

The Foundation for Alcohol Research and Education (FARE) welcomes the opportunity to make a submission to Food Standards Australia New Zealand (FSANZ) on Proposal P1050 – Pregnancy warning labels on alcoholic beverages. FARE has been involved with this issue for a number of years and is pleased to see it reach the final stages prior to mandating.

The Foundation for Alcohol Research and Education (FARE) is an independent, not-for-profit organisation working to stop the harm caused by alcohol.

Alcohol harm in Australia is significant. Nearly 6,000 lives are lost every year and more than 144,000 people are hospitalised making alcohol one of our nation's greatest preventive health challenges.

For more than a decade, FARE has been working with communities, governments, health professionals and police across the country to stop alcohol harm by supporting world-leading research, raising public awareness and advocating for changes to alcohol policy.

FARE is guided by the World Health Organization's (2010) *Global strategy to reduce the harmful use of alcohol* for stopping alcohol harm through population-based strategies, problem directed policies, and direct interventions.

## **Submission to Proposal P1050 – Pregnancy warning labels on alcoholic beverages**

Submission to Proposal P1050 – Pregnancy warning labels on alcoholic beverages. Please submit this to FSANZ as a word document (if required, a pdf of the submission may also be provided in addition to the word document).

For information about making a submission, including what your submission should include, visit the FSANZ website at [information for submitters](#).

### **Name and contact details (position, address, telephone number, and email address):**

Foundation for Alcohol  
Research and Education, 1/40 Thesiger Court, Deakin ACT 2600,

Phone:

Email:

### **A. For organisations, the level at which the submission was authorised:**

Foundation for Alcohol Research and Education (FARE)

### **B. Summary (optional but recommended if the submission is lengthy):**

FARE commends FSANZ for the work undertaken to date to progress mandatory pregnancy warning labels outlined within *Proposal P1050 – Pregnancy warning labels on alcoholic beverages* (the Proposal). The labelling scheme is the first pregnancy warning scheme in the world to be introduced consistently and comprehensively, which provides a unique opportunity to follow the changes closely through evaluation and monitoring. This will inform other countries in their endeavours to introduce similar schemes. Currently, countries such as

France and South Africa have limited mandatory pregnancy warning labelling schemes, but these are not prescribed to the level of detail that is contained within the Proposal. Neither of these countries have labels that mandate a combination of text and pictogram.

FARE supports most of the proposed changes to the *Food Standards Code* (the Code) and in particular the application of both a pictogram and warning text in a box, prescribed in red, white and black. However, there are a number of issues that need to be rectified in order for the scheme to be most effective. Importantly, the Proposal has outlined a scheme that is taken from the point of view of the size of beverage containers, with little justification of why these categories were chosen. Nor does this Proposal take into account the level of risk related to different strength products. These issues are discussed in this response. In summary, the changes that are sought cover four key areas:

- 1) Revise the range of containers that require the pictogram only to products <100 ml and harmonising products requiring a large pictogram (9 mm) with warning text (3 mm) to all products ≥100 ml.
- 2) Align the requirement for pregnancy warning labels to products with an alcohol content ≥0.5% alcohol by volume (ABV), thus ensuring consistency with national alcohol guidelines in both Australia and New Zealand that abstinence is the safest option during pregnancy.
- 3) Implement a 12-month transition timeframe, as has occurred in other countries. This will allow sufficient time for the industry to adapt their labelling schemes to comply with the changes to the Code.
- 4) Outline a clear plan to inform consumers about the changes to the Code and to implement comprehensive evaluation and monitoring, including the development of a comprehensive enforcement and compliance plan.

#### **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)**

The comprehensive literature review that was undertaken to inform the Proposal provides a great deal of insight into the existing evidence around the effectiveness of warning labels. It also indicates that there is limited evidence relating to pregnancy labels on a number of detailed issues, such as optimal font size. It is clear that FSANZ approached the literature review with the intention to provide an inclusive overview of existing research relevant to the proposed policy option. However, the execution of the literature review has several issues that significantly affect its quality.

Firstly, there is a lack of synthesis of findings. Each study has been described in separate paragraphs without analysis. Unfortunately, without this analysis it is unclear how the literature review supports decisions made within the Proposal. 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).

Secondly, the scope of the literature review and how this literature has been treated within the review is also limited. It is unclear how the quality assessment of each study was undertaken. Appendix A of the literature review outlines the criteria used. However, without a clear description of what type of studies were included in the search (qualitative, quantitative, mixed methods, or all types of studies) it is difficult to judge whether these criteria are adequate and appropriately applied to identified studies. It is also not clear how these criteria were applied to studies with different methodological approaches and how these are then compared.

Furthermore, there is no description of how each study is scored based on these criteria and what were the cut-off points for 'low', 'medium', or 'high' quality.

Lastly, while it is reassuring to know that the literature review will be peer reviewed, no information is provided on who is undertaking the review. This makes it difficult to determine whether or not this will be of benefit or not. Nor is it clear what the outcome will be if changes are required following peer review.

#### **E. Consumer testing of warning statements (section 3.1.2)**

The consumer testing undertaken by FSANZ clearly demonstrates and confirms previous research by FARE and others, that the current text 'Its safest not to drink while pregnant' is ambiguous and ineffective in informing all consumers about the risks of alcohol consumption and pregnancy. This was emphasised by the finding that 20 per cent of women in Australia and New Zealand interpreted the message in a manner that did not align with public health advice. It is concerning that this has been the main message used on alcoholic beverages to inform members of the public for eight years and highlights the urgency of addressing the matter.

While FARE supports the message that has been chosen as the warning text for the labels, further justification is required to support the reasons for this choice. The consumer testing clearly indicates that the longer message "*Any amount of alcohol can cause lifelong harm your unborn baby*" performed better across most of the indicators tested. Apart from "*Any amount of alcohol can harm your baby*" being a shorter statement, it is not clear why this message was chosen. That said, the shorter statement has tested relatively well across the different domains and across both countries, but it is not clear why a longer message was tested if it was not going to be chosen. This decision appears to contradict the consumer testing process and its purpose.

