

## **EUROCARE POSITION ON**

### **Notification of Draft Regulations Under Section 12 of the Public Health (Alcohol) Act 2018**

**TRIS Notification Number: 2022/441/IRL**



**SEPTEMBER 2022**

#### **THE EUROPEAN ALCOHOL POLICY ALLIANCE (EUROCARE)**

The European Alcohol Policy Alliance (Eurocare) is an alliance of non-governmental and public health organisations with around 50 member organisations across 23 European countries advocating the prevention and reduction of alcohol related harm in Europe. Member organisations are involved in advocacy and research, as well as in the provision of information to the public; education and training of community care workers; the provision of workplace and school-based programmes; counselling services, residential support and alcohol-free clubs for problem drinkers.

The mission of Eurocare is to promote policies to prevent and reduce alcohol related harm, through advocacy in Europe. The message, in regard to alcohol consumption, is “less is better”.



## SUMMARY

Globally, in Europe and in all EU Member States, many people are not fully aware of, misunderstand or underestimate the risks for morbidity and mortality due to alcohol use. Alcohol packaging is used as a promotional tool to decrease the perception of the level of harm and increase products' appeal, especially among the young, including young women. For the public health community, packaging and labelling is an important medium for communicating health messages. Health warnings and labelling messages on alcohol products and packages are a cost-effective means to increase public awareness of the health effects of alcohol use and key components of a comprehensive, integrated approach to alcohol policies that governments can use to reduce alcohol-related harm.

In October 2018, Ireland adopted its Public Health (Alcohol) Act 2018 which introduced a range of provisions to reduce population alcohol consumption and alcohol-related harms. In June 2022, Ireland notified the European Commission of its Draft Regulations setting out its proposals for the rules on alcohol information. These include rules for alcohol content, energy values and health warnings labelling on containers, documents and notices in licenced premises and rules for online sales.

The Draft Regulations propose labelling alcohol containers with three warnings: "Drinking alcohol causes liver disease", a silhouette of a pregnant woman enclosed in a red strikethrough circle, and "There is a direct link between alcohol and fatal cancers". Rules are set out on labelling the quantity in grams of alcohol contained in the container, the energy value in kilojoules and kilocalories contained in the container, and the public health information website.

The rationale is part of a broad package of measures to support Ireland's policy to reduce the devastating harm caused by alcohol. More specifically, data shows that the Irish population is not aware of the health risks of alcohol and the draft regulations submitted here are designed to ensure that Irish consumers are directly informed of those risks and are assisted to make healthier choices about their alcohol consumption.

More effective labelling is supported by the European Union and the World Health Organization. It is consistent with the EU's duty to promote a high level of consumer protection and public health. Giving consumer information helps fulfil their right to information. The Draft Regulations are adopted under powers retained by Member States under EU law and constitute an evidence-base, proportionate measure. There are already a number of examples of Member States taking initiatives on alcohol labelling. In view of the Irish Government's ambition to reduce alcohol harm through a comprehensive programme of action, and the possibility of delays to harmonisation at EU-level, the Commission should support Ireland's commendable steps.

We urge the Commission to support Member States in their fight against the devastating effects of alcohol. We, therefore, ask the Commission to issue a detailed opinion on the Draft Regulations to support its adoption.



*(Alcohol Action Ireland 's visual mock-up of what the proposed on-product labels will look like)*

## **BACKGROUND**

In 2009, the Government of Ireland introduced a decision to include alcohol in a National Substance Misuse Strategy. A Steering Group was established to advise Ministers on a new Strategy and the Steering Group Report on a National Substance Misuse Strategy was published in February 2012. This set out a range of recommendations.<sup>1</sup>

Following the publication of the Steering Group Report, on 17 December 2015, the government of Ireland introduced the Public Health (Alcohol) Bill 2015 ('the Bill') to Parliament. This faced extensive lobbying, supported by the alcohol industry, to weaken the evidence-based measures it sought to introduce. The Public Health (Alcohol) Act 2018 was then adopted on 17 October 2018 ('the Act').

The Act introduced a range of provisions to reduce population alcohol consumption and alcohol-related harms. These include minimum pricing, labelling of alcohol products, health warnings, alterations to licensing rules, restrictions to exposure and sale of alcohol in certain premises and circumstances, restrictions on advertising and sponsorship, as well as enforcement measures.

## **ALCOHOL-RELATED HARMS**

The Regulatory Impact Analysis accompanying the Bill ('RIA') noted that alcohol:

- was responsible for at least 83 deaths every month in 2011;
- is associated with 8,836 attendances in 2012 to specialised addiction treatment centres;
- is involved in one of every three poisoning deaths in Ireland in 2012 and remains the substance implicated in most poisonings;
- is a contributory factor in half of all suicides and in deliberate self-harm;
- is one of the factors associated with higher rates of self-harm presentations to hospitals on Sundays, Monday Public Holidays and around the hours of midnight;
- is associated developing health problems, including alcohol dependence, liver cirrhosis, cancer and injuries;

- is a factor in many assaults, including sexual assaults, and in rape, domestic violence and manslaughter;
- is a factor in many road collisions including a quarter of fatal road collisions; and
- alcohol-related cancers are estimated to more than double for females and increase by 81% for males up to 2020.

