Accepted version

Please cite as: Nikhil Gokani, 'Booze, Bottles and Brussels: Member States' Dilemma on Alcohol Health Warnings' (2024) 2 Journal of European Consumer and Market Law 97-102.

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Booze, Bottles and Brussels: Member States' Dilemma on Alcohol Health Warnings

I. Introduction

Alcohol is a causal factor in more than 200 diseases, injuries and disabilities.[1] It is a psychoactive substance which can cause addiction. Even at lower levels of consumption, alcohol is associated with increased risks of heart diseases and stroke, liver cirrhosis, cancers and foetal alcohol disorders.[2] In the EU, alcohol consumption causes between 255,000 and 290,000 deaths per year. Beyond health, alcohol results in significant social and economic losses to individuals and society at large.[3]

Despite negative consequences of drinking alcohol, consumer awareness of its harms is low. The World Health Organization (WHO) has repeatedly called on States to provide consumers with essential information through alcohol labelling.[4] The EU has itself acknowledged the importance of consumer alcohol information.[5] This reflects the foundation of EU consumer protection policy that consumers can be empowered through becoming well-informed.[6] Effectively designed labelling not only helps inform consumers but can also correct the misleading impression created by the promotional marketing on alcohol packaging, increases the public acceptability of complementary measures on alcohol control, and can contribute to

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[1] WHO, 'Statistical Classification of Diseases and Related Health Problems' (10th revision, WHO 1992).

[2] M Griswold et al, 'Alcohol Use and Burden for 195 Countries and Territories, 1990–2016: A Systematic Analysis for the Global Burden of Disease Study 2016' (2018) 392(10152) The Lancet P1015-1035.

[3] WHO, 'Status Report on Alcohol Consumption, Harm and Policy Responses in 30 European Countries 2019' (WHO Regional Office for Europe 2019).

[4] WHO, 'Global strategy to reduce the harmful use of alcohol' (WHO 2010); WHO, 'Global alcohol action plan 2022-2030 to strengthen implementation of the Global Strategy to Reduce the Harmful Use of Alcohol (WHO 2021); WHO Europe, 'European action plan to reduce the harmful use of alcohol 2012–2020' (WHO Europe); WHO Europe, 'European framework for action on alcohol 2022–2025' (Regional Committee for Europe 2022).

[5] Commission, 'An EU strategy to support Member States in reducing alcohol related harm' (Communication) COM (2006) 0625 final.

[6] Commission, 'New Consumer Agenda Strengthening consumer resilience for sustainable recovery' (Communication) COM (2020) 696 final; G Howells, 'The Potential and Limits of Consumer Empowerment by Information' (2005) 32(3) Journal of Law and Society 349; N Gokani, 'Healthier Food Choices: From Consumer Information to Consumer Empowerment in EU Law' (2024) Journal of Consumer Policy (forthcoming); M Friant-Perrot and A Garde, 'From BSE to Obesity – EFSA's Growing Role in the EU's Nutrition Policy' in A Alemanno and S Gabbi (eds), *Foundations of EU Food Law and Policy: Ten Years of the European Food Safety Authority* (Routledge 2014); O Bartlett and A Garde, 'On the Rocks: A Few Sobering Thoughts on the Growing EU Alcohol Problem' in T Hervey et al (eds), *Handbook on European Health Law* (Elgar 2017); C Willett, 'Re-theorising Consumer Law' (2018) 77(1) Cambridge Law Journal 179-210; C MacMaoláin, *Food Law: European, Domestic and International Frameworks* (Hart 2015).

the reduction in harms as part of a broader comprehensive package of measures addressing the determinants of alcohol consumption.[7]

The EU has regulated alcohol labelling since the early years after its inception.[8] Current rules in Regulation 1169/2011 on the provision of food information to consumers (FIC Regulation)[9] require alcoholic beverages with a content over 1.2% alcohol by volume (ABV) to include alcohol strength on the label.[10] This does not apply to beverages with 1.2% ABV or less. Similar health-related information, including an ingredients list and a nutrition declaration, which are required on the labels of most food products, are exempt for alcoholic beverages above 1.2% ABV.[11] Moreover, EU law does not require other health-related information to appear on labelling. In particular, there is a growing momentum on the need to warn consumers through labelling of the effects of alcohol consumption.[12] This has culminated in the European Commission (Commission) committing to make proposals on alcohol health warning labelling in Europe's Beating Cancer Plan of 2022. Unfortunately, however, the 2023 deadline has passed with no formal development.[13]