Lastly, it is not clear who will be peer reviewing the findings. It is noted that during targeted consultations the alcohol industry requested an opportunity to peer review the consumer testing findings. FARE seeks reassurances that an independent peer review will be undertaken by a third party for this research.

#### **F. Pictogram (section 3.2.2.2)**

The pictogram, in general, appears to have been developed with noticeability in mind. In particular, the colour scheme is optimal and is commended. Previous research suggests that colours such as green create the perception of safety (in consumption), whereas red indicates a warning.<sup>1</sup> A key recommendation that consistently appears in the literature is the need for the pictogram and warning text to be of sufficient size for it to be noticeable to consumers.

However, the suggested size of the pictogram to be placed on products within the 200–800 ml category is too small (indicated to be 6 mm in diameter) to meet the noticeability criteria outlined above. No justification is provided as to why the size of this pictogram has been reduced from 8 mm as proposed in June 2019 (page 83 of the Proposal). The size of this suggested pictogram (6 mm) is smaller than some of the pictograms currently used in the voluntary scheme. For example, Figure 1 shows a bottle of wine (187 ml), where the label covers a large area of the bottle and the pictogram itself is close to 10 mm in diameter. Thus, it is reasonable to expect that alcohol products can include a prominent full warning mark (warning text and pictogram), where the pictogram is 9mm in diameter (see further information in Table 1).

FARE's agrees with including only the pictogram at 8mm in diameter on containers under 100 ml (see section I).



**Figure 1. Jacob's Creek Chardonnay 187ml (12.9% ABV), 1.9 standard drinks.**

Research published by Tinawi et al. (2018) into the effectiveness of warning labels in New Zealand found that the area of the pictogram on alcohol products ranged from 41 mm<sup>2</sup> to 57 mm<sup>2</sup>, corresponding to 7.2–8.5 mm diameter. The average size of the pictogram on alcohol products was 7.6 mm in diameter.<sup>2</sup> This size of the pictogram was said to be the same size as that of a frozen garden pea.

Furthermore, the researchers found that “*pregnancy-related pictogram occupied between an average 0.13 per cent (wine) and 0.21 per cent (ready-to-drink) of the available surface area of the alcohol beverage container (i.e. less than 1/400<sup>th</sup> of the available space)*”.<sup>3</sup> While sampled products in the study by Tinawi and colleagues varied in size, it shows that a pictogram size of 9mm (see section I) is feasible.

Research undertaken by Deakin University in 2018 found that more participants in focus groups commented on the small size of the health warning relative to the overall product brand labels. This led to participants questioning whether the warnings were sincere, given their perceived small size and discreet placement.<sup>4</sup> For example, participants said:

*I don't think it's displayed well enough for it to be a serious warning...because it's so tiny, it doesn't feel like they're caring whether we see the label or not. I don't see it as a legitimate warning (female, Group 1)*

*I sort of think they've put it as a small label because at the end of the day they're trying to sell a product... they don't want people to notice it too much (male, Group 3)*

*They've crammed it into an inconspicuous corner (male, Group 2).<sup>5</sup>*

In addition, the research undertaken by Hall & Partners in 2018, commissioned by FARE, also demonstrated that the current pictogram was too small to effectively attract attention. This recommended that if the size was increased, the pictogram has the potential to draw the attention of the consumer. Thus, the decision to reduce the pictogram to 6mm (in the 200–800 ml category) appears to go against research evidence and FSANZ's own literature review about noticeability.

It is important that the pictogram chosen by FSANZ undergoes further evaluation. There are several different 'pregnant lady' pictograms used around the world, some of which have been consumer tested and others that have not. The 2018 Hall & Partners research tested several different pictograms (including the one chosen by FSANZ) and how people understood these. This research found that while people understood the pictogram, it did not significantly impact behaviour intentions.<sup>6</sup> Thus, while the proposed pictogram is generally understood by consumers to mean 'do not consume alcohol during pregnancy,' it does not mean that it is the 'best' or most 'effective' pictogram to communicate government advice around not drinking during pregnancy. Thus, FSANZ needs to plan a detailed evaluation program of the labelling scheme to ensure that the proposed pictogram is the most appropriate one. An evaluation would be able to provide further information on the impact of the pictogram.

Research from France has shown that the pregnancy pictogram warning introduced in 2007 had been noticed by 66.1 per cent of women who took part in a cross-sectional survey five years following implementation (N=3,603). Drinkers were more likely to have seen the pictogram than non-drinkers, and 98.6 per cent reported that the pictogram means that pregnant women should abstain from alcohol. The study concluded that *"the pictogram does not warn the consumers about the nature of Fetal Alcohol Spectrum Disorder (FASD). It simply instructs them to avoid drinking without explicating the reason."* Furthermore, the size and colour of the pictogram are not mandated, though the article suggests that most producers print the pictogram at a size of 1/8 to 1/2 inch (3.2–12.7 mm).<sup>7</sup> Since the French pictogram does not have a uniform size, further evidence is required to determine if consumers notice and understand the pictogram and/or warning label. This is why a comprehensive evaluation of the proposed warning labels is needed following implementation (see section O).

#### **G. Warning statement (section 3.2.2.3)**

As noted in section E, FARE supports the warning statement in the Proposal. However, FARE seeks further clarification as to why the longer statement that appeared to test better across all variables in the consumer research was not chosen or even why a long statement was tested if it was not to be chosen.

#### **H. Design labelling elements (section 3.2.2.4)**

Overall, the proposed warning mark (pictogram and warning text) addresses key issues affecting the legibility of the warning; these are the colour and contrast. FSANZ is to be commended for proposing that the warning mark should consist of a pictogram, signal wording and warning text, and that these appear within a box. FARE is very pleased that the warning mark is also to appear in black and red and be on a white background. This is a significant statement that accepts and reflects the seriousness of the impacts of alcohol consumption during pregnancy and that consumers need to be informed about these dangers. However, the proposed font size of the warning statement is too small.

