <http://www.nytimes.com/health/guides/disease/alcoholism/possible-complications.html>
- R. Paasma; Clinical Study of Methanol Poisoning: Handling Large Outbreaks, Treatment, with Antidotes, and Long-term outcomes; Faculty of Medicine, University of Tartu; 20R.
- Paasma, K.E. Hovda, A. Tikkerberi, D. Jacobsen; Methanol Mass Poisoning in Estonia: Outbreak in 154 patients; *Chemical Toxicology*; 2007; 45,152-157
- Pablo Marquez; Cost Benefit Analysis, Value of a Statistical Life and Culture: Challenges for Risk Regulation; MPRA Paper No. 2639; 2007
- Poison data System (NDPS): 31st Annual Report, NDPS Report 2013; *Clinical Toxicology*; 2014; 52, 1032-1283
- http://www.transportation.gov/sites/dot.gov/files/docs/VSL%20Guidance_2013.pdf
- Toronto Public Health Fact Sheet 'Non-palatable (toxic) alcohol use', February 2011
- Westman J., Wahlbeck K., Laursen T.M., Gissler M., Nordentoft M., Hallgren J., Arffman M., Osby U., 2015. Mortality and life expectancy of people with alcohol use disorder in Denmark, Finland and Sweden. *Acta Psychiatr Scand*; 131(4): 297-306.
- Vaillant GE. A 60-year follow-up of alcoholic men. *Addiction*. 2003; 98(8):1043-51.

Annex 1 – Abbreviations

BD	- Background Document
BG	- Bulgaria
bw	- body weight
CAS number	- Chemical Abstracts Service number
CBA	- Cost Benefit Analysis
CEE	- Central and Eastern Europe
CLP	- Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
CMR	- Carcinogenic, Mutagenic or Toxic for Reproduction
CSR	- Chemical Safety Report
CZ	- Czech Republic
da	- denaturated alcohol
DNEL	- Derived No-Effect-Levels
DS	- Dossier Submitter
EC	- European Commission
ECHA	- European Chemical Agency
EE	- Estonia
EU	- European Union
F+	- Extremely Flammable
LT	- Lithuania
LV	- Latvia
MS	- Member State
O	- Oxidizing
PC	- Public Consultation
POD	- Point of Departure
RAC	- Committee for Risk Assessment
REACH	- Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
RMO	- Risk Management Option
RO	- Romania
SEAC	- Committee for Socio-Economic Analysis
SK	- Slovakia
SME	- Small and Medium-Sized Enterprise
T	- Toxic
T+	- Very Toxic
US	- United States of America
WHO	- World Health Organization
VOLY	- Value of Life Year
VSL	- Value of Statistical Life
wwf	- windshield washing fluid

Annex 2 - List of Tables

Table 2 - 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 3- 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
<i>Central estimate</i>	<i>56 458</i>	<i>73 395</i>	<i>84 687</i>
Higher estimate	73 980	96 174	110 970

Table 4 - 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 5 and 6 reflects the numbers for Poland (31 fatal cases) without the potential additional fatalities (which are due to the unknown source).

Table 5 - 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 6 - 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)¹⁶ 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-28.¹⁷

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 €3 615 131.¹⁸

Table 7 - Total number of fatalities needed to offset the costs based on VSL

	Lower estimate		Central estimate		Higher estimate	
<i>Cost Euro</i>	27 839 055	56 301 082	40 367 327	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 8 - Estimation of benefits based on VSL

		Lower estimate	Central estimate	Higher estimate
		1 980 946	3 943 466	5 942 837
<i>Fatalities</i>	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

¹⁶

<http://www.heatwalkingcycling.org/index.php?pg=requirements&act=vsl&PHPSESSID=q3jkco40bnm8aj7pon2v765o5>

¹⁷ 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

¹⁸ 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