**AMPHORA – Alcohol Public Health Research Alliance**

**Deliverable D1.5 – Report of the toxicological assessment of untaxed alcohol in Europe**

**Annex: Recommendations on unrecorded alcohol**

**AMPHORA**

**WP7 Drinking environments and harm reduction**

# Deliverable 1.5 Report of the toxicological assessment of untaxed alcohol in Europe

This work package is split into two distinct work areas (drinking environments and chemical analysis). The deliverable presented below presents the second aspect of the package, focused on chemical analysis.

## 1. Background to the study

The consumption of unrecorded alcohol constitutes a worldwide phenomenon of a significant scale.[1,2] In the WHO region Europe, the average unrecorded adult per capita alcohol consumption 2005 was 2.67 L pure ethanol, which is 22% of the total consumption of 12.20 L (own calculation based on WHO, in press[3]).

'Unrecorded' is an overview category for any kind of alcohol that is not taxed as beverage alcohol or registered in the jurisdiction where it is consumed.[4,5] According to WHO nomenclature (see the Global Information System on Alcohol and Health on www.who.int), unrecorded alcohol products include homemade informally produced alcohols, illegally produced or smuggled alcohol products, as well as surrogate alcohol that is not officially intended for human consumption. Some common examples of surrogate alcohol include mouthwash, perfumes, and eau-de-colognes, which are alcohol products manufactured on a large scale. Such alcohol may be produced with human consumption in mind, but to evade taxation it is officially classified as 'shaving water' or 'mouthwash'.[4,6]

Despite concerns about potential harms from the chemical composition of unrecorded alcohol, there are surprisingly few data on the problem in the European Region.[7] Pilot studies with limited numbers of samples conducted in Lithuania, Hungary and Poland[4,8] pointed to several possible problems especially relating to a higher alcoholic strength of unrecorded alcohol as well as ethyl carbamate contamination in home produced fruit spirits. The WHO suggested it as important to obtain a systematic overview of the compounds in unrecorded alcohol from all European countries, so that national surveys of unrecorded alcohol can better identify the presence of relevant compounds and assess how much of a problem exists. If unrecorded alcohol is found to contain toxic components not found in recorded alcohol, additional policy measures can be taken.7,9 This study reports the results from the Alcohol Measures for Public Health Research Alliance (AMPHORA) project, which assessed the quality of unrecorded alcohol in a Europe-wide study (over 100 samples predominantly homeproduced or counterfeited alcohols).

## 2. Research methods

For details on methodology, see also Research Protocol.

The methodology including sampling, chemical analysis and toxicological interpretation was previously described in full detail.[10] In short, the sampling was facilitated by a public open call on the AMPHORA webpage (www.amphoraproject.net), in which all interested parties were invited to send samples from all European Union member states and neighbouring countries, but the majority of samples were sent in by members of the AMPHORA project. The samplers were asked to apply a risk-oriented approach and to chose products likely to be contaminanted. They were also asked to choose only unrecorded alcohol clearly intended for human consumption (i.e. no after- shaves or similar products sold in drug stores clearly not for human consumption).

The chemical analyses were conducted by validated routine or reference methods normally used for testing recorded alcohol. Alcoholic strength was determined by Fourier transform infrared spectroscopy.[11] Volatile components were analyzed on the basis of the Reference Methods for the Analysis of Spirits using gas chromatography (GC) with a flame-ionization detector (FID).[12,13] Ethyl carbamate (urethane) was determined using GC with tandem mass spectrometry (GC-MS/MS).[14] Anionic composition[15] and conductivity[16] were measured. All samples were screened for unknown substances (including flavour compounds) using gas chromatography with mass spectrometry (GC-MS),[17] the GC/MS assay also included phthalates.[18] Screening for metals was conducted using semi-quantitative inductively coupled plasma mass spectrometry (ICP-MS).[19] The absinthe from Switzerland was quantitatively analyzed for thujone.[20] Wine and beer samples were screened for aflatoxins using a commercially available test-kit (Aflacard Total, R-Biopharm, Darmstadt, Germany). The toxicological interpretation of results was conducted according to the AMPHORA criteria previously published.[10]

