

## SUBMISSION TEMPLATE

### Policy options targeted consultation paper: *Pregnancy warning labels on packaged alcoholic beverages*

#### Overview

This submission template should be used to provide comments on the policy options targeted consultation paper: *Pregnancy warning labels on packaged alcoholic beverages*.

#### Contact Details

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<b>Date of submission:</b>	14 June 2016

**If we require further information in relation to this submission, can we contact you?**  Yes  
No

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**If yes, please state why:**

## Submission Instructions

Submissions should be received by 5pm AEST on 14 June 2018. The Food Regulation Standing Committee reserves the right not to consider late submissions.

Please complete the attached template for your submission. Note that submissions may not be drawn upon in preparing the decision regulation impact statement (DRIS) to recommend a preferred policy option to the Australia and New Zealand Ministerial Forum on Food Regulation (the Forum) if they:

- are not supported by evidence;
- do not directly answer the questions in the Policy options targeted consultation paper; and/or
- do not use this template.

Please do not change the template.

Where possible, submissions should be lodged electronically. Please send your submission to: [FoodRegulationSecretariat@health.gov.au](mailto:FoodRegulationSecretariat@health.gov.au) with the title: *Submission in relation to pregnancy warning labels on packaged alcoholic beverages*.

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GPO Box 9848  
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If you need to attach documents to support your submission, please make it clear which question/s they relate to.

## Consultation questions

Please insert your comments against the consultation questions below. These questions correspond to specific sections of the Consultation Paper. If you cannot answer the question or it doesn't apply, please write "nil response" or "not applicable".

**1: Are these appropriate estimates of the proportion of pregnant women that drink alcoholic beverages? Do you have any additional data to show changes in drinking patterns during pregnancy over time? Please specify if your answers relate to Australia or New Zealand.**

The data from the National Drug Strategy Household Survey (NDSHS) undertaken by the Australian Institute of Health and Welfare (AIHW) has more than 24,000 participants and provides, amongst other information, insight into the behaviour of pregnant women when it comes to alcohol. The data from the NDSHS applies only to Australia.

The key points relating to estimates of the proportion of pregnant women that drink alcoholic beverages are as follows:

- 98.8% of pregnant women either abstained from drinking alcohol or decreased their consumption (96.6% in 2007).
- 55.6% of pregnant women did not consume alcohol when pregnant – this represents a 39% increase in the proportion of pregnant women who abstained from consuming alcohol since 2007.
- 43.2% of pregnant women consumed less alcohol compared to when they were not pregnant – in 2007 this figure was at 56.6% which shows that more pregnant women are abstaining from alcohol altogether instead of decreasing their consumption.

The NDSHS also provides the following data in relation to drinking patterns during pregnancy:

- 97.3% of pregnant women consumed a maximum of 1-2 drinks during each drinking occasion (95.8% in 2013).
- A large majority (81%) consume alcohol on a monthly or less basis (77.9% in 2013).

Further, the NDSHS shows that 74.8% of pregnant women completely abstained from drinking alcohol upon knowing they were pregnant.

In addition to the NDSHS data, more detailed studies into the pattern of alcohol consumption amongst pregnant women indicates that the majority of alcohol consumption by women occurs before they are aware they are pregnant. For example, one study shows that of pregnant women, 62% drank in their first trimester but that fell to 7% in the second trimester, indicating the majority of women cease consuming alcohol upon awareness of pregnancy<sup>1</sup>.

### Key points:

- 98.8% of pregnant women in Australia either abstain from drinking alcohol or decrease their consumption.
- Of the women that do consume alcohol when pregnant, 97.3% consume 1-2 drinks on any single occasion.
- Once women become aware that they are pregnant, the overwhelming majority cease consuming alcohol.

<sup>1</sup> O'Keeffe, L.M., Kearney, P.M., McCarthy, F.P., Khashan, A.S., Greene, R.A., North, R.A., Poston, L., McCowan, L.M., Baker, P.N., Dekker, G.A., et al. 2015. Prevalence and predictors of alcohol use during pregnancy: findings from international multicentre cohort studies. *BMJ Open* 5(7): e006323.

**2: Are these appropriate estimates of the prevalence and burden (including financial burden) of FASD in Australia and New Zealand? Please provide evidence to support your response.**

Currently in Australia there is no data available that provides sufficient detail on the prevalence or burden of FASD on a nation-wide basis. There are a number of reasons for the lack of FASD data in Australia as follows:

- FASD is a spectrum disorder with multiple contributing factors, making it difficult to diagnose.
- In Australia there is no routine screening for FASD in infancy or childhood.
- There has been no national register to record both diagnosis of FASD as well as pertinent information about the pregnancy and parents.

We consider it essential, that in formulating a response to FASD, that there be accurate nation-wide information on the prevalence of FASD. In addition, there needs to be comprehensive information collected to be able to better predict pregnancies at risk of a FASD outcome.

As outlined in question 3, labelling forms only a part of the solution to FASD and without this information, it is difficult, if not impossible for a holistic and targeted approach to FASD. This is because without knowing both the prevalence of FASD and those at risk of FASD pregnancies, sufficiently targeted approaches to decreasing FASD cannot be formulated.

We understand that the Federal Government has embarked on the initial stages of implementing a FASD diagnostic tool along with the FASD Australian Register (FASDAR). However, there is as yet no substantial data available from FASDAR to appropriately inform a comprehensive strategy to target at-risk pregnancies.

While there is no accurate information on overall prevalence of FASD in Australia, some studies have shown the following prevalence data for subgroups:

- The prevalence of FASD in indigenous Australian children is much higher than for non-indigenous Australian children, an observation in keeping with findings from other indigenous populations<sup>2,3,4,5,6</sup>.
- According to Western Australian data, there is an approximate 1.5 times risk of a FASD diagnosis in indigenous compared to non-indigenous infants<sup>7</sup>.
- For specific indigenous population groups such as the Fitzroy Valley, the reported rates are higher than for other Australian indigenous communities<sup>8</sup>.
- Overall population rates are substantially lower than in North America, France and Sweden and have remained relatively stable over the decades for the majority of Australian States and Territories<sup>5,6</sup>.