The literature review concludes that larger text size impacts attention to the message but does not indicate or conclude what the actual font size should be. This is a significant issue that is not given enough weight in the literature review. There is limited research on font sizes of warning text in relation to alcohol, however, studies have been done with other products. A study exploring design aspects of warning text (red with red borders) on a pesticide bottle found a linear relationship between text size (starting at 8pts) and the perceived urgency of the warning. Of the design aspects explored, text size had the largest effect.<sup>8</sup> In addition, a study exploring design elements that influence the likelihood of reading a warning label on laundry detergent showed that a font size of 10 pts (about 3.5 mm) increased the likelihood of reading the warning, compared to a warning at 8 pts (about 2.8 mm).<sup>9</sup>

Current pregnancy warnings on alcohol products differ in size. Research by Tinawi et al. (2018) in New Zealand showed that only 34 per cent of products had a pregnancy warning text. Of products that did, most had the warning text in a small font size. On average, the warning text 1.6 mm, with the largest font on imported beer (2.1 mm), followed by New Zealand beer (1.5 mm), wine (1.4 mm), and smallest on ready-to-drink (RTD) products (1.3 mm).<sup>10</sup> Siggins Miller conducted an evaluation of pregnancy warning labels in 2013-14 where legibility was judged as low, standard or high, as per Standard 1.2.9 of the Code. The study found that 92 per cent of all products were standard or above standard legibility (font size of 1.5 mm for small packaging and 3.0 mm for larger packaging). The proportion of products at standard legibility ranged from 75 to 97 per cent (all white wine and red wine <\$11, respectively) and above standard 0 to 15 per cent (red wine and full beer, and white wine, respectively).<sup>11</sup> The second evaluation, carried out in 2017, showed that 93 per cent of products were of standard or above standard legibility. The range for standard legibility was 71 to 96 per cent (international beer and red wine >\$20) and above standard 2 to 38 per cent (all red wine and white wine >\$20, respectively).<sup>12</sup> Comparing the two evaluations, a higher proportion of products overall were above standard legibility in 2017 than in 2014 (14 per cent and 8 per cent, respectively). Considering such a high proportion of products are already at the standard (or above standard legibility according to the legibility requirements in Standard 1.2.9 of the Code, the mandatory labels should feature the same minimum requirements.

Given the lack of literature around optimal font size, FSANZ should evaluate what font size resonates best with consumers and attracts the most attention, as part of a wider evaluation of the warning labels.

FARE contends that for all proposed warning text, a minimum font size of 3.0 mm should be required. This is so that packaged alcohol requirements align with other products within the Food Standards Code (that require warning text at 3.0 mm). The Proposal does not outline the reasons for a font size smaller than other warning text set out in the Code being chosen, particularly when the views from public health stakeholders were to set a minimum font size of 3.0 mm. FARE notes that the Food Standards Code (Standard 1.2.3) sets out requirements in relation to legibility, prominence and language. While the Standard is non-prescriptive as to where the warning label appears, the Code states that: “...the words for each warning statement are prescribed and must be written using the text and size of type required in the Code” (emphasis added by FARE). The FSANZ *Warning and Advisory Statements and Declarations* user guide for Standard 1.2.3 outlines that “Warning statements must be a minimum size of type of 3 mm and in the case of small packages (defined in Standard 1.1.1 as a package with a surface area of less than 100 cm<sup>2</sup>) a minimum size of type of 1.5 mm.”<sup>13</sup> It is not clear from the Proposal why the font size (2.1 mm and 2.8 mm, respectively) are smaller than FSANZ’s own guidance on font sizes of warning statements. Even members of the alcohol industry recommend larger font sizes, for example, Wine Australia states that the minimum font size for the volume statement for a 750 ml bottle of wine is prescribed as 3.3 mm.<sup>14</sup>

FARE is unaware of any valid reasons why the prescribed font size of the warning text be smaller than 3.0 mm as prescribed in the Code in relation to Standard 1.2.3. The literature review supports the notion that larger text has a greater impact in terms of noticeability and attention. While the literature is sparse in relation to specific font sizes on alcohol bottles, or other products, a font size of a minimum of 3.0 mm (around 8.5 pts) would be in line with: existing requirements within the Code, and would align with evidence that larger font size is more effective in attracting attention from the consumer.




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

FARE agrees with the developed warning label design in relation to the:

- pictogram
- use of the phrase 'HEALTH WARNING'
- warning statement (see comment in sections E and G)
- box border
- white background on the pictogram and warning label itself
- 3.0 mm of clear space around the label.

However, FARE recommends that firstly, the pictogram only be applied for products <100 ml (rather than ≤200 ml as proposed) and secondly that the 200–800 ml label category be abandoned. To FARE's knowledge, there is no evidence to suggest how the developed categories (≤200 ml, 200–800 ml, and >800 ml) have been created. To ensure that this is clearly articulated, FARE has redrafted Table 10, page 33 of the Proposal. Table 1 of this submission outlines FARE's proposed changes. The recommended changes will create a pregnancy warning label schedule that is supported by the evidence, rather than contradicted by it. Further, FARE's comments on multipacks are covered in section O.

**Table 1. FARE revised schedule for pregnancy warning label on packaged alcohol products**

Alcoholic beverage volume	Single container and each layer of packaging other than the outer package, and individual portion packs (i.e. in a multipack)		Outer package or package containing individual portion packs (i.e. multipacks) including a carton containing several multipacks	
	Label required	Minimum Size	Label required	Minimum Size
< 100 ml		8 mm diameter	 <b>HEALTH WARNING</b> Any amount of alcohol can harm your baby	Pictogram 11 mm diameter
≥ 100 ml	 <b>HEALTH WARNING</b> Any amount of alcohol can harm your baby	Pictogram 9 mm diameter  Font size 3.0 mm (8.5 point)		Font size 3.5 mm (10 point)

The reasons for these recommended changes to the labelling categories is outlined below.

## 1. That only packaged alcohol under 100 ml carry the pictogram

The cut-off for products that are to display the pictogram only should be reduced from ≤200ml to products <100 ml, as consulted on in June 2019. The reasons for a 100 ml cut-off are that:

1. many products under 200 ml already have pictogram or pictograms and text larger than proposed labels, thus demonstrating there is sufficient space on the label for the full pregnancy mark on products over 100 ml
2. the level of risk related to the ABV of the product has not been considered.

