

RESPONSE TO THE NOTIFICATION OF DRAFT REGULATIONS UNDER SECTION 12 OF THE *PUBLIC HEALTH (ALCOHOL) ACT 2018*. TRIS Notification Number: 2022/441/IRL

SPECTRUM is a research consortium of academic, public health agencies and advocacy partners working together to generate new evidence to inform the prevention of non-communicable diseases (NCDs). SPECTRUM provides a unique overview of NCD prevention strategies including action on price, availability and marketing of tobacco, alcohol and unhealthy food products, and industry influence on health policy. We investigate the conduct and influence of unhealthy commodity industries (UCIs) in driving unhealthy consumption, build understanding of the systems that perpetuate those drivers, and support the prioritisation of political, social and other measures to prevent harm to health and reduce the social health gradient.

SPECTRUM is not linked with, nor does it collaborate or cooperate with members of the alcohol, tobacco or food industries. The SPECTRUM Consortium is funded by the UK Prevention Research Partnership (grant reference MR/S037519/1). UKPRP is an initiative funded by the UK Research and Innovation Councils, the Department of Health and Social Care (England) and the UK devolved administrations, and leading health research charities.

The University of Bath, as a research partner within the SPECTRUM Consortium, focuses research on understanding and addressing the commercial determinants of health with a view to identify relevant public health interventions. A key tenet of research within the department of health is developing and generating evidence to inform policy.

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SPECTRUM supported by the University of Bath welcomes the opportunity to respond to the TRIS notification 2022/441/IRL of Draft Regulations Under section 12 of the *Public Health (Alcohol) Act 2018*. SPECTRUM strongly supports the proposed regulations as set out overleaf.

Under section 12 of the *Public Health (Alcohol) Act 2018*:

Labelling of alcohol products and notices in licensed premises

It shall be an offence for a person to sell, to a person who is in the State, an alcohol product the container of which does not bear in the prescribed form:

- (i) a warning that is intended to inform the public of the danger of alcohol consumption,
- (ii) a warning that is intended to inform the public of the danger of alcohol consumption when pregnant,
- (iii) a warning that is intended to inform the public of the direct link between alcohol and fatal cancers,
- (iv) the quantity in grams of alcohol contained in the container concerned,
- (v) the energy value expressed in kilojoules and kilocalories contained in the container concerned, and
- (vi) details of a website, to be established and maintained by the Executive, providing public health information in relation to alcohol consumption¹.

SPECTRUM supports the Irish government's intention to implement the measures as stated above on the following grounds:

- Protection of Population from Burden of Alcohol Related Harms
- Alignment with EU and Global Policy
- A Consumers right to Know
- Proportionate Measure

Brief History of Policy Context

The approach to alcohol related harm from a public health perspective was first put forward in a report by the Psychiatric Service in Ireland in the early 80s². Following this, the Department of Health assigned responsibility to a Health Promotion Unit for development of up-to-date policy recommendations, which eventually resulted in the National Alcohol Policy Ireland Report (1996), calling for various environmental measures to reduce the level of alcohol related harm³. Progress however proved slow, until rising rates of alcohol harm could no longer be ignored. In 2009, a National Substance Misuse strategy group was formed which subsequently published a seminal report in 2012⁴. This report outlined several recommendations to address the harms associated with alcohol in Ireland. Growing public pressure along with increasing healthcare costs around this time strengthened the Irish government's resolve to formulate adequate alcohol control policies resulting in the proposal of the Public Health (Alcohol) Bill⁵. Despite opposition to the bill, on the 17th of October 2018, the president of Ireland signed the *Public Health (Alcohol) Act 2018* (PHAA) into law¹. The PHAA provides a set of evidence-based measures to reduce alcohol consumption in Ireland, based under the five pillars of Supply Reduction (availability), Prevention, Treatment, Rehabilitation and Research.