**Key points:**

- In order to be able to formulate a comprehensive and effective policy approach to FASD (including but not limited to the role that labelling plays in relation to FASD), accurate, nation-wide information on the prevalence of FASD and information to create an informative picture of at risk pregnancies is needed.
- Currently, Australia has no reliable data on the prevalence of FASD on a nation-wide basis, although there is some data on discrete subgroups of the population.

<sup>2</sup> May, P. A. (1991). Fetal alcohol effects among North American Indians: Evidence and implications for society. *Alcohol Health & Research World*, 15(3), 239-248.

<sup>3</sup> Burd L, Moffatt ME. (1994). Epidemiology of fetal alcohol syndrome in American Indians, Alaskan Natives, and Canadian Aboriginal peoples: a review of the literature. *Public Health Rep.* 109(5):688-93

<sup>4</sup> Stratton KR, Howe CJ, Battaglia FC, Institute of Medicine. (1996). *Fetal alcohol syndrome—diagnosis, epidemiology, prevention, and treatment.* Washington, DC: National Academy Press.

**3: Do you have evidence that the voluntary initiative to place pregnancy warning labels on packaged alcoholic beverages has resulted in changes to the prevalence of FASD, or pregnant women drinking alcohol, in Australia or New Zealand? Please provide evidence to justify your position.**

In order to be able to answer this question, it is important to understand the role that labelling plays in the policy response to FASD. In essence, warning labels as a stand-alone tool will not act to change the drinking behaviours of pregnant women. Instead, warning labels provide a catalyst for awareness raising (see Question 13 for further details on value of labelling).

Understanding the role that labelling plays and the need for a multifaceted approach, the industry, through DrinkWise, has undertaken work to provide front-facing, targeted approaches to reducing the prevalence of FASD. These have included:

- retail point of sale information;
- development of resources for use in clinical settings;
- indigenous adaptation of the Alcohol Guidelines for use by healthcare workers (in partnership with the Aboriginal Drug and Alcohol Council of South Australia);
- online tools, videos and medical advice via the DrinkWise website and parents' retail sites;
- messaging in cellar doors and winery restaurants;
- convenience advertising of gender specific pregnancy messaging in licensed venues and shopping centres;
- media interviews;
- editorial and advertising in broadcast and print media;
- partnering with Red Dust and the Northern Territory Government to deliver alcohol and FASD education in communities, schools and supported accommodation in remote locations of the Central Desert area of the Northern Territory.

Industry's example of connecting with the target audience and providing bespoke solutions to help reduce the prevalence of FASD connects on all levels with pregnant women, including the medical/clinical setting. It also acknowledges the prevalence of FASD is higher in indigenous populations and provides culturally appropriate approaches. ABA believes it is due to these multifaceted approaches that there has been a shift in the behaviour of women resulting in 98.8% of women either abstaining or reducing consumption during pregnancy.

**Key points:**

- There is no evidence to suggest that labelling on its own is able to reduce the prevalence of FASD or alcohol consumption while pregnant.
- Industry, through DrinkWise has undertaken a multifaceted approach to FASD and encourages the Government to also look to labelling as part of the solution and not the final solution.

<sup>5</sup> Sampson PD, Streissguth AP, Bookstein FL, Little RE, Clarren SK, Dehaene P, Hanson JW, Graham JM Jr.(1997) Incidence of fetal alcohol syndrome and prevalence of alcohol-related neurodevelopmental disorder *Teratology* 56(5):317-26.

<sup>6</sup> Chambers CD, Hughes S, Meltzer SB, Wahlgren D, Kassem N, Larson S, Riley EP, Hovell MF (2005) Alcohol consumption among low-income pregnant Latinas. *Alcoholism, clinical and experimental research* 29:2022-2028.

<sup>7</sup> Srikartika VM, O'Leary CM. (2015). Pregnancy outcomes of mothers with an alcohol-related diagnosis: a population-based cohort study for the period 1983-2007. *BJOG*. 122(6):795-804.

<sup>8</sup> Fitzpatrick JP, Latimer J, Olson HC, Carter M, Oscar J, Lucas BR, Doney R, Salter C, Try J, Hawkes G, Fitzpatrick E, Hand M, Watkins RE, Tsang TW, Bower C, Ferreira ML, Boulton J, Elliott EJ. (2017). Prevalence and profile of Neurodevelopment and Fetal Alcohol Spectrum Disorder (FASD) amongst Australian Aboriginal children living in remote communities. *Res Dev Disabil*. 65:114-126.

4. Variation in labelling coverage and consistency, and some consumer misunderstanding associated with the current voluntary pregnancy warning labels in Australia and New Zealand were identified as reasons for possible regulatory or non-regulatory actions in relation to pregnancy warning labels on alcoholic beverages.