Firstly, there are a number of packaged alcohol products between 100 ml and 200 ml that already apply a pictogram alone or along with text. This is demonstrated in Figure 2 that shows a range of containers that fall below and above the cut-off at 200 ml.



**Figure 2: A range of alcohol products that fall below and above the cut-off proposed 200 ml pictogram category**

It should be noted that ten out of these 13 products feature the pregnant pictogram, ranging from 5.0 mm to 11.0 mm in diameter.

Figure 3, below demonstrates the range of alcohol products that will fall below the proposed  $\leq 200$  ml pictogram category, shown within the red shaded area. This Figure and Figure 1 (page 3) show that a bottle of Jacob's Creek Chardonnay (12.9% ABV, 187 ml) contains 1.9 standard drinks and a bottle of Vodka Cruiser Lush Guava (4.6% ABV, 275 ml) contains 1.0 standard drink. Under the Proposal the bottle of wine that contains almost twice as many standard drinks of alcohol will carry only the pictogram whereas a RTD that has less alcohol will require pictogram and text. This is illogical and not based on the risk of the product but the size of the container.



**Figure 3: The same range with products  $\leq 200$  ml (within the red highlighted area) that will be in the pictogram only category, as per the Proposal.**

It should be noted that the Jacob's Creek Chardonnay (12.9% ABV, 187 ml) product within this image and in Figure 1 (page 3) has a label size of approximately 52 mm (width) x 63 mm (height) with a pictogram close to 10 mm. The label in the example is of similar size to what the Proposal suggests for products over 800 ml. Thus, it is possible to have a larger pregnancy warning label on products from 100 ml and above.

Figure 4 below demonstrates the range of products that would feature a pictogram only under 100 mls only. This shows that the range of products is substantially smaller.



**Figure 4: The same range with only those products >100 mls (within the blue highlighted area) that should be within pictogram only category.**

Secondly, and more importantly, the proposed label categories do not differentiate products according to risk level, but rather on the volume of the product and container size. Research indicates that drinking at higher levels, that is frequent, high intake or heavy episodic drinking (consuming a larger amount of alcohol in one occasion), increases the risk of FASD, in particular, the most severe forms.<sup>15,16</sup> This is because the blood alcohol concentration (BAC) increases and has a more negative impact on the developing fetus than moderate consumption.<sup>17</sup> Therefore, the relative risk of alcohol products needs to be considered not just the size of the container, but the number of standard drinks within it. This should be an overriding consideration of the labelling and the need for a prominent warning with both text and pictogram. Thus, it is possible to have a larger pregnancy warning label on products from 100ml and above.

Figure 5 shows an example of a 200 ml bottle of vodka, sold by Dan Murphy's, which contains 6.3 standard drinks. Under the proposed labelling scheme, this product would only feature the pictogram. This product has a large number of standard drinks, which, if consumed on one occasion, would represent heavy episodic drinking and associated with higher risk.



**Figure 5. Axel Vodka, 200ml (40% ABV), 6.3 standard drinks. Source: Axel Vodka.<sup>18</sup>**

Similarly, Figure 6 shows a bottle of Kweichow Moutai Flying Fairy which is also sold in 200 ml at 53% ABV which means the bottle contains 20.9 standard drinks. Under the proposed scheme both the box and bottle would only carry the pictogram. FARE argues that a product with that high ABV should carry the full warning text and pictogram (at the size outlined in Table 1). However, we appreciate that a pragmatic decision needs to be made and therefore maintain that only small containers under 100 ml display the pictogram.



**Figure 6: Kweichow Moutai Flying Fairy, 200ml (53% ABV), 20.9 standard drinks. Source: Dan Murphy's.<sup>19</sup>**

The examples above demonstrate that it is possible for the alcohol industry to apply bigger warning labels on products between 100 ml and 200 ml. For smaller products, there is still ample space to include a pictogram of the proposed size (8 mm) as shown in Figure 7 of a 50 ml bottle with the pictogram 8 mm in diameter.



**Figure 7: Example of Absolute Vodka, 50 ml (40% ABV), 1.6 standard drinks.**

## **2. Deletion of the 200–800 ml labelling category**

For all products of  $\geq 100$  ml, FARE argues that in line with text requirements in the Code and overall legibility evidence (see section H), the proposed label size should feature a pictogram 9mm in diameter and warning text at a minimum of 3.0 mm.

The Proposal states that “a 750ml bottle of wine *may* not be larger than a 500ml bottle of beer” (page 29, emphasis added by FARE). However, Figure 8 features a 700 ml bottle of vodka, with an overall label of approximately 60 mm (width) x 45 mm (height). This is a similar size to the 187 ml bottle of wine with a label size of 52 mm (width) x 63 mm (height). This demonstrates that labels on different sized (volume) of products can be similar. Thus, it is clear that industry can amend the size of their overall product labels (as per the example in Figure 2) to accommodate various stylistic and design choices, as a significantly smaller surface area of the whole vodka bottle is taken up by the product label as compared to the label on the 187 ml wine bottle.



**Figure 8. Example of label sizes, Smirnoff Vodka 700ml (37.5% ABV), 21 standard drinks and Jacob’s Creek Chardonnay 187ml (12.9% ABV), 1.9 standard drinks.**

As demonstrated in Figure 2, the actual label size of these products regardless of container size are remarkably similar. The vast majority of alcohol products on the market will fall within the 100 to 800 ml range and thus a full pregnancy warning mark, of sufficient size and legibility, should be required on these products. This will reflect both the Proposal as consulted on in June 2019 and is supported by the literature review, rather than contrary to the evidence. For smaller products, there is still ample space to include a pictogram of the proposed size (8 mm) as shown in Figure 7 (pictogram size 8 mm).

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

While FARE appreciates that labelling has been set on the premise of the definition of alcoholic beverages, which has also been the case in other countries, there are some concerns with this approach.