## 3. Results

The full raw data results are attached as a separate Excel table and are summarized in Tables 1 and 2.
In total 115 samples of unrecorded alcohol from 16 European countries have been received for analysis. Most of the samples were spirits (n=81). The rest predominantly were wine products (table wine, sparkling wine or fortified wine, n=32), while only 2 beers were submitted. Most of the spirits belonged to the group of home-produced (fruit) spirits, the exception were the samples from Norway, Poland and the UK, which were neutral alcohols (vodka), which had been smuggled, counterfeited or relabelled. None of the samples obviously was a surrogate alcohol.
For a sub-set of samples (n=49), price information was available and average prices of the comparable group of recorded alcohol was provided. On average, the price of unrecorded alcohol was 45% of the price of recorded alcohol. The exception was the counterfeited products from the UK, which were sold at exactly the same price.
For 49 of the samples, the labelling provided information on alcoholic strength or such information was provided by the vendor. In most cases the information was in acceptable accordance with our analyses. The average difference between labelling and analysis was 2% vol (50% were higher, 50% were lower than labelled). This difference was slightly higher than the legal tolerances in the EU (0.3% vol for spirits, 0.5% vol for beer and wine, see 21). Only in one exceptional sample (Raki from Albania), the alcoholic strength was stated as being 20% vol, while our analyses detected it to be 44.0% vol.
The results of our analyses for alcohol quality are summarized in table 1. One half of the samples (n=57) showed adequate quality according to the AMPHORA standards.10 The other half (n=58) showed one or several deficits with exceedance of the AMPHORA limits. The most prevalent problem was ethyl carbamate contamination with 29 samples above the AMPHORA limit of 0.4 mg/l; 17 samples were higher than 1 mg/l, and 10 samples showed very high contamination above 2 mg/l. The second most prevalent problem was copper contamination in 20 samples, followed by manganese contamination (16 samples), and comparably high levels of acetaldehyde (12 samples). All other parameters were only seldom problematic (limit exceedance in less than 10 samples).
The quantitative results are summarized in Table 2. The average alcoholic strength of the wine products was 14.9% vol, while the one of the spirits was 47.8% vol. Parameters not shown in the tables were below limits (e.g. thujone in the Swiss clandestine absinthe was 1.1 mg/l) or not detectable in any of the samples (e.g. arsenic, antimony). None of the beers and wines contained aflatoxins.

## 4. Toxicological assessment

While we have indeed detected quality problems in half of the sampled unrecorded alcohols in Europe, we want to stress that this not necessarily implies health hazards. As detailed in our methodology paper, the AMPHORA limits are typically based on acceptable daily intakes, which are derived from no-observed adverse effect levels in animal experiments with additional safety factors (typically 100).[10] The limits therefore intend to exclude health risks for lifetime daily consumers of such products. Therefore, the samples with slight exceedance of methanol, higher alcohols, or ethyl acetate levels do not allow formulating a general public health problem, as on a population base the intake of these substances would be negligible due to the low incidence. For the same reason, we can also exclude acute health effects (such as methanol poisonings) for individual drinkers of these beverages. Regarding chronic toxic effects, it is unlikely in our opinion that individuals would have a lifetime daily consumption of products highly contaminated with methanol, higher alcohols or ethyl acetate levels. Experience shows that these volatile substances are highly variable due to different effects (natural variation in fruit composition, high variation between batches due to microbiological influences during fermentation and due to distillation technology).[22] For these reasons, we judge methanol, higher alcohols, ethyl acetate, lead, nickel, boron, aluminium, cadmium, and phthalates as being of low relevance for health effects of unrecorded alcohol. In the following, we therefore focus on copper, manganese, acetaldehyde and ethyl carbamate, which all had incidences above 10% in our sample.

