

TRIS NOTIFICATION 2022/441/IRL (Ireland)

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

Date received: 21/06/2022 End of Standstill: 22/09/2022

Historical Background

On 27 January 2016, Ireland submitted a TRIS notification of a comprehensive new public health alcohol bill, covering advertising restrictions, minimum unit pricing, labelling, sponsorship, structural separation and other proposed measures:

- The Bill provoked detailed opinions from Austria, Bulgaria, Czech Republic, France, Germany, Italy, Poland, Portugal, Romania and Spain, whilst comments were issued by Denmark, the Netherlands, Slovakia, the UK and the European Commission.

On 19 January 2018, Ireland then submitted a further TRIS notification, focusing on the labelling and advertising elements of the Bill and incorporating amendments passed during the process.

- The Bill provoked detailed opinions from Bulgaria, Italy and Portugal, whilst comments were issued by Denmark, France, Greece, Poland, Romania, Slovakia, Spain, the UK and the European Commission.

On 21 June 2022, Ireland then submitted the latest TRIS notification, focusing on the labelling elements of the Bill and incorporating further amendments passed during the process:

- This notification allows countries and the European Commission (as well as other stakeholders including industry bodies) to issue further comments and detailed opinions, but also allows the European Commission potentially to delay or postpone the legislation since it clearly concerns matters where the European Commission has announced its intention to bring forward proposals for mandatory EU legislation in 2022 and 2023.

Content of the latest TRIS notification

The Bill would oblige all alcoholic beverages sold on the Irish market to carry on the label:

- A warning that states “*Drinking alcohol causes liver disease*”;
- A symbol, under the form of a pictogram, warning on dangers of alcohol consumption when pregnant;
- A warning that states “*There is a direct link between alcohol and fatal cancers*”;
- The grams of alcohol in the container;
- The number of calories in the container;
- A link to a website www.askaboutalcohol.ie.

General messages on the new notification

With the new provisions introduced, both some of the individual measures and the totality of the measures in the Irish Public Health (Alcohol) Bill represent a significant, unjustified and disproportionate barrier to the free movement of goods.

- The Bill relates to areas where the European Commission has already announced its intention to bring forward in 2022 and 2023 mandatory rules for the labels of alcoholic beverages.
- The Bill mandates measures that are inconsistent and incompatible with existing harmonised EU legislation around the provision of food information to consumers.
- The Bill neglects the specific mutual recognition of products where they are legally marketed with an equivalent symbol having the same purpose.
- With science showing that moderate alcohol consumption can be compatible with a balanced, healthy lifestyle, it is a misleading, unjustified and disproportionate barrier to trade to require all alcoholic beverages sold on the Irish market to carry health warnings focused on two health conditions, to the exclusion of the broader picture on health effects and causes.

Member States and the European Commission are therefore encouraged to contest the measures being put forward as an unjustified and disproportionate barrier to trade, block the current proposals and issue a detailed opinion in response to TRIS notification 2022/441/IRL

I. Background to the latest notification

The current notification is the result of a process which started on 25 January 2016, when Ireland submitted a notification to the European Commission of the draft Public Health (Alcohol) Bill 2015 (the “draft Bill”). Ireland later submitted a second notification, on 19 January 2018, with amendments to the draft Public Health (Alcohol) Bill 2015. The draft Public Health (Alcohol) Bill, as amended, included, among other things, provisions on health labelling for alcohol products. According to the brief statement of grounds of the Irish notifications, the aim of the draft legislation was to reduce alcohol consumption in Ireland to 9.1 litters per person per annum by 2020 and to reduce the harms associated with alcohol (such as alcohol related cancers).

On 2 May 2018, the European Commission commented on the draft Bill, as amended. The European Commission confirmed that it “*encourages Member States to take action against alcohol-related harm. However, it underlines those national measures should be evidence-based, proportionate and implemented on a non-discriminatory basis*”. In addition, the European Commission highlighted that national measures should also be compatible with EU law. In particular, the European Commission expressed strong concerns about the proportionality of the requirement for labels on alcoholic beverages to carry health warnings and the impact on exports of alcoholic beverages to Ireland.