With little progress at EU level, alcohol labelling measures are receiving greater attention at the Member States' level. Most significantly, in May 2023, Ireland adopted its Public Health (Alcohol) (Labelling) Regulations 2023 adopting new rules requiring mandatory labelling of alcoholic beverages with health information.[14] These rules have been strongly welcomed by the public health community. However, questions as to compatibility with EU law have been raised by industry actors and some Member States.[15]

This article assesses the effectiveness of EU law to support the introduction of national measures on mandatory alcohol health warning labels to promote a high level of health and consumer protection. Section II explores the legal developments on alcohol health warning labelling at the national level and identifies the core legal uncertainties the Member States face. Section III explores the first of these uncertainties and argues that the Member States retain competence under EU law to introduce national measures on alcohol labelling, providing these comply with the wordings of the FIC Regulation and are proportionate. Section IV, using the Irish labelling rules as a case study, then considers the second challenge and shows that national warning labelling can meet the explicit provisions in the FIC Regulation on fair information practices. Section V, again using the Irish case study, addresses the third challenge to show that national labelling can be effectively designed to satisfy a proportionality assessment, while meeting public health and consumer protection objectives. Section VI concludes that EU law is not a barrier to effective mandatory alcohol health warning labels at the national level and, therefore, calls on the Member States to gather the political will to introduce national rules to protect consumers.

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[7] WHO, 'Health Warning Labels on Alcoholic Beverages: Opportunities for Informed and Healthier Choices' (WHO 2021); E Jané-Llopis et al, 'What is the Current Alcohol Labelling Practice in the WHO European Region and What Are Barriers and Facilitators to Development and Implementation of Alcohol Labelling Policy?' (WHO 2020); WHO Europe, 'Alcohol Labelling: A Discussion Document on Policy Options' (WHO Europe 2017).
[8] Council Directive 79/112/EEC on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer [1979] OJ L 33/1.
[9] Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers [2011] OJ L 304/18 (FIC Regulation).
[10] Article 9(1)(k) FIC Regulation.
[11] Articles 9(1)(b), 9(1)(l) and 16(4) FIC Regulation.
[12] (n 4).
[13] Commission, 'Europe's Beating Cancer Plan' (Communication) COM (2021) 44 final.
[14] Public Health (Alcohol) (Labelling) Regulations 2023 <https://www.irishstatutebook.ie/eli/2023/si/249/made/en/print> (Irish Regulations).
[15] See responses to the Irish TRIS notification at <https://technical-regulation-information-system.ec.europa.eu/en/notification/17834> accessed 10 November 2023.

II. National developments on alcohol labelling

National measures on alcohol labelling have been introduced to promote consumer protection and public health. Ingredient labelling is currently voluntary under EU law[16] but, under a derogation,[17] nine Member States have maintained national rules on ingredients labelling.[18] A nutrition declaration is also voluntary under EU law and, while no Member State requires a full nutrition declaration,[19] Ireland will require energy labelling from May 2026.[20]

Other forms of health-related labelling are not explicitly addressed under EU law and several Member States have introduced national mandatory labelling rules. These have focused on two issues: mandatory labelling relating to the age of consumption, as required by Slovenia and Germany, and labelling against drinking during pregnancy, as required by France and Lithuania.[21]

In January 2016 and February 2018, Ireland notified the Commission and the Member States of its Public Health (Alcohol) Bill.[22] Amongst a wide range of provisions addressing alcohol consumption and harm, section 12 of the Bill proposed new requirements for mandatory health warning labelling of alcohol sold in containers. In October 2018, Ireland signed this into law as its Public Health (Alcohol) Act 2018 (Irish Act).[23] In June 2022, Ireland subsequently notified its Draft Regulations under section 12 of the Act and, in May 2023, signed these into law as its Public Health (Alcohol) (Labelling) Regulations 2023 (Irish Regulations).[24] From May 2026, non-reusable 'alcohol product containers' will be required to include the following labelling.[25]

The responses to Ireland's notification under the Technical Regulation Information System ('TRIS')[26] were mixed.[27] The Commission did not reply to the notification. Comments were received from 91 stakeholders. The majority were civil society organisations representing public health and consumer interests and who expressed strong support. Industry bodies from

[16] (n 11).
[17] Article 41 FIC Regulation.
[18] Jané-Llopis et al (n 7).
[19] For certain grapevine products, ingredients labelling and nutrition declaration became mandatory from December 2023. See Articles 119(1)(h) and (i) Regulation (EU) No 1308/2013 of the European Parliament and of the Council establishing a common organisation of the markets in agricultural products; Article 6(a) Regulation (EU) No 251/2014 of the European Parliament and of the Council on the definition, description, presentation and labelling of aromatised wine products.
[20] (n 14).
[21] See e.g. Protection of Young Persons Act (Jugendschutzgesetz) of 2002.
[22] <https://www.oireachtas.ie/en/bills/bill/2015/120/> accessed 27 October 2023.
[23] <https://www.irishstatutebook.ie/eli/2018/act/24/enacted/en/html> accessed 22 October 2023. See C MacMaoláin, 'An Unhealthy State: Using Legislation to Address Public Health Issues in Ireland' (2019) 25(4) European Public Law 487.
[24] (n 14).
[25] Irish domestic law questions are outside the scope of this paper on EU law.
[26] 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 [2015] OJ L 241/1 (TRIS Directive).
[27] (n 15).

