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Illicit alcohol: public health risk of methanol poisoning and policy mitigation strategies 2 Louise Manning1* and Aleksandra Kowalska2, 3 Citation: Manning, L.; Kowalska, A,: 1 Royal Agricultural University, Stroud Road, Cirencester, Gloucestershire, UK GL7 6JS louise.man-4 Title. Foods 2021, 10, x. ning@rau.ac.uk ORCID iD 0000-0002-9900-7303 ² Maria Curie-Skłodowska University, pl. Marii Curie-Skłodowskiej 5, 20-031 Lublin, Poland aleksandra.kowhttps://doi.org/10.3390/xxxxx alska@umcs.lublin.pl ORCID iD 0000-0003-3854-951X * Correspondence: louise.manning@rau.ac.uk Louise Manning Academic Editor: Firstname Last Abstract: Illicit (unrecorded) alcohol is a critical global public health issue because it is produced without regulatory and market oversight with increased risk of safety, quality and adulteration is-10 Received: date sues. Undertaking iterative research to draw together academic, contemporary and historic evi-11 Accepted: date dence this paper reviews one specific toxicological issue: methanol; in order to identify the policy Published: date 12 mitigation strategies of interest. A typology of illicit alcohol products, including legal products, il- 13 Publisher's Note: MDPI stays neulegal products and surrogate products, is created. A policy landscape matrix is produced that syntral with regard to jurisdictional thesizes the drivers of illicit alcohol production, distribution, sale and consumption, policy 15 claims in published maps and institumeasures and activity related signals in order to inform policy development. The matrix illustrates 16 tional affiliations the interaction between capabilities, motivations and opportunities and factors such as access, culture, community norms and behavior, economic drivers and knowledge and information and gives 18 insight into mitigation strategies against illicit alcohol sale and consumption which may prove of 19 value for policymakers in various parts of the world. 20 Copyright: © 2021 by the authors. Submitted for possible open access Keywords: fraud; unrecorded alcohol; illicit; alcohol; methanol; policy 21 publication under the terms and 22 conditions of the Creative Commons Attribution (CC BY) license (https://creativecommons.org/license s/bv/4.0/). 23 1. Introduction 24 25 Alcohol is consumed before, during and after meals, to celebrate birth and mourn 26 death, to socialize, as a relaxant and as a deliriant [1]. Globally, alcohol use is one of the 27 important risk factors for non-communicable human disease [2,3]. The harmful use of alcohol results in around 2.5 million deaths a year, and alcohol consumption is the third 29 highest risk factor for disease and disability. In middle-income countries, alcohol is the 30 biggest risk factor, often related to multiple social problems, including dependence [4]. A 31 reduction in alcohol consumption is associated with lower risk of heart disease and can-32 cer. There are some studies which indicate that moderate alcohol intake has a preventive 33

effect on cardiovascular disease [5] but negative consequences of regular consumption of 34 alcohol often exceed the benefits. Alcohol is addictive, lacks nutrition value and may be a 35 key cultural component in the human obesity dilemma [6,7], but the exact impact is un-36 clear [8,9]. 37 Global consumption of alcohol in 2005 was an average of 6.13 litres of pure alcohol 38 per individual aged 15 years or over with 28.6% of this amount being unrecorded alcohol 39 i.e. illegally produced or homemade or sold outside government controls and jurisdiction [4]. The World Health Organization (WHO) estimates consumption increased to 6.4 litres 41 in 2016, an increase of 4.4% compared to 2005 [10]. Drinking patterns and associated social 42 norms vary between countries and social groups, and, consequently the harmful use of 43

alcohol use [2], six times more per capita than South-East Asia and twenty times more than the Eastern Mediterranean, the region with a high Muslim majority [4]. Cultural norms of abstinence in some communities, often driven by religious beliefs and re-48 strictions, influence the social norms around alcohol consumption [12]. When considering 49 deaths attributed to alcohol, the more significant health burden is with men showing 7.4% 50 of all male deaths being attributed to alcohol consumption compared to 1.4% with women 51 and lower socioeconomic status and educational levels are linked to a greater risk [4.13]. 52 Over a quarter of total alcohol consumed globally is unrecorded, illicit, or otherwise 53

described as unreported [3,10]. The WHO describes unrecorded alcohol as: 54 "alcohol that is not taxed and is outside the usual system of governmental control, 55 because it is produced, distributed and sold outside formal channels" [5] 56