II. Introduction

The proposed legislation referred to in TRIS Notification No. 2022/441/IRL, contained in the Public Health (Alcohol) Bill 2015, contains extremely wide-ranging measures aimed at reducing the consumption of alcohol in Ireland. The labelling rules apply to all alcoholic beverages sold in Ireland, including regular alcohol containers and reusable containers. There is no specific mutual recognition of products legally manufactured or marketed in other EU Member States.

In accordance with settled case-law, all measures of a Member State which are capable of hindering, directly or indirectly, actually or potentially, trade within the European Union are to be considered as measures having an effect equivalent to quantitative restrictions within the meaning of Article 34 Treaty on the Functioning of the European Union (TFEU).

Such measures may, however, be justified on grounds of the protection of health and life of humans, under Article 36 TFEU, but only if such measures are appropriate for securing the achievement of the objective pursued and do not go beyond what is necessary in order to attain it. It must be borne in mind that a restrictive measure can be considered to be an appropriate means of securing the achievement of the objective pursued only if it genuinely reflects a concern to secure the attainment of that objective in a consistent and systematic manner.

In that context it is interesting to note that the Irish Regulatory Impact Assessment attached to the notification and the Bill states that the societal cost of alcohol was €3.7 billion in 2007 and is €2.2 billion in 2015, a €1.5 billion drop in eight years, showing that the issue to be addressed by the Bill was already shrinking.

Further, national legislation or practice cannot benefit from the derogation laid down in Article 36 TFEU if human life and health can be as effectively protected by measures that are less restrictive of trade within the European Union.

It is apparent that the adoption of this legislation would:

- Supersede the intention of the European Commission to legislate in this area.
- Contradict existing harmonised EU legislation.
- Impose obstacles to producers in other Member States wishing to export alcohol products to Ireland, particularly products that are new to the market.
- Introduce requirements for labelling that would apply only in Ireland leading to a degree of territorial isolation.

Many aspects of the proposed provisions, as well as the package of provisions taken as a whole, infringe the free movement of goods provisions of the TFEU and constitute an infringement of Article 4 of the Treaty of the European Union (TEU) in so far as they jeopardise the attainment of the Union’s objectives. They also pre-empt activity in areas where the European Commission has already announced its intention to bring forward legislation and are inconsistent with existing EU harmonised legislation on the provision of food information to consumers.

III. Content and type of national measures

The measures were previously notified in 2016 and 2018, and are currently consigned in the 2018 Public Health (Alcohol) Act:

Labelling of alcohol products and notices in licensed premises

12. (1) Subject to subsection (2), 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 consumption.

The 2022 Draft Regulations detail the precise presentation and wording of warnings listed in (i), (ii), (iii), of the website mention in (vi), and of the information requirements relating to grams of alcohol in (iv) and the energy value (v) with pre-established templates and minimum sizes.

More precisely, the 2018 Public Health (Alcohol) Act is completed with the following national measures:

- For section 12(1)(i) of the Act of 2018: “Drinking alcohol causes liver disease”
- For section 12(1)(ii) of the Act of 2018, a black, white and red logo on pregnancy
- For section 12(1)(iii) of the Act of 2018: “There is a direct link between alcohol and fatal cancers”
- For section 12(1)(vi) of the Act of 2018: “Visit www.askaboutalcohol.ie”
- For sections 12(1) (i) to (vi) of the Act of 2018, the specified text should not contain any other mention than the prescribed information in the dedicated surface area.

For regular prepacked alcoholic drinks, these details are to be set out in a set form, with varying minimum sizes, prescribed colours on white background, in Times New Roman font.

IV. Objections to Entire Draft Regulation

A. A clear barrier to trade for companies based outside the Irish market

The provisions apply to a manufacturer of products where that product is “for sale in the state”. Manufacturers may well not know in which Member State their products are going to be sold by wholesalers and distributors. With that in mind, manufacturers often attempt to produce labelling that will satisfy the requirements of a number of Member States. The provisions would require special labelling for the Republic of Ireland, the result of which may well be that products would have to be produced and packaged especially for the Irish market, which is not large.

The imposition of an Irish-only label will put current producers and distributors based outside of the Irish market at a disadvantage to the significant Ireland-based producer industry. In terms of the costs to be incurred, this will discourage producers and distributors from entering the Irish market and puts Ireland at regulatory divergence from everywhere else in the EU. Such a requirement would be a significant trade barrier between Member States and prevent free movement at distribution level. This impact would be particularly pronounced for small and medium sized economic operators and is likely to mean that such operators can no longer operate in the Irish market.