across the globe responded opposing the measure. Comments were issued by six Member States and detailed opinions by nine Member States. These focused on internal market issues, which is not surprising as the TRIS mechanism is designed to elicit internal market concerns. Nevertheless, mixed within such comments, several Member States also expressed support for the underlying objectives. France stressed 'that they defend an ambitious approach to combating the harmful uses of alcohol', Poland observed that 'all consumers have the right to reliable and accurate information about the health risks associated with the products they consume' and Croatia stated that it 'supports efforts to reduce the harmful effects of drinking and implement the World Health Organi[z]sation's strategic goals and recommendations to reduce the harmful effects of alcohol, one of the most important being alcohol labelling.'[28]

Nevertheless, the feedback from industry and some Member States raises questions as to the compatibility of the Irish Regulations, and alcohol health warning labelling in general, with EU law.[29] In turn, this also raises questions of the effectiveness of the current EU rules to support the Member States in introducing national labelling measures. An analysis of the TRIS responses to the Irish rules shows that the expressed legal concerns focused on three key areas. First, the proposals constituted a discriminatory barrier to free movement (Section III). Second, the rules were not consistent with existing EU harmonisation (Section IV). Third, the regulations were not proportionate (Section V).

III. National competence in alcohol labelling

The first group of legal uncertainties related to national alcohol health warning labelling considers such labelling as a barrier to the free movement of goods. This section explores the extent to which the EU has harmonised alcohol labelling and thereby pre-empted national action, and the residual competence retained by the Member States to introduce national rules.

There are no provisions in EU law explicitly addressing alcohol health warnings. Nonetheless, national labelling measures would still fall within the broad scope of the FIC Regulation. Article 1 sets out its scope as covering food information intended for the final consumer given by food business operators at all stages of the food chain, without prejudice to requirements in more specific legislation. The FIC Regulation is adopted under the EU's internal market competence pursuant to Article 114 of the Treaty of the Functioning of the European Union (TFEU). This is a shared competence. With a shared competence, the Member State's action is constrained to the extent the EU has acted.[30] As this section will show, the FIC Regulation appears to be a measure of partial harmonisation, adopting different degrees of harmonisation. Consequently, the Member States may introduce national rules on mandatory alcohol health warnings subject to certain conditions.

1. Matters not specifically harmonised

In respect of matters not 'specifically harmonised' by the FIC Regulation, there appears to be minimum harmonisation: Article 38(2) permits the Member States to adopt certain national measures.[31] If alcohol health warning labelling is not 'specifically harmonised', the Member

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[28] (n 15).

[29] Other challenges, particularly political and ethical arguments, were also put forward but are beyond the scope of this legal paper.

[30] Case C-16/83 *Prantl* ECLI:EU:C:1984:27. See R Schütze, 'Supremacy Without Pre-Emption? The Very Slowly Emergent Doctrine of Community Pre-Emption' (2006) 43 Common Market Law Review 1023; A Alemanno and A Garde, 'The Emergence of an EU Lifestyle Policy: The Case of Alcohol, Tobacco and Unhealthy Diets' (2013) 50(6) Common Market Law Review 1745.

[31] Alternatively, this could also be interpreted as maximum harmonisation with a broad derogation. See Gokani (no 6).

States may not undermine the protection in the FIC Regulation but may exceed it, subject to general EU Treaty rules. That is to say that, under minimum harmonisation, the FIC Regulation sets the floor of the standard of protection whereas the Treaties set the ceiling. Health warnings are not explicitly mentioned in the FIC Regulation, which suggests health warning labelling is not 'specifically harmonised'.[32] The Member States may, under this view, introduce national measures.

2. Matters specifically harmonised

In respect of matters which are 'specifically harmonised' by the FIC Regulation, there appears to be maximum harmonisation: A declared desire to create uniform protection in Recital 13[33]; the exclusivity clause in Article 6 which prohibits the sale of non-compliant goods; and the market access clause in Article 38(1) which precludes national measures unless authorised by EU law.