Whilst the proportion of unrecorded alcohol in Europe is about 21.9% of total per 57 capita alcohol consumption, this rises to 56.2% in the Eastern Mediterranean and to 69% 58 of consumption in South East Asia [4,14]. The proportion of unrecorded alcohol as a percentage of total alcohol is as high as 59% in Bhutan, 44.4% in Kuwait, 42.3% in Uganda 60 and 40.1% in the Republic of Moldova [3]. Thus, illicit alcohol sales form a large propor- 61 tion of total sales in many countries, are unregulated and there is an associated public 62 health risk that is worthy of further research. Undertaking an iterative narrative review of 63 literature to draw together academic, contemporary and historic evidence, this paper re-64 views one specific toxicological issue associated with unreported alcohol: methanol con-65 tamination; in order to identify the policy mechanisms of interest that can be explored in 66 further research. A typology of illicit (unrecorded, unreported) alcohol products is created 67 and a policy landscape matrix synthesizes the drivers of illicit (unrecorded, unreported) alcohol production, distribution, sale and consumption in order to inform policy devel-69 opment. 70

2. Illicit alcohol production

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Alcohol is one of the top four most reported fraudulent commodities after meat, seafood and milk [15]. Illicit alcoholic products are a significant health challenge, especially 73 where adulterants, such as methanol, have the potential to cause harm [16,17]. Adultera-74 tion is described here as when a drink contains an additional material, such as methanol, 75 or is adjusted using extraneous, substandard, or inferior ingredients which are often un-76 declared to the purchaser, thus rendering the product fraudulent [18,19]. Activities to cir-77 cumvent religious restrictions, alcohol related taxes, or simply individuals motivated by 78 economic gain to produce and then sell illicit products, has led to the multiple fatal case 79 study incidents that form the focus of this study. False declaration associated with wine 80 is a major issue of concern [20-22]. Adulteration of alcohol includes the non-disclosed use 81 of ethylene glycol and methanol to fortify (raise the alcohol level), and/ or improve taste 82 [23-26]. However, despite improved detection methods [27-29], the adulteration of alcohol 83 products remains a concern at local, national and international scales. The 2018 European 84 Union (EU) Report on the EU customs enforcement of intellectual property rights (IPR) 85 shows that there has been a significant increase (>50% increase compared to 2016) in the 86 numbers of alcohol beverages detained at the EU border in 2017 [30]. The Republic of 87 Moldova was the main country of provenance for alcoholic beverages suspected of in-88 fringing one or more intellectual property rights (IPR) arriving in the EU. 89

Traditionally, discussion on the food safety issues associated with alcoholic bever-90 ages has focused on chemical and physical food safety hazards such as glass or metal from 91 the processing line. Carcinogenic components in alcoholic beverages, such as acetalde-92 hyde, ethyl carbamate, formaldehyde, and acrylamide are of concern as well as heavy 93 metals being present [31,32]. However, one of the main concerns is methanol and this is 94 now considered. 95

Homemade or informally produced alcoholic beverages are mostly fermented bev-96 erages made from sorghum, millet, maize, rice, wheat or fruits [4]. Methanol can be pro-97 duced in the fermentation process and its presence along with ethanol in distilled spirits

alcohol disproportionately affects certain individuals, families and communities more 44 than others [11]. In 2015, European regions had the highest prevalence of heavy episodic 45

might be a health hazard [26]. The consumption of methanol causes not only death, but 99 also blindness [24], although, the problems usually stem from illegal methanol addition 100 to spirits [alcoholic drinks]. Methanol is also a raw material found in a variety of products 101 including anti-freeze, solvents, paints, varnishes [25,26], hand sanitizer, cough mixtures, 102 rubbing products and mouthwash, so if these products are intentionally consumed, it can 103 prove fatal. Antifreeze, windscreen wash fluid and other products containing ethylene 104 glycol and methanol are low cost [24] compared to alcohol and freely available globally. 105 Direct consumption of alcohol-based products has also led to fatalities including con- 106 sumption of cologne/perfume [33,34]; bath lotion [35]; methylated spirits [36] and direct 107 consumption of windscreen wash fluid [37]. In their research from 1992-2001 in Turkey, 108 Yayci et al. [33] note a gender influence with methanol poisoning with men having the 109 predominant fatalities (89.1%) compared to females (10.9%). In Africa, methanol poison- 110 ing from illicit alcohol production and sale is a particular health concern [23,38,39,40]. In 111 1963 in Spain, methanol was used to adulterate mixed alcohol liqueurs and this incident 112 led to fifty-one deaths [41]. However, this issue is also a contemporary challenge as in Iran in 2018, seventy-six people died, 460 were hospitalized and 768 were made ill from a methanol poisoning incident [42]. These illicit alcohol products are made in a domestic setting 115 or in semi-industrialized illegal stills [23] and during the COVID-19 pandemic, some false 116 and misleading information about the positive effect of drinking alcohol on preventing or 117 curing a possible infection was disseminated in (social) media [43]. This resulted in a 118 methanol related mass poisoning outbreak in Iran, where nearly 300 people died in March 119 2020 [44]. For a wider perspective of the impact of methanol poisoning, a search of academic and grey literature to determine public health incidents (n=68) associated with 121 methanol related poisoning is synthesized in Table 1. This table has been collated before 122 the COVID-19 outbreak so that the potential impact of the pandemic on the supply chain 123 and social behavior is excluded from the analysis. 124