Overview of Alcohol Related Harm

Globally

In 2016, The World Health Organization listed alcohol as a cause of approximately 3 million deaths worldwide⁶. Comparative risk assessments from this year, demonstrated that alcohol represents the 7th leading risk factor for all deaths and disability globally, and amongst the 15–49 year old age group, is the primary risk factor for mortality⁷. More than 230 disease

classifications are associated with the harmful misuse of alcohol such as cardiovascular diseases, HIV/AIDS, and tuberculosis⁸. Recent research by Runggay *et al.*⁹, found 4.1% of all new cancers were attributable to the consumption of alcohol. Additionally, the social and economic consequences associated with alcohol use are ever increasing in magnitude⁶, such as an increasing risk of unemployment and absenteeism from employment due to high levels of alcohol consumption¹⁰.

Critical to also acknowledge is the impact of the COVID -19 pandemic on alcohol related harm. Recent figures from the Office for National Statistics (UK) revealed a 19.6% increase in alcohol related deaths in England and Wales in 2020 compared to the previous year. There were 7,423 deaths recorded in total which represents the highest annual level since estimates began in 2001¹¹. In the US, data analysed from the National Centre for Health Statistics, revealed both the amount and rate of alcohol related deaths between 2019-2020 saw a 25% approximate increase¹². The indirect effect of COVID- 19, such as drinking to cope with isolation and interrupted treatment access are also likely to have contributed to this increase in alcohol related deaths^{12,13}. Survey data from Ireland, with 4 in 5 respondents consuming alcohol, reported an increase in alcohol consumption levels particularly in younger adults post the initial Covid lockdown in April 2020¹⁴. As higher levels of alcohol consumption are not immediately reflected in hospital admissions, this raises concern as to the burden of alcohol related harm in the years to come.

While data relating to the overall association between COVID -19 and alcohol related harm is yet to be published, in due course it is reasonable to assume, that the mutually reinforcing relationships between the two epidemics of COVID-19 and alcohol related harm will have exacerbated the ever-growing burden on healthcare systems across the globe and therefore heightens the need for responsive alcohol control policies¹⁵.

Ireland

Data from 2019, revealed per capita consumption of pure alcohol in Ireland was 10.8 litres per adult (aged 15 or over). This volume of alcohol equates to 113 bottles of wine, or 436 pints or 40 bottles of vodka. Survey research, however, shows every 1 in 4 abstains from alcohol, meaning even higher quantities of alcohol are consumed by those who drink. This data revealed that in total 52.3% of Irish people who drink are classified as hazardous drinkers¹⁶. Underage drinking is a stark problem in Ireland with most adolescents consuming alcohol before the legal age¹⁷. A particular concern in Ireland is binge drinking or heavy episodic drinking. A study analysing adolescent health and well-being from 1990-2016, found the prevalence of binge drinking among Irish girls aged 15-19 was more than 55%. Ireland placed third highest in this category out of a total of 195 countries¹⁸. More recent data from the Health Research Board (HRB) highlighted the prevalence of heavy episodic drinking amongst males aged 25-34 years of age was 62.8%, followed by 60.9% for those aged 15 -24 years¹⁶. Figures from 2018, placed Ireland 8th highest on the list of monthly binge drinking out of 194 countries assessed⁶. The dangers of binge drinking, where one consumes more than 6 single drinks on a single sitting, have long been documented and logically the greater the alcohol consumption, the greater risk of disease¹⁹.

The link between alcohol and mental health has also been highlighted in Ireland, with 30% of presentations of self-harm to hospitals relating to alcohol in 2018¹⁶. While the relationship between alcohol and suicide is complex, studies have shown an association between

alcohol use, feelings of depression and risk of suicide^{20,21}. The HRB report found that young adults in the possible dependence category were more likely to have made a suicide attempt¹⁶.

The annual cost to the Irish exchequer of alcohol related harm in 2015 was thought to be upwards of €2.35 billion²³ and the tangible costs to others estimated at €863 million in 2021¹⁶. The estimated tangible costs of alcohol related harm include costs to/from: the healthcare system (€793 million), alcohol related road accidents (€258 million), alcohol related crime (€686 million), accidents at work (€185 million) and premature mortality (€65 million)²².