The mandatory particulars have been fully considered and listed, suggesting that mandatory labelling particulars have been 'specifically harmonised' and, therefore, remain subject to maximum harmonisation.[34] If alcohol health warning labelling is 'specifically harmonised', the Member States may not undermine the protection in the FIC Regulation but may exceed it, subject to general Treaty rules, where the FIC Regulation itself allows. That is to say, under maximum harmonisation, the FIC Regulation sets the floor of the standard of protection as well as the ceiling, and sets out options and requirements if Member States want to raise the ceiling within the limits of the Treaties.

The FIC Regulation includes a derogation which could allow the Member States to exceed the set maximum standards. Article 39(1) states that the Member States 'may, in accordance with the procedure laid down in Article 45, adopt measures requiring additional mandatory particulars for specific types or categories of foods, justified on grounds of at least one of the following: (a) the protection of public health; (b) the protection of consumers…'. Alcohol is likely to constitute a specific category of food, as it is a sub-set of beverages categorised based on its drug content. This would be consistent with other uses of 'categories' in the FIC Regulation, such as for caffeinated beverages.[35] Alcohol labelling could be justified as a measure of public health and consumer protection. Providing that the Member State does 'notify in advance the Commission and the other Member States of the measures envisaged and give the reasons justifying them', Article 45 provides that the measure may be adopted if the Commission does not reply negatively within three months of notification.

In the case of Ireland, its notification relied on Article 45. As the only purpose of the Article 45 procedure is to give effect to Article 39, Ireland implicitly invoked the Article 39(1) derogation. The Commission did not reply negatively, or at all, which allowed Ireland to move past this procedural hurdle.[36]

Therefore, irrespective of whether health warnings labelling is specifically harmonised or not, the Member States are able to move forward subject to the explicit wording of the FIC

[32] Case C-485/18 *Groupe Lactalis* ECLI:EU:C:2020:763.
[33] Case C-478/07 *Budějovický Budvar* ECLI:EU:C:2009:521, para 107; Case C-547/14 *Philip Morris Brands and Others* ECLI:EU:C:2016:325, para 77.
[34] Case 60/86 *Commission v United Kingdom* ECLI:EU:C:1988:382.
[35] Annex III FIC Regulation.
[36] In the Member State and industry responses to the Irish notification, the Commission was requested to block the Irish provisions under the TRIS Directive as EU harmonisation is being considered. However, this is not likely possible as Article 45(5) FIC Regulation explicitly exempts itself from the TRIS Directive procedures.

Regulation and the limits imposed by the Treaties.[37] These will be dealt with in the next two sections respectively.

IV. National alcohol health warning labelling as fair information practices

This section explores whether national health warning labelling could satisfy the minimum protection under the FIC Regulation. It uses the Irish alcohol health warning labelling as a case study.

The Irish Regulations require the following alcohol labelling: A 'health warning' that 'Drinking alcohol causes liver disease',[38] a 'health symbol' of a silhouette of a pregnant woman in black superimposed with a red circle and strikethrough,[39] a 'health warning' that 'There is a direct link between alcohol and fatal cancers'[40] and 'health information' referring to 'Visit www.askaboutalcohol.ie'. The Irish Regulations also set out visibility and design requirements.[41] The combined area of all elements shall have a width and height of at least 60 millimetres and 30 millimetres respectively. In the case of an alcohol product the largest surface area of which is less than 80 square centimetres, the area shall cover an area of not less than 75 per cent of its size. The labelling shall be surrounded by a black border of between one and two millimetres. The labels may be attached to the container by means of an adhesive flag label provided this is not easily removable.

The minimum protections of the FIC Regulation, which the Member States may not undermine, are set out in Article 7 as 'fair information practices'. Food information shall be 'accurate', 'clear and easy to understand', and 'not be misleading' particularly as to the 'characteristics of the food' or 'by attributing to the food effects or properties which it does not possess'.

1. Accurate

The Irish labelling is accurate when assessed against both the ordinary meaning of this word and the principle of scientific consensus. The evidence that 'Drinking alcohol causes liver disease' is well-stablished, even with relatively low levels of consumption, and increases with higher consumption.[42] The evidence on the dangers of drinking during pregnancy is also clear. Alcohol intake can affect the ability to conceive, brings about pregnancy complications, and interferes with foetal development known as foetal alcohol spectrum disorders including low birth weight, small for gestational age and preterm birth.[43] No amount of alcohol is considered safe during pregnancy. There is also well-established evidence that 'There is a direct link between alcohol and fatal cancers'. Alcohol is classified as a group 1 carcinogen by the WHO International Agency for Research on Cancer, as there is a proven causal link between alcohol and at least seven cancers.[44] The risks arise irrespective of the type of alcohol consumed,

