August 23, 2022

Subject: Ireland Public Health (Alcohol) (Labeling) Regulations 2022 (TRIS Notification 2022/441/IRL, June 6, 2022)

To Whom it May Concern:

On behalf of the Distilled Spirits Council of the United States, Inc. (DISCUS) and its member companies, I am pleased to submit our views on Ireland's Public Health (Alcohol) (Labeling) Regulations 2022 (TRIS Notification 2022/441/IRL, June 6, 2022). We also reiterate the concerns we previously detailed in our submissions dated September 7, 2016, in response to the WTO notification (G/TBT/N/IRL/2), and in April 20, 2018, in response to the notification made through TRIS system (Public Health (Alcohol) Bill 2015 (TRIS Notification 2018/22/IRL, January 19, 2018)).

As we have previously indicated, we are committed to combatting the harmful use of alcohol in all forms. We acknowledge that beverage alcohol products can be abused and result in harm. For these reasons, throughout the decades, we have focused upon and pursued solutions that effectively address and combat the harmful use of alcohol. We fully support the public health objective of combating all forms of harmful drinking and, for individuals of legal drinking age who choose to drink, encouraging moderate alcohol consumption. Some individuals of the legal drinking age should not consume alcohol at all, and we support that decision.

Our specific concerns regarding the proposal are detailed below.

I. The Proposal Undermines Work at the European Level Under the Beating Cancer Plan and the EU Parliament's Special Committee on Beating Cancer

Currently, there is no EU-wide beverage alcohol warning statement requirement, and beverage alcohol products over 1.2% a.b.v. are exempt from nutrition labeling requirements. We are concerned that the proposal undermines the ongoing work at the EU-level on mandatory health warnings and nutrition labeling requirements.

As part of the EU's Beating Cancer Plan, we understand that the EU will propose regulations to require health warnings by the end of 2023 and a nutrition declaration on labels before the end of 2022. In February 2022, the EU Parliament's Special Committee on Beating Cancer voted on and issued its "Report on strengthening Europe in the fight against cancer – towards a comprehensive and coordinated strategy" (BECA), which proposes language about moderate and responsible drinking on labeling, instead of health warnings.



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In December 2021, the EU launched a public consultation and survey seeking general feedback on, among other things, requiring ingredient and nutrition information on beverage alcohol products, which may either appear 'on label' or 'off label' with a QR code 'on label'.

As such, the Irish requirement would be duplicative of an EU-wide requirement and could create confusion among consumers.

Accordingly, we respectfully request that the EU submit a detailed opinion to block Ireland's adoption of the proposal as the EU continues its work on EU-wide mandatory health warnings and nutrition declaration requirements.

II. The Warning Statements Are Misleading and Not Based on the Current State of Research

Under Article 5 (1) and (3), beverage alcohol containers must bear warnings that "Drinking alcohol causes liver disease" and "There is a direct link between alcohol and fatal cancers." As noted above, DISCUS fully supports the collective public health objectives of encouraging adults who choose to drink to do so in moderation and responsibly, recognizing that some individuals should not drink at all. However, we question the appropriateness of the proposed warning statement, which uses inaccurate and disproportionate wording.

The proposed wording of these statements is inaccurate and not grounded in scientific evidence. The association between alcohol and the risk of developing cancer or liver disease is complex and depends on a number of factors – it is certainly not "direct," as described in the proposed language, nor is it inevitably fatal.

Scientific research reports that the potential risk for developing these diseases may be impacted by a multitude of other factors, such as other lifestyle choices, environmental factors, age, and genetics. For example, according to the American Liver Foundation, there are several other common factors that may increase the risk of liver disease, including viruses, poor diet and obesity, genetics, autoimmune disease, and reactions to medications, illegal drugs, and toxic chemicals – to imply that alcohol consumption is the sole "cause" of liver disease is false and stigmatizing. And in the case of alcohol-related liver disease, the American Liver Foundation also notes that, in the cases when liver disease is related to alcohol consumption, it is related to excessive consumption of alcohol.^[1]

^[1] See https://liverfoundation.org/for-patients/about-the-liver/the-progression-of-liver-disease/ (last accessed Aug. 5, 2022).



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Current scientific data shows that the level of consumption is a key factor in evaluating health risks, yet the proposed warnings make no distinction and inaccurately suggest that any amount of consumption would lead to liver disease or a fatal cancer. This failure to differentiate between moderate and excessive alcohol consumption is also inconsistent with the Irish Ministry of Health's low-risk guidelines on the responsible consumption of alcohol^[2] and may confuse adult consumers who choose to drink responsibly.