Country	Year	Incident	Casualties	Source	
Spain	1963	Methanol used in mixed alcohol li- queurs	51 died	41	
apua New Guinea	1978	Mixture of methanol and isopropanol	369 ill; 4 irreversibly blinded; 18 died	26; 36	
Italy	1986	Methanol adulterated wine	90 hospitalized; 23 died	45	
Cambodia	1998	Methanol poisoning	>400 ill; 60 dead	46	
China	1998	Methanol poisoning	>200 ill; 27 died	28; 34	
India	1998	Methanol poisoning	97 cases; 28 died	26	
Madagascar	1998	Methanol poisoning	200 died	47	
Serbia	1998	Methanol poisoning	>90 ill; 43 died	28; 34	
Bangladesh	1999	Methanol poisoning	121 died	34; 46	
Kenya	1999	Methanol poisoning	24 died	34; 46	
Bangladesh	2000	Methanol poisoning	>100 ill; 56 died	28;46	
Canada 2000		Methanol poisoning	>12 ill; 2 died	34	
El Salvador 2000		Methanol poisoning from low quality alcohol	>200 ill; 117 died; 19 ill; 19 died	28; 34; 46	
Estonia (Pärnu)	2001	Illegal spirits with 50% to 100%	154 ill; 68 died	26; 28; 34;48	
India	2001	Methanol poisoning	>120 ill; 27 died	28; 34	
Kenya	2001	Methanol poisoning	120 died	34; 46	
Madagascar	2002	Methanol poisoning	40 ill; 11 died	28; 46; 47	
Norway	2002-2004	Methanol poisoning	59 ill; 17 died	28	
Saudi Arabia	2002	Methanol poisoning	19 died	34; 46	
Taiwan	2002	Methanol poisoning	9 died	34	
Botswana	2003	Methanol poisoning	>45 ill; 9 died	28; 34	

Table 1. Examples of toxic methanol incidents (1963-2020) highlighted in the academic literature and the media search (n=68) 125

Tunisia	2003	Methanol poisoning	16 ill; 3 died	26
Iran	2004	Methanol poisoning	62 ill; 17 died	28; 34
Kenya	2004	Methanol poisoning	23 died	34
Turkey	2004	Methanol poisoning	21 died	34
Kenya	2005	Methanol poisoning	174 ill; 49 died	28; 34
Russia	2005	Methanol poisoning	33 died	34
Turkey	2005	Methanol poisoning	23 died	34
Iran	2006	Methanol poisoning	42 ill; 6 died	34
Nicaragua	2006	Methanol poisoning	801 ill; 48 died	28; 34
Russia	2006	Methanol poisoning (2 incidents)	60 ill; 3 died; 13 died	28; 34
India	2008	Methanol poisoning	285 ill; 150 died	28; 34
Mongolia	2008	Methanol poisoning	>32 ill >11 died	34
India	2009	Methanol poisoning	63 ill; 20 died >275 ill 136 died	28; 34
Indonesia	2009	Methanol poisoning	45 cases; 25 died	28; 34
Uganda	2009	Methanol poisoning	77 ill; 27 died; 189 ill; 89 died	28; 34
Cambodia	2010	Methanol poisoning	17 died	34
India	2010	Methanol poisoning	10 died	34
Indonesia	2010	Methanol poisoning	5 ill; 3 died	34
Kenya	2010	Methanol poisoning	>17 died	34
Uganda	2010	Methanol poisoning	189 ill; 89 died	34
Ecuador	2011	Methanol poisoning	>770 ill; 51 died	28; 34
Haiti	2011	Methanol poisoning	40 ill; 18 died	28; 34
India	2011	Methanol poisoning (multiple inci-	>370 ill; 170 died; >167 ill; 143 died; 100 ill;	28; 34
		dents)	31 died	
Kenya	2011	Methanol poisoning	29 died	34
Russia	2011	Methanol poisoning	19 ill; 4 died	34
Sudan	2011	Methanol poisoning	>137 ill; 71 died	28, 49
Turkey	2011	Methanol poisoning	22 ill; 5 died	34
Cambodia	2012	Methanol poisoning from contamina-	367 ill; 300 hospitalized; 49 people died	28; 34
		tion of rice wine	· · · · · · · · · · · · · · · · · · ·	
Czech Republic	2012	Methanol poisoning	121 hospitalized; 41 deaths	50; 51
Honduras	2012	Methanol poisoning	48 ill; 24 died	28; 34
India	2012	Methanol poisoning	37 ill; 17 died; 100 ill; 31 died	34
Iran	2013	Methanol poisoning	694 ill; 8 died	28
Libya	2013	Methanol poisoning from illegal alco-	1066 ill; 101 deaths	25
, in the second s		hol		
Pakistan	2013	Methanol poisoning from illegal alco-	8 deaths	25
		hol		
Kenya	2014	Two incidents of methanol poisoning	Incident 1 - 341 ill; 100 dead; Incident 2 -	25
,		1 0	126 ill; 26 dead	
Nigeria	2015	Methanol poisoning from a locally	89 dead	51
0		beverage.		
Turkey	2015	Methanol poisoning	32 dead	26
Russia	2016	Methanol poisoning from consump-	57 hospitalized; 49 died	35
		tion of bath lotion	* · ·	
Iran	2018	Methanol poisoning Sept 7 – Oct 7	768 ill; 460 hospitalized; 76 died	42
		2018		
Malaysia	2018	Methanol poisoning from counterfeit	45 died	53
		alcohol		
India	2019	Methanol poisoning	130 died	53
Costa Rica	2019	Methanol poisoning	20 died; 45 ill	54