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[37] Several other considerations, including fundamental rights and freedoms, are beyond the scope of this paper.
[38] Regulation 5(1) Irish Regulations.
[39] Regulation 5(2) Irish Regulations.
[40] Regulation 5(3) Irish Regulations.
[41] In addition, the label shall include 'the quantity in grams of alcohol contained in the container concerned' and 'the energy value expressed in kilojoules and kilocalories contained in the container concerned', both defined in the Irish Regulations as 'health information'. This labelling is beyond the scope of this paper on warnings.
[42] M Roerecke et al, 'Alcohol Consumption and Risk of Liver Cirrhosis: A Systematic Review and Meta-Analysis' (2019) 114(10) American Journal of Gastroenterol 1574.
[43] N O'Connor and S Whaley, 'Brief Intervention for Alcohol Use by Pregnant Women' (2007) 97(2) American Journal of Public Health 252; P Nilsen et al, 'Is Questionnaire-Based Alcohol Counseling More Effective for Pregnant Women Than Standard Maternity Care?' (2010) 19(1) Journal of Women's Health 161;
[44] International Agency for Research on Cancer, 'IARC Monographs on the Evaluation of Carcinogenic Risks to Humans' (IARC 2012).

exist at lower consumption levels and increase with higher consumption. There is no safe level of drinking for cancer risk.[45]

2. Clear, easy to understand and non-misleading

The requirement that information is 'clear and easy to understand' relates to legibility and visibility.[46] Even if the Irish labelling could be more visible, such as through being on the front of packaging, it is likely to meet this requirement not least as it appears against a white background, is within a black box and has a minimum size. The 'clear and easy to understand' requirement also relates to the clarity of meaning and there does not appear to be ambiguity in the messages in the labelling. The requirement for clarity of meaning can also be related to the prohibition on 'misleading' information. In line with broader consumer protection in the internal market, compliance with information rules is assessed against the behaviour of the 'average consumer who is reasonably well-informed and reasonably observant and circumspect taking into account social, cultural and linguistic factors'.[47] This notional average consumer is an active player in the market who reads information, has background knowledge, is critical towards information, does not take information literally, and will not be misled easily if sufficient information is available.[48]

As regards the Irish pregnancy warning, it is likely that an average pregnant woman who is reasonably well-informed and reasonably observant and circumspect would understand that the message is conveying the idea that drinking during pregnancy is unsafe and not advised. Even though this assessment is a matter for the courts, empirical evidence is not excluded. In this respect, research shows, for instance, that the French pregnancy pictogram was noticed by 66.1% of women and 77.3% of drinkers and, of those, 98.6% thought that it suggested abstinence.[49]

The TRIS responses allude to the Irish labelling being alarmist in that it might not sufficiently convey a message that the health effects are influenced by both consumption amounts and frequency. This argument has little merit. As regards the pregnancy warning, this simply advises women not to drink during pregnancy as per national health guidance in Ireland. The message that 'There is a direct link between alcohol and fatal cancers' communicates an association with fatal cancers but does not refer to a direct causal relationship, notwithstanding the well-established evidence on causation. The warning that 'Drinking alcohol causes liver disease' is not misleading, as liver disease occurs with even relatively low levels of consumption. An average consumer would have the common knowledge and critical ability to know that the health effects of alcohol are a matter of probability, are dose-dependent and can arise with any level of consumption. The warnings are even accompanied with a further message directing consumers to an alcohol health awareness website, giving more detailed information on these risks. Moreover, the use of 'causes' is consistent with many decades of EU warnings developments. For instance, the warning that 'Smoking kills' and that 'Smoking causes mouth and throat cancer' are accurate and non-misleading even if not all smokers will die from the tobacco use or develop such cancers. The Irish messages are generic, objective statements of scientific fact, not seeking to convey person-specific probability to any individual.

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[45] B Anderson et al, 'Health and Cancer Risks Associated with Low Levels of Alcohol Consumption' (2023) 8(1) Lancet Public Health e6-e7.
[46] For a full analysis of the meaning of these provisions see Gokani (note 6).
[47] Case C-210/96 *Gut Springenheide* ECLI:EU:C:1998:369.
[48] For an overview of the relevant case law see B Duivenvoorde, *The Consumer Benchmarks in the Unfair Commercial Practices Directive* (Springer 2015).
[49] A Dumas et al, 'Warning About Drinking During Pregnancy: Lessons from the French Experience' (2018) 15(1) Reproductive Health 20.

