



Proposal P1050: Pregnancy warning labels on alcoholic beverages

Submission to Food Standards Australia New Zealand

October 25, 2019

Alcohol Healthwatch is an independent charitable trust working to reduce alcohol-related harms and inequities. We are committed to working in accordance with the principles of the Treaty of Waitangi and the cornerstones of the Ottawa Charter. We are contracted by the Ministry of Health to provide a range of regional and national health promotion services. These include: providing evidence-based information and advice on policy and planning matters; coordinating networks and projects to address alcohol-related harms, such as alcohol-related injury and fetal alcohol spectrum disorder; and coordinating or otherwise supporting community action projects.

Thank you for the opportunity to provide feedback on Proposal P1050: Pregnancy warning labels on alcoholic beverages.

If you have any questions on the comments we have included in our submission, please contact:

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Note: this submission has been authorised by the Director of Alcohol Healthwatch,

Summary

1. Alcohol Healthwatch applauds FSANZ for undertaking consumer testing to underpin the proposal regarding pregnancy warning labels on alcoholic beverages.
2. Alcohol Healthwatch supports the labelling proposal that includes the use of a health warning, text and pictogram, as well their application to layers of packaging. However, we recommend the following amendments to the proposal:
 - Require labels to be applied to all products with $\geq 0.5\%$ ABV
 - Include the words 'lifelong harm' in the warning statement (as requested by whānau living with FASD)
 - Reduce the transition time from 24 months to 12 months
 - Require a full warning label (9mm pictogram and 3mm text) to be applied to all products $\geq 100\text{ml}$
3. Alcohol Healthwatch supports calls by whānau living with FASD that appraisal of the costs to the industry to re-label their products demeans their day-to-day experiences and challenges associated with FASD. Even in the presence of the increased costs to the industry, these can be passed on to the consumer. In contrast, FASD can cause lifelong difficulties that have on-going social, physical, mental and economic costs to families.
4. Finally, Alcohol Healthwatch requests that FSANZ commit to being responsible to raise public awareness of the new labelling requirements, and not leave it to organisations that have limited funding to carry out an evidence-based, resourced, and on-going awareness campaign.

Introduction

5. Under normal circumstances, the onus for demonstrating safety of a harmful product falls on producers. Typically, data is required to be submitted that demonstrates their product meets New Zealand's standards for safety.
6. In relation to the evidence of the harms from the use of alcoholic products during pregnancy, as well as evidence pertaining to effective labelling requirements to warn of the dangers, it appears that the burden of proof has particularly fallen on those other than the producers. Alcohol Healthwatch **strongly recommends** that consideration be given to where the responsibility for public safety lies as Proposal P1050 progresses through its various stages.
7. Whilst alcohol happens to be classified as a food, it must be recognised that is also a drug. Typically, drug companies are required to demonstrate that their product is *safe* to bring to the market. Even in the situation when a drug company demonstrates that their product is 'safe' or contains ingredients that could have side effects, these dangers must be labelled across the range, regardless of product size.
8. In relation to alcohol, it is a known teratogen linked to adverse and serious public health harms. The seriousness of these harms necessitates a high standard of consumer information. We **strongly support** the extent that FSANZ has gone to ensure the label selected is the most effective it can be, recognising the statutory obligation to do so. Warning labels will not be effective if they are inconsistent or misleading, or absent across the full range of products.

9. Given Alcohol Healthwatch has previously submitted on the need to mandate effective labels, this submission primarily responds to the specific labelling aspects of design, size, placement criteria and the principles on which these are based.
10. However, principles and obligations should not be limited to the question of effectiveness. Decisions must be consistent with the articles of the founding document for Aotearoa New Zealand, the Treaty of Waitangi, the UN Convention on the Rights of Indigenous People and last but by no means least, the Convention on the Rights of the Child. These must remain in sharp focus to guide decisions, currently as well as into the future.

