



The Australian College of Midwives (ACM) is the peak professional body for midwives in Australia who are registered with, and regulated by, the Nursing and Midwifery Board of Australia (NMBA). The ACM's position is that women be attended during pregnancy, birth and postnatally by a midwife who is registered with the NMBA.

We are pleased to make a submission to Food Standards Australia New Zealand (FSANZ) on Proposal P1050 – Pregnancy warning labels on alcoholic beverages.

Submission to Proposal P1050 – Pregnancy warning labels on alcoholic beverages

A. Name and contact details (position, address, telephone number, and email address):

Australian College of Midwives
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B. For organisations, the level at which the submission was authorised:

Australian College of Midwives

C. Summary (optional but recommended if the submission is lengthy):

It is clear from the results of the literature review and the consumer testing that the existing messaging has not been successful in educating/advising women or the community that women should not drink in pregnancy. And as such it is past time that a clear and consistent, mandatory set of labelling are developed and implement to educate and protect the public.

We are aware that industry have been pushing back hard and focusing on the cost burden to their business, however we feel it is imperative to remind FSANZ that alcohol is a known teratogen (i.e. causes birth abnormalities) and aside from all of the other effects it can have on people who drink, for the pregnant woman it has the potential 'side-effect' of causing lifelong brain injury in their fetus. We are disappointed that despite industry being aware of this, they would prefer to use their power and influence to delay changes. We believe that women deserve better and remind FSANZ that they are responsible for ensuring the safety of the public.

It is imperative that the messaging be not only mandated across all alcoholic beverages, but

that it be changed to be a message that is understood to convey the meaning of the guidelines. Time is of the essence as we have had ineffective messaging for a number of years, and the industry has been able to choose as to whether they will engage with the messaging or not. There needs to be minimal delays in implementing a clear and consistent message to all consumers that alcohol should be avoided in pregnancy.

There are a number of items we will respond to as per the consultation structure but in summary our main points are as follows:

- As an organisation that works alongside midwives, who care for women during pregnancy, we would strongly push for a 12-month transition and implementation period. Women have for too long been provided with substandard information from industry, that is not consistently applied across alcoholic beverage that has caused confusion and has resulted in women continuing to drink during pregnancy. The changes once implemented will finally support the advice that midwives provide to women as part of their antenatal education. FSANZ is in a unique position to ensure that the number of children to be affected by FASD related health complications can begin to reduce within 12 months – reducing the cost burden to the health industry and the community as well as the emotional turmoil of families affected. 12 months is sufficient time for an industry that is aware of the negative impact of their product on the growing fetus to make a socially acceptable change to their product line to protect the public and future generations.
- The labelling needs to be consistent with current food labeling standards. We would strongly support 2 levels of product labelling to streamline the process as well as packaging labeling that allows for a pictogram only on products smaller than 100ml and every other product to have labelling that meets food labeling standards requiring a large pictogram (9 mm) with warning text (3 mm). We do not support the interim labelling size for the 200ml-800ml products as we believe this creates an additional level of labeling that is superfluous to the requirements of this process and creates a risk in relation issues raised in section J.
- We would prefer the labelling to use the strongest supported phrase: 'Any amount of alcohol can cause lifelong harm to your baby' as it polled the highest although the chosen statement "Any amount of alcohol can harm your baby" did poll well (just not as well) and so we would be supportive of this use (although justification for the shorter statement is lacking).
- We request that the labelling be applied to all alcoholic beverages over 0.5% alcohol by volume (ABV), to ensure that there is a consistent message for the public, for all alcoholic beverages that women may consume. This will also align to the national alcohol guidelines in both Australia and New Zealand that abstinence is the safest option during pregnancy.
- We request that a clear and detailed plan is developed that steps out the initiatives to educate consumers about the changes to the Code. FSANZ will need to ensure that as well as working alongside industry and health organizations that there is a centralized coordinated plan that includes resources as required. Noting that the current details in the plan are considered to be insufficient and lacking in detail
- Further that FSANZ will provide a clear and detailed plan for in-depth and evaluation and monitoring that will commence once the labelling has been implemented. This will be needed to ensure implementation and compliance as well as detail the rules around enforcement. Noting that the current details in the plan are considered to be insufficient

and lacking in detail.