B. Legislating where the Commission has announced its intention to adopt or propose mandatory requirements governing the labelling of alcoholic beverages

On the basis of Article 6, paragraph 3, of Directive 2015/1535, the European Commission should issue a negative opinion and block the continued passage of the Irish legislation by recalling its intention to act in this area of alcohol labelling, as already previously expressed in its Communication of the Europe Beating Cancer Plan, stating:

“The Commission will review its promotion policy on alcoholic beverages and in addition 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.”

Such a position would fit with the very purpose of this standstill clause, as directly stated in point 15 of the recitals of Directive 2015/1535:

“It is inherent in the internal market that, in particular where the principle of mutual recognition cannot be implemented by the Member States, the Commission adopts or proposes the adoption of binding acts. A specific temporary standstill period has been established in order to prevent the introduction of national measures from compromising the adoption of binding acts by the European Parliament and the Council or by the Commission in the same field”.

There are complex scientific and policy issues inherent in developing health warnings on labels of alcoholic beverages, issues which the Commission is in the process of examining on an EU-wide level. No Member State should be able to pre-empt this process with its own national requirements, which if adopted, would very likely spill over into other State's markets as a natural consequence of the common EU market. The Commission has the authority, and indeed the obligation, to safeguard its own prerogatives by issuing a negative opinion and blocking the Irish legislation.

V. Objections to Specific Provisions

A. The quantitative labelling requirements are inconsistent and incompatible with the rules harmonised by Regulation 1169/2011

Alcohol content labelling (Regulation 12(iv) of the draft regulation on the quantity in grams of alcohol contained in the container concerned)

Alcohol content labelling is harmonised at the EU level. Article 9 (List of mandatory particulars) of Regulation 1169/2011 on the provision of food information to consumers, which requires that alcoholic beverages >1,2% abv bear their alcoholic strength by volume should, together with Article 28 (Alcoholic strength) and Annex XII, specifically harmonise alcohol content labelling for such beverages. Indeed, Regulation 1169/2011 sets out not only the mandatory information that must be included, but also its presentation.

Contrary to the flexibility applied around labelling alcoholic beverages' ingredients, for which national measures are explicitly permitted to be maintained (also note: maintained but not introduce new measures) by Article 41, no EU legal authority specifically allows Member States to adopt national rules regarding the labelling of alcohol content, and in fact they are prohibited from doing so:

Article 38 National measures

1. As regards the matters specifically harmonised by this Regulation, Member States may not adopt nor maintain national measures unless authorised by Union law. Those national measures shall not give rise to obstacles to free movement of goods, including discrimination as regards foods from other Member States.

2. Without prejudice to Article 39, 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.

Article 41 Alcoholic beverages

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.

Allowing Member States to require the display of alcohol content in some other way than as set out in this Regulation (e.g., in grams in addition to the % in volume which in any case remains mandatory) would be contrary to the harmonisation that is pursued at EU level. Therefore, alcohol content should fall within Article 38.1 prohibiting Member States from adopting national measures unless authorised by Union law. While alcohol products are indeed a distinct category of food, for which public health protection measures could be justified under Article 39, indicating alcohol content by grams per container is not an additional measure to the mandatory particulars of Article 9.1 that require its presentation in percentage abv. Rather, indicating alcohol content by grams per container is a different presentation of the same information required by the Article 9.1.k mandatory particular. The objective of Regulation 1169/2011 was obviously to fully regulate labelling of alcohol content at EU level, reducing to null both the Member States' margin of discretion to require additional information (unless explicitly authorised such as maintaining the list of ingredients of Article 41) and any leeway in its application by food business operators in order to ensure that the end consumer receives easily understandable, standardised information on alcohol content.

As noted in section IV.A, the proposed Draft measures also violate the second part of Article 38.1 *'national measures shall not give rise to obstacles to free movement of goods, including discrimination as regards foods from other Member States'*.

Whilst the example template layout of the 2022 draft regulation is very unclear -- nowhere does it display that the information (xxx grams) relates to the content of the container only – the draft regulation is very clear in requiring the quantity in grams of alcohol "contained in the container concerned".