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Table 2. Typology of illicit (unrecorded, unreported) alcohol production (Adapted from 63-65)

Product type	Legal products		Illegal products		Surrogate products	
Product examples	Homemade or informally produced alcoholic beverages <u>or</u> Product smuggled from country where product was legal to an alter- native market		Counterfeit or informally produced product		Antifreeze, bath lotion, cologne, methyl- ated spirits, mouthwash, windscreen wash	
Product description	Home-made and legal for home consumption but not for sale	Legal in country of production but not in coun- try of consump- tion	Illegally pro- duced in coun- try of consump- tion at home or larger scale manufacturing	Illegally produced in country of produc- tion and transferred illegally (smuggled) to country of con- sumption	Legally produced in country of con- sumption but not for human con- sumption	Legally produced in country of consump tion but not for hu- man consumption and then exported
Distribution	Within national boundaries	Across borders	Within national boundaries	Across borders	Within national boundaries	Across borders

4. Results

Within the typology there are three categories where illicit alcohol is produced, dis-175 tributed, sold and consumed: legally produced products that can then access an alternative or illicit market/supply chain; illegally produced products that can be sold in an al-177 ternative supply chain or can pass into a legal supply chain and thirdly surrogate products 178 that are not produced for human consumption. It is worth noting that production of illicit 179 alcohol is often carried out in unhygienic and uncontrolled conditions, and contra-180 band/smuggled alcohol products are beyond the safeguards of the official control of im-181 ported foodstuffs. Workers in facilities producing illicit alcohol, and the general public in 182 the area, can be exposed to the risk of industrial accidents e.g. explosion [66]. So having 183 described the typology how can governance frameworks be developed to address with 184 regard to illegal alcohol production and sales? 185

There is a strong economic driver for individuals and organizations to engage in il-186 licit practices [16]. Factors that frame and incentivize this activity include weak public and 187 private institutions, corruption, low Gross Domestic Product (GDP), a low tax morale, 188 high taxes or complex tax systems [67,68] and the price differential between illegal and legal alternatives [68]. The classic "fraud diamond" model proposes that four factors influence the potential for illicit behavior: motivation, capability, opportunity and pressure 191 [69]. The main **motivation** for illicit behavior may be the economic gain derived, to cir-192 cumvent cultural or religious restrictions on access to alcohol and/or to support an indi-193 vidual's own alcohol dependence. Capability i.e. the ability of an individual or organiza-194 tion to undertake deceptive activities requires both the knowledge and equipment to pro-195 duce alcohol for home use, evading the associated taxes and excise duty, or otherwise to 196 distribute and sell illicit alcohol. The **opportunity** to supply illicit alcohol, either to them-197 selves or others, is also a factor of influence and such opportunity is mediated by the level 198 of regulatory governance in particular countries. Thus, there are both economic and social 190 drivers of illicit alcohol production, distribution, and sale and these form **pressure** that 200 leads to the development of socio-economic networks with inter-related strategies, activities, and dynamic components that drive illicit alcohol consumption or other forms of alcohol-based product abuse [70]. In order to understand these drivers and their interre-203 lationship in more depth, a conceptual policy landscape matrix has been postulated (Fig- 204 ure 1) that illustrates the interaction between capabilities, motivations and opportunities 205 and factors such as access, culture, community norms and behavior, economic drivers and 206 knowledge and information. Pressure was not taken into consideration as a single issue 207 here, but seen to be embedded implicitly in all aspects of the policy landscape matrix. The 208 matrix provides an opportunity to consider policy implications for reducing illicit alcohol production, distribution, sale and consumption, policy measures that could be employed 210