Moreover:

- using the most recent datasets (from 2019), it is now estimated the annual alcohol related deaths is 1,543, suggesting that four people die every day in Ireland from alcohol related harm and illness;<sup>2</sup> and
- there has been a general upward trend in the number of alcohol-related hospitalisations in Ireland since 1995. The number of wholly alcohol-related discharges increased from 9,420 in 1995 to 18,348 in 2018, an increase of 94.8%. From 1995 to 2018, the number of bed days accounted for by alcohol-related conditions increased by 216%, from 56,264 to 177,892. The length of stay for alcohol-related conditions increased by 71.6%, from a mean of 6.0 days in 1995 to a mean of 10.3 days in 2018;<sup>3</sup>

The National Drug and Alcohol Survey 2019–20 found that:

- 74.2% of respondents reported having consumed alcohol in the last 12 months, corresponding to 2,904,000 of the general population in Ireland aged 15 years and older;
- the median age at which 15–24-year-olds initiated alcohol consumption has increased from 16 years to 17 years since 2002–03.
- one-third (34.1%) of current drinkers typically consume at least 6 standard drinks per drinking occasion, which increases to one-half for male drinkers;
- two-fifths (39.9%) of drinkers engaged in heavy episodic drinking at least once per month; and
- the prevalence of alcohol use disorder in the general population was found to be 14.8%, corresponding to one in every seven or 578,000 adults in Ireland.

The RIA further rightly acknowledged that there is no safe limit of alcohol consumption for the risk of cancer. To support this conclusion in the RIA, Eurocare draws attention to the work of

the International Agency for Research on Cancer, whose 2020 World Cancer Report stated that there is no lower risk threshold, and so the risk of some cancers, including breast cancer is increased by any alcohol consumption.

The RIA further noted that:

- alcohol-related illness cost the healthcare system €793 million;
- alcohol-related crime cost an estimated €686 million;
- alcohol related road accidents cost an estimated €258 million in 2013; and
- the cost of lost economic output due to alcohol was estimated to be €641 million in 2013.

The OECD has estimated, based on Ireland's current use of alcohol, that the burden of health care costs alone will consume 4.1% of its health expenditure.<sup>4</sup> Previous estimates of the societal cost of problem alcohol use have produced estimates of €2.4-3.7 billion per year, with annual healthcare costs alone having been estimated at €0.8-1.5 billion.<sup>5</sup>

## **PUBLIC HEALTH (ALCOHOL) ACT 2018**

For alcohol sold in containers, section 12 of the Act prohibits sales of alcohol products to anyone in the state without labelling on the container in the prescribed form. This labelling concerns:

- 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;
- v. the energy value expressed in kilojoules and kilocalories contained in the container; and
- vi. details of a website providing public health information in relation to alcohol consumption.

It is an offence to contravene this requirement.

Section 12 permits the Minister for Health to prescribe the form of warnings under (i), (ii) and (iii) above, including its size and colour, and the size, colour and font type of the printed material. It also permits the Minister to prescribe the form of the information under paragraphs (iv), (v) and (vi) above, including the size, colour and font type of the printed material.

In adopting regulations, the Minister shall take into account any expert research available to him or her on effectiveness, and shall have regard to:

- a) the rate of alcohol consumption;
- b) patterns of alcohol consumption;
- c) health-related risks caused by alcohol consumption;
- d) data from health services relating to alcohol related presentations at health facilities;
- e) other societal harm caused by alcohol consumption; and
- f) such other matters as he or she considers appropriate (section 12(11)).

These provisions come into operation on the day the Minister may appoint but this shall not be earlier than 3 years after the date on which the order is made (section 1(3) of the Act).

Section 12 also contains provisions on alcohol information on alcohol in reusable containers, in licensed premises, and for sales online.

## **DRAFT REGULATIONS**

### *NOTIFICATION*

The Bill was notified to the Commission on 27 January 2016 under the Technical Regulation Information System (TRIS) under Directive (EU) 2015/1535 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services. Amendments were notified on 3 February 2018. As regards the proposals on labelling of alcohol products, the Commission's response on 2 May 2018 stated that it could not assess the draft measure without more detailed information.

On 21 June 2022, Ireland provided the detailed information to the Commission by notifying its draft regulations under section 12 of the Act ('Draft Regulations').

This notification was sent under the TRIS. It was also sent under Articles 40, 43, 44 and 45 of Regulation (EU) No. 1169/2011 on the provision of food information to consumers

### *ALCOHOL INFORMATION*

Part 2 of the Draft Regulations sets out the rules for labelling of alcohol containers. The Draft Regulation states that there will be three warnings:

- "Drinking alcohol causes liver disease";
- a silhouette of a pregnant woman enclosed in a red strikethrough circle; and
- "There is a direct link between alcohol and fatal cancers".

Rules are set out on labelling the quantity in grams of alcohol contained in the container, the energy value in kilojoules and kilocalories contained in the container, and the public health information website.

The size, colour, font, layout, etc are specified.

The labelling will appear similar to the following typical example, as set out in Schedule 1 of the Draft Regulations.