It requires alcohol content to be displayed in grams per container as opposed to the strict EU format specified in Annex XII of Regulation 1169/2011 which frames the decimal place, the precise wording '% vol' and the optional indication 'alcohol'/'alc.' of % by volume. Moreover, unless otherwise specified in EU law, or possibly in pre-existing national law adopted before 12 December 2011 (cf. Article 42: *"In the absence of Union provisions referred to in Article 23(2) concerning the expression of net quantity for specified foods in a different manner to that provided for in Article 23(1), Member States may maintain national measures adopted before 12 December 2011"*), the net quantity should be expressed in units of volume for liquids. The Irish consumer (and for internal market purposes, all EU consumers) is for this reason accustomed to information being primarily provided in units of volume for liquids.

This additional alcohol content by grams per container indication may therefore introduce confusion for the consumer who will be presented with varying data with no further explanation on possible equivalencies. Instead of a harmonised presentation across the entire EU, alcohol content for products sold in Ireland will be presented both % by volume (which in any case remains mandatory by application of Regulation 1169/2011) and in grams per container.

For a coherent approach to labelling, alcohol content should follow the same measuring rules so can be easily understood by consumers. The indication of grams per container instead of percent by volume is not to our knowledge a measure which was in place before December 2011, and Ireland does not justify why a different presentation is an absolute and proportionate necessity to solve public health issues linked to alcohol consumption.

Energy / calorie labelling (Regulation 12(v) on the energy value expressed in kilojoules and kilocalories contained in the container concerned)

Article 29 of Regulation 1169/2011 on the scope of application of nutrition declaration provisions does not exclude alcoholic drinks which should therefore be considered as covered by EU legislation on nutrition information – despite its applicable provisions deviating from the common rules by application of Article 16.4 (*"Without prejudice to other Union provisions requiring a list of ingredients or a mandatory nutrition declaration, the particulars referred to in points (b) and (l) of Article 9(1) shall not be mandatory for beverages containing more than 1,2 % by volume of alcohol."*).

Therefore, in this area of shared competence, the EU has exercised its competence, thereby limiting Member States' possibility to intervene. More precisely regarding national measures that are made under Regulation 1169/2011, Articles 38 and 39, Article 16.4 explicit harmonises nutrition information for beverages with more than 1,2% by volume of alcohol. This is in contrast to Article 41 of Regulation 1169/2011, which specifically allows existing national measures on lists of ingredients to be maintained.

The Commission shared the same point of view in its report of 13 March 2017¹ regarding mandatory labelling of alcoholic beverages, pointing out an increasing risk to the unity of the internal market: *"Even if the provisions for the nutrition declaration are fully harmonised, some Member States are also notifying national measures addressing the nutrition declaration for alcoholic beverages. Such national initiatives contribute to an increased risk of market fragmentation"*.

The Irish notification provides no specific public health rationale justification for labelling energy differently from the EU framework in Regulation 1169/2011 or for applying a calories per container approach for the labelling of alcoholic beverages but not for other drinks and foodstuffs.

The templates that are imposed upon the labelling of alcoholic drinks are significantly flawed in that they also fail to inform the consumer of the fact that the energy value displayed relates not to 100g of product nor to a portion, but to the content of the container. The Irish consumer (and for internal market purposes, all EU consumers) is accustomed to information being primarily provided per 100 ml for liquid, and only optionally per portion which does not always coincide with the content of a container. The container unit involves further inconsistencies with EU law as it contrasts with the rigorously framed units for nutrition information (per 100g, per portion or consumption unit). This double presentation, with no further explanation (since no additional mention is allowed according to the Draft Regulations) can only complicate and blur the information received by the consumer. As such, the proposed templates in the Schedules are contrary to Article 4.1.c of Regulation 1169/2011 according to which nutrition information should allow consumers to make informed choices:

Article 4 Principles governing mandatory food information

1. Where mandatory food information is required by food information law, it shall concern information that falls, in particular, into one of the following categories:

(...)

(c) information on nutritional characteristics so as to enable consumers, including those with special dietary requirements, to make informed choices.

Wherever nutrition information relating to food is made mandatory, it should be provided clearly enough to be fully understood by consumers. In our opinion, this is not the case with the draft regulation.

While it is true that Article 30.4 of Regulation 1169/2011 allows nutrition information presented on beverages with more than 1,2% alcohol to be limited to energy information only, it should nonetheless follow the prescribed format.