As it is difficult to quantify the costs to the wider society, the estimated costs are often dismissed and given insufficient acknowledgment. Alcohol related harm extends far beyond the individual drinker to families, children, co-workers, communities, and society as a whole. A report by Hope *et al.* (2018) found domestic problems in the home to be a major side effect, particularly affecting women²³. The children of parents who misuse alcohol are more likely to suffer from mental illness in adulthood, are at a higher risk of displaying antisocial behaviour and more susceptible to form problematic relationships in later life culminating in greater costs to the social and healthcare sectors²⁴⁻²⁶.

To further highlight the extent of alcohol related harm in Ireland, stark figures from the Health Research Board's comprehensive report revealed:

- 1094 alcohol related deaths were recorded in 2017 with >70% of those deaths in the under 65 age group
- 94% increase in hospital discharges related to alcohol from 1995-2018
- 71.6% increase in hospital length of stay due to alcohol related conditions 1995-2018
- 3496 discharges for alcohol liver disease in 2018¹⁶.

Considering all of the above, SPECTRUM firmly supports all provisions of the *Public Health (Alcohol) Act 2018* to address the growing burden of alcohol related harm in Ireland.

Alignment with EU and Global Policy Recommendations

Global

Reducing alcohol related harms holds particular significance within the United Nation's Sustainable Development Goals, in particular SDG 3- 'Ensure Healthy Lives and promote well-being for all at all ages'. Target 3.5 explicitly declares a commitment to strengthen the prevention and treatment of substance abuse, including narcotic drug abuse and harmful use of alcohol²⁷. As signatories to the UN convention, it is our duty to work towards said target.

In 2010, the World Health Organization set out its plan to reduce the harms associated with alcohol use in the 'Global Strategy to Reduce the Harmful Use of Alcohol 2010' report. This strategy aimed to guide action at all levels and recommended several policy options which could be adjusted at the national level to achieve a reduction in the harms associated with alcohol use²⁸. This report presented clear guidance to member states that action must be taken in order to reduce the burden of alcohol related illness.

Reiterating this call, The World Health Assembly in 2013 endorsed the Global Action Plan on NCDs 2013-2020, which aimed for a 10% reduction in the harmful use of alcohol and included a list of 'Best Buys' as cost-effective measures to tackle alcohol harms, updated in 2017^{29,30}. These included:

- Increase excise taxes on alcoholic beverages
- Enact and enforce bans or comprehensive restrictions on exposure to alcohol advertising (across multiple types of media)
- Enact and enforce restrictions on the physical availability of retailed alcohol (via reduced hours of sale)
- Enact and enforce drink-driving laws and blood alcohol concentration limits via sobriety checkpoints
- Provide brief psychosocial intervention for persons with hazardous and harmful alcohol use
- Carry out regular reviews of prices in relation to level of inflation and income
- Establish minimum prices for alcohol where applicable Enact and enforce an appropriate minimum age for purchase or consumption of alcoholic beverages and reduce density of retail outlets
- Restrict or ban promotions of alcoholic beverages in connection with sponsorships and activities targeting young people
- Provide prevention, treatment and care for alcohol use disorders and comorbid conditions in health and social services
- Provide consumer information about, and label, alcoholic beverages to indicate, the harm related to alcohol.

Appreciating Ireland's *Public Health (Alcohol) Act 2018* as a whole, its provision are closely aligned with WHO's mandate, and in particular significance to the Draft Regulations under Section 12 of the *Public Health (Alcohol) Act 2018* to '*Provide consumer information about, and label, alcoholic beverages to indicate, the harm related to alcohol*'.