<b>xx grams</b> <b>xxx kJ/</b> <b>xxx kcal</b>	<b>DRINKING ALCOHOL</b> <b>CAUSES LIVER DISEASE</b>
	<b>THERE IS A DIRECT LINK</b> <b>BETWEEN ALCOHOL AND</b> <b>FATAL CANCERS</b>
	Visit <a href="http://www.askaboutalcohol.ie">www.askaboutalcohol.ie</a>

Part 3 of the Draft Regulations sets out the rules for a document provided with alcohol sold in reusable containers. Part 4 of the Draft Regulations sets out the rules for the notice to be displayed in licensed premises. Part 5 of the Draft Regulations sets out the rules for information to be given with online sales.

### **RATIONALE**

Ireland's TRIS notification notes that:

- the volume and patterns of alcohol consumption in Ireland are responsible for an enormous public health burden and economic costs;
- alcohol consumption levels in Ireland have remained extremely high in recent years; and
- consumption in children is high.

The TRIS states that the rationale is that:

- the data shows that the Irish population is not aware of the health risks of alcohol and the draft regulations submitted here are designed to ensure that Irish consumers are directly informed of those risks and are assisted to make healthier choices about their alcohol consumption;
- despite the public health burden caused by alcohol consumption, awareness of the health harms remains low especially among younger age groups. 16% do not know if it is safe to consume alcohol while pregnant, 79% do not know of the breast cancer risk and those aged 15-24 were typically less aware of the risks than others. There is a demand to know more. 78% believe that government has a responsibility to implement public health measures to address high alcohol consumption and 95% support including details of alcohol-related harms on labels; and
- the draft regulations are designed to be effective in accordance with international best practice and to be proportionate including a very long lead-in time (3 years) which will not begin until the regulations have been finalised and options available for businesses to minimise the impact on their processes. Additional provisions designed to facilitate businesses include reducing the minimum dimensions of the health information for alcohol containers of a smaller size and allowing for the use of a flag label to contain the required information.

The Explanatory and Financial Memorandum accompanying the Bill also stated that the aim of this provision is “to ensure that consumers are provided with access to health information on alcohol products regardless of the manner of purchase e.g. in a shop, in a pub, or on-line”.<sup>6</sup>

On introducing the legislation to Parliament in December 2015, the Minister for Health, Leo Varadkar TD, outlined that “The provisions aim to ensure consumers are provided with health

information on alcohol products, regardless of the manner of purchase, be it in a shop, in a pub or online. Labels on alcohol products, websites where alcohol is sold online and documents with kegs or casks must contain the following information: health and pregnancy warnings, the quantity of alcohol in grams, the energy value, and details of an alcohol public health website”.<sup>7</sup> The public have made it clear that they wish to improve their health literacy through effective and reliable communication.

These measures are part of a broader strategy to reduce alcohol-related harms. As the Explanatory and Financial Memorandum accompanying the Bill stated, “It is expected that the effective implementation of the suite of measures contained in the Steering Group Report on a National Substance Misuse Strategy along with the measures provided for in this Bill will significantly reduce consumption and related harm.” In this respect, labelling and health warnings will help to build public support for the Irish alcohol comprehensive policy approach and thus contribute to a reduction in consumption.

## **EUROPEAN UNION AND GLOBAL POLICY**

### *EUROPEAN UNION*

In the EU strategy to support Member States in reducing alcohol related harm of 2006,<sup>8</sup> the Commission highlighted five priority themes. To prevent alcohol-related harm among adults and reduce the negative impact on the workplace, the Commission set out the aim “To provide information to consumers to make informed choices” and noted that “information activities and campaigns...can be used to mobilise public support for interventions”.<sup>9</sup> For the priority theme to “Inform, educate and raise awareness on the impact of harmful and hazardous alcohol consumption, and on appropriate consumption patterns”, the Commission stated that the aim is to “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.” It stated the rationale was that “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.”<sup>10</sup>

In Council Recommendation on drinking of alcohol by young people of 2001, it was stated that “It is important that young people should be able, using the information presented on the products, to know what they are drinking”.<sup>11</sup> The 2017 report from the Commission regarding the labelling of the list of ingredients and the nutrition declaration of alcoholic beverages states that the “Commission has not identified objective grounds that would justify the absence of information on ingredients and nutrition information on alcoholic beverages”.<sup>12</sup>

Europe's Beating Cancer Plan of 2021 outlines a “political commitment to leave no stone unturned to take action against cancer”. Under the proposed prevention actions on “Saving lives through sustainable cancer prevention”, it outlines the need to “give people the information and tools they need to make healthier choices”. The Plan recognises that “Alcohol-related harm is a major public health concern in the EU. In 2016, cancer was the leading cause of alcohol-attributable deaths with a share of 29%, followed by liver cirrhosis (20%), cardiovascular diseases (19%) and injuries (18%)”. The plan commits the Commission 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”.<sup>13</sup>

On the 13 December 2021, the Commission launched an Online Public Consultation on proposed revisions to Regulation (EU) No. 1169/2011 on the provision of food information to consumers (‘FIC’), in accordance with the Better Regulation Guidelines. The OPC closed on 7 March 2022. The consultation sought the views of stakeholders on proposals across four Initiatives including alcohol labelling. As clearly pointed out in the Commission’s report on the consultation, the majority of respondents (between 67% and 94%), ‘Strongly agreed’ or ‘Agreed’ that: “A list of ingredients and nutritional information should be provided to consumers for alcoholic beverages as is the case for other foods and beverages” and “The type of information provided to consumers should be the same for all categories of alcoholic beverages (eg beers, wines, spirit drinks...)”.