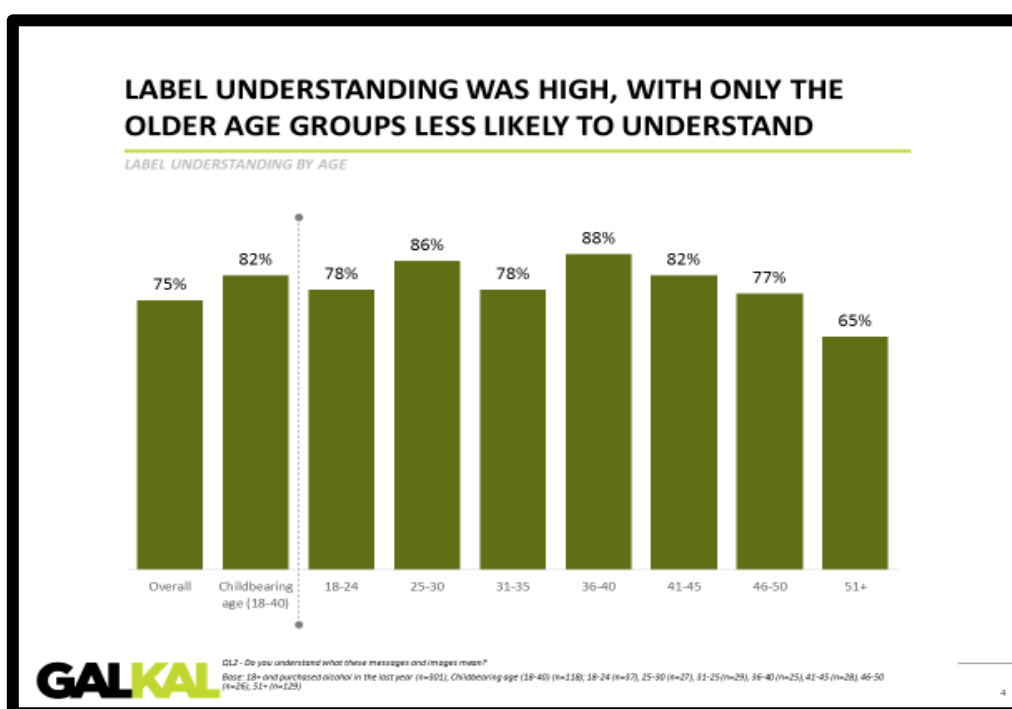
Are there any other issues with the current voluntary labelling scheme that justify regulatory or non-regulatory actions? Please provide evidence with your response.

In answering this question, it is important to review the information regarding voluntary labelling coverage and consistency, as well as consumer understanding of the labels. Siggins Miller has conducted a second evaluation of the voluntary labelling initiative. The report from this evaluation shows that:

- coverage of products with pregnancy health message has increased from 59.8% in 2004 to 75.3% in 2016;
- 93% of the pregnancy health labels were assessed as standard or above in terms of legibility; and
- 90% of the pregnancy health labels were assessed as standard or above in terms of prominence.

This establishes that pregnancy warning labels in Australia are highly consistent across the board.

The latest evidence base available shows that the current voluntary pregnancy warning labels in Australia are in fact well understood. In consumer research by Galileo Kaleidoscope, commissioned by DrinkWise, it was found that the understanding of the pregnancy label pictograms and the message that *It's safest not to drink while pregnant* were high.



As such, ABA submits that implementing regulatory or non-regulatory labelling based on issues coverage, consistency and consumer understanding does not have a sufficient evidence base and therefore should not be implemented. In addition, there are no other issues that would warrant regulatory or non-regulatory actions.

**Key points:**

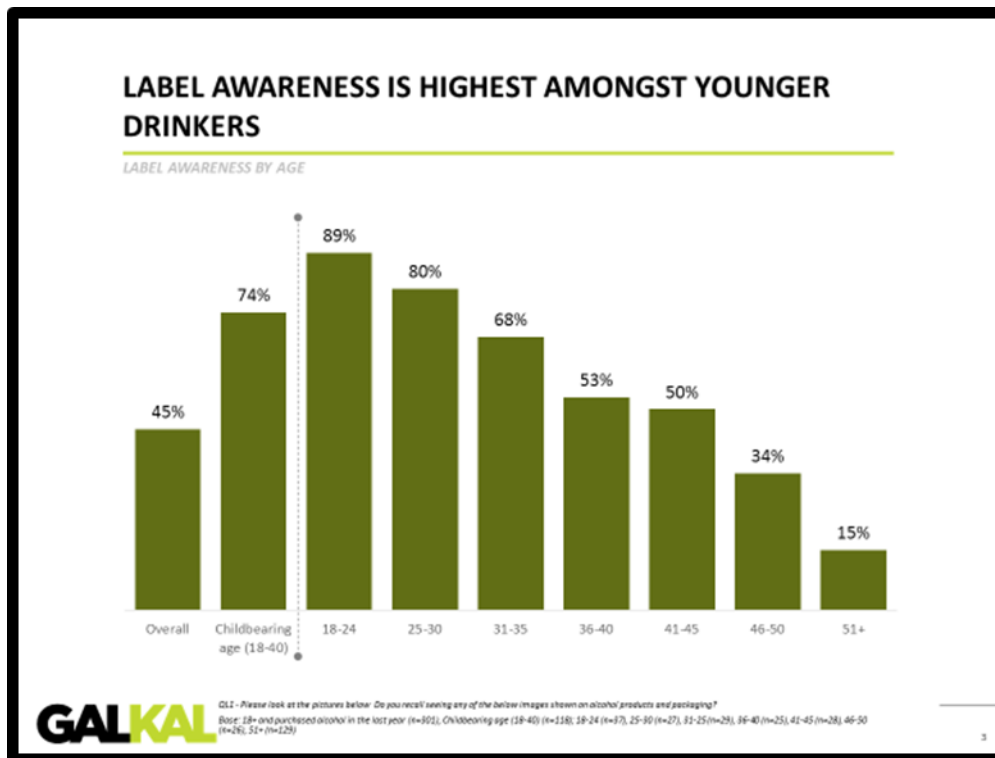
- Issues of coverage, consistency and consumer understanding are not evidence-based concerns and should not be used as the basis for implementing labelling regulation.
- There are no other issues that would warrant regulatory or non-regulatory actions.

**5: Has industry undertaken any evaluation on the voluntary pregnancy warning labels? If so, please provide information on the results from these evaluations.**

DrinkWise Australia initiated an independent evaluation of pregnancy warning labels through Galileo Kaleidoscope. The evaluation found that there were very high levels of both awareness and comprehension of the pregnancy pictogram and the message *It's safest not to drink while pregnant*.