Subsequent to the guidance on 'Best Buys', the WHO published its SAFER initiative in 2018 to reduce morbidity and mortality caused by the harmful use of alcohol using, evidence-based and cost-effective interventions³¹:

- **Strengthen** restrictions on alcohol availability
- **Advance** and enforce drink driving counter measures
- **Facilitate** access to screening, brief interventions, and treatment
- **Enforce** bans or comprehensive restrictions on alcohol advertising, sponsorship, and promotion
- **Raise** prices on alcohol through excise taxes and pricing policies

Again, this initiative, reinforced Ireland's decision to implement evidence-based and cost-effective interventions to reduce levels of alcohol related harm through the provisions of the *Public Health (Alcohol) Act 2018*.

Recent developments in global alcohol policies directives saw the publication of the Draft Action Plan (2022-2030) to effectively implement the global strategy to reduce the harmful use of alcohol as a public health priority³². Key action areas incorporated within this plan include:

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- Action Area 2: *'On the basis of evidence of the nature and magnitude of alcohol-attributable public health problems, advocate for the development and implementation of high-impact strategies and interventions and other actions to prevent and reduce alcohol-related harm. This includes placing a special emphasis on protecting at-risk populations and those affected by the harmful drinking of others; preventing the initiation of drinking among children and adolescents; preventing drinking in pregnancy; and preventing FASDs, including by providing information about the risks of drinking when planning pregnancy or breastfeeding'*
 - Action Area 8: *'Ensure appropriate consumer protection measures through the development and implementation of labelling requirements for alcoholic beverages that display essential information for health protection on alcohol content in a way that is understood by consumers and also provides information on other ingredients with potential impact on the health of consumers, caloric value and health warnings.'*

This mandate further substantiates and reinforces the necessity to implement Ireland's Draft Regulations under Section 12 of the *Public Health (Alcohol) Act 2018*.

European Level

For several years, the WHO European Region has promoted alcohol policy initiatives in an attempt to address alcohol consumption levels and associated harms. Evidence dates back to 1995 as outlined in the European Charter on Alcohol calling for member states to *'inform people of the consequences of alcohol consumption on health, family and society and of the effective measures that can be taken to minimize harm'*³³. The European Alcohol Action Plan 2000-2005, proceeded to set out practical measures for achieving the aim of reducing alcohol related harm in a call for action to *'ensure that regulations governing the alcohol content, packaging and marketing of alcoholic products lay down product safety standards, prohibit false claims and provide relevant warnings'*³⁴. A particular concern to the region was surrounding alcohol and young people which prompted the Declaration on Young People and Alcohol adopted in 2001³⁵ with member states declaring comprehensive dedication to reducing alcohol-related harm in young adults.

In 2006, an EU strategy to support Member States in reducing alcohol related harm set out a number of aims including: *'To provide information to consumers to make informed choices'* and *'To increase EU citizens' awareness of the impact of harmful and hazardous alcohol consumption on health, especially the impact of alcohol on the foetus, on under-age drinkers, on working and on driving performance.'* In the rationale for said aim the commission explicitly stated:

*"Citizens have the right to obtain relevant information on the health impact, and in particular on the risks and consequences related to harmful and hazardous consumption of alcohol, and to obtain more detailed information on added ingredients that may be harmful to the health of certain groups of consumers"*³⁶.

The European Commission, in discussions around the mandatory labelling of alcoholic beverages, later stated that *'the Commission has not identified objective grounds that would*

justify the absence of information on ingredients and nutrition information on alcoholic beverages' ³⁷.

Following a synthesis of evidence from the WHO European region on current labelling practices (2020), the primary policy considerations to achieve a reduction in the harms associated with alcohol included but not limited to³⁸:

- establish labelling that includes all recommended nutritional values and lists all ingredients.
- establish labelling that includes the harm done by alcohol relevant to the whole population (e.g., cancer), pregnancy-related harm, harm to minors, drinking and driving warnings, and recommendations on lower-risk drinking guidelines indicated as standard drinks in countries where this would be applicable.
- favour mandatory regulation over voluntary commitments

A recent communication from the commission titled '*Europe's Beating Cancer Plan*' (2021) signalled a renewed political willingness to implement adequate alcohol policies to curb alcohol related illness. A specific commitment was made to '*propose a mandatory indication of the list of ingredients and the nutrition declaration on alcoholic beverage labels before the end of 2022 and of health warnings on labels before the end 2023*'³⁹. This commitment was echoed at the 9th European Alcohol Policy Conference (2022) attended by policy makers, researchers, and civil society organisations.