Research on the efficacy of public health warnings also shows that warning labels using alarmist language are not generally effective, reinforcing the need to carefully craft language that is supported by the current state of science. In particular, alcohol warnings employing fear and warning against *all* alcohol consumption have been deemed to undermine the credibility of the source and thus the effectiveness of all warnings offered by the same, even those that are not disproportionate.

Furthermore, the proposed warning only focuses on cancer and liver disease, failing to address any other health issue. This creates the impression that the only possible health risks that might be associated with alcohol consumption relate to these two diseases. Consumers would be best served by a warning about health risks more generally so they may consider their individual risk factors with their healthcare provider. In the United States, for example, all beverage alcohol products are required to have the following statement on their containers:

GOVERNMENT WARNING:

(1) According to the Surgeon General, women should not drink alcoholic beverages during pregnancy because of the risk of birth defects. (2) Consumption of alcoholic beverages impairs your ability to drive a car or operate machinery, and may cause health problems.

This requirement was imposed by the Alcoholic Beverage Labeling Act of 1988. By having the same statement, consumers receive consistent, uniform and clear information regarding the health hazards that may result from the consumption or abuse of beverage alcohol products. This statement is broad in scope and provides consumers with a non-confusing reminder of such hazards.

As discussed above, this important public health objective would be best managed through the EU-wide level—work that is currently underway with BECA and the "Beating

^[2] Ireland's Ministry of Health has established alcohol consumption guidelines, thereby assisting adult consumers who choose to drink in making responsible and educated choices regarding their alcohol consumption. Specifically, the Ministry of Health has defined a standard drink to contain approximately ten grams of alcohol and issued low-risk guidelines for beverage alcohol consumption of up to 17 standard drinks in a week for men and 11 for women.



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Cancer Plan"—to ensure that consumers receive consistent information that is grounded in scientific evidence. These proposed warning statements are also at odds with other global agreements and efforts. As it does not reflect the current state of scientific research, this proposed warning runs contrary to the WTO's Agreement on Technical Barriers to Trade, which states that "available scientific and technical information" should be considered when establishing technical regulations with public policy objectives, such as protecting public health and safety. The proposed statement is also inconsistent with the World Health Organization Global Alcohol Strategy, which is aimed at curbing the <a href="https://example.com/health-left-scientific-new-marked-english-scientific-new-mar

We respectfully submit that consumers would be best served by a health warning label that is consistent throughout the EU and one that accurately reflects the current state of scientific data. If Ireland is to proceed with a different national labeling requirement, however, we request that the warning statement be revised to address health risks generally and provide information in a non-confusing and accurate manner consistent with the current state of research.

III. If Adopted, It Would Create a Significant Barrier to the Free Movement of Goods Through the EU Internal Market

We are concerned that if adopted, the proposal would create unnecessary obstacles to trade in violation of Ireland's and the EU's obligation under Article 2.2 of the WTO Agreement on Technical Barriers to Trade and introduce a significant barrier to the free movement of goods through the EU internal market.

Some EU Member States have enacted mandatory health warning statements or pictograph requirements, which have already fractured the EU-common market. If adopted, the Irish proposal would force U.S. distilled spirits exporters to re-label or repackage product destined for the market, further fragmenting the single market. Therefore, companies exporting to the EU will have to make special production runs for products destined for Ireland, thus inhibiting the free movement of goods within the EU's internal market. In addition to the costs associated with special production runs, companies exporting product specifically labeled for Ireland will necessarily be required to keep separate inventories. This requirement would severely limit the opportunities for exporters to reallocate product from other EU markets to Ireland in response to customers' requests, creating inefficiencies and increased operating costs.

In light of the work on EU-wide mandatory health warnings and nutrition declaration requirements and Ireland's proposed three-year phase-in for the labeling requirements, it could cause confusion and uncertainty for producers concerning the implementation of the



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requirements. In fact, there is a risk that some products would be re-labeled only to have to be re-labeled further given the different timelines for implementation of potentially duplicative labeling requirements.

If Adopted, Flexibility Should be Provided to Deliver the Information 'Off Label' through an 'On Label' QR Code or Website Reference

We urge Ireland to provide flexibility for the required information to appear 'off label' on a website through a QR code or website reference provided 'on label. This option limits the impact on the EU-single market by allowing the continued use of EU-wide labels, while allowing for the inclusion of the proposed requirements. In fact, EU Legislators have adopted rules related to wine (Regulation (EU) 2021/2117, December 2, 2021) to allow the list of ingredients and nutrition information to be provided by "electronic means identified on the package or on a label attached thereto." Providing the information through easy-to-use online tools empowers adult consumers to make informed and responsible choices.