Regarding the metals copper and manganese, the toxicological judgement is difficult as both are essential elements for humans and only toxic above certain thresholds. The WHO provisional maximum tolerable daily intake for copper is 0.5 mg/kg bw/day[23] and the tolerable daily intake for manganese is 0.06 mg/kg bw/day.[24] For copper, the Organisation Internationale de la Vigne et du Vin (OIV) limit for wine is 1 mg/l (no limit for manganese),[25] while the EU drinking water limits are 2 mg/l for copper and 0.05 mg/l for manganese.[26] Copper and manganese among other metals are also often found in recorded wines.[27] While the AMPHORA limits (based on OIV and drinking water limits) may be exceeded by several samples, the tolerable daily intakes cannot be reached by even excessive unrecorded alcohol consumption. The exception is copper in one sample from Hungary (52 mg/l), for which the consumption of approx. 0.5 l would exceed the tolerable daily intake. While manganese contamination, which is predominantly seen in the wine products, probably occurs due to natural contents in the soil, the high copper contamination levels (> 10 mg/l) found in some distilled spirits are probably due to corroded copper pipes or fittings in the distillation equipment. While there is limited evidence from animal experiments that copper may cause cirrhosis of the liver,[23] it is unclear if or how metal ingestion influences and interacts with the metabolical changes induced by ethanol.[28]

Regarding acetaldehyde, we have previously discussed the risk assessment in detail.[29] In the current samples, the acetaldehyde contents were generally comparable to recorded alcohols[30] with the exception of two wines from Slovenia (636 and 661 g/hl pa) and a homebrewed wine from the Netherlands (190 g/hl pa). These three products with very high contents have probably only a restricted marketability due to their oxidised off-taste, so that we do not expect a large scale ingestion of highly acetaldehyde contaminated wines and beers in Europe. The IARC judged acetaldehyde associated with alcohol consumption as carcinogenic to humans (group 1) with sufficient evidence in causing cancer of oesophagus, head and neck.[31] As this judgement also refers to recorded alcohol, we currently see no basis for the assumption that acetaldehyde may pose a large additive risk in unrecorded alcohol in Europe.

Finally, the only quality problem consistently found throughout most European countries was ethyl carbamate, which is an IARC group 2A carcinogen.[32] In a Europe-wide risk assessment based on a large monitoring, the EFSA concluded that ethyl carbamate in alcoholic beverages indicates a health concern, particularly with respect to stone fruit spirits.[33] Ethyl carbamate was also seen as health risk in alcoholic beverages including unrecorded alcohol in Brazil.[34] The current finding of ethyl carbamate in unrecorded alcohol confirms our previous studies from Hungary and Poland, where we had also detected ethyl carbamate contamination.[4,8] The problem appears to occur wherever people home-produce spirits from fruit materials, and especially from stone-fruits, without the application of mitigative measures to avoid this contamination.[35] Again this is no problem specific to unrecorded alcohol. If we compare ethyl carbamate contents in the unrecorded alcohols to our samples from recorded small distilleries in Germany, with the distributions showing no significant differences.

It must be noted that our survey of recorded spirits is not representative for the German market (as many of the larger producers apply quality control measures regarding this contaminant), but using a risk-oriented sampling we specifically analyze samples from distilleries with past problems or without implementation of measures to avoid ethyl carbamate. As governmental alcohol control laboratory, we object against samples with more than 1 mg/l ethyl carbamate and inform the producers about the code of practice for the prevention and reduction of ethyl carbamate contamination, as recommended by the European Commission.[36] The European Commission also recommended that the Member States monitor levels of ethyl carbamate in stone fruit spirits and stone fruit marc spirits during the years 2010, 2011 and 2012. The problem will be that unrecorded alcohol is not normally included in such monitoring programs conducted by food control authorities, which only visit registered businesses. The high level of ethyl carbamate contamination in our samples suggests that unrecorded alcohol should be included in the monitoring to allow for an adequate exposure assessment. Past risk assessments (e.g. by EFSA[33]) probably have considerably underestimated the ethyl carbamate exposure, if we assume that much of the unrecorded alcohol production (especially in the traditionally fruit spirit producing countries, such as Hungary, Austria, Romania, Slovenia etc.) would be contaminated with ethyl carbamate. Further research is certainly necessary to classify the volume of consumption of the different types of unrecorded alcohols.