It is a positive step that FSANZ has considered the alcohol content at which the pregnancy warning label should be applied. FARE maintains that pregnancy warning labels should be applied on products from 0.5% ABV and above. The fact is that products between 0.5% ABV and 1.15% still contain alcohol and the omission of warning labels on those products is in contradiction to the National Health and Medical Research Council (NHMRC) guideline that women who are pregnant abstain from all alcohol.<sup>20</sup> FARE's view, therefore, is that it is important to create a homogenous structure whereby the 'no alcohol' message is reinforced through labelling of products >0.5% ABV and above. Secondly, research has shown that some products indicated as no alcohol or low alcohol still contains alcohol at far higher levels than indicated. According to a Canadian study *"six products from one company, that claimed to contain no alcohol, had ethanol levels between 1.2–1.8% of ethanol"*.<sup>21</sup> Considering the variability of alcohol content in different products, and the recommendation for women to not consume alcohol during pregnancy, it is reasonable that beverages from 0.5% ABV and higher should carry the pregnancy warning.

While FARE appreciates that the issue of fermented drinks, such as Kombucha and Kefir, and brewed soft drinks which may contain alcohol (as a by-product of fermentation) is a separate issue to this consultation, discussions around alcohol content and labelling of such products should be held to ensure consistency. This is important as pregnant women may choose these products as an 'alcohol-free' alternative and may unknowingly consume alcohol. Research undertaken has shown that 23 per cent of products tested in Victoria contained more than 1.15% ABV<sup>22</sup> and another survey found that Kombucha products contained as high as 5.3% ABV. In the latter survey, 15 per cent of products did not carry a warning label regarding alcohol content.<sup>23</sup> The application of a pregnancy warning label is important to ensure consumers are fully informed of the choices they are making and if the products they are consuming contain alcohol.

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

FARE agrees with this the approach taken to different types of sales, outlined in section 3.2.4.

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

FARE is supportive of FSANZ's approach that for a multipack, the pregnancy warning label would be required on each individual product as well as the packaging containing the individual portion. FARE is supportive of the approach where a single beverage (for example, whisky) is sold in a box, the pregnancy warning label is required on all packaging layers. However, clarification is required for the Proposal for outer packaging of alcoholic beverages in the smallest category (proposed as under 200 ml, see section I for comments on the container categories) which will only carry a pictogram. It is unclear what products this sort of packaging refers to, as outer packaging of an individual portion within a multipack will require a larger full

warning label. FARE thus believes that the same principle should apply to smaller outer packaging (see Table 1).

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

FARE agrees with the updated costs and benefits that FSANZ has undertaken. FARE agrees with FSANZ assessment and the conclusion from the 2018 Decision Regulatory Impact Statement that the “...*mandatory option represents the greatest net benefit to the community.*”

FARE also agrees with FSANZ assessment that the “*proposed mandatory pregnancy warning label would support 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)**

FARE maintains that the transition period should not be longer than 12 months. In France, the pregnancy pictogram was required to be placed on alcoholic beverage containers one year following the date of publication of the order that mandated pregnancy warning.<sup>24</sup> Similarly, Mexico’s mandatory labelling scheme outlined that the labelling scheme (Chapter 9) would come into force 365 calendar days after the publication of the Standard in the Official Gazette: “*The entry into force of Chapter 9 and its sub-points will be applicable for all products that are produced, manufactured, imported and distributed as of that date, so you must plan the printing program in accordance with its production [Google Translate]*”.<sup>25</sup> The labelling requirements introduced to alcoholic beverages in the USA also had a 12-month transition period, as stated in Paragraph 215 of the Federal Alcohol and Administration Act.<sup>26</sup>

FARE argues that a 12-month transition period has been introduced elsewhere and within the Proposal, there is no evidence suggesting that a longer transition period is required. In light of the transition times elsewhere, it is possible to mandate the pregnancy warning labels to be placed on alcoholic beverages within one year from the publication of the new Standard.

The targeted consultation background paper supplied by FSANZ notes that the transition period for the implementation of labels is likely to be two years. However, this differs from the usual 12-month transition period for variations to the Food Standards Code.

We do not consider that adequate evidence has been provided by FSANZ or the Decision Regulation Impact Statement (DRIS) to support an additional transition period from the standard 12-month transition timeframe.

At the consultation event in January 2019, a FSANZ representative suggested that a longer transition time may be required for health professionals to ensure that they are across label changes and are giving the correct advice about alcohol consumption and pregnancy. The need for a longer transition time based on the needs of health professionals was strongly refuted at the time. It was noted that the health professional colleges (such as the Royal Australian and New Zealand College of Obstetricians and Gynaecologists and Australian Medical Association) already have clear guidelines on the risks of alcohol consumption during pregnancy and that education with health professionals has been occurring for a number of years. Further, clearer labels are likely to assist health professionals when speaking to patients about their alcohol consumption.

It is likely that sections of the alcohol industry will argue that there is a need for longer transition timeframes to allow small producers to change their labels. However, in Australia and New Zealand, the bulk of all alcohol sold is by large producers. Thus, an extension for the whole industry is without adequate justification. It has taken an inordinate amount of time for alcohol

pregnancy warning labels to become a mandatory labelling requirement and any further delay cannot be justified against the health and societal implications of FASD.

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

FARE has no other comments on the draft variation that are not otherwise covered in the sections above. In relation to the draft Code, FARE agrees with the developed warning labels in relation to the pictogram, the use of the phrase 'HEALTH WARNING', the statement (see comment in sections E and G), border, white background on the pictogram and warning label itself, the clear space around the label, but argues that the font size needs to be larger (see section H) and a larger warning label should appear on  $\geq 100$  ml. A revised requirement for the pictogram and warning label in relation to the draft variation in the Code is provided in Table 2.