Comments to specified sections of P1050 Call for Submissions (CFS) report

Literature review on the effectiveness of warning labels (section 3.1.1 of CFS)

11. The literature review shows that multiple exposure to the same warning across different situations leads to stronger beliefs in the health risks of alcohol. Size (i.e. noticeability) of warnings appears to be a key factor in enabling an individual to evaluate product risk.
12. It is clear that there remain huge gaps in effectively informing the public of the dangers associated with prenatal alcohol exposure. Proposal 1050 is set to remedy this gap, provided that decisions made going forward reflect the evidence and principles of effective labelling.
13. It is important to note that passive information, on its own and however it is conveyed, may not strongly influence levels of consumption. However, it is one component of a systems-wide approach to addressing the harms from prenatal alcohol exposure. It must be recognised that pregnancy warning labels to date have been non-existent or inconsistent, having the potential to increase harm rather than reduce it. Without doubt, this needs to be addressed.
14. It must also be recognised that the opportunity this proposal presents is greater than the sum of its parts. It is an opportunity to create a foundational message that is consistent and visible, and that 'across the board' can be disseminated in multiple modes and mediums; in effect potentiating one other. It would be a glaring omission and incomprehensible for that opportunity to be lost in the mire of detail, or minimised in any attempt to placate producers.

Consumer testing of warning statements (section 3.1.2)

15. Alcohol Healthwatch **applauds** FSANZ for undertaking consumer testing to guide these next steps regarding the content and design of the label. We welcome FSANZ recognising its obligations under the Treaty of Waitangi to ensure this research included Māori and Pacific people in New Zealand.
16. However, Alcohol Healthwatch **suggests** that limiting the consumer testing research to only four previously selected statements is no guarantee that the messages selected are the best that can be. We describe the implications of this later in our submission.

Pictogram (section 3.2.2.2)

17. Alcohol Healthwatch **supports** the use of the selected pictogram, which has become universally-recognised since the French Government mandated it in 2006.

18. Alcohol Healthwatch **believes** that the majority of the public in New Zealand and Australia are likely to grasp the meaning of the pictogram. However, we have **strong concerns** regarding the use of the pictogram on its own (i.e. without accompanying text warnings) for some alcohol products. This is described later.
19. Alcohol Healthwatch **does not support** the proposed size of the pictogram for products within the 200–800 ml category (indicated as 6 mm in diameter). We believe it is too small to meet the noticeability criteria outlined in the consultation.
20. We further note that 6mm is smaller than some of the pictograms currently used in the voluntary scheme implemented by alcohol producers in New Zealand and Australia. Researchers have described pictograms of this size to equate to the same size as that of a frozen garden pea.¹
21. Alcohol Healthwatch **believes** there is no justification provided as to why the size of this pictogram has been reduced from 8mm as proposed in June 2019 (page 83 of the Proposal).
22. The size of the pictogram is important. Research undertaken by Deakin University in 2018 found that participants in focus groups tended to judge and compare the size of health warnings relative to other features on labels.² Small health warnings, relative to other information portrayed, can result in participants questioning the seriousness of the warning. This supports more recent research³ showing that pictograms that are smaller in size are less effective in attracting attention.
23. Alcohol Healthwatch therefore **recommends** that the minimum diameter for the pictogram on all alcoholic products $\geq 100\text{ml}$ is 9mm. The justification for the 100ml threshold is described later. For products $< 100\text{ml}$, the minimum pictogram diameter can remain at 8mm.

Warning statement (section 3.2.2.3)

24. Alcohol Healthwatch **strongly supports** the proposal for the warning label to include a pictogram, signal wording and warning text, and that these appear within a box.
25. Alcohol Healthwatch **strongly supports** the use of the phrase 'HEALTH WARNING', in red lettering, surrounded by a box with white background.
26. Of the four labels tested in consumer research, Alcohol Healthwatch **recommends** that the statement '*Any amount of alcohol can cause lifelong harm to your baby*' is the preferred warning statement.
27. The consumer testing, though limited to four messages, indicated a preference for strong, clear and factual statements. We concur, and recommend further improvements to the proposed warning statement to enhance effectiveness.
28. Alcohol Healthwatch **believes** that the inclusion of the word '*amount*' speaks only to the matter of quantity. Alcohol Healthwatch **prefers** the lead words to be '*Any alcohol...*'. This can be read as applying to any type of alcohol, any time of exposure, as well as any amount; all of which are critical considerations in the way in which alcohol affects the fetus.
29. Alcohol Healthwatch **believes** that whilst the word 'harm' is familiar as well as being a

useful, simple word to use in a warning statement, it has low specificity. When used alongside the word 'can' (i.e. can harm), Alcohol Healthwatch believes that this further reduces gravitas.