Dominican Republic	2019	Methanol poisoning (ten tourists in	Around 10 deaths	55
		twelve months)		
Malaysia	2019	Methanol poisoning (3 clusters)	6 died; 19 ill	56
Iran	2020	Methanol poisoning as the result of	296 died, 2197 ill; 824 hospitalized	57
		Covid-19 Outbreak		

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This historic and contemporary evidence positions the social and economic impact of illicit alcohol supply where methanol is the key adulterant. The next section of the paper considers the methodology used and how to create a typology for illicit alcohol products. 130

3. Materials and Methods

The aim of this iterative narrative review is to critique existing literature and frame 132 the context of illicit (unrecorded) alcohol production that are emergent from the academic 133 and grey literature searches. A case study based narrative is developed to identify the 134 nature of the incident, country, year incident occurred, and the number of casualties (Ta-135 ble 1). The cases are designed to be qualitative and indicative rather than a quantitative 136 representation. Search terms such as "alcohol AND illegal AND unreported AND methanol AND deaths AND casualties" were used to create a snowball academic literature 138 review until data saturation was reached i.e. no more incidents could be found or further 139 material did not add to the emergent narrative or evidence base. The search was undertaken in the English language only. This is a limitation of the study because in many coun-141 tries where methanol poisoning is a public health issue, English is not the first language. 142 However, the common language of the researchers was English. Further work could be 143 undertaken in the future extending the search string and then searching in a range of lan-144 guages. The databases used in the search were Science Direct, Google Scholar and Google 145 for the grey literature sources. There was no limitation on age of source in the search, but 146 relevance was considered and any sources deemed not to be relevant were excluded. The 147 case study approach allows for a more holistic enquiry that seeks to be exploratory, explanatory and descriptive [58] in order to drive a causal investigation [59]. Case study 149 analysis is an accepted method for considering business fraud [60-62]. A limitation of this 150 approach is the risk of selection bias and this is considered in the analysis of the findings. 151

The second stage was to develop a typology of illicit alcohol products. The typology 152 uses four categories. Illicit alcohol products can be summarized as four main categories: 153 (1) illegally produced or smuggled alcohol products (including illegal homemade alco- 154 hol); (2) alcohol products that are legitimate, but not in the jurisdiction of their consumption: (3) legal but homemade, and (4) surrogate non-beverage alcohol products not in-156 tended for human consumption e.g. industrial alcohol, or alcohol based mouthwash, per-157 fume etc. [63,64]. These characterizations focus on the products themselves rather than 158 considering their modes of distribution. Illicit trade can also be considered in terms of 159 both the product (legal/illegal) and the modes of distribution (legal/illegal; within borders or cross borders) i.e. (1) legal products being illegally distributed within national bound-161 aries; (2) illegal products being distributed within national boundaries; (3) legal products 162 being illegally distributed across borders; and (4) illegal products being distributed across 163 borders [65]. Based on these elements and the incidents in Table 1, a typology has been 164 developed (Table 2) that extends product type and product description and considers 165 mode of distribution either within national borders or between countries. 166

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at the state (public) and the market (private) level and the potential data sources (signals)	211
that can arise.	212
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Figure 1. Drivers of illicit alcohol production, distribution, sale and consumption, policy measures and activity related signals (Adapted from: 38, 65, 70-75)

Policy Landscape Matrix

C	Capabilities	Motivations	Opportunities	Policy Measures	Activity Related Signals
cheap r to-use duo Simplio Simp tion/co	access to relatively materials and easy- technology to pro- ce illicit alcohol city of illicit alcohol duction method olicity of adultera- ounterfeiting of al- ohol products	Historical evidence of illicit alcohol production by individuals and pres- ence of production, distribution and sale infrastructure in a given culture The consumer is usually unable to check the authenticity/legality of alco- hol products so illicit activity is likely to go undetected Introducing ban on the sale of alcohol products not supported by cultural values Legislative framework e.g. markets with weak laws, or where laws may be strong but the penalties weak, or where the police/judiciary do not ef- fectively enforce existing laws A lack of enforcement of laws	Accessibility to materials Availability of production tech- nology Availability [or not] of detection technology Accessibility of illcit alcohol in- frastructure Transparency of supply chain net- work Ineffective regulatory and market surveillance, monitoring and veri- fication programs that fail to re- duce opportunities for illcit be- havior	Effective regulatory and market surveillance, moni- toring and verification programs Implementing product testing programs Product authenticity screening tests incl. metha- nol detection tests Regulatory activity to ra- duce accessibility to mate- rials that can be used to produce illicit alcohol Grograms to undertake trend analysis of the inci- dence of illicit alcohol deaths and related illess Programs to identify the procurement of suspect materials likely to be used in illicit activity	Cost of materials that can be used to produce illicit alcohol Historical data on incidence of illicit alcohol production Data from monitoring and surveil- lance programs Data from border surveillance activ- ity e.g. RASFF (Rapid Alert System for Food and Feed) Trend analysis data of incidence of il- licit alcohol deaths and related illness Market analysis to identify incidents of procurement of suspect materials likely to be used in illicit activity