V. National alcohol health warning labelling as proportionate

Even if a national measure complies with the express wording of the FIC Regulation and does not undermine the minimum harmonisation protection, it must also comply with the limits set in the Treaties. In particular, a measure shall be proportionate, which it is when it is suitable and necessary to achieve its legitimate objective.[50]

(a) Legitimate objective

For a proportionality assessment, it is essential to understand the objectives underlying the adoption of a measure. As the Irish Regulations have been introduced under the derogation of Article 39 FIC Regulation, the objectives are limited to 'the protection of public health' and 'the protection of consumers'. Alcohol consumption control clearly falls within these broad grounds. The CJEU has consistently held that combating alcohol-related harm is an important and valid goal and that it is for the Member State to choose the degree of protection.[51]

The primary objective for health messaging labelling is to protect consumers through informing them. The Irish Minister for Health outlined that the measure aims 'to ensure consumers are provided with health information'.[52] The TRIS notification noted that 'the Irish population is not aware of the health risks of alcohol' and the Regulations 'are designed to ensure that Irish consumers are directly informed of those risks'. The Explanatory and Financial Memorandum accompanying the Bill stated that '[i]n order to empower Irish consumers to make healthier choices about their alcohol consumption' the Regulations inform consumers 'of the risks associated with alcohol products at the point of purchase and at the point of consumption.'[53]

In addition to informing consumers, the Irish documents also refer to other objectives. This reflects that the Irish Regulations are one of a suite of measures in the Public Health (Alcohol) Act 2018. While informing consumers appears to be the primary objective,[54] this is part of a broader, secondary objective of reducing consumption. This follows from the Explanatory and Financial Memorandum stating: 'It is expected that the effective implementation of the suite of measures…will significantly reduce consumption and related harm'. This was then repeated in Ireland's World Trade Organization (WTO) notification.[55]

(b) Suitability

Under the suitability limb of proportionality, it is necessary to determine whether the proposed labelling can attain its objectives of protecting consumers by informing them and protecting public health by contributing to the reduction in consumption as part of a broader suite of measures.[56]

It is for the Member State to adduce specific evidence substantiating its arguments.[57] Following the Commission's silence on the TRIS notification, and its support at the WTO Committee on

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[50] Case C-456/10 *Asociación Nacional de Expendedores de Tabaco y Timbre (ANETT)* ECLI:EU:C:2012:241, para 45. Sometimes a third limb is also added on balancing costs and benefits ie proportionality in a strict sense.
[51] Case C-333/14 *Scotch Whisky Association and Others* ECLI:EU:C:2015:845.
[52] Seanad Éireann debate - Thursday, 17 Dec 2015 Vol. 244 No. 11 <https://www.oireachtas.ie/en/debates/debate/seanad/2015-12-17/11/> accessed October 19 2023.
[53] Ibid.
[54] One might say that Ireland could have made its primary and secondary objectives more explicit.
[55] Ireland World Trade Organization notification, G/TBT/N/IRL/4, 06/02/2023.
[56] Case C-456/10 (n 50). See Alemanno and Garde (n 30).
[57] Case C-42/02 *Lindman* ECLI:EU:C:2003:613, para 25; Case C-227/06 *Commission v Belgium* ECLI:EU:C:2008:160, para 63.

Technical Barriers to Trade,[58] it is unlikely the Commission would bring a direct action against Ireland. With indirect actions, for instance brought by industry actors, it is for the national court, rather than the CJEU, to assess the legality of the measure.[59] The national court asks whether, from the evidence submitted, it can reasonably be concluded that the labelling measure is appropriate for the objectives.

In respect of the primary objective, evidence demonstrates that there is a deficit of knowledge about the health consequences of alcohol consumption, as Ireland's literature review confirmed and the evidence on which has since grown.[60] Studies show that alcohol health warnings specifically lead to increased knowledge of health risks, including cancer, liver disease and pregnancy.[61] The labelling aims to inform consumers. The design of the label is supported by insights from conducted consumer interviews.[62] Further support can be found in analogous research on food and tobacco labelling and risk communication.[63] Indeed, the idea that labelling informs consumers has a long history in the EU,[64] with the CJEU finding that to give consumers easy access to information it should appear on the labelling.[65] Moreover, EU law already requires certain food products to be labelled with health warnings.[66]

As regards the secondary objective, there is also evidence supporting the contribution of labelling to reduction in harms or consumption. There is growing evidence that alcohol health warnings reduce consumption.[67] Further support is provided by less direct evidence. Analogous food labelling and warnings increase healthy intentions and improved purchased outcomes, and tobacco warnings reduce initiation and increase quit intentions.[68] In this respect, Ireland is not expected to prove conclusively the effects of a specific labelling scheme, which has not yet been implemented on a mandatory basis anywhere[69] and the court 'may take into consideration the possible existence of scientific uncertainty as to the actual and specific effects'.[70] Moreover, labelling opens up broader societal discussions, which can also lead to increased public support for other measures. The fact that the measure may be capable of procuring such additional benefits is a factor supporting that measure,[71] as it genuinely reflects Ireland's commitment to secure the attainment of the objective in a consistent and systematic manner.[72]