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

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

- We were pleased to see that the literature review included both Australian and international papers although we were unable to determine the weighting criteria that was applied to the level of evidence in each paper from the details provided. We were also disappointed to see that a peer review of the literature review did not take place before the plan was drafted and that it is unclear how the feedback that may be received will be implemented. We are also concerned by the potential for the liquor industry undertaking the peer review as we believe this must be undertaken independently of the stakeholders to avoid bias and conflict of interest.
- In addition, we are confused as to why elements as identified in the literature review as beneficial are not implemented as part of the plan.
- For example, page 12 of the Proposal states that "larger, front of pack, warnings using colour, signal words and pictorial elements are likely to attract more attention than warning labels lacking those elements." This conclusion from the literature review is not supported by the Proposal where the minimum font size has been set as smaller than the standard requirements for other warning texts in the Code (Standard 1.2.9).

E. Consumer testing of warning statements (section 3.1.2)

From the Executive summary **"The aim of the study was to identify which of the statements conveyed the government advice not to consume any alcohol during pregnancy in a manner that was believable, credible, convincing, and of relevance to women of childbearing age and the broader community"**

- ACM are pleased to see that robust consumer testing on the text was undertaken. However, it was disappointing that consumer testing on the whole label (including colours and pictogram) was not undertaken as the literature showed there was a paucity of evidence in this space and this was an ideal opportunity.
- In regards to the statements that were tested we were pleased to see that there were a number for consumers to test as well as the current statement that is in use. When linking to the aim of the study it was interesting to note that the current warning is insufficient and does not convey the safety message it is intended to.
- Whilst we can see that there was rationale to omit the term 'unborn' from the testing it would have been an ideal opportunity to determine the impact of the use of this term for this subject.
- In section 3.1.2.4.1 Comprehension - the Statement "Any amount of alcohol can cause lifelong harm to your baby" was the best performer. Further in section 3.1.2.4.5 Statement that best conveys the message – in both Australia and New Zealand more than 50% of participants (women and those in the proximate pregnant category) selected "Any amount of alcohol can cause lifelong harm to your baby" and yet this is not what has been selected as the final statement. Was the rationale behind this purely

based on making the length as short as possible?

- We were unable to determine from the write up whether the full cohort from Australia and New Zealand (1002 test subjects from each) actually participated or what percentage of each this resulted in. Understanding that engagement in surveys is typically less than 50% of the initial target population.
- We are concerned that there is potentially more emphasis being placed on the desires of the producers and labelling than on the need to make the warning clear and effective – e.g. with an emphasis such as the need to 'take up less space on the label'

F. Pictogram (section 3.2.2.2)

- We are pleased that as per the literature review (section 3.1.1.1.5 Pictorials) a pictogram has been included as the inclusion enhances the message, draws attention to the text.
- We are pleased that specific guidelines are to be set on colour and layout to ensure visibility and conformity of messaging.
- The pictogram was not part of the consultation so it is unclear if it is the best pictogram to be used. We draw attention to the feedback from the Aboriginal and Torres Strait Islander community (section 3.2.2.4.2 Stakeholder views) in regards to their concerns about the woman holding a wine glass (and its relativity to women who don't drink wine) and the image being of a black woman (and this being perceived to be reflective of Aboriginal or Torres Strait Islander women). The consumer testing phase would have been an ideal opportunity to assess the best pictogram to use.
- The image is one that people clearly resonate with and are familiar with although we note that current messaging has not been effective in advising women not to drink and so we wonder whether using the same pictogram that has not been effective, but with new messaging, might muddy the waters.
- We support the pictogram only on the smaller containers but we strongly suggest that the smaller container needs to be capped at less than or equal to 100mL and that for larger containers it needs to be the larger pictogram and the warning text.
- We do not support the FSANZ proposal to create middle range label where the pictogram would be reduced to 6mm in the 200–800 ml category. This is not supported by the literature review results and creates an additional level of complexity in labelling requirements.

G. Warning statement (section 3.2.2.3)

- We support the intended warning label text and format such that there is a clear HEALTH WARNING, the pictogram, a clear and consistent message, a white background and a clearly defined space around the label.
- As per section 2.3 Alcohol labelling requirements in the Code – "The term warning statement is defined in the Code (section 1.1.2—2) and the exact wording of warning statements is prescribed. Warning statements are required to be written in a font size of at least 1.5 mm for a small package and of at least 3 mm for all other sized packages (section 1.2.1—25)." – we are therefore curious as to why FSANZ would suggest a mid-sized label that does not conform to the code (for the 200mL-800mL containers)
- We believe that HEALTH WARNING as opposed to PREGNANCY WARNING is an

acceptable term as the message is targeting the whole community not just women, although women are one of the central foci.