It has been suggested that the large differences in cirrhosis mortality rates between Hungary, Romania and Slovenia and the rest of Europe could be due to the composition of unrecorded alcohol products[37] rather than differences in the volume of consumption.[38,39] While several of the contaminants detected in this study (especially copper and ethyl carbamate) could be liver toxic above certain thresholds, the typical human exposure is more than 100 fold less than threshold doses in animals. First efforts in comparative quantitative risk assessment using the margin-of-exposure model, have also shown that acetaldehyde and ethyl carbamate in alcoholic beverages are 100 or 1000 times less potent than ethanol itself.[40] Therefore, while further research in this area is certainly necessary, we currently judge that volume of alcohol consumption and/or drinking patterns but not alcohol quality predominantly contribute to the differences in mortality. Unrecorded alcohol may contribute to this by the fact that unrecorded alcohol is often higher in strength as clearly shown in our sample (see also Ref. 8) and its lower price may further contribute to higher drinking amounts.

One possible conclusion from this study is therefore that unrecorded alcohol may bring a health risk due to a lower cost than legal alcohol leading to higher consumption. Unrecorded alcohol also bears the problem that the consumer is generally not informed about the amount of alcohol he consumes (more than 50% of samples were unlabelled). Chemical composition of unrecorded alcohol is most probably unlikely to pose a substantial additional health hazard in Europe. Nevertheless, for reasons of precautionary consumer protection, concepts how to avoid contamination problems in unrecorded home production as well as in recorded small-scale production should be developed. For health-relevant substances regularly found in recorded and unrecorded alcohol alike (e.g. ethyl carbamate, acetaldehyde, metals), the implementation of enforceable limits into the European law should be demanded for all types of alcoholic beverages. The problem of unrecorded alcohol should be implemented in holistic alcohol policy strategies.[1]

The methodological limitation of our study is the limited number of samples analysed, which is neither representative for the whole of Europe, nor for the individual European countries or even regions within those countries. We specifically asked the sampling institutions to provide samples of lower quality likely being contaminated using a risk-oriented approach (see Ref. [10] for details on sampling) and the number of problematic samples identified validates that most samplers apparently followed this approach (we had no means to check the rationale of each sampling otherwise). Considering this risk-oriented sampling, we think that we would have rather overestimated than underestimated the risk of unrecorded alcohol. A further limitation of the study is the fact that we were not able to sample any surrogate alcohol samples (i.e. non-beverage alcohols, e.g. denatured or cosmetic alcohols). Our sample also over-proportionally includes countries with low unrecorded alcohol consumption (see table 1), while some with the highest unrecorded consumption were not included at all (Baltic states). In western Europe surrogate alcohol is apparently not sold for human consumption, while in the Baltic states and Russia sampling was problematic or impossible not only because the sampler would have made himself liable to prosecution, but also because parcel services declined to transport such samples.

## 5. Time plan and status

The table below provides details of the status of the time plan for the research.

| Task | Month | |
|---|---|---|
| Collection of samples of unrecorded alcohol in Europe | Jan-Dec 09 | Finished |
| Analysis of collected samples | Jan 10-Jul 10 | Finished |
| Data interpretation and risk assessment | Aug 10 -Jul 11 | Finished |
| Report on research findings | Aug-Dec 11 | Finished |
| Recommendations on unrecorded alcohol | Jan-Dec 12 | Finished |
| Dissemination of findings | Jan-Dec 12 | Ongoing |

## 6. Outputs

1. Some aspects of the following publications on method development were based on partial AMPHORA funding (primarily, AMPHORA samples were used for method validation):

- **Method development for metal analysis:** Lachenmeier DW, Samokhvalov AV, Leitz J, Schoeberl K, Kuballa T, Linskiy IV, Minko OI, Rehm J. The composition of unrecorded alcohol from eastern Ukraine: is there a toxicological concern beyond ethanol alone? Food Chem Toxicol. 2010 Oct;48(10):2842-7
- **Method development for phthalate analysis:** Leitz J, Kuballa T, Rehm J, Lachenmeier DW. Chemical analysis and risk assessment of diethyl phthalate in alcoholic beverages with special regard to unrecorded alcohol. PLoS One. 2009 Dec 2;4(12):e8127.

- **Method development for alcohol analysis:** Lachenmeier DW, Godelmann R, Steiner M, Ansay B, Weigel J, Krieg G. Rapid and mobile determination of alcoholic strength in wine, beer and spirits using a flow-through infrared sensor. Chem Cent J. 2010 Mar 23;4:5.
- **Method development for formaldehyde analysis:** Jendral JA, Monakhova YB, Lachenmeier DW. Formaldehyde in Alcoholic Beverages: Large Chemical Survey using Purpald Screening followed by Chromotropic Acid Spectrophotometry with Multivariate Curve Resolution. Int J Anal Chem 2011, in press.