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[58] Meetings on 21-23 June 2023 and 8-10 November 2023. Summary statements available at <https://epingalert.org/en/TradeConcerns/Details?imsId=794&domainId=TBT>.
[59] Case C-55/94 *Gebhard* ECLI:EU:C:1995:411, para 19.
[60] A Hope 'Alcohol Literature Review' (Department of Health 2014).
[61] G Dossou et al, 'The Effectiveness of Current French Health Warnings Displayed on Alcohol Advertisements and Alcoholic Beverages' (2017) 27(4) European Journal of Public Health 699.
[62] (n 55). Ideally, this would have been published.
[63] See e.g. D Hammond et al, 'Effectiveness of Cigarette Warning Labels in Informing Smokers About the Risks of Smoking: Findings from the International Tobacco Control (ITC) Four Country Survey' (2006) 15(Suppl 3) Tobacco Control iii19-iii25.
[64] (n 6).
[65] Case C-85/94 *Piageme* ECLI:EU:C:1995:312, paras 23-26; Case C-385/96 *Goerres* ECLI:EU:C:1998:356, paras 23-25.
[66] Article 24(1) & Annex V Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives [2008] OJ L 354/16.
[67] N Schoueri-Mychasiw et al, 'Examining the Impact of Alcohol Labels on Awareness and Knowledge of National Drinking Guidelines: A Real-World Study in Yukon, Canada' (2020) 81(2) Journal of Studies on Alcohol and Drugs 262.
[68] (n 63).
[69] A Garde, 'Freedom of Commercial Expression and Public Health Protection: The Principle of Proportionality as a Tool to Strike the Balance' in N Shuibhne and L Gormley (eds), *From Single Market to Economic Union: Essays in Memory of John A Usher* (Oxford University Press 2012).
[70] Case C-333/14 (note 51), para 57.
[71] Case C-333/14 (note 51), para 48.
[72] Case C-333/14 (note 51), para 37; Case C-161/09 *Kakavetsos-Fragkopoulos* ECLI:EU:C:2011:110, para 42; Case C-98/14 *Berlington Hungary and Others* ECLI:EU:C:2015:386, para 64.

(c) Necessity

Under the necessity limb of the proportionality test, it must be determined whether a less intrusive measure could be equally effective as the proposed labelling to attain the objectives. If there are equally effective alternative policy options, Ireland is bound to choose the least intrusive one.[73]

The CJEU has held that it is for the applicant initiating the case, not for the Member State, to show the effectiveness of an alternative option. Several measures can help inform consumers about health risks of alcohol consumption, such as education in schools, public information campaigns or interventions in healthcare settings. These are not, however, *equally* effective. Labelling is available at *both* the point of (potential) purchase and the point of (potential) consumption. Labelling is available on every container. It is targeted so that everyone can see the label, but its visibility will generally be in proportion to the number of containers a person consumes. Warning labelling also mitigates the effect of promotional marketing messaging on labelling. Ongoing costs are minimal.

The CJEU has consistently held that labelling is less restrictive than other interventions and the Irish messages are also designed to be less intrusive relative to other forms of labelling, such as those giving effect to tobacco control.[74] The messages do not assert a consumer will develop any disease. The design of the label is also conservative and does not go as far as to say alcohol 'kills', as tobacco warnings do, despite the evidence on alcohol deaths. The Irish label, while visible, is not required to be larger than 60mm wide and 30mm tall, and even smaller for small containers. Only black and red colours are required, reducing labelling costs. There are no significant location requirements so, for instance, the label can appear on the back of the packaging. Once implemented there would be minimal ongoing costs for industry actors and the government. Labels can be updated as part of the product design lifecycles within the three-year transition period. Stickers can be used to reduce costs even further.[75] Moreover, the labelling burden falls on the seller rather than the manufacturer.[76]

Another alternative might be for off-label information provided through an on-label QR code. However, it is clear that information is most effective when presented on packaging. In 2022, 7% of individuals aged between 16 and 74 had never used the Internet, reaching as high as 14% in some Member States. Scanning QR codes often requires a specialised mobile application, a reliable data connection and sufficient data bandwidth. Around 44% of Europeans lack basic digital skills.[77] Scanning QR codes is time-consuming and makes comparisons difficult. As stated in the Commission's report on alcohol labels of 2017, the majority of consumers 'never or rarely' use off-label information sources to access alcohol health information.[78] In fact, the report concluded that QR code use 'is so infrequent that at this point its contribution to consumer information seems negligible.'[79] Indeed, the CJEU has