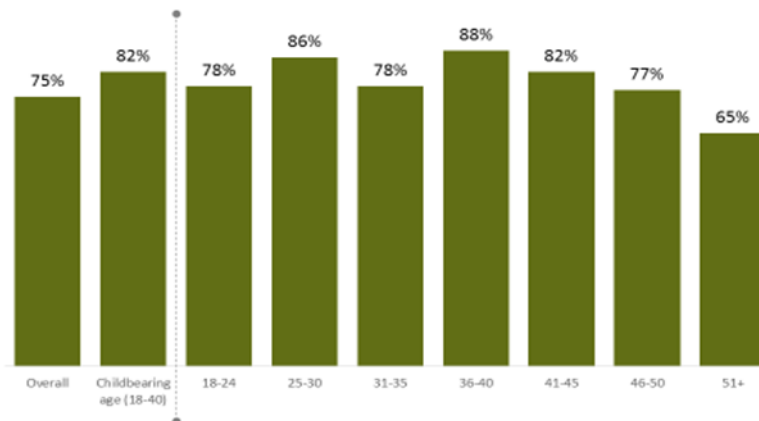
The sample of 301 participants found that:

- 75% of those who had purchased packaged alcohol in the last 12 months had seen the DrinkWise pregnancy labels.
- Over two thirds of consumers thought the labels provided useful information.
- 41% of participants who had seen the labels reported that they had done something different as a result of seeing this information, such as sharing the information with others or reducing their consumption.
- Label awareness was high amongst younger drinkers. In particular, 74% of those at child bearing age were aware of the label.
- Label understanding was high. In particular, 82% of those at child bearing age understood the label.



## LABEL UNDERSTANDING WAS HIGH, WITH ONLY THE OLDER AGE GROUPS LESS LIKELY TO UNDERSTAND

LABEL UNDERSTANDING BY AGE



**GALKAL**

Q12 - Do you understand what these messages and images mean?

Base: 18+ and purchased alcohol in the last year (n=892). Childbearing age (18-40) (n=118), 18-24 (n=37), 25-30 (n=27), 31-35 (n=29), 36-40 (n=25), 41-45 (n=28), 46-50 (n=26), 51+ (n=23)

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### Key points:

- An independent evaluation of the current DrinkWise labels has found high levels of both awareness and understanding of the label.
- The results of the evaluation indicate that the voluntary scheme has been successful in meeting the objectives of awareness raising.



6: Considering the potential policy options to progress pregnancy labelling on alcoholic beverages and address the implementation issues:

a) Are there additional pros, cons, and risks associated with these options presented that have not been identified? Please provide evidence to support your response.

#### Option 1a) Status Quo

Pros:

- The infrastructure for the voluntary adoption of labels has already been set up by DrinkWise. This includes the website portal, modernised suite of logos, trademark licensing agreement and Style Guide, all of which have received enthusiastic support from the alcohol beverages industry.
- In the last few months alone, an additional 98 producers have downloaded the logo for use. The current momentum to adopt voluntary labelling is sustainable and is expected to be broadly adopted across cider, craft beer, and independent spirits and winemaker categories also.
- DrinkWise is prepared to make adjustments to the current Style Guide if there is confusion surrounding the use of the green colour on the pregnancy pictogram.
- Awareness of pregnancy health labels in Australia is at an all-time high (see Question 4). Further use of the DrinkWise pictogram will ensure that labelling awareness, consistency and consumer understanding of the intended message will keep increasing.
- DrinkWise continues to deliver targeted education efforts about alcohol and pregnancy, with labelling being one element of an overall strategy to promote evidence-based approaches. Supporting the existing labelling infrastructure is a complimentary approach to support DrinkWise's initiatives.

#### Option 1b) Voluntary Industry Self-Regulated

Pros:

- DrinkWise has already invested a significant amount of time and effort into the development of the Style Guide which the body that would be responsible for administering the code could leverage off.
- The DrinkWise Trademark Licensing Agreement and Style Guide contains relevant clauses that can fast-track the development of an Industry Code. The standards and expectations for the labels can be easily standardised and also reduces the potential for misinformation for consumers.
- Given DrinkWise's existing monitoring and auditing processes, this can be extended to include additional enforcement and reporting obligations.
- DrinkWise's existing infrastructure for the voluntary adoption of labels enables any changes to be rolled out more effectively, quickly and smoothly.
- There are already high levels of awareness surrounding the DrinkWise pictogram (see Question 4), and any non-DrinkWise labelling would have to rebuild this awareness from scratch.

#### Option 1c) Voluntary with Government Style Guide

Cons:

- The duplication of the existing DrinkWise system is redundant. The DrinkWise infrastructure has enough flexibility to accommodate increased adoption of labelling and to adjust for enforcement and reporting obligations (see Option 1b).
- The nullification of DrinkWise's recent efforts to approach numerous representative groups (i.e. cider, craft beer, etc.) to adopt the pregnancy labels.
- There is potential for contradiction with DrinkWise's existing program of work surrounding alcohol and pregnancy issues.
- There is a real risk that the achievements in awareness and comprehension under the DrinkWise program achieved to date will be reversed by introducing a new style guide.

#### Option 2) Mandatory

Cons:

- Given the encouraging reduction in numbers of women drinking at risky levels during pregnancy, as well as high levels of abstainers during the same time period (see Question 1), there is insufficient evidence to suggest that mandatory labelling will accelerate these trends. In contrast, there is sufficient evidence to suggest that mandatory labelling will not impact at-risk subpopulations who are already drinking at excessive levels despite high awareness of the health warnings (see Question 13).
- Existing users who have voluntarily adopted DrinkWise labelling will be unfairly penalised.
- The additional costs associated with Option 2 will be passed on to consumers, who are by and large moderate and responsible alcohol consumers.