2. The following publications were fully based on AMPHORA funding:
- **Full methodology for toxicity assessment:** Lachenmeier DW, Schoeberl K, Kanteres F, Kuballa T, Sohnius EM, Rehm J. Is contaminated unrecorded alcohol a health problem in the European Union? A review of existing and methodological outline for future studies. Addiction. 2011 Mar;106 Suppl 1:20-30.
- **Full results and toxicological interpretation:** Lachenmeier DW, Leitz J, Schoeberl K, Kuballa T, Straub I, Rehm J. Quality of illegally and informally produced alcohol in Europe: Results from the AMPHORA project. Adicciones, in press.

3. Results were presented at several EU and WHO alcohol policy conferences (Stockholm 2009, Madrid 2010). Planned talks for conferences in Zurich 2011 and Poznan 2011.

## 7. Research management

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Table 1: Quality problems in unrecorded alcohol from 16 European countries

| Country | Unrecorded consumption [L of pure alcohol adult per capita (percentage of total consumption)] [a] | Sample number | Type of alcohol | Samples with quality problems | Quality problems detected[b] |
|---|---|---|---|---|---|
| Albania | 2.1 (31%) | 1 | Spirit (Raki, grape spirit) | 1 (100%) | EC (1), Cu (1) |
| Austria | 0.6 (5%) | 30 | Stone-fruit spirits | 10 (33%) | EC (9), MeOH (2), HA (1) , Cu (1) |
| Croatia | 2.5 (17%) | 6 | Spirits (Pear, plum and marc) | 6 (100%) | EC (6), Cu (6) |
| Czech Republic | 1.5 (9%) | 8 | Spirits (predominantly stone-fruit spirits) | 2 (25%) | EC (2), Pb (1), Cd (1) |
| Germany | 1.0 (8%) | 10 | Spirits (from sugar, fruits) | 5 (50%) | EC (4), AA (1), DBP (1), Cu (1) |
| Hungary | 4.0 (25%) | 2 | Spirit and wine | 2 (100%) | EC (1), AA (1), Cu (1), B (1) |
| Italy | 2.4 (22%) | 2 | Spirit and beer | 1 (50%) | Cu (1) |
| The Netherlands | 0.5 (5%) | 3 | Spirit, wine, beer | 2 (67%) | AA (1), Cu (1), Mn (1) |
| Norway | 1.6 (20%) | 4 | Spirits (smuggled alcohol) | 0 (0%) | - |
| Poland | 3.7 (27%) | 3 | Spirits (vodka, relabelled) | 1 (33%) | Cu (1) |
| Romania | 4.0 (26%) | 9 | Spirits and wines | 9 (100%) | EC (4), AA (2), Cu (3), Pb (1), Mn (2), B (2), Al (1) |
| Russia | 4.7 (30%) | 1 | Spirit (samogon) | 0 (0%) | - |
| Slovenia | 3.0 (20%) | 14 | Spirits and wines | 12 (86%) | AA (6), EA (1), Cu (1), Pb (2), Ni (2), Mn (9), B (1) |
| Spain | 1.4 (12%) | 18 | Spirits and wines | 7 (39%) | EC (2), AA (1), Cu (3), Mn (4), B (1), Al (1) |
| Switzerland | 0.5 (5%) | 1 | Spirit (absinthe) | 0 (0%) | - |
| | | | | | |
| UK | 1.7 (13%) | 3 | Spirits (vodka, counterfeit) | 0 (0%) | - |

[a] Data taken from the Global Status Report on Alcohol[3] and the Comparative Risk Assessment on Alcohol within the Global Burden of Disease 2005 study. Characteristics of per-capita (age ≥15 years) average alcoholic beverage consumption by country 2005 (average of available data 2004–06) from WHO Global Alcohol Database. Unrecorded consumption was mainly derived from surveys or by local experts based on fragmented data (see also Rehm et al.[2]).
[b] Compounds above AMPHORA limits.[10] Number of positive samples stated in brackets. Abbreviations: EC ethyl carbamate, MeOH methanol, Cu copper, HA higher alcohols, Pb lead, Cd cadmium, AA acetaldehyde, DBP Di-Butyl phthalate, B boron, Mn manganese, Al aluminium, EA ethyl acetate, Ni nickel