**Table 2. Revised requirement for the pictogram and warning label in relation to the draft variation in the *Food Standards Code***

Column 1	Column 2	Column 3	Column 4
<i>Package or packaging</i>	<i>Size of the *pregnancy warning pictogram or the pictogram of a *pregnancy warning mark</i>	<i>Size of signal words and statement of a pregnancy warning mark</i>	<i>Size of clear space outside a pregnancy warning mark</i>
A package (including each layer of packaging) of a *prescribed alcoholic beverage with a volume of < <del>200 ml</del> 100 ml	At least 8 mm diameter	Not applicable	Not applicable
<del>A package (including each layer of packaging other than the outer package) of a prescribed alcoholic beverage with a volume of &gt; 200 ml and <math>\leq</math> 800 ml</del>	<del>At least 6 mm diameter</del>	<del>At least 6 point (2.1 mm)</del>	<del>At least 3 mm</del>
A package (including each layer of packaging other than the outer package) of a prescribed alcoholic beverage with a volume of $\geq$ <del>800</del> 100 ml.	At least 9 mm diameter	At least <del>8</del> 8.5 point ( <del>2.8 mm</del> 3.0 mm)	At least 3 mm
<del>An outer package (other than the outer package of a prescribed alcoholic beverage with a volume of <math>\leq</math> 200 ml).</del>	<del>At least 11 mm diameter</del>	<del>At least 10 point (3.5 mm)</del>	<del>At least 3 mm</del>
1. An outer package or a package (including each layer of packaging) of a prescribed alcoholic beverage that contains individual portion packs.  2. <del>To avoid doubt, a reference to a package or packaging in item 1 does not include an individual portion pack.</del>	At least 11 mm diameter	At least 10 point (3.5 mm)	At least 3 mm

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

In addition to the responses above, FARE has the following comments to make, that:

- 1) greater representation is required from first nations peoples
- 2) the pregnancy warning labels need to be accompanied by a comprehensive public education campaign
- 3) industry-led labelling components such as 'Get the facts' should be abandoned and removed from all packaging
- 4) consideration be given to the exclusion of certain areas on alcohol products where warning labels (pictogram and warning text) cannot be applied
- 5) FSANZ need to establish a robust and comprehensive evaluation plan
- 6) FSANZ should outline a clear monitoring and compliance framework
- 7) that trade agreements are not a barrier to the most effective placement options for pregnancy warning labels.

### **1. Greater representation is required from First Nations Peoples**

The views of First Nations Peoples to the Proposal are generally lacking, within the consumer testing, stakeholder engagement and evaluation.

For the consumer testing, it is noted that it was possible to obtain a sufficient sample of people who identified as Maori/Pacific people for analysis. It is a shame that a similar opportunity was not extended to Aboriginal and Torres Strait Islander people in Australia. It would be of interest to know if the text messages tested would work the same across with different population groups, including those with whom English is not their first language.

Further, the Proposal highlights that only two Indigenous Australian stakeholders were consulted. It is disappointing that a greater representation was not sought from first nations people in Australia and New Zealand. The Indigenous stakeholders that were consulted have raised valid points about the drinking vessel the woman is holding and if this would capture an Indigenous audience in remote communities who may not use this vessel. This may be the same for other elements of the label design that have not been extensively consulted on with Aboriginal and Torres Strait Islander people or with Maori/Pacific people. Indeed, the number of alcohol industry stakeholders who have been consulted seem to far outweigh the number of public health stakeholders and first nations stakeholders that have been consulted.

FARE also urges FSANZ to undertake ongoing evaluation of both the pictogram and warning text with people for whom English is not their first language, Cultural and Linguistically Diverse (CALD) groups, migrant populations, Aboriginal and Torres Strait Islander peoples and Maori/Pacific peoples. Research has shown that people in remote and very remote areas have a number of unique needs related to communications and physical distance. In particular, the more isolated an Indigenous community, the greater likelihood that English will be only a second or third language.<sup>27</sup> It is important that there is a particular focus within the evaluation on how well the warning label and its elements (pictogram and warning text) are understood by at risk, minority, and other vulnerable people.

### **2. The pregnancy warning labels need to be accompanied by a comprehensive public education campaign**

FARE has consistently advocated for mandatory pregnancy warning labels to be accompanied by a consumer education campaign, that is wide ranging and across various media. The education section within the Proposal is extremely weak. It cannot be left to public health agencies with limited funding to educate consumers about the labelling changes. The Australian and New Zealand Governments have a duty to inform members of the public and health professionals about these changes and funding should be made available to do so.

In Australia, there is a lack of awareness about the NHMRC Alcohol Guidelines. This is due in part to the lack of education and awareness campaigns to inform people about the Alcohol Guidelines. For example, FARE's 2019 Annual Alcohol Poll found that only one in five Australians (18 per cent) were aware of the actual content of the Alcohol Guidelines.<sup>28</sup> Additionally, there have not been improvements in the percentage of Australians who can correctly estimate the recommended number of standard drinks in order to prevent both short and long-term harm. In 2019, 31 per cent of people were able to correctly estimate the recommended number of standard drinks to prevent long-term harm, compared with 38 per cent in 2011. For short-term harm, awareness this was nine per cent in 2019 compared with ten per cent in 2011.

Awareness of alcohol harm and pregnancy in Australia appears to be slowly improving. FARE's annual polling has shown an increase in the percentage of people who are aware that the recommended maximum number of alcoholic drinks a pregnant woman can have on any one day to avoid harm to the fetus is zero. In 2012, 61 per cent of respondents made the correct estimate (zero consumption) this has increased to 78 per cent in 2019.<sup>29</sup> However, despite this awareness one in four pregnant women in Australia continue to drink alcohol after knowledge of their pregnancy.<sup>30</sup> One study has found that 40 per cent of women were unaware that alcohol consumption during pregnancy could harm the fetus.<sup>31</sup> Added to this, the 2016 evaluation of the *Women Want to Know* project found that one in ten GPs and specialists (and three per cent of midwives) believe that one or two drinks per day could be safely consumed without any risk to the fetus. Therefore, there is a need to continue to raise awareness across all Australians about the risks of consuming alcohol during, pregnancy and warning labels on packaged alcohol are one opportunity to do this.

A qualitative review in 2011 of the promotional products and communications materials produced by the Australian Government Department of Health for the National Alcohol Strategy found that:

*There is low awareness of the NHMRC Guidelines.... These findings suggest that the Guidelines will not engage the community nor influence attitudes towards the consumption of **alcohol merely by virtue of their existence or being the 'official' recommendations**. Similarly, a 'low key' approach [to promotion] is unlikely to have a significant impact. A strategy based on 'general education' is too passive and does not challenge drinking habits which are seen to be hugely enjoyable and an integral part of Australian's social lives.<sup>32</sup> (Emphasis added by FARE)*

Unfortunately, for alcohol and pregnancy, Australia has never had an awareness campaign at the national level. The funding assigned to the new National FASD Strategic Action Plan 2018-2028 is inadequate, with only \$1.47 million allocated to prevention.