- Whilst we would have liked to have seen 'unborn' tested in the consumer testing process to determine the impact, we are happy with the statement and feel that it is effective. In addition, by not using the term 'unborn' there is a level of applicability of the statement to women who are breastfeeding – which would not occur if the term 'unborn' were used.
- We note that to ensure the message is clear and lacking in any ambiguity that the current 'DrinkWise' messaging will be required to be removed. We believe it is essential as the messaging 'enjoy in moderation' creates confusion in the messaging

H. Design labelling elements (section 3.2.2.4)

From Executive summary "As stated in the DRIS (page 50), the **primary objective** of pregnancy warning labels on packaged alcoholic beverages is to provide a clear and easy to understand trigger to remind pregnant women, at both the point of sale and the potential point of consumption, to not drink alcohol. A **secondary objective** of pregnancy warning labels on packaged alcoholic beverages is to provide information to the community about the need for pregnant women to not drink alcohol."

- We believe that the elements of the warning label that FSANZ has outlined addresses the primary and secondary objectives and we are pleased that the elements will be strictly applied.
- We note that the label location will not be prescribed even though the literature showed that a front placed label would be most effective. We draw attention to the labelling that has been required for cigarette packaging that ensures the warning is front and center so that the health message cannot be ignored and this was shown to be effective (Section 3.1.1.1.3 Location).
- The literature review identified that larger labelling is more effective (Section 3.1.1.1.2 Size) as it is more noticeable, and yet the labeling that has been defined for the 200mL to 800mL containers is smaller than the Food Standards minimum sizing details. As such we do not support the 200–800mL category nor the font size <3mm, as they are not in line with FSANZ's own standards (the Food Standards Code - Standard 1.2.3).

I. Summary of proposed pregnancy warning label design (section 3.2.2.5)

- ACM believes FSANZ has generally met the aims for the warning label:

DRIS stated the pregnancy warning labels should	Planned labels
"include text that is readable and possibly the same size as all information on the product label	A clear consistent statement Acceptable sizing for containers greater than 800mL. The sizing for 200mL-800mL needs to be rethought and aligned with the Food Standards Code - Standard 1.2.3
use short warning messages, and words such as 'WARNING' or 'HEALTH WARNING' to indicate it is a warning label	HEALTH WARNING is a clear message appropriate for this target audience
be separated from other information on the	the clear border around the warning box

label (for example, placed in boxes with borders and away from messages such as enjoy in moderation)	and the pictogram as well as the defined background colour It is however unclear whether the 'DrinkWise' messaging will be required to be removed. We believe this is essential as the messaging 'enjoy in moderation' creates confusion in the messaging
use contrasting colours, noting that the colour green should not be used as it can cause confusion and that the colour red receives the most attention and is readily associated with being a warning.	The colours chosen (black and red) are clear and consistent across the messaging and draw suitable attention to the message.

- We again reiterate the need to have only 2 levels of labelling
 - Containers 100mL or less – pictogram only
 - Containers 101mL and over – full warning label
- The table in the literature review does not clearly identify the number of products between 100mL and 200mL stating only spirits/liqueurs, but indeed there are spirits wines, sparkling wines and ready to drink containers, many of which have more than one standard drink and as such we believe that the level of risk related to the ABV of the product should also be factored into the rationale behind labelling.

J. Beverages to carry the pregnancy warning label (section 3.2.3)

- We support labelling to be present on all containers although we prefer this to include those that have an ABV of 0.5% and above as this is consistent with the message that no alcohol should be consumed during pregnancy.

K. Application to different types of sales (section 3.2.4)

- ACM support the planned approach taken to different types of sales, outlined in section 3.2.4.

L. Application to different types of packages (section 3.2.5)

- ACM are supportive of FSANZ's approach for containers, multipacks and packaging, such that the warning label would be required on each individual product as well as the packaging containing the individual portion pack.

M. Consideration of costs and benefits (section 3.4.1.1 of CFS)

From the executive summary "This updated and extended consideration of costs and benefits supports the conclusions of the 2018 DRIS that only a small proportion of FASD cases need to be prevented to offset the costs of label changes to industry"

- ACM believe that making the labelling mandatory will address the costs to the community of alcohol related complications of the newborn and as such it represents the most benefit to the community.