## *GLOBAL*

The World Health Organization (WHO) adopted its Global strategy to reduce the harmful use of alcohol in 2010. In Area 8 on “Reducing the negative consequences of drinking and alcohol intoxication”, policy options and interventions included “providing consumer information about, and labelling alcoholic beverages to indicate, the harm related to alcohol”.<sup>14</sup> The WHO ‘Best buys’ and other recommended interventions for the prevention and control of noncommunicable diseases recommend that States should “Provide consumer information about, and label, alcoholic beverages to indicate, the harm related to alcohol”.<sup>15</sup>

The WHO draft Global alcohol action plan 2022-2030 to strengthen implementation of the Global Strategy to Reduce the Harmful Use of Alcohol, agreed at the 150th session of the Executive Board in 2022, proposed that Member States “Ensure appropriate consumer protection measures through development and implementation of labelling requirements for alcoholic beverages that display essential information for health protection on alcohol content in a way that it is understood by consumers, other ingredients, caloric value and health warnings.”<sup>16</sup>

The WHO Europe European action plan to reduce the harmful use of alcohol 2012–2020, in addressing strategies and actions to reduce the negative consequences of drinking and alcohol intoxication, stated that “Health warning labels should be placed on all alcoholic beverage containers as part of broader communication and point-of-purchase health campaigns to reduce the harmful use of alcohol. Once phased in, alcohol warning or information labels cost very little and, at the very least, remind consumers and society at large that alcohol is no ordinary commodity.” It continued that “Measures could be taken to introduce a series of warning or information labels on all alcoholic beverage containers and on all commercial communication materials for alcoholic beverages. The content of the messages can usefully be advised by public health bodies. The focus of such messages might be to address issues of immediate concern such as drinking during pregnancy or while driving, or to cover the long-term risks of alcohol use, such as high blood pressure and cancer.”<sup>17</sup>

In a number of third countries, such as the USA, Brazil, Canada, China, India, Mexico, New Zealand, Russia, and Switzerland, it is mandatory to provide the list of ingredients for certain

alcoholic beverages.<sup>18</sup> Pregnancy warning labels will be mandatory on alcoholic beverages in Australia and New Zealand<sup>19</sup> and South Korea requires cancer warnings on alcohol containers. Technical regulation 047/2018 on the safety of alcohol beverages of the Eurasian Economic Union states that alcohol labelling shall display the statement “excessive alcohol consumption is harmful to your health” and must take up at least 10% of the label.

## **PROMOTING CONSUMER PROTECTION**

### *HIGH LEVEL OF CONSUMER PROTECTION AND PUBLIC HEALTH*

Article 168 of the Treaty on the Functioning of the European Union (‘TFEU’) provides that “A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.”<sup>20</sup> Article 9 mandates that “In defining and implementing its policies and activities, the Union shall take into account requirements linked to the...protection of human health.” Article 169 provides that “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”. Article 12 states that “Consumer protection requirements shall be taken into account in defining and implementing other Union policies and activities.”

### *CONSUMERS’ RIGHT TO KNOW*

Alcohol is not an ordinary commodity. It is, however, defined in EU law as a food.<sup>21</sup> Regulation 178/2002 on the general principles and requirements of food law (‘General Food Law Regulation’)<sup>22</sup> states that “Food law shall pursue... the general objectives of a high level of protection of human life and health and the protection of consumers' interests, including fair practices in food trade”.<sup>23</sup> It further lays down 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.”<sup>24</sup>

Nutrition and ingredients labelling is largely regulated by Regulation (EU) No. 1169/2011 on the provision of food information to consumers (‘FIC’). The FIC asserts that “In order to achieve a high level of health protection for consumers and to guarantee their right to information, it should be ensured that consumers are appropriately informed as regards the food they

consume.”<sup>25</sup> It further states that “food labels should... assist consumers who want to make better-informed food and dietary choices”<sup>26</sup> and that “one of the objectives pursued by this Regulation is to provide a basis to the final consumer for making informed choices”.<sup>27</sup> Article 1 of the FIC states that it “lays down the means to guarantee the right of consumers to information”.<sup>28</sup>

Europe’s Beating Cancer Plan of 2021 explicitly recognises that “Improving health literacy on cancer risks and determinants: Improving access to and understanding of risk factors and health determinants is vital to improve health outcomes, especially for complex diseases like cancer. Europe’s Beating Cancer Plan will launch actions to give people the information and tools they need to make healthier choices.”<sup>29</sup> The Commission further committed to explore “measures to improve consumer information”.<sup>30</sup>

The opening lines of the New Consumer Agenda of 2020 states that consumers expect “to be empowered to make informed choices”.<sup>31</sup> Providing consumers with information is at the heart of the EU Consumer Strategies for 2007–2013<sup>32</sup> and 2012–2014.<sup>33</sup>

The consumer’s right to information is enshrined in the EU’s constitutional treaties. Article 169 TFEU states that “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”. Indeed, Article 11 of the Charter of Fundamental Rights of the European Union provides that freedom of expression and information includes the right “to receive... information and ideas without interference”. This is also guaranteed under Article 19 of the International Covenant on Civil and Political Rights, Article 10 of the European Convention on Human Rights, and Article 19 of the Universal Declaration of Human Rights. Providing a right to an environment which promotes healthy decisions about alcohol consumption is arguably implied under the right to health and right to an adequate standard of living.