Following the 72nd Regional committee meeting of the World Health Organization in Europe (September 2022) member states have unanimously agreed to adopt the '*European Framework for Action on Alcohol, 2022-2025*'. This framework sets out 6 priority areas necessary to achieve the target of a 10% relative reduction in alcohol per capita consumption by 2025 and targets 3.4 and 3.5 of the Sustainable Development Goals while contributing to the effectuation of the European Programme of Work, 2020–2025⁴⁰.

A salient priority area set out by the framework includes:

'Health information, with a focus on labelling:

- Independent mandating, monitoring and enforcement, working in the interests of public health and consumer rights and free from influence or interference from corporate interests
- Statutory labelling, informed by WHO guidance, including nutrition and ingredients and health warnings
- If self-regulation is permitted, requirements that the advice of independent and nationally recognized public health agencies has been sought and followed
- Research to understand the effects of health warning labels
- Consideration of principle of a statutory "right to know" in relation to alcohol content and risks'

In light of the above, Ireland's Draft Regulations under Section 12 of the *Public Health (Alcohol) Act 2018* are undeniably in harmony with current EU and global guidelines.

Countries already working towards reducing alcohol related harms through the use of health warning labels include Australia and New Zealand who are currently implementing a

pregnancy warning label⁴¹, and South Korea is required to label alcohol products from a choice of three messages, two of which list cancer risk⁴².

In France, Alcohol beverages must also carry a statement highlighting that consumption of alcoholic drinks during pregnancy, even in small amounts, can seriously damage a child's health or a pictogram indicating the dangers of drinking when pregnant. In Ireland, alcohol product labels must feature: health warnings about the danger of alcohol consumption; health warnings about the danger of drinking alcohol when pregnant; health warnings about the direct link between alcohol and cancers; details of a government public health website; the quantity in grams of alcohol contained in the container; and nutritional info (KJ and Kcal). Additionally, in Lithuania, alcoholic beverages must be marked with warning graphics regarding the harm alcohol can cause to pregnant women^{43,44}.

Preservation of Consumer Rights

Ireland's Draft Regulations under Section 12 of the *Public Health (Alcohol) Act 2018* rely on the protection of the rights of consumers established on public health grounds as enshrined in the Treaty on the Functioning of the European Union⁴⁵. Article 168 states: '*A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities*'. The union elaborates on this goal, stating that '*union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health.*'

Included in this article the Union also states that: '*The European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, may also adopt incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health, and measures which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol, excluding any harmonisation of the laws and regulations of the Member States.*'

As evidenced above, the promotion of public health is integral to the functioning of the European Union. In line with this objective Ireland has proposed measures to improve population health, prevent alcohol related illnesses and to counter risk factors associated with alcohol related harm (i.e., insufficient health warnings).

Consumer protection embodies a fundamental objective within the TFEU, as declared in Article 169 - '*In order to promote the interests of consumers and to ensure a high level of consumer protection, the Union shall contribute to protecting the health, safety and economic interests of consumers, as well as to promoting their right to information, education and to organise themselves in order to safeguard their interests.*'

Article 169 also provides that member states adopting regulations to support consumer protection, in accordance with and to supplement policies pursued by the union shall not be prevented from- '*maintaining or introducing more stringent protective measures. Such measures must be compatible with the Treaties. The Commission shall be notified of them.*' Ireland, therefore, has submitted it's Draft Regulations under Section 12 of the *Public Health (Alcohol) Act 2018* in perfect alignment with EU directives in both the protection of public

health and the consumers right to know.

To further corroborate Ireland's draft regulations, it is necessary to acknowledge the treatment of alcohol as a consumable 'food' product within EU law as stated within the general principles and requirements on food law⁴⁶.