30. Alcohol is the leading preventable cause of permanent neuro-disability in countries where drinking alcohol is normalised. Whilst not every level of exposure will necessarily result in Fetal Alcohol Spectrum Disorder (FASD), the literature is clear that any amount (including from low to moderate exposure) can alter the way the brain functions and consequently lead to lifelong impairment to a greater or lesser degree; even though the impairment may not meet the threshold required for an FASD diagnosis. Alcohol Healthwatch **believes** that the word 'harm' on its own insufficiently conveys the correct message.¹
31. Warning statements must be evaluated on their effectiveness of conveying consistent, objective and effective health information. To be reasonable and effective, the warning text must be strong, clear and believable, and in an appropriate size and placement. The consumer testing that underpins the proposed warning statement found that the statement '*Any amount of alcohol can cause lifelong harm to your baby*', was consistent with the need to identify the problem and explain the consequences if exposed to the problem.
32. We recognise the balance needed between conveying the strength of the evidence versus readability. However, the serious outcomes associated with prenatal alcohol exposure (e.g. lifelong disability or disease, miscarriage or stillbirth) warrants a clear and accurate warning message. A slightly longer-worded statement should not be a barrier to providing an accurate reflection of the gravity of the problem requiring prevention.
33. Alcohol Healthwatch **supports** the longer, fuller message of '*Any amount of alcohol can cause lifelong harm to your baby*', however prefers a shorter, more concise option being "***Any alcohol can permanently harm your baby***". We believe this is reasonable to consider on the basis that the consumer testing options were predetermined and non-exhaustive.
34. This warning statement meets all of the principles of effectiveness as set out in section 3.1.2.2 of the Background Paper, as follows:
 - identifies the problem – *alcohol harm*
 - explains the consequences if exposed to the problem - *permanent harm*
 - directly refers to low levels of alcohol consumption - *any alcohol*
 - avoids definitive language that harm will always occur - *can*
 - uses personalised language to increase relevance – *your baby*
 - is as short as possible. – *seven words only (one less than the FSANZ preferred option)*.
35. Equally important, the reference to 'permanent' remains consistent with the attributes of the preferred options identified by consumer testing across Australia and New Zealand (page 26 of the Background Paper).

¹ This evidence was covered more fully during the key stakeholder engagement stage and therefore does not need reiterating in this submission.

Design labelling elements (section 3.2.2.4)

36. Alcohol Healthwatch **agrees** that labelling design elements should:
- Use short warning messages and words such as 'Health Warning' to indicate it is a warning label
 - Clearly separate warning statements and pictograms from other information on a label (e.g. *enjoy in moderation*) by providing a border around the warnings, requiring ample clear space used around the warning label, etc.
 - Use contrasting colours
 - Avoid the use of the colour green, as it can cause confusion. The colour red receives the most attention and is readily recognised as being a warning.
37. Alcohol Healthwatch **recommends** that the warning label must appear on the **front** of an alcoholic product or its packaging.
38. The Background Paper, indicates that the '*guidance for standard drink labelling and the recycle logo recommends a larger label height (12-14 mm) than that for the voluntary pregnancy warning label (8 mm box height with a pictogram of about 5 mm diameter)*'. Alcohol Healthwatch **does not support** these smaller requirements for alcohol and pregnancy warning labels. The reasons for this are unclear. If the label is to meet the criteria of effectiveness, then equivalency with other similar requirements or greater volume would seem reasonable. To set a lower requirement for a new and different health advisory label of critical health importance, seems unjustifiable.
39. Research examining the voluntary labels applied to date has shown that 82% of the labels were 5mm in diameter and a further 12% were closer to invisible (96% unnoticeable).⁴ In no way should this small size be considered a starting benchmark for mandatory labelling requirements.
40. In addition, FSANZ must give consideration to the locations on alcohol products where labels cannot be applied. This could include, for example, the bottom or necks of products.