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Culture, community norms and penavior	cohol production in many communities (influence of media, and informal com- munication channels) Whistleblowing may oc- cur in the illicit alcohol in- dustry but is not common Community acceptance of illicit behavior for income generation	Business strategy Community norms codified in public policies, laws and regulations Community norms codified in infor- mal standards and codes Corruption level Enforcement of formal policies (effec- tive compliance checks and adequate penalties) Negative effect of globalization on Muslim countries cultural norms con- cerning alcohol Subculture of illicit alcohol drinking Victimization Widespread homemade alcohol Alcohol dependence Destructive behavior	quaintances (friends, relatives) producing homemade alcohol and/or consuming alcohol surro- gates The (special) place of alcohol in the culture of each nation Functions which alcohol products fulfil (physiological, psychologi- cal, social and cultural, economic and political)	economic and social condi- tions of communities neighborhoods	 Social data on use of alcohol at the community or household level Data on the level of alcohol dependence Hospital and public health data on cases Economic status at personal, household and community level Population movement Kin and friendship networks, Demographic composition Involvement in community organizations and political processes Educational status, and nature of the local business community
ECONOBILC drivers	Household disposable in- come The cost of the infrastruc- ture and its operation Price of equipment Price of materials Labor intensity	Level of competition Per capita income Price of licit alcohol (including taxes) resulting in economic availability Price of materials Restrictions on retail availability Price differences in and between coun- tries	The production of illicit alcohol/ adulteration of alcohol provides opportunities for rising income (corporate income, household in- come etc.)	Targeting alcohol availa- bility through implement- ing purchase taxes Implementing pricing in- terventions for licit and il- licit alcohol and reducing the legal loop-holes that	Affordability of legal alcohol Household income Price differential between legal and illicit alcohol Price of equipment and materials used to produce illicit alcohol Price differential between countries

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	Time consumption of the process of illicit alcohol production			allow producers, distribu- tors and sellers of illicit al- cohol to flourish Using taxation in health- oriented alcohol policy	Public health data on cost to econ- omy of associated ill-health
				such as specific tax rates or the use of Minimum Unit Pricing (MUP)	
dge, informa	The knowledge to make illicit or homemade alco- hol handed down from one generation to the next The influence of social media and informal chan- nels which facilitates com- munication and exchange of information	Sharing of knowledge/expertise Sharing of information that allows in- dividuals to make illicit alcohol The public perception that illicit alco- hol production (including moonshine and homemade alcohol) is not a bad thing Low awareness of the risks coming from consuming illegal alcohol	Availability of information Availability of knowledge to make homemade alcohol The production of hooch/bootleg alcohol/moonshine might be closely linked with the history, traditions and culture of the re- gion	Public health programs on the health issues associ- ated with alcohol and il- licit alcohol consumption Industry guidance on the measures to take to reduce the risk of purchasing il- licit alcohol Guidance focuses specifi- cally on young people with regard to the dangers of illicit alcohol	Survey results on level of consumer awareness of illicit alcohol consump- tion

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The policy implications are addressed in the four areas of the policy landscape matrix 221 (Figure 1): with policy measures related to access, knowledge and information, economic 222 drivers, and culture, community norms and behavior and these are now considered in 223 turn. 224

Access related policy measures

Effective regulatory and market surveillance, monitoring and verification programs 226 reduce opportunities for illicit behavior to remain undetected. Policy measures such as 227 implementing product testing programs as part of a wider policy initiative will identify 228 harmful alcohol at the point of production, sale or distribution. Non targeted product authenticity screening tests are of value as well as targeted adulterant specific testing such 230 as for the presence of methanol [77,78]. A coordinated surveillance program is required 231 across specific trading areas such as the EU, otherwise if one member state is contributing 232 less to systems such as the RASFF database; or there is a variance in national arrangements 233 of food control systems (in accordance with "Official Control Regulation"), this will cre-234 ates the possibility for a member state to become a "back door" for allowing illicit alcohol 235 products to then have free movement of food within the EU [79,80]. Regulatory activity 236 to reduce accessibility to materials that can be used to produce illicit alcohol should be 237 introduced as well as programs to identify the procurement of suspect materials likely to 238 be used in illicit activity. Further as part of wider public health surveillance there should 239 be programs adopted to ensure trend analysis of the incidence of illicit alcohol deaths and 240 related illness through integration of public health data from hospitals and the commu- 241 nity. 242