*'Definition of "food"- For the purposes of this Regulation, "food" (or "foodstuff") means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans. "Food" includes drink'*⁴⁶.

Article 8 of the general principles and requirements on food law upholds the protection of consumer interests in declaring that *'Food law shall aim at the protection of the interests of consumers and shall provide a basis for consumers to make informed choices in relation to the foods they consume.'* However, alcoholic beverages, under EU law, which contain more than 1.2% of alcohol by volume, are exempt from compulsory declaration of the ingredients list and nutritional information contained within⁴³.

Considering the classification of alcohol as a food product, it therefore should fall under the same EU regulations that all other products defined as food do. An exemption based on alcoholic volume is in direct conflict with food safety regulations in neither protecting the interests of the consumer nor enabling consumers to make informed choices.

Notwithstanding this exemption, salient legislation regarding food information to consumers (FIC), substantiates Ireland's Draft Regulations under Section 12 of the *Public Health (Alcohol) Act 2018*. Under FIC member states have an obligation to provide consumers with sufficient nutritional information to make informed choices, with a view to promoting public health across the Union: *'the provision of food information shall pursue a high level of protection of consumers health and interests by providing a basis for final consumers to make informed choices and to make safe use of food, with particular regard to health, economic, environmental, social and ethical considerations.'* Article 4 of the FIC sets out the principles governing mandatory food information:

- Information on the identity and composition, properties or other characteristics of the food;
- Information on the protection of consumers' health and the safe use of a food. In particular, it shall concern information on:
- Compositional attributes that may be harmful to the health of certain groups of consumers;
- Durability, storage and safe use;
- The health impact, including the risks and consequences related to harmful and hazardous consumption of a food;
- Information on nutritional characteristics so as to enable consumers, including those with special dietary requirements, to make informed choices.

To reiterate, as alcohol beverages are classified as 'food' under EU, all of the above should therefore apply.

The EU recognises the need for *'mandatory indications of the list of ingredients and the nutrition declaration for all alcoholic beverages'*⁴⁸. The EU has committed to revision of the

FIC regulation supported by it's 'Europe's Beating Cancer Plan'³⁹.

In sum, it is clear, that Ireland's objective through adoption of the Draft Regulations under Section 12 of the *Public Health (Alcohol) Act 2018* complies with, and supports, EU targets to strengthen consumer information on public health grounds.

Proportionality of Draft Regulations under Section 12 of the *Public Health (Alcohol) Act 2018*

Cited in the preamble to the Treaty on the Functioning of the European Union, is the affirmation from parties to the treaty that the primary collective objective is '*the constant improvements of the living and working conditions of their peoples*'⁴⁵. The WHO recognises the social determinants of health as the '*conditions in which people are born, grow, work, live, and age, and the wider set of forces and systems shaping the conditions of daily life*' (47). In order to achieve the overriding objective of the union, it is incumbent upon each member state to promote a healthy environment for its population while promoting economic growth. In relation to Ireland's Draft Regulations under Section 12 of the *Public Health (Alcohol) Act 2018*, in accordance with EU law, Article 36 provides the legal basis on which the measure is proposed:

'The provisions of Articles 34 and 35 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States'.

To support the absence of arbitrary discrimination or an intent to restrict trade, the justification to protect human health, in addition to evidence delineated above, is set out below:

Cancer Warning

Due to the proven causal link between alcohol and several types of cancer, the International Agency for Research on Cancer has classified alcohol as a group 1 carcinogen⁵⁰⁻⁵². The World Cancer Research Fund International details its research findings⁵³ based on substantial evidence that:

- Alcoholic drinks increase the risk of:
 - mouth, pharynx and larynx cancers
 - oesophageal cancer (squamous cell carcinoma)
 - breast cancer (pre and post-menopause)

- Two or more alcoholic drinks a day (30 grams or more) increases the risk of:
 - colorectal cancer
 - three or more alcoholic drinks a day (45 grams or more) increases the risk of stomach cancer
 - liver cancer.