**b) Are there other potential policy options that could be implemented, and if so, what are the pros, cons and risks associated with these alternate approaches? Please provide evidence to support your response.**

Nil response.

**7: Which option offers the best opportunity to ensure that coverage of the pregnancy warning labelling is high across all types of packaged alcoholic beverages, the pregnancy warning labels are consistent with government recommendations and are seen and understood by the target audiences? Please justify your response.**

As outlined in Question 5, DrinkWise pregnancy warning labels are well understood. There are also high levels of awareness, indicating that they are seen by consumers. As indicated in Question 4 there are high levels of coverage which continue to grow and labels provide consistency across the board.

As such, Options 1a or 1b which allow the DrinkWise model to be used as the basis will provide the best opportunity to ensure high levels of coverage, consistency, comprehension and awareness.

**8: Do you support the use of a pictogram? If so, do you have views on what pictogram should be used (e.g. pregnant woman holding beer glass or wine glass), and also, what colour/s should be used, and why? Do you have any views on size, contrast, and position on the package? Please provide research or evidence to support your views.**

In relation to the use of the pictogram, warning text and colour requirements on labels, ABA strongly supports the use of the DrinkWise labelling standards as guidelines for industry. The reasons for this can be summarised as follows:

- Understanding of the DrinkWise labelling is currently high (see Question 4). Changes to the label may jeopardise this.
- Changes to the labelling system will unfairly punish those who are already compliant (see Question 21).
- Increase costs associated with the changes will be passed onto the consumer when this can be avoided (see Question 23).

**9:** Do you support the use of warning text on a label? Why or why not? Do you have views on what text should be used, and if so, what is it? Do you support the use of warning messages already used in other markets? Please provide research or evidence to support your views.

Refer to Question 8.

**10:** Do you have views on what colour should be used for text, and whether green should be permitted? Do you have any views on size, contrast, and position on the package? Please provide research or evidence to support your views.

Refer to Question 8.

**11:** Should both the text and the pictogram be required on the label, or just one of the two options? Please justify your response.

Refer to Question 8.

**12:** Are you aware of any consumer research on understanding and interpretation of the current DrinkWise pictogram and/or text? What about other examples of pictogram and/or text?

Refer to Questions 4 and 5 above.

**13: Describe the value of pregnancy warning labels. Please provide evidence to support your views.**

The value of pregnancy warning labels is centred more on increasing awareness as opposed to changing behaviours. This means that while pregnancy warning labels may act as a catalyst for raising awareness of the risks associated with alcohol consumption while pregnant, they do not result in women changing their drinking behaviours while pregnant.

Some of the key components of the research regarding the value of pregnancy labelling are as follows:

- There is reasonable evidence to suggest that labelling increases consumer awareness of the label and draws attention to the message on the label<sup>9,10</sup>.
- However, the myth that warning labels increase risk perceptions or prompt consumers to alter their existing drinking behaviour has been repeatedly debunked<sup>1,2,11</sup>. This is particularly pertinent to at-risk groups whose excessive alcohol consumption is often multi-factorial and who are unlikely to respond to broad-based measures<sup>12,13,14</sup>.
- The effectiveness of warning labels in capturing the consumer's attention is limited<sup>15</sup>. Such broad-based measures often miss their mark by a wide margin because individual differences in the consumer dictate what information they pay attention to on a product, such as one's existing consumption habits<sup>16,17</sup> or health goals<sup>18</sup>.
- Awareness is insufficient to prevent alcohol exposure or to prevent other factors which reinforce maintenance of alcohol consumption in early pregnancy. There has been no corresponding evidence to suggest that there has been a decrease in the incidence of FAS in the United States since warning labels were introduced, which has remained relatively stable over the past two decades<sup>19,20,21</sup>.

This leads to the important issue: if labelling by itself does not create a change in behaviour when it comes to alcohol consumption during pregnancy then what are the factors that will? The research indicates that the following points are most likely to cause behavioural change when it comes to consumption of alcohol while pregnant:

- A strong combination of intrinsic factors (e.g. self-confidence and motivation) and extrinsic factors (e.g. previous experience of pregnancy and other drug habits) are strong contributors to one's attitude, which is the primary influence of behaviour and a much stronger predictor of alcohol consumption during pregnancy than awareness and knowledge<sup>22,23</sup>.
- Differences in risk perception vary according to individual experience<sup>24</sup>, such as whether the woman has had a previously healthy pregnancy<sup>25</sup> or is an existing "at-risk" individual, and is a key determinant in attitude tolerance towards alcohol consumption during pregnancy.
- Both community, individual and brief medical interventions should take into consideration the role partners can play and the frequent co-occurrence of smoking and alcohol consumption.
- By reinforcing the need for an integrated approach to promoting a healthy pregnancy, including timely antenatal care; appropriate maternal nutrition; folate supplementation; and efforts to reduce the use of alcohol, tobacco and illicit drug use in pregnancy, targeted interventions for women at higher risk of alcohol consumption during pregnancy are mostly likely to cause behavioural change.

**Key points:**

- Pregnancy warning labels are most valuable in raising awareness. However, awareness is insufficient in causing behavioural change.
- In order to achieve behavioural change in pregnant women a multifaceted targeted approach is needed.

<sup>9</sup> Wilkinson, C., & Room, R. (2009). Warnings on alcohol containers and advertisements: international experience and evidence on effects. *Drug and Alcohol Review*, 28(4), 426–35. <https://doi.org/10.1111/j.1465-3362.2009.00055.x>

<sup>10</sup> Stockley, C. S. (2001). The effectiveness of strategies such as health warning labels to reduce alcohol-related harms - an Australian perspective. *The International Journal on Drug Policy*, 12(2), 153–166.