There is therefore a multitude of incompatibilities affecting the Draft Regulations:

- they require energy to be expressed per container only, raising concerns in light of Articles 32.2 and 33.2 of Regulation 1169/2011,
- the container is not an appropriate portion or consumption unit – it introduces a third type of measure that is likely to create additional confusion for consumers and inconsistency with EU law,
- the container unit is not clearly stated, is not easily recognisable, and is not quantified, contradicting Articles 33.1 and 33.4 of Regulation 1169/2011.

In our opinion, the sum of above inconsistencies with EU law cannot be remedied by Article 35 of Regulation 1169/2011 on additional forms of expression and presentation, for which the general criteria are not met.

B. The health warnings are unjustified and disproportionate

The new proposals to have specific warnings on the direct link between alcohol and fatal cancers and alcohol and liver disease are unjustified and disproportionate. They would be highly misleading and would have unpredictable consequences, notably on the overall extent to which moderate consumption may be pursued by individuals in the knowledge that such responsible consumption behaviours by healthy adults may be compatible with a balanced lifestyle.

The Irish Government has not presented scientific or evidence-based arguments to justify the introduction of these warning labels. In its 2018 TRIS notification, 2018/22/IRL section 9 "brief statement of grounds" it was stated that *"There is irrefutable evidence that alcohol causes cancer and that there is a direct causal*

¹ 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, https://food.ec.europa.eu/system/files/2017-03/fs_labelling-nutrition_legis_alcohol-report_en.pdf

link between certain fatal cancers and alcohol misuse.” However, while consuming alcohol may be a risk factor for or correlated with some cancers, it is not necessarily the cause of individual cancers. A warning that drinking alcohol causes liver disease is also misleading on an individual level where there is no direct causation between moderate consumption and liver disease, and alcoholic liver disease is most strongly associated with high levels of excessive alcohol consumption over an extended period.

As far as we are aware, no new expert research has been published. The latest TRIS notification by Ireland still appears to refer to the Regulatory Impact Assessment (“RIA”) completed in 2016. The RIA from 2016 cited a 2011 paper as authority for the statement “*There is no sensible limit of alcohol consumption below which the risk of cancer is decreased.*”

However, the association between alcohol and cancer risk is complex and cannot be adequately explained in a single warning label. About 7 of the estimated 200 cancers are reported to be alcohol related, i.e., alcohol intake increases the risk of those cancer types. The relationship between alcohol and cancer however depends on individual factors, multiple lifestyle factors, and the amount of alcohol consumed. The 2018/22/IRL section 9 “brief statement of grounds” states “*All alcohol related cancers show evidence of a dose-response relationship*”. However, for most cancer types, risk is associated with regular heavy drinking². Some studies have reported an association between moderate alcohol consumption and an increased risk of breast cancer^{1,3,4}.

Risks should therefore be conveyed in a way that allows consumers to understand them in context^{5,6}, whilst risk communication must balance the benefits and risks of alcohol consumption⁷. A focus on one condition alone does not give a full or accurate picture to help consumers make an informed choice about their drinking choices. Warning labels should be proportionate to the risks faced by consumers, but cancer labels do not allow consumers to have a proportionate view of the effects of moderate alcohol consumption. To make informed choices about their drinking, consumers should be provided with full information on health impacts. Alcohol is associated with both health benefits and risks⁸ and moderate alcohol consumption can be part of a well-balanced lifestyle^{9,10,11,12,13}. Moderate consumption of alcohol may be associated with certain health benefits, including a protective effect against cardiovascular disease, the leading cause of death and disability worldwide^{14,15}, and diabetes. It is to be noted in this regard that Regulation (EC) No 1924/2006 on nutrition and health claims prohibits alcoholic beverages from bearing affirmative health claims. As a result, if a warning is considered, it must take into account the health benefits that cannot be stated explicitly so that the warning does not overstate the net risk to the consumer.

The Irish Government has also presented no evidence concerning how consumers will respond to the proposed health warnings regarding cancer and liver disease. It cannot simply be assumed that consumers will understand warnings, much less heed them by changing their behaviour in the manner desired by the authors of the warnings. This may be particularly true in the context of substances such as alcoholic beverages that have strong cultural histories, associations with enjoyable and beneficial human interactions, and effects that are sought and immediately perceived by consumers. The net effect of the millions of warnings on alcoholic beverage containers proposed by the Irish Government may well be

² World Health Organization (WHO) and International Agency for Research on Cancer (IARC), *Consumption of alcoholic beverages*, in *A review of human carcinogens: Personal habits and indoor combustions*. 2012, Author: Lyon, France. p. 377-504.