- Further ACM agrees that the labelling aligns to the Australia and New Zealand government advice and messages for women not to drink any alcohol during pregnancy to reduce the risk to the health and safety of the unborn child” (p.50).

N. Transitional arrangements (section 4.1 of CFS)

- Drinkwise advise that their 2019/20 financial year planning for the FASD Awareness Program “has been scheduled, using current messaging, with funding by Industry and assets already in place”. However, the literature review and the consumer testing both showed that the current messaging is ineffective and indeed may even be causing harm due to the inconsistent messaging and understanding of the messaging. Therefore, the messaging needs to be replaced expediently and should not be delayed or allowed to continue for any longer than absolutely necessary.
- Further, FSANZ noted that the majority of Industry stocked labelling for 4 months. Therefore, the solution and transition should be targeting to the majority of Industry with potential exemptions or extensions on request and after careful consideration.
- Therefore, ACM do not support the 2-year suggested transition arrangements and request FSANZ to implement as 12-mnth transition phase. We believe this is adequate time of the industry to make the required changes. Noting that this is an industry that were given over 5 years to voluntarily implement changes to educate and protect the community and yet the majority chose not to.
- If required, ACM would be supportive of stickers being produced for over stickering of products that are still on shelves after the transition period that do not have the required warning labels to ensure that all alcoholic products carry the educational warning content. This will ensure that there is a consistent, Australia wide message. Noting that for international products it appears that the warning label may be included as a supplementary label (e.g. sticker)(as per section 2.5 Free trade agreements). If a supplementary label is acceptable for these products then it should also be acceptable for Australian produced alcoholic beverage containers that were packaged prior to the labelling becoming mandatory and enforceable.
- We noted some potential concerns from industry that the new additions would not be acceptable to the export market. However, there is nothing in the literature to advise details pertinent to Australia’s main exports and their pregnancy warning label requirements. Further, in Section 3.3.2 World Trade Organization (WTO), whilst there are no international standards on pregnancy warning labels on alcoholic beverages the literature review noted that making the addition is “unlikely to have a significant effect on international trade”

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

- The draft variation to the Australia New Zealand Food Standards Code will need to be reviewed once the feedback has been collated and any further changes made as there are elements – as we have provided feedback for above – that would need updating.
- e.g. size of labeling, labelling requirements, transition timeframe, volumes for labelling requirements etc.

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

Location of the label.

From the executive summary “The location of the pregnancy warning label on alcoholic beverage containers is not prescribed, giving industry flexibility with the positioning of the warning label.”

- ACM would suggest that a front of product label would be most effective.
- Failing that being mandated we believe it is essential that FSANZ take steps to ensure that labelling cannot occur on the underside of the container or on the neck of a bottle (in the section that is torn away on opening)

Education.

From the Executive Summary “It is well recognised that labelling is one part of a broader suite of measures aimed to raise awareness of the risks of drinking alcohol during pregnancy. It is expected public health agencies will incorporate reference to the pregnancy warning label in their education materials thereby drawing attention to the labelling requirement and linking the warning label message to broader education messages about FASD”

And “The DRIS emphasises pregnancy warning labels need to be complemented by broader activities and targeted interventions to achieve behaviour change and ultimately a reduction in the prevalence of FASD.”

- ACM support the intention of the proposal but believe that too much reliance has been placed on health agencies without any attention being made to required budgets and requirements to develop and implement the required educational activities and resources.
- This needs to be undertaken centrally and coordinated such that there is consistency in content and implementation.
- There should be commitment from FSANZ/government to inform consumers about these changes.
- Any educational content/campaign should not be implemented by the industry.
- The uptake and understanding of the education also needs to be evaluated to ensure that it is meeting the requirements, and if not it can be improved.

Evaluation

- The section on monitoring is worryingly brief. A plan needs to be in place before the program commences and should start as soon as the labelling is mandated to ensure that implementation is consistent and industry is compliant.
- The label validity needs to be tested – such as the text, size, pictogram and placement.
- The evaluation process should not rely on research funding but be built in by FSANZ/government.
- FSANZ should/could be thinking longer term about research opportunities that this implementation will create.
- The evaluation also needs to include provision for enforcement of compliance and implications for when industry does not comply.

DrinkWise messaging

- The industry supported/paid DrinkWise messaging has been shown to be ineffective. In addition, it is not free from bias as it is developed by the very industry supplying the product. The messaging is not consistent with the Australia and New Zealand

messaging around alcohol in pregnancy and as such it should be removed from all packaging.