**Table 2:** Quantitative distribution of health-relevant compounds in unrecorded alcohol from Europe

| Compound | Sample number | Samples above limit | Mean [a] | Median [a] | Minimum | Maximum |
|---|---|---|---|---|---|---|
| Alcoholic strength (wine & fortified wine) (% vol) | 28 | - | 14.9 | 14.5 | 9.6 | 23.5 |
| Alcoholic strength (spirits) (% vol) | 82 | - | 47.8 | 43.1 | 20.8 | 88.8 |
| Ethyl carbamate (mg/L) | 108 | 29 (27%) | 0.5 | 0.1 | n.d. | 5.4 |
| Acetaldehyde (g/hL pa) | 101 | 12 (12%) | 36.3 | 11.5 | n.d. | 667 |
| Methanol (g/hL pa) | 101 | 2 (2%) | 397 | 270 | 0.6 | 1552 |
| Sum of higher alcohols (g/hL pa) | 101 | 1 (1%) | 319 | 314 | n.d. | 1416 |
| Ethyl acetate (g/hL pa) | 101 | 1 (1%) | 101 | 46 | n.d. | 1238 |
| Copper (mg/L) | 108 | 20 (19%) | 2.5 | 0.1 | n.d. | 52 |
| Lead (mg/L) | 108 | 4 (4%) | 0.03 | 0.003 | n.d. | 1.4 |
| Nickel (mg/L) | 108 | 2 (2%) | 0.03 | n.d. | n.d. | 1.5 |
| Manganese (mg/L) | 108 | 16 (15%) | 0.2 | n.d. | n.d. | 2.0 |
| Boron (mg/L) | 108 | 5 (5%) | 0.8 | n.d. | n.d. | 8.2 |
| Aluminium (mg/L) | 108 | 2 (2%) | 0.1 | n.d. | n.d. | 3.1 |
| Cadmium (mg/L) | 108 | 1 (1%) | - | - | - | 0.04 [b] |
| Di-Butyl phthalate (mg/L) | 115 | 1 (1%) | - | - | - | 63.2 [b] |

[a] Samples below detection limit were calculated as zero. Abbreviations: n.d. not detectable; pa pure alcohol.
[b] Occurring only in 1 single sample.

AMPHORA

**WP7 Drinking environments and harm reduction**

**Recommendations on unrecorded alcohol**

The recommendations about unrecorded alcohol were presented and developed during several meetings of AMPHORA experts with alcohol policy specialists (see Deliverable 1.5.). The recommendations were detailed in Lachenmeier et al. (2011).

The following points were the major findings from WP7 (see Deliverable 1.5.)

1. Unrecorded alcohol may bring a health risk due to a lower cost than legal alcohol leading to higher consumption.
2. Unrecorded alcohol bears the problem that the consumer is generally not informed about the amount of alcohol he consumes (more than 50% of samples were unlabelled).
3. Chemical composition of unrecorded alcohol is most probably unlikely to pose a substantial additional health hazard in Europe.

Recommendations:

1. The problem of unrecorded alcohol should be implemented in holistic alcohol policy strategies.
2. For reasons of precautionary consumer protection, concepts how to avoid contamination problems in unrecorded home production as well as in recorded small-scale production should be developed.
3. For health-relevant substances regularly found in recorded and unrecorded alcohol alike (e.g. ethyl carbamate, acetaldehyde, metals), the implementation of enforceable limits into the European law should be demanded for all types of alcoholic beverages.

Further research gaps (not directly based on AMPHORA results):

1. Provide better estimates of the size of the market and of measurement of the amount of consumption (see Anderson and Baumberg (2006) and in WHO Regional Office for Europe (2009)
2. Especially in settings with higher levels of unrecorded production and consumption, increasing the proportion of consumption that is taxed may represent a more effective pricing policy than simple increase in excise tax (Babor et al. 2010).

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