³ Bagnardi, V., et al., *Alcohol consumption and site-specific cancer risk: A comprehensive dose-response meta-analysis*. British Journal of Cancer, 2015. **112**(3): p. 580-593.

⁴ Choi, Y.J., S.K. Myung, and J.H. Lee, *Light alcohol drinking and risk of cancer: A meta-analysis of cohort studies*. Cancer Research and Treatment, 2017.

⁵ Risk and Regulation Advisory Council, *A practical guide to public risk communication: The five essentials*. 2009.

⁶ Spiegelhalter, D., *Risk and uncertainty communication*. Annual Review of Statistics and Its Application, 2017. **4**(1): p. 31-60.

⁷ Louise, J., et al., *Mandatory cancer risk warnings on alcoholic beverages: What are the ethical issues?* American Journal of Bioethics, 2015. **15**(3): p. 3-11.

⁸ Rehm, J., et al., *The relation between different dimensions of alcohol consumption and burden of disease: An overview*. Addiction, 2010. **105**(5): p. 817-843.

⁹ Loef, M. and H. Walach, *The combined effects of healthy lifestyle behaviors on all cause mortality: A systematic review and meta-analysis*. Preventive Medicine, 2012. **55**(3): p. 163-170.

¹⁰ Zhang, X.Y., et al., *Dietary patterns, alcohol consumption and risk of coronary heart disease in adults: A meta-analysis*. Nutrients, 2015. **7**(8): p. 6582-6605.

¹¹ Singh, B., et al., *Association of Mediterranean diet with mild cognitive impairment and Alzheimer's disease: A systematic review and meta-analysis*. Journal of Alzheimer's Disease, 2014. **39**(2): p. 271-282.

¹² Perez-Martinez, P., et al., *Lifestyle recommendations for the prevention and management of metabolic syndrome: An international panel recommendation*. Nutrition Reviews, 2017. **75**(5): p. 307-326.

¹³ Sofi, F., et al., *Mediterranean diet and health status: An updated meta-analysis and a proposal for a literature-based adherence score*. Public Health Nutrition, 2014. **17**(12): p. 2769-2782.

¹⁴ GBD 2016 Causes of Death Collaborators, *Global, regional, and national age-sex specific mortality for 264 causes of death, 1980-2016: A systematic analysis for the Global Burden of Disease Study 2016*. The Lancet, 2017. **390**(10100): p. 1151-1210.

¹⁵ GBD 2016 DALYs and HALE Collaborators, *Global, regional, and national disability-adjusted life-years (DALYs) for 333 diseases and injuries and healthy life expectancy (HALE) for 195 countries and territories, 1990-2016: A systematic analysis for the Global Burden of Disease Study 2016*. The Lancet, 2017. **390**(10100): p. 1260-1344.

wholesale ignoring and discounting of the message, which diminishes the credibility of public health messages generally.

For example, the Irish Government does not explain whether it has considered the potential that its proposed warnings will prompt some consumers of alcoholic beverages to substitute other substances, such as cannabis, pharmaceuticals, or illicit drugs, with potentially greater health and societal costs. It does not explain whether its proposed warnings may prompt reduced consumption by health-conscious moderate drinkers, whose consumption level may have net benefits. And it apparently has not considered research that has shown that some groups, particularly those most at-risk of harm, may be least sensitive to warning labels¹⁶.

Furthermore, there are effective alternatives to warning labels to inform the public about health risks associated with alcohol that are more appropriate for conveying a complete picture of a complex issue and less injurious to trade¹⁶. For example:

- Mass media campaigns have demonstrated effectiveness in raising awareness of the health risks of alcohol¹⁷
- Education has shown effectiveness in raising knowledge of the risks of alcohol consumption¹⁸
- Heavy drinkers, who are at particular risk of harm to health, require more support than the general public to reduce their drinking^{19,20,21}. These include screening and brief intervention, tailored advice, and also treatment²².

Such alternatives, while not as simple as compelling alcoholic beverage manufacturers to provide a brief warning on the labels of their products, are much more easily justified and proportionate to the issue to be addressed.