Of note, a dose-response relationship between alcohol consumption and alcohol related cancers is observed⁵². Even consuming low levels of alcohol increases the risk of breast cancer in women⁵⁵ and it is now established that no level of alcohol consumption improves health⁵⁶.

The Lancet's population study on the global burden of cancer attributable to alcohol consumption, reported 380 alcohol- attributable cases were found in women with 670 cases recorded in men in Ireland in 2020. Ireland, along with a number of Northern and Western European countries placed in the highest national-level age-standardised incidence rates for women⁹.

The Health Research Board of Ireland, reporting on data from 2017, found from that year alone, 10,667 alcohol-attributable discharges were due to cancer with 28.8% due to breast cancers, 22.8% due to oesophageal tract cancers and 23.0 % due to oropharyngeal cancers¹⁶.

Danger of Alcohol Consumption during Pregnancy

The World health Organization⁵⁷, the Centres for Disease Control and Prevention⁵⁸ and the Health Service Executive of Ireland⁵⁹ all state that there is no safe level of alcohol consumption during pregnancy. This advice is based on scientific evidence that consuming alcohol at the time of conception⁶⁰ and during pregnancy can put the baby at risk⁶¹⁻⁶³, and of particular significance is the risk of Foetal Alcohol Spectrum Disorder (FASD) which encompasses a wide range of physical and mental disabilities due to the consumption of alcohol during pregnancy. FASD can cause lifelong problems for a child such as: hyperactivity and poor attention, learning difficulties, lower IQ, behavioural issues, and mental health problems⁶⁴. The prevalence of alcohol use during pregnancy in Ireland was reported as 60.4%, and prevalence of FASD estimated at 89.7 per 10, 000 placing the country within the top 5 countries globally for both indicators⁶⁵.

It is estimated that globally 1 in 67 women who consume alcohol during pregnancy will give birth to a baby with FASD. This estimate translates to 119 000 children every year⁶⁵. Members of the research group FASDcare within the School of Medicine in Trinity College Dublin recently commented that the figures above do not take into account the number of undiagnosed or misdiagnosed cases of babies born with FASD in Ireland, therefore, the true extent of harm caused by alcohol consumption during pregnancy is more than likely far greater⁶⁶. Treatment of FASD largely requires specialised health services which increases the burden on health care systems requiring advanced training and expertise of healthcare professionals⁶⁴.

It is pertinent to note, in presenting the evidence to substantiate the Draft Regulations under Section 12 of the *Public Health (Alcohol) Act 2018* that the Court of Justice of the European Union (CJEU) has on several occasions, in its judgements, acknowledged the importance of reducing alcohol related harm in the promotion of public health⁶⁷⁻⁷⁰. The Court's judgement on the case of *Scotch Whisky Association and Others v The Lord Advocate and The Advocate General for Scotland*, stated that it was evident the proposed alcohol control regulations pursued public health interests protected by Article 36 TFEU and further declared: 'It is for the Member States, within the limits imposed by the Treaty, to decide what degree of protection they wish to assure'⁷⁰.

Ireland has therefore set out a comprehensive set of provisions to ensure its citizens are better protected from alcohol related harms.

In abidance with EU law, it is incumbent on Ireland to provide sufficient evidence to support its proposed regulations. The Regulatory Impact Assessment provided with the original bill, delineated the evidence supporting the policy provisions²². The Irish Government reasonably concluded from the evidence that the proposed regulations under Section 12 of the *Public Health (Alcohol) Act 2018* were necessary to protect public health and henceforth submitted the notification to the EU. In an EFTA court ruling on the control of tobacco products, competence was assigned to the member state in establishing the suitability and necessity of the proposed measure, and acknowledged that in the absence of evidence to disprove the likelihood of an improvement of public health post implementation of the proposed measures, adjudication would support the public health policy⁷¹.

Ireland's proposed regulations under Section 12 of the *Public Health (Alcohol) Act 2018*, should be both supported and commended by the European Union.