Given the time, effort, and money invested in developing the pregnancy warning labels, the very limited section on education in the Proposal is disappointing.

### **3. Industry-led labelling components such as 'Get the facts' should be abandoned**

Consumers have a right to be informed about products that can harm themselves or their unborn baby. The provision of this information should be free from industry influence, particularly an industry driven by profit through the consumption of its products. It is clear that the voluntary pregnancy labelling scheme implemented by DrinkWise has failed to sufficiently inform consumers about the risk of alcohol consumption during pregnancy and should have been abandoned years ago. There are a number of concerns with the voluntary scheme and directing consumers to 'Get the facts' on the industry-funded DrinkWise website is one of them.

A study of 561 Australians showed that no participants (spontaneously) recalled the 'Get the facts' logo, and only 7.3 per cent had ever visited the website.<sup>33</sup> A qualitative study of the DrinkWise labels further showed that some participants stated that the warning messages did not encourage them to seek further information about alcohol misuse, including from the DrinkWise websites.<sup>34</sup> Similar findings have been demonstrated through research in the UK, where it was noted that the *"conscious and proactive decision needed by each individual to access this information"* at the point of consumption made the provision of health information online of limited use in that situation.<sup>35</sup>

In addition, reference to an industry-funded website should be avoided, in the broader sense of health communication. There is consistent proof that the alcohol industry's health information regarding alcohol, misrepresents and distorts evidence. A 2017 research study led by the London School of Hygiene and Tropical Medicine (UK) found that DrinkWise and similar alcohol industry-owned websites that claim to educate the public about drinking responsibly, consistently mislead the public about the long-term health risks of alcohol consumption. The 2017 study concluded that *"the alcohol industry appears to be engaged in the extensive misrepresentation of evidence about the alcohol-related risk of cancer."*<sup>36</sup> A more recent study analysing information about alcohol and pregnancy, fertility, and breastfeeding on websites of industry-funded organisations concluded that compared to public health organisations, alcohol industry-funded organisations were less likely to include information about, for example, Fetal Alcohol Syndrome (FAS) and other pregnancy-related risks (for example, miscarriage). When these websites did discuss the risks associated with alcohol use during pregnancy, it was framed around safety, with the uncertainty of a 'safe limit' being emphasised and using words such as 'debate' or 'confusion', suggesting that drinking during pregnancy may be safe. Furthermore, industry websites emphasised that drinking when pregnant is an individual choice and that only certain drinking patterns during pregnancy are associated with risk. Some industry-funded organisations also suggested that factors other than alcohol contribute to FAS.<sup>37</sup>

These websites and the direction of consumers to seek information via the Internet are not a substitute for having effective warning labels on the products. The proposed amendments to the Standard, (albeit with FARE recommended changes needed), will achieve the primary objective as per the DRIS which 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."* The application of the 'Get the facts' logo and website on packaged alcohol labels should be abandoned by the alcohol industry and removed from all packaging. This logo is neither informing consumers nor giving them the facts. Removal of the logo would also free up space on the label for health information.

#### **4. Consideration be given to the exclusion of certain areas on alcohol products where warning labels (pictogram and warning text) cannot be applied**

FSANZ needs to give due consideration to the exclusion of locations in which warning labels (pictogram and warning text) can be applied. This should include, for example, the bottom or necks of products. Similarly, FSANZ should require the outside packaging of alcohol products to also have warning labels, such as the outside boxes or cartons in multipacks.

The evaluation undertaken by Siggins Miller in 2014 found that 81 per cent of alcohol products located the DrinkWise pregnancy labels on the back of the product. Of all the products in the 2014 sample, three per cent (n=30) of products placed the label on top or bottom of products and two per cent (n=18) on the neck of products.<sup>38</sup> This was predominantly within the RTD, premium and craft beer and international beers. The 2017 evaluation showed that of products with DrinkWise labels, 65 per cent had the pregnancy label placed on the back label. Additionally, the label was found on the front (1.6 per cent, n = 27), side (20.6 per cent, n=354)

or top or bottom (9.7 per cent, n=219) of products.<sup>39</sup>

The Siggins Miller evaluations did not cover multipacks and their packaging. This issue was considered in audits by IPSOS Social Research Institute (commissioned by FARE) in 2012 and 2013. The 2012 audit included 205 single items and 45 multipacks. Multipacks were within beer/cider, mixed drinks and RTD categories.<sup>40</sup> Only 13 per cent of multipacks featured a DrinkWise message (this included other consumer information messages such as 'Kids and alcohol don't mix').

This audit also found that 98 per cent of the DrinkWise consumer information messages took up less than five per cent of the label or face of the package on which they were located (most were closer to one to two per cent of the label). Similar results were found in 2013 where 86 per cent took up less than five per cent of the label. For 14 per cent of products, the DrinkWise consumer information message took up five to ten per cent of the label.

The 2013 audit included 55 multipacks or cartons. Of these, only 15 per cent carried any of the DrinkWise consumer information messages and most were located on the bottom of packaging.<sup>41</sup>

For a number of brands both in 2012 and 2013, the DrinkWise label was applied to single bottles or cans but not the associated four-pack, six-pack or carton packaging. Compared to single products, these labels were most commonly found on the bottom of multipacks.

These audits demonstrate the confusing array of label locations and placement across products. The audits also found that across both years the labels were most commonly located on the edges of product labels and rarely featured in central or prominent locations. This highlights the need for FSANZ to give consideration to both the labelling requirements for product packaging and the exclusion of places where labels are positioned such as the bottom and necks of products.