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- <sup>11</sup> MacKinnon, D. P., Nohre, L., Pentz, M. A., & Stacy, A. W. (2000). The alcohol warning and adolescents: 5-year effects. *American journal of public health, 90*(10), 1589.
- <sup>12</sup> Hankin, J. R., Sloan, J. J., Firestone, I. J., Ager, J. W., Sokol, R. J., & Martier, S. S. (1996). Has awareness of the alcohol warning label reached its upper limit?. *Alcoholism: Clinical and Experimental Research, 20*(3), 440-444.
- <sup>13</sup> Gladstone, J., Levy, M., Nulman, I., & Koren, G. (1997). Characteristics of pregnant women who engage in binge alcohol consumption. *Canadian Medical Association Journal, 156*(6), 789-794.
- <sup>14</sup> Stutts, M. A., Patterson, L. T., & Hunnicutt, G. G. (1997). Females' perception of risks associated with alcohol consumption during pregnancy. *American Journal of Health Behavior, 21*(2), 137-146.
- <sup>15</sup> Thomsen, S. R., & Fulton, K. (2007). Adolescents' attention to responsibility messages in magazine alcohol advertisements: an eye-tracking approach. *The Journal of Adolescent Health, 41*(1), 27-34.
- <sup>16</sup> Maynard, O. M., Munafò, M. R., & Leonards, U. (2013). Visual attention to health warnings on plain tobacco packaging in adolescent smokers and non-smokers. *Addiction, 108*(2), 413-9.
- <sup>17</sup> Munafò, M. R., Roberts, N., Bauld, L., & Leonards, U. (2011). Plain packaging increases visual attention to health warnings on cigarette packs in non-smokers and weekly smokers but not daily smokers. *Addiction, 106*, 1505-1510.
- <sup>18</sup> Bialkova, S., & van Trijp, H. C. M. (2011). An efficient methodology for assessing attention to and effect of nutrition information displayed front-of-pack. *Food Quality and Preference, 22*(6), 592-601.
- <sup>19</sup> May PA, Gossage JP, Kalberg WO, et al. Prevalence and epidemiologic characteristics of FASD from various research methods with an emphasis on recent in-school studies. *Dev Disabil Res Rev. 2009;15*(3):176-192
- <sup>20</sup> Popova S, Lange S, Probst C, Parunashvili N, Rehm J. Prevalence of alcohol consumption during pregnancy and Fetal Alcohol Spectrum Disorders among the general and Aboriginal populations in Canada and the United States. *Eur J Med Genet. 2017 Jan;60*(1):32-48
- <sup>21</sup> Astley, S. J. (2004). Fetal alcohol syndrome prevention in Washington State: evidence of success. *Paediatric and Perinatal Epidemiology, 18*(5), 344-351.
- <sup>22</sup> Meillier, L. K., Lund, A. B., & Kok, G. (1997). Cues to action in the process of changing lifestyle. *Patient education and counseling, 30*(1), 37-51.
- <sup>23</sup> Chambers, C. D., Hughes, S., Meltzer, S. B., Wahlgren, D., Kassem, N., Larson, S., ... & Hovell, M. F. (2005). Alcohol Consumption among Low-Income Pregnant Latinas. *Alcoholism: Clinical and Experimental Research, 29*(11), 2022-2028.
- <sup>24</sup> Raymond, N., Beer, C., Glazebrook, C., & Sayal, K. (2009). Pregnant women's attitudes towards alcohol consumption. *BMC public health, 9*(1), 175.
- <sup>25</sup> Testa, M., & Reifman, A. (1996). Individual differences in perceived riskiness of drinking in pregnancy: antecedents and consequences. *Journal of Studies on Alcohol, 57*(4), 360-367.

**14: Which is the option that is likely to achieve the highest coverage, comprehension and consistency? Please provide evidence with your response.**

As demonstrated throughout this submission, the evidence shows that the current system has achieved significant results. These are tangible, evidence-based results from independent evaluations such as Siggins Millers and Galileo Kaleidoscope reports. Any regulatory change cannot be justified considering that the evidence clearly shows the success of the current system. Any notion that regulatory action can be justified is theoretical and has no basis that has been proven in the marketplace.

As outlined in Question 5, the current system using DrinkWise labelling as a guide has achieved high levels of awareness and comprehension. As outlined in Question 4, the current labels have achieved high levels of coverage and consistency. This combination illustrates that as far as labelling is able to make an impact, the current labels are working well.

There is no evidence that higher regulation will improve the outcomes relating to coverage, comprehension, consistency or awareness when it comes to labelling.

Instead, it is more likely that any changes to the current guidelines will reverse the progress that has been made to date in achieving comprehension and awareness in the target audience and the wider community. It should be noted that the level of coverage, consistency, awareness and comprehension did not occur instantaneously. Instead like any other awareness program it took time to develop these outcomes.

In 2014 and 2017 respectively, the Department of Health engaged Siggins Miller Consultants to undertake evaluations of DrinkWise's voluntary labelling initiative. Overall, significantly more respondents in the total sample indicated that they were aware of any messages or campaigns about drinking alcohol when pregnant from the first (62.4%) to the second evaluation (71.1%). The most recent evaluation of the DrinkWise labelling, there was 74% awareness amongst those of child bearing age.

As such, in order to ensure longevity and continual improvement in labelling outcomes Options 1a and 1b will provide the best outcomes.

**Key points:**

- There are high awareness and comprehension levels under the current system.
- Coverage and consistency levels are high under the current scheme.
- Option 1a or Option 1b provide the best option for coverage, comprehension, consistency and awareness as the current system has already proven to be successful.

**15: Which option is likely to achieve the objective of the greatest level of awareness amongst the target audiences about the need for pregnant women to not drink alcohol? What evidence supports your position?**

Refer to Question 14 where issues of awareness have also been considered.