Knowledge and information related policy measures

Following the methanol poisoning in Iran in 2018, Aghababaeian et al. [42] state that 244 incidents often occur in low-income Islamic countries and so effective educational pro-245 grams are required to raise public awareness of the health issues involved. These pro-246 grams can use a range of media and communication channels to explain the dangers of 247 production, consumption, distribution and sale of illicit alcohol. Abramowicz et al. [81] 248 underline in their study that activities undertaken via education/ prevention schemes 249 should be aimed at a particular group of consumers, appropriately profiled and fully tai-250 lored to their needs. Growing children and adolescents are a key target group here since 251 they often undertake new forms of behavior and experimentation, including using alco-252 hol, in order to determine their place in the society [82]. 253

Industry guidance on the measures to take to reduce the risk of purchasing illicit 254 alcohol is also important. Shapira et al. [83] in their study on methanol levels in illegal 255 alcoholic beverages sold in a low socio-economic area of Tel-Aviv state there is a need to 256 inform shopkeepers about labeling regulations, and "make information and health warn-2.57 ings accessible to the foreign-born population residing in the area," i.e. that information 258 must be accessible, context specific and available if required in a range of languages. The 259 more alcohol marketing that young people are exposed to, the more alcohol they will con-260 sume, indeed restrictions on access to alcohol for young people may actually promote this 261 illicit parallel market [84], creating an "underground economy" as demand remains the 262 same, but can no longer be met through legal supply routes. 263

Economic related policy measures

Economic related policy measures that have, or could be adopted include: targeting alcohol availability, implementing purchase taxes [38], implementing pricing interventions for licit and illicit alcohol and reducing the legal loop-holes that allow producers, distributors and sellers of illicit alcohol to flourish [71]. In Europe, there is a long-standing debate about the effectiveness of using taxation in health-oriented alcohol policy such as specific tax rates or the use of Minimum Unit Pricing (MUP) [76] as have Australia and 270

 the UK including Scotland [85]. In Canada, Social Reference Prices (SRPs) for alcoholic
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 beverages i.e. "floor" or "minimum" prices for a given "unit" or "standard drink", have
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 been set [86]. As inter alia alcohol tax regimes vary across territorial domains and product
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 categories, this leads to differential pricing of similar products between markets, and be 274

 tween products categories within a given market. This might increase the incentive for
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 illicit behavior.
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The main opposition to this policy approach comes from the alcohol industry and 277 free-market-oriented think tanks [85]. Transnational alcohol corporations, in contrast to 278 tobacco corporations in their market sector, continue to have a significant impact on alco-279 hol policy globally [76,87,88]. As a rule, consumption of licit alcohol declines as price in-280 creases [72]. Consumption of illicit alcohol may grow as licit alcohol price increases, how-281 ever, raising taxes on licit (recorded) alcohol together with reinforcing measures against 282 unrecorded alcohol might lead to a decline in total alcohol consumption. Moreover, when 283 restrictions are placed on the retail availability of licit alcohol, whilst consumption of licit alcohol decrease [72], consumption of illicit alcohol may increase unless the protection 285 against unrecorded alcohol sale and consumption is strengthened. Furthermore, produc-286 ers of illicit alcohol tend to increase prices when recorded alcohol beverages prices are on 287 the rise. These phenomena limit the effectiveness of economic policy measures and make 288 it hard to find the optimum fiscal solution. 289

Culture, community norms and behavior related policy measures

Illicit alcohol use, as with drug use, is associated with specific social networks, so 291 social causation and neighborhood mitigation processes may discourage illicit alcohol use 292 [73]. Madureira-Lima and Galea [89] created an Alcohol Control Policy Index (ACPI) in- 293 cluding policies from the WHO's Global Strategy to Reduce the Harmful Use of Alcohol. 294 These are leadership, awareness, and commitment; health services' response; community 295 action; drink driving policies and countermeasures; availability of alcohol; marketing of 296 alcoholic beverages; pricing policies; monitoring and surveillance, reducing the negative 297 consequences of drinking and alcohol intoxication; and the focus of this study, reducing the public health impact of illicit alcohol and illegally produced alcohol. In Iran, nine out 299 of the ten policy measures have been introduced, excluding pricing policy [90]. However, 300 some communities, especially low-income groups, have an innate cultural relationship 301 with illicit alcohol consumption and in these social groups addressing illicit alcohol within 302 a wider alcohol management plan is of value [91,92]. Thus, for policies to be effective they 303 need to reflect the social context in which they are adopted. 304