In proposals concerning consumer protection, Article 114 requires the Commission to take as a base a high level of protection. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective.

## COMPATIBLE WITH THE INTERNAL MARKET

### *MEMBER STATE COMPETENCE*

The FIC recognises the importance of Member States level measures on alcohol labelling. Article 41 of the FIC permits Member States, pending the adoption of the Union provisions, to maintain national measures as regards the listing of ingredients for beverages containing more than 1.2% by volume of alcohol. In the case of alcohol that is not prepacked, the FIC permits Member States to make the ingredients list mandatory, as well as the nutrition declaration in either full or abridged form.<sup>34</sup>

Furthermore, Article 38(2) of the FIC expressly authorises Member States to adopt national measures concerning matters not specifically harmonised by the FIC provided that they do not prohibit, impede or restrict the free movement of goods that are in conformity with this Regulation. Moreover, Article 39(1) FIC permits Member States to adopt measures requiring additional mandatory particulars for specific types or categories of foods justified on the grounds of public health and/or the protection of consumers.<sup>35</sup> Alcohol would constitute a “specific types of categories of food”. For measures under Article 39(1), Member States shall notify the Commission and the other Member States of the measures envisaged and give the reasons justifying them.<sup>36</sup> Following consultation, if the Commission has not given a negative opinion, the Member State may take the envisaged measures three months after the notification.<sup>37</sup> If, within those three months, the Commission provides a negative opinion, the Commission shall initiate an examination procedure to determine whether the envisaged measures may be implemented subject, if necessary, to appropriate modifications.<sup>38</sup> Notifications under Article 39(1) FIC are specifically excluded from the requirements of the Technical Regulations Information System.<sup>39</sup>

Mandating additional particulars on energy, alcohol content and health warnings will help ensure that alcohol information is compatible with Article 7(2) of the FIC, which requires that food information shall be accurate, clear and easy to understand for the consumer. Moreover, the labelling will serve to give a more accurate overall impression of the risk of alcohol, to help counteract the misleading and promotional nature of alcohol labelling and marketing, and

thus satisfy the requirement that food information shall be non-misleading information as required by Articles 7(1)&(4) of the FIC, including for vulnerable consumers and the average consumer who is reasonably well-informed and reasonably observant and circumspect.<sup>40</sup>

#### *PROPORTIONATE MEASURE*

Measures may be justified for the protection of the health and life of humans as well as the defence of the consumer. The Court of Justice of the European Union ('CJEU') has repeatedly confirmed that combating alcohol-related harm is an important and valid public health goal.<sup>41</sup> Member States "enjoy a margin of discretion in determining, according to particular social circumstances and to the importance attached by those States to a legitimate objective under [Union] Law".<sup>42</sup> It is for Ireland to decide what degree of protection is assured within the provisions of the Treaties.<sup>43</sup> The draft labelling rules are a proportionate measure. A measure is proportionate when it is suitable and necessary to achieve its objective.<sup>44</sup>

Under the suitability limb of proportionality, it is necessary to determine whether labelling can attain its internal market, consumer protection and public health objectives. The CJEU has held that restrictive measures can be considered to be an appropriate means of securing the achievement of the objective pursued if it genuinely reflects a concern to secure the attainment of that objective in a consistent and systematic manner.<sup>45</sup> In this respect, the introduction of alcohol labelling is one of a broad package of measures, as part of a general public health led strategy in Ireland, designed to combat the devastating effects of alcohol.

Ireland is required to adduce specific evidence substantiating its arguments.<sup>46</sup> However, that burden of proof cannot extend to creating the requirement it must prove, positively, that no other conceivable measure could enable the legitimate objective pursued to be attained under the same conditions.<sup>47</sup> It is for the national court called on to review the legality of the national legislation concerned to determine the relevance of the evidence adduced in order to determine whether that legislation is compatible. On the basis of the evidence, that court must examine objectively whether it may reasonably be concluded from the evidence submitted by the Member State concerned that the means chosen are appropriate for the attainment of the objectives pursued. The national "court may take into consideration the

possible existence of scientific uncertainty as to the actual and specific effects on the consumption of alcohol of a measure... for the purposes of attaining the objective pursued.”<sup>48</sup>

The EFTA Court has stated that it must be sufficient for the authorities to demonstrate that, even though there may be some scientific uncertainty as regards the suitability and necessity of the disputed measure, it was reasonable to assume that the measure would be able to contribute to the protection of human health.<sup>49</sup> The Court continued “in the absence of convincing proof to the contrary, a measure of this kind may be considered suitable for the protection of public health”.<sup>50</sup> As a result of the application of a precautionary approach, the court may grant a rather wide margin of manoeuvre to Ireland in selecting measures whose effects cannot be proven because they have never been applied or because their effectiveness cannot easily be demonstrated due to multiple environmental factors.