V. Mutual Recognition of Existing Pregnancy Pictograph Warnings

Pregnancy pictograph warnings similar to what Ireland is proposing are already required in France and Lithuania. Lithuania included in its regulation a mutual recognition provision under which Lithuania agreed to recognize pregnancy warnings used in other EU countries, as well as in third countries. Under the provision, products may be sold in Lithuania without restrictions and without enforcement of the requirements of the decree "if they are labelled with warnings of different shape or size about the potential impacts of consuming alcohol during pregnancy."

Accordingly, we respectfully request that Ireland recognize products that contain similar but not identical pregnancy pictograph warnings without requiring a labeling change.

VI. Alcohol and Energy Content Should be Provided Consistent with Existing EU Requirements

Under the proposal, the quantity of grams of alcohol in a container and the energy value expressed in kilojoules and kilocalories in a container are required to appear on the label.



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Under the EU Food Information for Consumers (EU FIC) regulation, the energy value and the amount of nutrients shall be expressed per 100 g or per 100 ml, and in addition it may be provided per portion basis or consumption unit (see Article 32 and 33 of EU Reg. 1169/2011).

DISCUS urges Ireland to require such information to be provided in line with the existing EU FIC regulation. A standard drink in Ireland is 10 grams of alcohol. A requirement to provide such information by "container" does not provide consumers with the basic information of the alcohol content in a serving of distilled spirits, wine, or beer in a manner to measure and moderate their drinking to help them make responsible consumption decisions.

VII. Alcohol Content Should be Provided by Volume

DISCUS seeks clarification regarding the rationale behind requiring the quantity of grams of alcohol to be provided. Grams of alcohol is not a measure that is understood by consumers and will create confusion if adopted in Ireland. In fact, EU Regulation No. 1169/2011, which seeks to harmonize health information, among other things, requires alcohol content to be presented in volume. As such, consumers are familiar with alcohol strength being measured in percentage alcohol by volume, and not by grams of alcohol.

VIII. The Proposal Should be Notified to the WTO's Committee on Technical Barriers to Trade

Finally, we are disappointed that the proposal has not been notified to the WTO's Committee on Technical Barriers to Trade (TBT) consistent with the EU and Ireland's obligations under the TBT Agreement. In fact, in June 2016 Ireland notified its Public Health (Alcohol) Bill to the WTO's TBT Committee for input from governments and interested stakeholders (G/TBT/N/IRL/2).

Article 2.9.2 of the TBT Agreement provides that notifications of draft technical regulations shall occur at an early stage when amendments can still be introduced and comments taken into account. Subsequently, the TBT Committee adopted procedures that recommend allowing a comment period of at least 60 days before a draft regulation is adopted. Transparency and the notice-and-comment period are important tools to ensure that trade flows smoothly, predictably and freely.

We request that Ireland and the EU notify the proposed regulation to the WTO's TBT Committee for stakeholder feedback, consistent with their international commitments.



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Conclusion

We support and applaud the aim of the proposal to combat alcohol abuse and "ensure that Irish consumers are directly informed of [the health risks of alcohol] and they are supported in healthier choices regarding their alcohol consumption." However, as noted above, we have several concerns with the proposal, including whether it will effectively accomplish its goals and, if implemented, that constitutes a barrier to trade.

In summary, we respectfully:

- request that the EU submit a detailed opinion to block Ireland's adoption of the proposal as the EU continues its work on EU-wide mandatory health warnings and nutrition declaration requirements;
- request that Ireland revise the warning statement to address health risks generally and provide information in a non-confusing and accurate manner consistent with the current state of research, if it is to proceed;
- urge Ireland to provide flexibility for the required information to appear 'off label' on a website through a QR code or website reference provided 'on label, if it is to proceed;
- request that Ireland recognize products that contain similar pregnancy pictograph warnings without requiring a labeling change;
- urge Ireland to require alcohol content and energy content information to be provided in line with the existing EU FIC regulation;
- seek clarification regarding the rationale behind requiring the quantity of grams of alcohol to be provided; and
- request that Ireland and the EU notify the proposed regulation to the WTO's TBT Committee.

Thank you again for the opportunity to provide comments on the proposal, and we would be pleased to clarify and of these points as needed.

Sincerely,

Robert Maron Vice President

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