Summary of proposed pregnancy warning label design (section 3.2.2.5)

41. Alcohol Healthwatch **agrees** with the major proposed elements of design but **does not agree** with exceptions to the proposed font size.
42. Alcohol Healthwatch **does not support** any warning label font size being <3mm. This proposed size is not in line with FSANZ's own standards, and would result in the continuation of the poor readability inherent in the industry-initiated voluntary labelling approach.
43. To ensure consistency, Alcohol Healthwatch **recommends** that the font for the warning text should be at least 3mm (as prescribed for other warning labels). In other words, all alcohol products 100ml and above should be required to display the same specific design features as those currently proposed for products greater than 800ml (with the font size increased to 3mm).
44. There is no strong justification for permitting labels with smaller font size requirements. The principle of noticeability and legibility - as illustrated in the experimental studies shown in the CFS - should take precedence over other considerations. These studies found that

increasing the size of warnings led to an increase in the noticeability of the warning. Similarly, the principle of consistency is a key consideration.

Beverages to carry the pregnancy warning label (section 3.2.3)

By alcohol content

45. Alcohol Healthwatch **does not support** the requirement for labels to only apply to products with 1.15% alcohol by volume (ABV) and above.
46. Alcohol Healthwatch **recommends** that all products with a 0.5% ABV and above should be subject to the proposed standard. This will create a consistent message across all products that may contain any alcohol.
47. Alcohol Healthwatch, along with other public health representatives, are calling for alcohol products of 0.5% ABV and above to be labelled with the pregnancy warning label. This would be in line with public health advice from health authorities internationally that state that no level of alcohol consumption is known to be universally safe for a developing fetus. Indeed, it is in accord with the very purpose of Proposal 1050.
48. Recent research⁵ has demonstrated the inconsistency of alcohol content found in fermented beverages that are not subject to alcoholic beverage labelling standards. This includes Kombucha and Kefir sodas. Their variability and uncertainty in alcohol content places pregnant consumers (as well as drivers, those on medication, those with an Alcohol Use Disorder, etc.) at significant risk. This concern needs to be addressed in the current consultation.
49. Because Proposal 1050 relates to the critical period of pregnancy where the health of the fetus is the paramount consideration, there is no valid reason (beyond convention) that the Standard should arbitrarily use the 1.15% ABV cut off.
50. Alcohol Healthwatch **believes** that the omission of beverages that contain a measurable level of alcohol would be contradictory to the existing health message to not drink any alcohol during pregnancy. Any omission would also be inconsistent with all other alcoholic beverages that require warning labels. Requiring a pregnancy warning on the range of fermented beverages mitigates a hidden universal risk.

By volume of product

51. Alcohol Healthwatch **does not support** the full warning (including both pictogram and text warning) applying only to products >200ml. We believe that this proposed range of products excludes the large and growing variability among beverage types and sizes. For instance, products in the <200ml range are no longer limited to smaller bottles of spirits or pre-mixed ready to drink product. Products less than 200ml may be the very products that appeal to women and present particular risk as the size of the container is designed for single occasion consumption, rather than being decanted from.
52. The tiered approach to labelling requirements should not, first and foremost, seek to align with current industry product and packaging processes. Labelling, first and foremost, is about informing consumers of the risks associated with alcohol consumption during pregnancy. Visibility is key. This should be the starting point for decisions relating to evidence-based labelling, not ensuring industry flexibility as it relates to their current

design of alcoholic beverages.

53. It also appears questionable why volume alone should determine labelling requirements, when alcohol content in a product equally matters.
54. There is a further risk that the industry may specifically design products containing <200ml to be exempt from particular labelling requirements.
55. Alcohol Healthwatch **recommends** that the 200–800ml and 800ml+ categories should be abandoned in favour of not differentiating container size for all products 100ml or greater. With tobacco warnings, there is no differentiating in size of health warnings in relation to size of the package. There is no reason not to do the same for alcohol harm warnings. The warning on these products ≥100ml should contain a pictogram of 9mm diameter minimum size, and text warning minimum font of 3.0mm. For products <100ml, the pictogram should be a minimum size of 8mm.