Whilst regulations should apply consistently^{23,24}, the Irish Government has also not justified the application of the labelling requirement solely to alcohol products and not to other products which may be categorised as presenting cancer risks. For example, many other common consumer goods and lifestyle factors can be associated with an increased risk of cancer:

- Eating processed meats (colorectal and stomach cancers^{25,26})
- Eating salt-preserved foods (stomach cancer¹⁷)
- Drinking very hot beverages (oesophageal cancer²⁷)
- Eating red meat (colorectal cancer¹⁸)
- Body fatness (11 cancer sites²⁸)
- Physical inactivity (liver, breast, endometrium^{29,30,31})
- Oral contraceptive use (breast³²)
- Hormone replacement therapy
- Long-term shift work that interferes with circadian rhythms (breast, skin, digestive system³³)

¹⁶ Ringold, D.J., *Boomerang effects in response to public health interventions: Some unintended consequences in the alcoholic beverage market*. Journal of Consumer Policy, 2002. **25**(1): p. 27-63.

¹⁷ Wakefield, M.A., B. Loken, and R.C. Hornik, *Use of mass media campaigns to change health behaviour*. Lancet, 2010. **376**(9748): p. 1261-1271.

¹⁸ Institute for Social Marketing, *Synthesis report on the effectiveness of alcohol education in schools in the European Union*. 2009, The Open University and University of Stirling.

¹⁹ O'May, F., et al., *The families and friends of heavy drinkers: Caught in the cross-fire of policy change?* Drug and Alcohol Review, 2017. **36**(2): p. 192-199.

²⁰ Ayyagari, P., et al., *Understanding the heterogeneity in price elasticities in the demand for alcohol for older individuals*. Health Economics, 2011.

²¹ Erickson, R.A., et al., *How do people with homelessness and alcohol dependence cope when alcohol is unaffordable? A comparison of residents of Canadian managed alcohol programs and locally recruited controls*. Drug and Alcohol Review, 2018; p. n/a-n/a.

²² Samson, J.E. and E.E. Tanner-Smith, *Single-session alcohol interventions for heavy drinking college students: A systematic review and meta-analysis*. Journal of Studies on Alcohol and Drugs, 2015. **76**(4): p. 530-543.

²³ Force, B.R.T., *Principles of Good Regulation*. 2003.

²⁴ Commission, E., *Free movement of goods: Guide to the application of Treaty provisions governing the free movement of goods*. 2010.

²⁵ World Cancer Research Fund International (WCRF) and American Institute for Cancer Research (AICR), *Diet, nutrition, physical activity and stomach cancer*. 2016: Washington, D.C.

²⁶ World Cancer Research Fund International (WCRF) and American Institute for Cancer Research (AICR), *Diet, nutrition, physical activity and colorectal cancer*. 2017: Washington, D.C.

²⁷ World Health Organization (WHO) and International Agency for Research on Cancer (IARC), *Press Release No. 244 IARC Monographs evaluate drinking coffee, maté, and very hot beverages*. 2016.

²⁸ World Cancer Research Fund International (WCRF) and American Institute for Cancer Research (AICR), *Continuous Update Project: Summary of strong evidence on diet, nutrition, physical activity and the prevention of cancer*. 2017: Washington, D.C.

²⁹ World Cancer Research Fund International (WCRF) and American Institute for Cancer Research (AICR), *Endometrial cancer report 2013: Food, nutrition, physical activity and the prevention of endometrial cancer*. 2013: Washington, D.C.

³⁰ World Cancer Research Fund International (WCRF) and American Institute for Cancer Research (AICR), *Diet, nutrition, physical activity and liver cancer*. 2015: Washington, D.C.

³¹ World Cancer Research Fund International (WCRF) and American Institute for Cancer Research (AICR), *Diet, nutrition, physical activity and breast cancer*. 2017: Washington, D.C.

³² Morch, L.S., et al., *Contemporary hormonal contraception and the risk of breast cancer*. New England Journal of Medicine, 2017. **377**(23): p. 2228-2239.

³³ Yuan, X., et al., *Night shift work increases the risks of multiple primary cancers in women: A systematic review and meta-analysis of 61 articles*. Cancer Epidemiology, Biomarkers & Prevention, 2018. **27**(1): p. 25-40.