The evidence that “Drinking alcohol causes liver disease” is well-established. Alcohol is a major risk factor for liver cirrhosis with risk increasing exponentially. Women may be at higher risk. Risk arises even with little alcohol consumption.<sup>51</sup> The rate of alcoholic liver disease (ALD) per 100,000 persons from 1995 to 2018 has increased steadily over the past 23 years, with the rate of ALD discharges in 2017 reaching the highest it has ever been since recording began at 102.3 discharges per 100,000 persons, representing a 261% increase from 1995.

The evidence that “There is a direct link between alcohol and fatal cancers” is also well-established. Alcohol is classified as a group 1 carcinogen by the International Agency for Research on Cancer (IARC) as there is a proven, causal link between alcohol and several types of cancer.<sup>52</sup> There is strong evidence that consuming alcoholic drinks increases the risk of mouth, pharynx and larynx, oesophageal and breast cancers. Two or more alcoholic drinks a day increases the risk of colorectal cancer while three or more alcoholic drinks a day increases the risk of stomach cancer and liver cancer.<sup>53</sup> The risk of developing cancer increases with increasing volume of alcohol consumed. The cancer risks from alcohol are the same, regardless of the type of alcoholic beverage consumed. Alcohol may increase risk of cancer even at very low levels of consumption. For example, women are at greater risk of developing breast cancer from consuming <21g of pure alcohol (approximately two standard drinks or more) per day.<sup>54</sup> A recent global Lancet study found that in 2020 there were approximately

1,000 alcohol related cancer cases in Ireland – 670 in men and 380 in women.<sup>55</sup> According to the Health Research Board, between 2012 and 2017, there were 55,097 discharges from Irish hospitals due to alcohol-related cancers.<sup>56</sup>

The evidence that alcohol should not be consumed during pregnancy is also well-established. Alcohol intake can affect the ability to conceive.<sup>57</sup> Alcohol can bring about pregnancy complications and impaired foetal development, including low birth weight,<sup>58</sup> small for gestational age<sup>59</sup> and preterm birth.<sup>60</sup> Alcohol can interfere with foetal development and cause a range of disorders on a continuum of severity, known as foetal alcohol spectrum disorders (FASD).<sup>61</sup> No amount of alcohol can be considered safe during pregnancy. A range of studies have found evidence of significant levels of drinking, including binge drinking, in pregnancy in Ireland both before and during pregnancy.<sup>62</sup> It is estimated that Ireland has the third-highest rate of FASD globally at 47.5 per 1,000 population.<sup>63</sup> It is estimated that an estimated 600 Irish babies are born each year with foetal alcohol syndrome, and more than 40,000 Irish people live with the condition.<sup>64</sup> Evaluation of the French mandatory health warning (pregnancy pictogram) showed that warning labels had been noticed by 66.1% of women and 77.3% of drinkers five years after their introduction<sup>65</sup> despite the warnings not being very visible or noticeable due to their size, location and other competing marketing elements on the packaging or advertisement.<sup>66</sup>

A warning label is effective when it increases the perception of risk. Warnings must be noticed, understood and be relevant. Consumer attention to warning labels is improved through effective design, including size, placement and pictorials.<sup>67</sup> There is evidence from real-world studies that alcohol health warnings on labels, if designed effectively to be visible and understandable, are effective to increase awareness and knowledge,<sup>68</sup> slow down drinking,<sup>69</sup> decrease drinking occasions<sup>70</sup> and decrease purchase occasions<sup>71</sup> over the longer term. Existing research on alcohol health warnings containing negative images shows that they elicit more negative emotions and reactance compared to text-only warnings, lower the product appeal, and improve believability. It is noteworthy that the alcohol industry has sought to stop studies on warnings.<sup>72</sup>

There is also clear evidence of the effectiveness of labelling and warnings based on extensive studies drawn from nutrition and tobacco labelling and health warnings. Regarding health warnings, evidence of impact of mandatory health warnings on labels was found on changing behaviour.<sup>73</sup> Simplicity of the label<sup>74,75</sup> and trust in the label and the institution responsible for the message<sup>76,77</sup> were the key facilitators found in reviews. The scientific evidence for tobacco products suggests that big pictorial pictures on both sides of the packet are more effective than text-only warnings on a range of outcomes, including being a deterrent for new smokers<sup>78</sup> and a means to increase cessation among current smokers.<sup>79</sup> In particular, tobacco health warnings challenge social norms and increase smokers' and potential consumers' awareness of warnings, knowledge and credibility of health risks, depth of processing, quit intentions and actual quitting.<sup>80</sup>

The necessity limb of proportionality assesses whether a less restrictive measure could achieve the declared goal of internal market objective and ensuring a high level of public health and consumer protection. If there are equally effective alternative policy options, Ireland is bound to choose the least intrusive one.<sup>81,82</sup> Consumer protection through informing consumers of and guidance is more readily demonstrated. Labelling is uniquely positioned to inform consumers at points of sale and consumption. There is arguably no other conceivable measure which has the reach of labelling, with well-designed health warning labels having the potential to outweigh exposure over any other public health or alcohol mass campaign.<sup>83</sup>