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[73] Case C-170/04 *Rosengren and Others* ECLI:EU:C:2007:313, para 43; Case C-147/03 *Commission v Austria* ECLI:EU:C:2005:427, para 63. See Alemanno and Garde (note 30).
[74] See also eg J Luzak, 'Who Calls the Tune? Stock Taking of Behavioural Consumer Protection in Europe' in H-W Micklitz at al (eds) *Research Methods in Consumer Law* (Edward Elgar 2018).
[75] Section 1(3) Irish Act; Regulation 10 Irish Regulations.
[76] Section 12(3) Irish Act.
[77] Commission, 'The Digital Skills Gap in Europe' <https://ec.europa.eu/newsroom/dae/document.cfm?doc_id=47880> accessed 3 November 2023.
[78] Commission, 'Mandatory labelling of the list of ingredients and the nutrition declaration of alcoholic beverages' (Report) COM (2017) 58 final.
[79] A Sarasa-Renedo et al, 'Provision of Ingredient, Energy and Full Nutrition Information on Alcoholic Beverages: An Assessment of Products Placed on the EU Market' (European Commission JRC 2022), 26.

emphasised the importance of on-label information, which has been used throughout the entire history of EU food law.

VI. Moving towards effective alcohol health warning labelling

In the WHO European Region consultation, governments identified that there 'is a lack of clarity and knowledge about the best type of law to implement' on labelling.[80] Implementing national laws is even more difficult in light of industry tactics opposing effective policy development and threatening legal action.[81] This article sought to provide further guidance for the Member States. This article demonstrated that EU rules circumscribe national action but the Member States retain competence to introduce proportionate health warning labelling. This is feasible, providing they do not undermine the minimum protection harmonised under the FIC Regulation, and providing procedural requirements are met. As the Irish case study showed, evidence-based labelling rules can satisfy minimum protections under the FIC Regulation. They can also satisfy proportionality limits, as the EU Health Commissioner has also asserted.[82]

This article put forward the case that EU food law is not necessarily a barrier to adopting national measures on alcohol health warning labelling. Even if national actions increase regulatory fragmentation, this is a natural consequence of the many derogations included in the FIC Regulation. The Member States must, therefore, take responsibility for moving forward independently.

The EU institutions must, nevertheless, support the Member States in tackling alcohol-related harm. At the very minimum, the Commission must respect the Member States' efforts by not blocking national labelling measures when notified by the Member States under the FIC Regulation derogation. The role of the EU institutions does not stop there. The EU has long regulated alcohol labelling under its internal market competence. The establishment of the internal market is a primary objective of, and justification for, the EU. Harmonisation can not only level the playing field for economic actors but can also bring about higher levels of consumer protection through increased choice, lower prices and improved safety. However, this can only be achieved where values of consumer protection and public health are adequately considered.

While unilateral progress at the national level is likely to motivate the EU to improve the level of harmonisation, as has happened in other fields such as with tobacco regulation, it is only necessary for the Member States to act now because the EU has not gathered the political will to move forward effectively. In proposing measures for the approximation of the laws in the Member States which have as their object the establishment and functioning of the internal market, and which concern health and consumer protection, the Commission is under a duty to take as a base a high level of protection taking account in particular of any new development based on scientific facts.[83] Tides appeared to be turning with the publication of Europe's Beating Cancer Plan of 2021, in which the Commission committed to introduce proposals on alcohol health warning labelling by the end of 2023. Unfortunately, the deadline has now

[80] WHO Europe, 'Final report on the Regional consultation on the implementation of the WHO European Action Plan to reduce the harmful use of alcohol (2012 – 2020): Prague, Czech Republic, 30 September – 1 October 2019' (WHO Europe 2022).
[81] J McCambridge, 'Alcohol Industry Involvement in Policymaking: A Systematic Review' (2018) 113 Addiction 1571.
[82] 'Answer given by Ms Kyriakides on behalf of the European Commission' <https://www.europarl.europa.eu/doceo/document/E-9-2023-000108-ASW_EN.pdf> accessed 23 November 2023.
[83] Article 114 TFEU.

passed with no formal action having been taken. The Commission is in a unique position to propose evidence-based, effective health messaging on alcohol labels across the entire EU. Providing this is done effectively, adopting such labelling would benefit both consumers and economic actors while allowing the Member States to fulfil their responsibilities to promote health. Consumer protection and public health is the responsibility of all stakeholders, and the Member States and the EU must all work together to tackle the devastating harms of alcohol.