Application to different types of sales (section 3.2.4)

56. Nothing to add.

Application to different types of packages (section 3.2.5)

57. Alcohol Healthwatch **agrees** that all layers of packaging must carry the full pregnancy warning label. As stated previously, we recommend that the threshold for requiring only the pictogram warning should be reduced to products of less than 100ml. This would equally apply to the warnings required on packaging of such products (that is, the outer packages of products <100ml should require the pictogram only).

Consideration of costs and benefits (section 3.4.1.1 of CFS)

58. Alcohol Healthwatch concurs with the FSANZ evidence-based statement in the CFS document that, *“...the proposed pregnancy warning label is likely to better convey government advice not to drink any alcohol during pregnancy, and attract consumer attention to greater extent than the warning labels commonly used in the voluntary initiative.”*
59. We also concur with the statement, *“FSANZ is of the view that no other realistic food regulatory measures exist at this stage....”*
60. However, Alcohol Healthwatch **strongly questions** the way in which the costs to industry have been measured against the cost of FASD. The Decision Regulatory Impact Statement shows that the break-even point for the number of FASD cases avoided over a 20-year period is low and the evidence supports the likelihood that this target would be achieved.
61. Our first concern regards the analysis of probable new cases of FASD in Australia and New Zealand, which is, at best, a significant underestimation. As pointed out in the Key Stakeholder submission from Alcohol Healthwatch since the DRIS was written, Canada has conducted a case-ascertainment prevalence of a nationally representative sample of a cohort of 8-year old children to arrive at a figure of 2-3% of the population having FASD⁶. It must also be recognised that 428 disease states have been identified as being associated with prenatal alcohol exposure (PAE)⁷.

62. Canada, like Australia and New Zealand, has similar patterns of drinking. There is no reason to believe Australia or New Zealand would have a FASD prevalence lower than Canada. On the contrary, as pointed out in our previous submission, levels of hazardous drinking among women have been rising⁸- and overall, are likely higher in Australia and New Zealand than in Canada.
63. The recent work of Greenmeyer et al⁹ would suggest that any cost comparison between FASD and those of the liquor industry is irreconcilable. The Paper identifies that
“Economic costs of FASD—a preventable disease—involve multiple sectors of society including direct costs (e.g., health care, education, social services, criminal justice system) and indirect costs (e.g., productivity losses). ... Despite the absence of cost data from multiple important cost categories, the annual estimates for cost of care for all individuals with FASD ranges from USD \$926 million to \$3.2 billion”.
64. Whilst we recognise the need for a cost-benefit analysis, Alcohol Healthwatch believes that comparing the costs associated with a harmful commodity with people’s lives diminishes the lived experience of those with FASD, especially when there exists a potential to pass on the increased costs to the consumer.
65. A recent peer-reviewed study¹⁰ has further highlighted how alcohol industry public communication approaches undermine and obfuscate key public health messages with regards to the harm from prenatal alcohol exposure. It is therefore imperative that the Government takes responsibility to inform citizens in a consistent and effective manner. Ireland has recently enacted legislation requiring that a label on an alcohol product has “details of a website, to be established and maintained by the Executive, providing public health information in relation to alcohol consumption.”¹¹ This approach is more suitable to enable consumers to be directed to the most credible source of information from an alcoholic product.
66. Alcohol Healthwatch further **believes** that any cost arising from relabelling can be passed on to consumers. Given that alcohol has never been more affordable than it is today¹², price increases can contribute to reduced consumption and harm.