## **5. FSANZ need to establish a robust and comprehensive evaluation plan**

It is imperative that FSANZ outline a plan for the ongoing evaluation of the labels following the end of the transition period. The impact of the labels should also be evaluated through regular data collection by FSANZ. FARE recommends that the evaluation and audit model undertaken by Siggins Miller be undertaken on a regular basis (every one to two years). This should also be complemented with qualitative work with those at higher risk, in particular, women with alcohol use disorder who need additional support through substance treatment services. Such research will be important to ensure the labelling scheme does not have any unintended consequences.

As outlined in this submission, the evaluation plan should include further evaluation of both the pictogram and font size of the warning text. As noted in section F, that while the proposed pictogram is generally understood by consumers to mean 'do not consume alcohol during pregnancy,' it does not mean that it is the 'best' or most 'effective' pictogram to communicate government advice around not drinking during pregnancy.

The evaluation plan should include whether the chosen pictogram is the most appropriate one, and consider:

- the impact of the pictogram on consumer behaviour
- the size of the pictogram and location/orientation of pictogram on products.

The evaluation also needs to evaluate the font size for the warning text that best resonates with consumers and attracts most attention.

This evaluation should also consider if and how the introduction of a 3 mm clear space around the outside of the warning box will moderate the confusion caused by statements 'Drink responsibly' and 'Drink in moderation' on alcohol labels. No evidence is provided in the Proposal to demonstrate that having a clear space around the box will affect this confusion. The DRIS is clear that consumers have found these statements confusing.

As outlined in the DRIS, page 2, the location of pregnancy warning labels next to or on the same label as contradictory information such as 'Enjoy in moderation' confuses the advice that pregnant women should not drink alcohol.<sup>42</sup> The DRIS recommends that pregnancy warning labels be separated from these conflicting statements.

However, the primary objective of the pregnancy warning label is to *"provide a clear and easy to understand trigger to remind pregnant women... to not drink alcohol"*. The clearest course of action to achieve this aim is that these other messages are removed and excluded from alcohol products.

Each year FARE conducts polling to examine Australians' relationship with alcohol. The 2015 Annual Alcohol Poll found that 92 per cent of drinkers classed themselves as responsible drinkers. This was regardless of the amount of alcohol they were drinking. This finding suggests that messages that encourage people to be responsible drinkers are ineffective because the majority of Australians already believe that they consume alcohol responsibly, even when their consumption does not suggest this.

It is clear that these messages are ambiguous as well as confusing to consumers and do not meet the objectives that the pregnancy warning labels on alcoholic beverages are trying to achieve.

Further, a clear evaluation plan would secure a better understanding of the effectiveness of the pregnancy warning label and may help inform other countries considering implementing similar schemes.

## **6. FSANZ should outline a clear monitoring and compliance framework**

The Proposal fails to outline how the pregnancy warning labels will be monitored and what are the compliance mechanisms. This is a significant failing of Proposal that needs to be amended.

Monitoring and compliance mechanisms have been set out in other areas managed by FSANZ. For example, in the mandatory folic acid/folate fortification scheme of flour with (amendment to Standard 2.1.1 in 2009) compliance mechanisms were set out as part of a review. This fortification of flour with folic acid is to prevent birth defects including neural tube defect and spina bifida.<sup>43</sup> Spina bifida prevalence is reported as 0.37 per 1000 population.<sup>44</sup>

Alcohol can also cause birth defects, which is estimated to affect 0.6 per 1000 population in Australia, based on a meta-analysis of the literature (only two studies included).<sup>45</sup> While difficult to compare (as spina bifida is detected during scans during pregnancy and FASD is not routinely screened for), this example signifies the importance of treating the alcohol pregnancy warning label intervention with similar commitment to the fortification of flour. A clear strategy should be outlined by FSANZ on how the labelling scheme will be monitored.

The Proposal also lacks information about the impact of non-compliance and enforcement of the scheme. At the moment, there are no impacts on alcohol producers for not implementing the labelling changes. FARE asks FSANZ to outline how the scheme will be enforced and what breaches and non-compliance to the Code will result in. For example, in France, the notification setting out the order stipulating that a pictogram is mandatory for all alcoholic beverage containers stated that non-compliance with the new regulations could result in a fine

of €6000 (about 10,000 AUD).<sup>46</sup> The monitoring and compliance regulations need to be clearly stipulated prior to the end of the transition timeframe and enforcement mechanisms clearly set out.

## **7. International trade agreements are not a barrier to the most effective placement options for pregnancy warning labels.**

FARE acknowledges Australia's international alcohol labelling obligations, but we strongly contest any view that these agreements may be a barrier to the most effective placement options for health warning labels. FARE notes two agreements are raised as potentially constraining choice in regards labelling, and specifically the front of pack labelling.

Firstly, the World Wine Trade Group (WWTG) Labelling Agreement preserves the right of countries to require "National Mandatory Information" which is applied just in that country. Article 5.4 further states that *"Nothing in this Agreement shall in any way prevent a Party from taking measures for the protection of human health and safety, provided such measures are in accordance with the provisions of the World Trade Organization (WTO) Agreement"*. Considering the potential for severe adverse health consequences from drinking during pregnancy, including stillbirth and FASD, labels that warn of the dangers are prima facie a measure for the protection of human health and safety. As such, nations may mandate conditions for pregnancy warning labels as long as they are in accordance with the WTO agreements.

The WTO agreements do not preclude warning labels on alcohol, and indeed at least 30 countries already have some form of mandated health warning. Placement and size are mandated in a number of countries, such as Kenya (no less than 30 per cent of the total surface area of the package) and Uzbekistan (not less than 40 per cent of the label area).<sup>47</sup> Similarly, a number of WTO member states have mandated front of pack requirements for nutrition labelling, using public health justifications. While both nutrition and alcohol labelling front of pack labelling requirements have been raised in the Technical Barriers to Trade (TBT) committee<sup>48</sup>, O'Brien et al. have concluded *"the way in which these provisions have been interpreted in WTO jurisprudence suggests that a government planning a well-designed, nondiscriminatory and evidence-based labelling regime would be likely to be able to defend it in the WTO"*.<sup>49</sup>

Secondly, nothing in the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) specifies or prohibits a particular location or orientation of labelling requirements, including the placement of supplementary labels.<sup>50</sup>

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