It is difficult to see which other measures could overcome the obstacles. Off-label information, particularly through QR codes, have been suggested by industry as an alternative even if it is clear that QR codes or other online information would not be equally effective as on-label information. While the EU population is familiar with the internet, in 2016 Eurostat found that 14% of the EU population had never used the internet. Scanning QR codes requires a specialised app and a reliable and strong data connection. Around 35% of Western Europeans do not own a smart phone. Furthermore, scanning a QR code is time-consuming - opening the app, pointing camera at the code, focusing the camera, loading the webpage. According to the Commission's own assessment, 44% of Europeans lack basic digital skills. Consumers consistently voice their desire for 'on-label' information, and there should be no difference between the provision of information between alcohol and non-alcoholic beverages. As stated

in the Commission's report on alcohol labels from 2017, the majority of consumers "never or rarely" use off-label information sources to access information on nutrition values and ingredients of alcoholic beverages.

Labelling also leads to public support for other measures and the fact that the measure "may be capable of procuring additional benefits...by contributing to the achievement of the general objective of combating alcohol misuse, not only cannot constitute a reason to reject such a measure, but is in fact a factor to support that measure".<sup>84</sup> Polling data commissioned by Alcohol Action Ireland found strong public support for health information labelling with 72% believing consumers have a right to be informed on the product and in advertising of the health risk from alcohol use with only 11% opposing such a move.<sup>85</sup>

Moreover, businesses in Ireland already include nutrition labelling and ingredients lists on no alcohol and low alcohol products (1.2% alcohol by volume or below). This labelling is achieved economically and without any compromise to product design. Indeed, many manufacturers produce country-specific labelling. To support industry, Ireland has established a significant lead-in time of three years following the adoption of the regulations<sup>86</sup> and the information may be provided on stickers to minimise costs and the need for re-labelling.<sup>87</sup>

## **FORTHCOMING EU PROPOSALS**

EU law permits Member States to introduce a variety of labelling measures. Existing measures are already divergent and fragmentation already exists in the internal market. EU Member States also have rules on disclosing ingredients list (Austria, Bulgaria, Croatia, Czechia, Greece, Ireland, Lithuania, Norway, Portugal, Romania). Some of the countries (Austria, Bulgaria) only have this requirement for beer. Nutritional values will also be required (Ireland, Norway). Warnings are also required on labels to warn consumers about potential health consequences of alcohol during pregnancy, either with a pictogram or with text (France, Lithuania).<sup>88</sup> The Norwegian Directorate of Health has recommended that alcoholic beverages be marked with a cancer warning.<sup>89</sup>

The Commission has committed to introduce proposals on the mandatory labelling of the list of ingredients and nutrition declaration on alcoholic beverage labels (by end of 2022) as well as health warnings (by end of 2023). Proposals have not yet been released.

The history of alcohol labelling regulation shows that EU-level rules will not be reached easily or soon. The process of adopting the FIC was the result of significant compromise and three years' negotiation over two Parliamentary terms. Even following its adoption, labelling rules had a long lead-in time. The EU legislative process for alcohol labelling will be even more complicated as the history of alcohol labelling shows. Directive 79/112/EEC relating to the labelling, presentation and advertising of foodstuffs required the Council, acting on a proposal from the Commission to "determine the rules for labelling ingredients and, possibly, indicating the alcoholic strength" within four years.<sup>90</sup> The Commission presented proposals in this regard in 1982<sup>91</sup> but this proposal was adopted only in part by Directive 86/197/EEC relating to alcoholic content. A further proposal was made in 1992<sup>92</sup> but the part which dealt with the ingredients list was split off with the common position. Subsequent proposals for ingredients labelling were also not agreed. When Regulation (EU) No. 1169/2011 on the provision of food information to consumers was adopted, its Article 16(4) required the Commission to produce a report addressing whether alcoholic beverages should in future be covered by the requirement to provide the energy value and the reasons justifying possible exemptions. This report was only published in 2017.

The Draft Regulations, once adopted, will not impede EU-level action. The plans by Ireland will serve as an example and help further develop the evidence base. Business will be given lengthy notice with the regulations coming force three years following their adoption. Moreover, once EU rules come into force, these will displace the Irish rules.

## **CONCLUSION**

We welcome the Commission's commitments to propose effective legislation on alcohol labelling and warnings. We urge the Commission to support Member States in their fight against the devastating effects of alcohol. We, therefore, ask the Commission to issue a detailed opinion on the Draft Regulations to support its adoption.

## NOTES

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[https://www.drugsandalcohol.ie/16908/2/Steering\\_Group\\_Report\\_on\\_a\\_National\\_Substance\\_Misuse\\_Strategy\\_-\\_7\\_Feb\\_11.pdf](https://www.drugsandalcohol.ie/16908/2/Steering_Group_Report_on_a_National_Substance_Misuse_Strategy_-_7_Feb_11.pdf)

<sup>2</sup> Global Burden of Disease Estimates of alcohol use and attributable burden in Ireland [https://alcoholireland.ie/wp-content/uploads/filebase/reports/21883\\_AAI\\_ICC\\_GBD\\_Policy\\_Paper\\_v4\\_online.pdf](https://alcoholireland.ie/wp-content/uploads/filebase/reports/21883_AAI_ICC_GBD_Policy_Paper_v4_online.pdf)

<sup>3</sup> O'Dwyer C, Mongan D, Doyle A and Galvin B (2021) Alcohol consumption, alcohol-related harm and alcohol policy in Ireland. HRB Overview Series 11, Health Research Board.