**16:** More information is required on the benefits of each of the regulatory options. Do you have any information on the benefits associated with each option in relation to social, economic or health impacts for individuals and the community? Please provide evidence with your response.

In order to maximise social, economic and health impacts for individuals and the community when it comes to FASD and alcohol consumption during pregnancy, it is important to note that regulation of label warning will not achieve significant benefits. As outlined in Question 13 the benefits of labelling are limited to increased awareness. Given that AIHW data shows that 98.8% of pregnant women either abstain from alcohol consumption or reduce consumption, it is indicative that awareness levels are already high.

Instead to maximise social, economic and health impacts for individuals, the focus should turn to policy options that will result in change to the behaviour of pregnant women when it comes to alcohol. Question 13 provides a brief outline of the factors that can result in behavioural change.

**Key points:**

- Warning labels play an important role in raising awareness, but are not a complete approach in and of themselves.
- Regulatory practices will not act to improve social, economic or health impacts for individuals and the community.
- To maximise outcomes for the individuals and the community, a multifaceted approach to FASD with a focus on policy options to change behaviour of pregnant women.

**17:** To better predict cost to industry associated with each option, can you provide further information that could inform the cost to industry associated with each of these approaches, particularly costings from a New Zealand industry perspective? Please provide evidence to support your response.

Maintaining the current status quo (as per Option 1a) is the most cost-effective option and it makes the most sense given the astonishingly high awareness of the need to reduce drinking when pregnant. Current awareness levels show 98.8% of all Australian women either stop drinking altogether or reduce their consumption when they find out they're pregnant<sup>26</sup>. A far more sensible approach would be to research why the women who know they should reduce their alcohol consumption when pregnant either resist altogether or do not reduce it enough.

Currently the number of women who either abstain from alcohol consumption or reduce their alcohol consumption is at 98.8%. The cost to government, industry and consumers to increase this level to 100% would be incredibly high. Best regulatory practices would require a balance in considering the cost of achieving 100% awareness, given that the current levels would indicate that there is 98.8% awareness.

The most cost-effective way to maintain the appropriate balance between the apparent desired increased level of regulation and prohibitive and damaging costs to industry would be Option 1b. While the overall use of voluntary labels is currently relatively high (see above), there remain some sectors that are still working towards adopting the labels. Industry stakeholders who become signatories to a self-regulatory code of practice will have increased flexibility to become more proactive in placing warning labels on their products.

In comparison, other options involving government monitoring and compliance, or any significant change in current labelling will deliver a massive cost to industry and directly punish those who have been compliant so far. For example, it may not be possible for many products to accommodate a new warning label without substantial change to the current packaging and labelling already. This action does not acknowledge pre-existing, strong industry efforts to introduce and adopt voluntary pregnancy labelling. Furthermore, the tighter and more prescriptive the regulation, the less cost-effective it will be to self-regulate.

The current two-tone, one-colour label that has been implemented can be fully adapted provided sufficient notice assuming a similar size.

However, the introduction of a two-colour logo could potentially require many small volume imported products' labels to undergo re-working and see changes made for basic mandatory labels to comply. In many instances, there will be challenges for back label designs that do not already utilise a red colour, given the limitations of existing printers for can manufacturing (which uses a five-colour process) or multi-market products (e.g. imported wine and spirits).

Consequently, Australia and New Zealand producers may have to incorporate their own labels or risk rising costs if labelling requirements end up driving away international producers who choose not to range their products in these markets, given how relatively small these markets are. This in turn will remove consumer choice and unfairly impact the vast majority of the population who drink responsibly.

It is also important to note that the cost to government at all levels will also be significant in any regulatory framework. This is because in any given framework, the government will be required to monitor and enforce the system to ensure compliance.

<sup>26</sup> Australian Institute of Health and Welfare 2017. National Drug Strategy Household Survey 2016: detailed findings. Drug Statistics series no. 31. Cat. no. PHE 214. Canberra: AIHW.



**18:** For Australia, is the estimated cost of \$340 AUD per SKU appropriate for the cost of the label changes? To what extent do these cost estimates capture the likely impacts on smaller producers? Should the cost estimates be adjusted upwards to capture disproportionate impacts on smaller producers?

The estimated potential direct costs of re-labelling, \$340 AUD per SKU, is a gross under-estimation. It is anticipated the cost related to this issue can range between \$5,000 AUD and \$20,000 AUD per SKU depending on the number of changes to the scheme's initial design.

If only one plate change is required (e.g. a single colour change to the bottle) this could be reduced to approximately \$5,000 AUD, provided significant planning and supply chain resources, particularly where multiple SKUs will be affected. Slower moving SKUs, such as spirits with higher stock levels, typically incur significant packaging costs when hard changes are implemented.

A system where companies can retain the use of their existing DrinkWise pictograms will reduce disruption. However, companies may still incur new costs associated with reporting and monitoring for compliance.

In the event of changes to the size, placement, colour, design, font or other characteristics of the pictogram, costs associated with novel creative development will be significantly more difficult to quantify, as well as the timeframe required for artwork changes. Costs vary depending on how much is being changed (i.e. bottle; bottle and wrap; bottle, wrap and carton), and the nature of the change (e.g. one colour, multiple colours, size changes, logo placement). Typically, the costs are estimated to be:

- \$1,500 per label (most bottles contain multiple labels)
- \$1,863 per wrap
- \$1,360 per pre-print carton
- \$1,284- \$1,898 per tray and carton

There is also concern that both mandatory and overly prominent labelling can result in significant impact on each brand's capability to differentiate themselves from competitors.

**Key points:**

- The estimated cost of \$340 AUD per SKU is a gross underestimation of the potential cost of relabelling.
- There are multiple factors that would contributed to the cost of relabelling and the more onerous regulation will result in higher costs.
- The cost of relabelling is not limited to future relabelling but also extends to issues such as dealing with current stock on hand.