Transitional arrangements (section 4.1 of CFS)

67. Alcohol Healthwatch **does not support** the two-year transition period and continues to support a 12-month period as being sufficient. It appears that the only rationale for rejecting a 12-month transition period (in favour of a two-year period) is to delay the provision of information to consumers and thereby favouring the desires of the alcohol producers.
68. For a non-essential beverage (harmful drug), of little to non-existent nutritional value, a two-year transition period is unnecessary, arbitrary and would be a minor consideration for the mostly multi-national corporations that own the alcohol supply chain in New Zealand. It must be strongly recognised that the public have waited long enough, through considerable voluntary time periods afforded to alcohol producers.
69. Two years is simply too long when one considers the lifelong harm that can result from prenatal exposure. As stated previously, costs can be offset in the marketplace.

70. It should also be noted that alcohol producers have, since 2011, been granted leave to voluntarily take on the role of public health advisor by adding their own mixed selection of warning labels to their products. Evidence clearly shows that their attempts have failed miserably, whilst further delaying evidence-based labels that effectively communicate the risks the public has a right to see.
71. Alcohol Healthwatch **believes** that there is nothing novel nor surprising in requiring a 12-month transition for this important Standard.
72. Alcohol Healthwatch is also **concerned** by the wording in the Background Paper, suggesting that:
“After the end of the two year transition period the majority of alcoholic beverages would be expected to carry the warning label.”
73. Alcohol Healthwatch is **concerned** that ‘majority’ (i.e. >50%) and ‘expected to’ are far from definitive indications that a two-year transition is a guarantee of compliance. This requires urgent attention.
74. In relation to this, Alcohol Healthwatch **requests** that FSANZ outlines the enforcement provisions relating to non-compliance with labelling, including the penalty for non-compliance.

Draft variation to the Australia New Zealand Food Standards Code (Attachment A of CFS)

75. Alcohol Healthwatch notes that FSANZ will be guided by its own processes regarding the Draft Variation. Assuming this follows normal protocols as required by Statute, there is no further comment to add.

Other comments (within the scope of P1050 – see section 1.5 of the CFS)

76. Section 4.3 of the CFS deals with education. This deserves further comment. Alcohol Healthwatch is one of very few charitable agencies able to promote prevention awareness, but does so with limited resources to do so effectively. Other non-statutory public health agencies do so mostly through personal interest, good will and solidarity.
77. Alcohol Healthwatch **requests** that FSANZ commits to taking responsibility for raising awareness of the changes, along with monitoring and evaluating the impact of the scheme. We suggest that it cannot be expected that public health NGOs and researchers alone will be able to take the responsibility for a Governmental-mandated change. This must be a shared responsibility within a civil society.

Conclusion

78. Alcohol Healthwatch strongly supports the mandating of effective pregnancy warning labels on all alcoholic beverages. Communities, including whānau affected by FASD, have been calling for this to happen for many, many years.
79. As previously stated, we commend the work of FSANZ to use an evidence-based and principled approach to underpin the decision-making process. It is imperative that this rigorous approach is carried out throughout all of the stages that are to follow.

80. The outcome of this process has the potential to fill a glaring gap in public health efforts to inform consumers of the harms associated with prenatal alcohol exposure. We believe that a comprehensive approach is required to preventing the risk of physical and neurodevelopmental harm caused by alcohol teratogenesis during gestation, of which labelling is one component.
81. The impact of preventing the harms from prenatal alcohol exposure cannot be overstated. The seriousness and long-term nature of the harms warrants a robust approach to decisions that impact consumer information.
82. We therefore ask those involved with the next stages in the decision-making process to never lose sight of the enormity of what this preventable disease is really all about. We consider that the public has held, and continues to hold, the right to be fully-informed about the gravity of the risk posed to the unborn baby from alcohol. A Government-mandated warning conveyed on products is the primary means to convey gravitas, as well as being a basic population health approach and civil society obligation.
83. Consistent, high-quality messaging via warning labels has the potential to support other public health approaches to reduce the risk from alcohol consumption during pregnancy, and also counter attempts by vested interest groups that may result in obscuring and obfuscating accurate information.
84. Alcohol Healthwatch is thankful to Food Standards Australia New Zealand staff for their diligent work and attention to detail in getting this often controversial and sensitive discussion and decision-making process to this point. We hope this submission helps to point a positive direction for the people of both nations moving forward.

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