<sup>4</sup> Preventing Harmful Alcohol Use. OECD (2021). <https://www.oecd.org/publications/preventing-harmful-alcohol-use-6e4b4ffb-en.htm>

<sup>5</sup> Spending Review 2021; Focused Policy Assessment of Reducing Harm, Supporting Recovery: An analysis of expenditure and performance in the area of drug and alcohol misuse. <https://www.drugsandalcohol.ie/34729/>

<sup>6</sup> <https://data.oireachtas.ie/ie/oireachtas/bill/2015/120/eng/memo/b12015s-memo.pdf>

<sup>7</sup> <https://www.oireachtas.ie/en/debates/debate/seanad/2015-12-17/11/>

<sup>8</sup> Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions an EU strategy to support Member States in reducing alcohol related harm COM/2006/0625 final

<sup>9</sup> Paragraph 5.3

<sup>10</sup> Paragraph 5.4

<sup>11</sup> Council Recommendation of 5 June 2001 on the drinking of alcohol by young people, in particular children and adolescents (2001/458/EC), [11]

<sup>12</sup> Report from the Commission to the European Parliament and the Council regarding the mandatory labelling of the list of ingredients and the nutrition declaration of alcoholic beverages COM/2017/058 final

<sup>13</sup> Europe's Beating Cancer Plan: Communication from the commission to the European Parliament and the Council

<sup>14</sup> Global strategy to reduce the harmful use of alcohol. World Health Organization 2010.

<sup>15</sup> WHO, 'Best buys' and other recommended interventions for the prevention and control of noncommunicable diseases

<sup>16</sup> WHO Europe European action plan to reduce the harmful use of alcohol 2012–2020, page 17.

<sup>17</sup> European action plan to reduce the harmful use of alcohol 2012–2020. WHO Regional Office for Europe.

<sup>18</sup> Report from the Commission to the European Parliament and the Council regarding the mandatory labelling of the list of ingredients and the nutrition declaration of alcoholic beverages COM/2017/058 final

<sup>19</sup> <https://www.foodstandards.gov.au/industry/labelling/Pages/pregnancy-warning-labels.aspx>

<sup>20</sup> TFEU, Article 168(1)

<sup>21</sup> Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [2002] OJ L 31/1, Article 2.

<sup>22</sup> Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [2002] OJ L 31/1.

<sup>23</sup> GFLR, Article 5(1).

<sup>24</sup> GFLR, Article 8(1)

<sup>25</sup> FIR, Recital 3.

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- <sup>26</sup> FIC, Recital 26
- <sup>27</sup> FIC, Recital 37
- <sup>28</sup> FIR, Article 1. See also FIR, Recitals 3, 17, 26 & 37.
- <sup>29</sup> Europe's Beating Cancer Plan: Communication from the commission to the European Parliament and the Council, para 3.1
- <sup>30</sup> Europe's Beating Cancer Plan: Communication from the commission to the European Parliament and the Council, para 3.4
- <sup>31</sup> Communication from the Commission to the European Parliament and the Council. New Consumer Agenda Strengthening consumer resilience for sustainable recovery (2020) 696 final, 1
- <sup>32</sup> COM(2007) 99 final
- <sup>33</sup> COM(2012) 225 final
- <sup>34</sup> FIC, Article 12(5) & 44; see Gokani N, Front-of-pack nutritional labelling: a tussle between EU food law and national measures 2022 47(2) European Law Review 153-174
- <sup>35</sup> FIC, Article 39
- <sup>36</sup> FIC, Article 45(1)
- <sup>37</sup> FIC, Articles 45(2)-(3)
- <sup>38</sup> FIC, Articles 45(4)
- <sup>39</sup> FIC, Article 45(5); under Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services; now repealed by Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services
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- <sup>42</sup> Sami Heinonen case (C-394/97), para 43
- <sup>43</sup> Rosengren case (C-170/04), para 39; Scotch Whiskey case, para 33
- <sup>44</sup> See O Bartlett O and Garde A, On the Rocks: A Few Sobering Thoughts on the Growing EU Alcohol Problem in Hervey T et al (eds), Elgar Handbook on European Health Law, Elgar 2017; Alemanno A and Garde A, The emergence of EU lifestyle risk regulation: new trends in evidence, proportionality and judicial review in Micklitz H and Tridimas T (eds) Risk in EU Law (Elgar 2015)
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- <sup>46</sup> Lindman case (C-42/02), para 25; Belgium case (C-227/06) para 63; ANETT case (C-456/10), para 50
- <sup>47</sup> Italy case (C-110/05), para 66
- <sup>48</sup> Scotch Whiskey case, para 57
- <sup>49</sup> Philip Morris case (Case E-16/10, judgment of 12 September 2011)
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- <sup>51</sup> Roerecke M et al, Alcohol consumption and risk of liver cirrhosis: a systematic review and meta-analysis Am J Gastroenterol 2019 Oct 114(10) 1574–1586

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