This is why the Europe Beating Cancer Plan sets out a framework for consideration of all cancer risks and proportionate proposals for reduction of these risks, taking into account the entire context. The Irish proposed regulation stands apart from this comprehensive approach and, thus, should be blocked pending the Commission's execution of its own commitment to consider alcohol health warnings on an EU-wide basis.

The proposed cancer warning labels would be unprecedented within the European Union on a legally sold foodstuff, and may mislead consumers as to the complex association not just between alcohol and cancer risk, but between alcohol and health in general.

If such health warnings are adopted across the board on the basis of little or no evidence, not only is this disproportionate, but it also risks undermining the credibility of public health messaging generally. Further, even if the evidence is generally supportive at population level of such measures on public health grounds, in order to be truly proportionate these need to be balanced against the freedom of choice of the individual consumer and so should properly inform on the basis of evidence rather than seek to cause alarm.

It has not been demonstrated that the health warnings are likely to achieve the stated objective to reduce underage drinking and overall alcohol consumption, and are disproportionate as this objective could be achieved by more effective and less trade restrictive means, such as public information campaigns. It is notable that significant progress has been achieved in Ireland in recent years on these two objectives in the absence of the measures proposed in the Bill.

Furthermore, the requirement that alcoholic beverage packages bear a reference to a website maintained by the Irish government is plainly unjustified and disproportionate. Whilst the Irish government is free to provide health information to Irish consumers, it need not commandeer the labels of products sold in the EU commerce in order to advertise the availability of this information. For example, a public information campaign using conventional advertisements, or other signage, potentially at the point of sale of alcoholic beverages within the Republic of Ireland, would serve the same purpose without infringing on EU prerogatives.

C. The pregnancy logo requirement must yield to mutual recognition of equivalent symbols

The brief statement of grounds in the notification presents data demonstrating that there is already an extremely high level of awareness in Ireland of the risks of consuming alcohol during pregnancy. Whilst, where the application of a pregnancy logo has been accepted at the time as a proportionate barrier to trade where it has been implemented in France and Lithuania, one might question the proportionality of applying such a measure to all alcoholic beverages exported to Ireland when the awareness is already so high. Other, less trade restrictive means may now be more proportionate for increasing awareness amongst the minority whose awareness remains low, in a context where the vast majority of alcoholic products available on the Irish market also already voluntarily include the logo on the label.

Operators selling to consumers in Ireland are also expected to comply with the provisions in the draft regulation, without any possibility of adjusting the above templates to conform with EU law or to other existing national provisions, such as the French or Lithuanian black and white pregnancy logo.

Even if Ireland adopts its own logo relating to consumption during pregnancy for drinks made on its own territory, Ireland should at the very least accept imports of products bearing a similar logo such as the one adopted in France and Lithuania when these products are legally marketed in another member State. This is in line with the constant and longstanding jurisprudence on the free movement of goods within the EU, the mutual recognition principle being one of the key tools to achieve the single market. Barriers to trade which may be justified by the protection of public health, according to Article 36 TFEU, must be interpreted strictly. This means, *inter alia*, that they must be proportionate to the purpose at stake.

This requirement has been reasserted in a particularly clear manner, for example, in a judgement of 15 November 2007 where the Court recalled that: *"in exercising their discretion relating to the protection of public health, the Member States must comply with the principle of proportionality. The means which they choose must therefore be confined to what is actually necessary to ensure the safeguarding of public health; they must be proportional to the objective thus pursued, which could not have been attained by measures which are less restrictive of intra-Community trade"* (Case C-319/05, judgement of 15 November 2007, Commission v/ Germany).

More precisely, the Court ruled in another case that: *"[a member State] is not entitled to prevent the marketing of a product originating in another Member State which provides a level of protection of the health and life of humans equivalent to that which the national rules are intended to ensure or establish. It is therefore contrary to the principle of proportionality for national rules to require such imported products to comply strictly and exactly with the provisions or technical requirements laid down for products manufactured in the Member State in question when those imported products afford users the same level of protection."* (Case C-188/84, judgement of 28 January 1986, Commission v/ France).

For these reasons, Ireland should at minimum insert in its legislation a mutual recognition clause in general and also specifically, according to which the details of form and colour provided for the health symbol regarding pregnant women is not applicable to products imported from Members States where they are legally marketed with an equivalent symbol having the same purpose.