**19:** Is the number of active SKUs used in the cost estimation appropriate? What proportion of SKUs on the market is from smaller producers?

Nil response.

**20:** Should there be exemptions or other accommodations (such as longer transition periods) made for boutique or bespoke producers, to minimise the regulatory burden? If so, what exemptions or other accommodations do you suggest?

Any change from the current position will result in significant operational requirements from all producers. With this in mind, all producers will be impacted equally and ABA recommends any obligations be industry wide. The timeframe in which these obligations must be met should reflect the significant amendments that will be required if any regulatory burden is imposed on industry.

**21:** To better predict the proportion of products that would need to change their label to comply with any proposed change, information on the type of pictogram and text currently used is required. Do you have evidence of the proportion of alcohol products that are currently using the red pictogram, and what proportion of products are using an alternate pictogram (e.g. green)? Do you have evidence on the proportion of alcohol products that are currently using the beer glass pictogram, or the wine glass pictogram? Please specify which country (Australia or New Zealand) your evidence is based on.

ABA's membership overwhelmingly utilises the DrinkWise logo in black and white. Additional colouring requirements would be onerous and expensive, resulting in higher compliance costs to industry that would in turn be passed onto the consumer.

Importantly, the introduction of mandated colouring or any other mandated aspect of the label that moves away from the existing DrinkWise pictograms will mean those who have been compliant to date will face significant costs in updating their labelling system to comply with any new mandatory requirements. It will mean those in the industry that have been proactive at their own expense will be liable to once again update labelling at a significant cost. This will essentially benefit those who have not been compliant to date with labelling initiatives as they will only have to pay for an update in labelling once.

Adopting a labelling system that punishes early adopters who have financially invested in a program and reward those who have not been proactive would not represent best-practice regulation.

**Key points:**

- Additional requirements beyond the DrinkWise guidelines, including colour, would be onerous and expensive to producers as well as customers.
- By introducing aspects of labelling beyond the DrinkWise guidelines, those who have been compliant to date will be disproportionately affected as they will have to pay for labelling updates twice, whereas those who have not been compliant will only have to pay once.

**22:** What would be the cost per year for the industry to self-regulate? Please justify your response with hours of time, and number of staff required. Please specify which country (Australia or New Zealand) your evidence is based on.

The quantification of annual costs for industry to self-regulate will be largely dependent on the type and number of changes that are put forward. For example, if there is a mandate on colouring or size of the labelling then there will be significant additional costs to monitoring the mandatory components.

It should also be noted that self-regulation provides an incentive for industry to produce the most efficient and therefore cost effective process for self-regulation. Any mandated processes for regulation would likely add a significant cost to the process.

**Key points:**

- The annual cost for industry to self-regulate will be dependent on the flexibility of the scheme, with more onerous regulatory requirements resulting in higher costs.
- Self-regulation provides strong incentive for industry to produce efficient and cost effective regulatory processes.

**23:** For each of the options proposed, would the industry pass the costs associated with labelling changes on to the consumer? Please specify which country (Australia or New Zealand) your evidence is based on.

Industry would pass on all additional costs associated with labelling changes to the consumer. This would include the cost to redesign labels, additional printing costs, regulatory costs and lost stock costs. It should be noted that these costs vary depending on the option that is implemented. Option 1a is the most cost effective to industry with option 2 being the most onerous. As such, the amount that is passed onto the consumer will be dependent on the option selected.

**Key points:**

- Industry will pass on any additional costs associated with labelling changes to the consumer.
- The cost to industry will be dependent on the option chosen – the more onerous the regulatory measures the higher the cost and in turn the higher the cost to consumers.

**24:** If you identified an alternate policy option in question 5, please provide estimates of the cost to industry associated with this approach.

Nil response

**25:** Based on the information presented in this paper, which regulatory/non-regulatory policy option do you consider offers the highest net benefit? Please justify your response.

ABA considers Option 1b to provide the greatest net benefit. The following factors have been considered in coming to this conclusion:

- Currently awareness levels, comprehension, consistency and coverage are all high (see Questions 4 and 5). It has taken considerable effort to produce these outcomes and is the result of consistency over time, particularly when it comes to awareness and comprehension. Any changes beyond Option 1b pose a real threat to reversing these outcomes resulting in less awareness, consistency and comprehension, which would be contrary to the policy goals.
- 98.8% of pregnant women either abstain or decrease consumption during pregnancy, indicating high levels of awareness of the issues with alcohol consumption. Labelling has a limited role to play in changing behaviours of pregnant women or in reducing the prevalence of FASD (see Question 13). When considering the introduction of onerous policy options, the potential benefits must be considered and in this context labelling has limited benefit to offer when it comes to achieving the policy objects of decreasing FASD and behavioural change in pregnant women. Placing any greater obligations on industry, when there is little more that can be achieved through labelling does not represent best regulatory practice.
- The potential cost of changes to introduce, regulate or monitor labelling will be passed onto the consumer. Option 1b, while not the most cost effective, strikes a balance between potential benefits and the cost to the consumer.
- Introducing any greater level of regulation than Option 1b will mean those in the industry that have been proactive at their own expense will be liable to once again update labelling at a significant cost. This will essentially benefit those who have not been compliant to date with labelling initiatives, as they will only have to pay for an update in labelling once. Adopting a labelling system that punishes early adopters who have financially invested in a program and reward those who have not been proactive would not represent best regulation practice.
- There is no evidence to suggest that any other option will produce better outcomes than those in Option 1b.

Overall, Option 1b provides reassurance to Government and the community that industry is committed to supporting pregnancy labelling in a way that does not present unnecessary regulation to industry or cost to consumers. It strikes a balance in recognising that while labelling does play a role in the policy solution and industry is committed to supporting its success, it is by no means a silver bullet to success when it comes to FASD or behavioural change.