Labelling

Public awareness of the harms associated with the consumption of alcohol is deficient. Data from the Alcohol Health Alliance (UK) revealed:

- Only one in five people (18%) can correctly identify the Chief Medical Officers' low risk weekly drinking guidelines of 14 units⁷²
- A third of people are unaware that it is safest not to drink in pregnancy⁷³
- Just a quarter of people know that alcohol causes breast cancer⁷³
- Around 60% of people do not know the calorie content of a medium glass (175ml) of wine, a pint, or a single measure (25ml) of 40% ABV spirits⁷².

Furthermore, Ireland's Department of Health's annual survey – 'Healthy Ireland' found that:

- 7% of respondents believed it to be safe to consume a small amount of alcohol while pregnant and 9% did not know⁷⁴
- 79% were unaware of the risk of breast cancer associated with drinking more than recommended amounts and 60% were unaware of the bowel cancer risk⁷⁵
- 52% were unaware of the increased risk of stomach ulcers and 49% were unaware of a relationship between alcohol consumption and high blood pressure⁷⁵.

From a public perspective there is strong support for improved labelling of alcohol products. A poll conducted for Alcohol Action Ireland by Ireland Thinks demonstrated that⁷⁶:

- 41% were in strong support of consumers having the right to be informed on the product and in advertising of the health risk from alcohol use
- 38% strongly support that alcohol products must display health warnings that clearly identifies the risk to pregnancy, of liver disease and fatal cancers from alcohol use
- 31% strongly support that alcohol products must display calorie information on all alcohol products.

It is evident that the provisions of Ireland's Draft Regulations under Section 12 of the *Public*

Health (Alcohol) Act 2018 are attempting to address the lack of consumer knowledge of the harms associated with alcohol consumption in accordance with the opinions of its citizens to do so.

Latest research on the impact of health messaging and product information on alcohol labelling yields promising insights into the potential effectiveness of well-designed alcohol labels in increasing awareness of safe consumption and alcohol related harms⁷⁷⁻⁷⁹. Research from Scotland indicates that the current health information and warnings on alcohol packaging is insufficient and is failing to inform adequately regarding the risks associated with alcohol consumption⁸⁰. The potential of health warnings to significantly reduce the selection of alcohol products has been identified⁸¹. Research from Canada, in a real-world setting, indicated strong public response in relation to warning labels, particularly in response to cancer warnings prior to interruption of the study⁸². A recent focus group conducted with young drinkers in Scotland, explored engagement with current labelling provisions⁸⁰. This research revealed that young drinkers found current health information and messaging on labels of alcohol products to be '*unnoticeable, obscure and ineffective*'. Evidently current labelling provisions are inadequate and well-designed labels can provide comprehensive consumer information to make informed choices. Further research in 2022, found that increased text or pictorial warning labels could counteract the acceptability of alcohol products and thus lead to a reduction in consumption⁸³.

To further substantiate Ireland's Draft Regulations under Section 12 of the *Public Health (Alcohol) Act 2018*, FIC recognises the significance of alcohol labelling provisions at the member state level. Article 41 FIC asserts: '*Member States may, pending the adoption of the Union provisions referred to in Article 16(4), maintain national measures as regards the listing of ingredients in the case of beverages containing more than 1,2 % by volume of alcohol.*' A corroborating defence of the draft regulations is also established on the grounds of Article 38- '*Member States may adopt national measures concerning matters not specifically harmonised by this Regulation provided that they do not prohibit, impede or restrict the free movement of goods that are in conformity with this Regulation*'⁴⁷.

While jurisprudence has not been established in relation to warning labels on alcohol products in the EU, the recently agreed 'European framework for action on alcohol, 2022–2025' together with 'Europe's Beating Cancer Plan' commits to formal adjudication without delay.

In conclusion, Ireland's Draft Regulations under Section 12 of the *Public Health (Alcohol) Act 2018* supports, guides and reinforces the objectives of the European Union as a whole to reduce alcohol related harms and promote the health and safety of its citizens.

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