Early warning systems (EWS) to reduce illicit alcohol sale and consumption

The development of an EWS is an essential policy measure to mitigate against illicit alcohol sale and consumption. EWS allow health officials to be alerted so they can minimize the health impact of an illicit alcohol or methanol incident on the population. Recognizing the types of signals of concern underpins the development of an EWS for illicit alcohol sale and consumption. Some signals may be weak i.e. imprecise early indicators of an impending event or they may provide stronger evidence of a potential incident [93,94]. The process of developing an EWS can be broken down into the following elements:

Monitoring phase – considering specific criteria and ensuring the data can be collected and is of the required granularity; 315

Analysis phase – assessing data, indicators, trends in order to be able to differentiate 316 critical events; 317

Prediction phase – depending on the level of criticality, early warning information 318 is generated and communicated to relevant stakeholders; and 319

 Implementation phase – appropriate measures are defined and implemented [95].
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 Signal detection theory reflects the challenging issue of detecting a given signal against a background of noise i.e. in a situation of uncertainty [96]. Signals or indicators
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 can be monitored to determine any trends and if these trends give cause for concern
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 (Phase 1). The analysis phase (Phase 2) requires signals to be assessed to determine any
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associations with other variables e.g. gender, age, location, frequency, distribution, symptoms, duration of illness, severity, and outcome [97]. The policy landscape matrix devel-326 oped in this research requires the translation of discrete signals and their amplification to 327 develop a risk signal. The signal can be characterized by its degree of relevance and also 328 by its strength i.e. the magnitude of evidence, single or multi-dimensional [98]. The signal 329 as a result can be validated to ensure that the information received is sufficient to suggest 330 causal association and support further action based on the information. Thus, regulatory 331 sampling can provide some signals, but other signals will come from both social and eco-332 nomic factors that influence illicit behavior. Signal detection and the wider policy pro-333 gram needs to be linked to sufficient resources that underpin information systems, policy 334 measures and reporting systems designed to reduce the risk of illicit alcohol to public 335 health. 336

In 2018, the WHO launched the SAFER initiative alongside the United Nations third 337 high-level meeting on prevention and control of noncommunicable diseases (NCDs) to 338 provide support in reducing the harmful use of alcohol through: (1) Strengthening re-339 340 strictions on alcohol availability; (2) Advancing and enforcing drink-driving countermeasures; (3) Facilitating access to screening, brief interventions and treatment; (4) En-341 forcing bans or comprehensive restrictions on alcohol advertising, sponsorship and pro-342 motion; (5) Raising prices on alcohol through excise taxes and other pricing policies [99]. 343 The WHO's document suggests eradicating illicit alcohol or bringing it under government 344 control in countries where informal markets are the main source of alcohol. Another sug- 345 gestion is to develop tax policies that make low-alcohol and nonalcoholic variations of 346 culturally preferred beverages more attractive and to introduce tax stamps to show that 347 duty has been paid on informal products. 348

5. Conclusion

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Illegal and unrecorded alcohol and its illicit substitutes lack the regulatory and mar-350 ket oversight that legal alcohol products would have, increasing the risk of safety, quality 351 and fraud issues. As illicit alcohol is produced without the management controls and ver-352 ification systems that are used in the legitimate supply chain, it is a cause of global concern 353 as it presents a clear personal risk to those that consume it. This research has drawn to-354 gether academic, contemporary and historic evidence on the impact of illicit alcohol pro-355 duction, distribution and consumption. The policy mechanisms that can be explored in 356 further research are identified. A typology of illicit alcohol products is created and a policy 357 landscape matrix synthesizes the drivers of illicit alcohol production, distribution, sale 358 and consumption in order to inform policy development. Policy measures are addressed 359 in four areas: (1) access; (2) culture, community norms and behavior; (3) economic drivers; 360 and (4) knowledge and information. Methanol, one of the main agents that causes alcohol 361 related disability or fatality, is shown in this work to be a significant and widely distrib-362 uted concern as a food related toxin with global impact. This public health harm needs to 363 be addressed by concerted action at regulatory and market levels. Further, the level of 364 reported illicit alcohol related health incidents identified in the academic literature, grev 365 literature and media sources described herein has provided strong supporting evidence 366 within a synthesized timeline of the locations and size of this global public health prob-367 lem. 368

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