

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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Date of submission:	14 June 2018

If we require further information in relation to this submission, can we contact you? Yes

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

OR mail to:

c/- MDP707
GPO Box 9848
Canberra ACT 2601

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.

This answer relates to Australia.

These are appropriate estimates of the proportions of pregnant women who drink alcohol during pregnancy.

- Data from the 2016 National Drug Strategy Household Survey (NDSHS) demonstrates that significant numbers of women are still drinking alcohol during pregnancy. In 2016, only 56 per cent of pregnant women reported that they abstained during pregnancy.
- Regarding trends over time, the NDSHS shows that the proportion of women consuming alcohol during pregnancy has declined since 2007. However, this decline has slowed; between 2013 and 2016, the proportion of pregnant women abstaining from alcohol slightly increased from 53 per cent to 56 per cent but this rise was not statistically significant.
- The NDSHS 2016 also showed that one in four women (25 per cent) consume alcohol after becoming aware of their pregnancy.¹

There are specific cohorts who are more at risk of continuing to drink alcohol during pregnancy. Women who are older (over 36 years) and women with a higher household income are more likely than other women to continue to drink during pregnancy. For women under 25, 90 per cent stopped drinking once they became aware of their pregnancy, compared to only 50 per cent for those aged 36 and older.²

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.

It is impossible to estimate the prevalence and burden of FASD with any degree of certainty. As noted in the consultation paper, prevalence is likely to be underestimated due in part to low diagnosis rates and limited diagnostic capacity among health professionals in Australia.³ An Australian FASD diagnostic tool was not released until 2016. There is also evidence that certain population groups are disproportionately affected, for example in Australia certain Aboriginal and Torres Strait Islander communities have been found to have a significantly higher prevalence.⁴

FARE is not aware of any comprehensive assessments of the financial burden of FASD in Australia and New Zealand. In fact, a systematic literature review conducted in Canada in 2011 on the economic impact of FASD found that there are no comprehensive assessments (i.e. encompassing all costs including direct healthcare, childcare systems and correctional services) of the economic impact of FASD in Canada, the United States of America (USA) or any other country. The review highlighted the “urgent need to provide an accurate cost estimate of FASD that would encompass all aspects of this disorder and the various sectors affected by this disability”.⁵

Individual studies on the prevalence and/or cost of FASD to healthcare, childcare systems and correctional services do exist. Taken together these studies demonstrate a substantial financial burden. For example studies have found:

- Young people with FASD are 19 times more likely to be incarcerated than young people without FASD in a given year.⁶
- A meta-analysis with data from eight countries found that the overall pooled prevalence of FAS^a and FASD among children and youth (0-20 years) in the care of a childcare system was six per cent and 16.9 per cent respectively.⁷ ‘Childcare system’ was deemed to include orphanages, foster care and child welfare systems.
- In Canada, in 2008-09, the estimated total direct healthcare costs of the 33,730 people identified with FAS was CAD\$6.7 million. In addition, the use of health services by individuals with FAS are likely to be underreported, therefore actual costs are likely to be higher.⁸
- Using the most conservative approach, a 2013 Canadian study found that FASD diagnostic evaluation requires 32 to 47 hours for one individual to be screened, referred, admitted, and diagnosed with a FASD diagnosis, resulting in a total cost of CAD\$3,110 to CAD\$4,570 per diagnosis.⁹

An economic analysis conducted by Health Technology Analysts in 2010 stated that, although there are no reliable estimates of the incidence of FASD in Australia or New Zealand, current international estimates are that 1 per cent of all pregnant women deliver a child with FASD. In Australia this translates to 2,599 children per year, while in New Zealand this translates to 581 children per year. The researchers modelled the cost of these cases conservatively, identifying an extra AU\$66 million and NZ\$16 million per annum to Australian and New Zealand taxpayers respectively. This represents a significant health and economic burden to society in both countries.¹⁰

In addition, drinking alcohol during pregnancy is linked to other health risks to mother and baby, which also incur societal and health costs.¹¹

The costs are further expanded at question 16.

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.

FARE does not have any evidence to this effect or know of any such evidence.

There is evidence to suggest that an improved mandatory warning label could influence behaviour and reduce the rates of pregnant women drinking alcohol.¹²

^a Throughout this submission, FARE has used the diagnostic terminology used in the source article. This does not necessarily reflect the change in diagnostic terminology that took place in Australia in 2016.

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.

A government-led mandatory scheme is necessary because:

- An effective, best-practice, consumer-tested warning label is unlikely to be developed voluntarily by the alcohol industry.
- An effective, best-practice, consumer-tested warning label is unlikely to be implemented if its use is optional.
- A voluntary scheme is unlikely to achieve full coverage, or even close to full coverage, as demonstrated by the current industry-led voluntary labelling scheme.

Research commissioned by FARE in early 2018 conducted by Hall & Partners (supplied to you as an embargoed confidential copy), investigated consumer understanding and interpretation of the two most commonly used consumer information message labels for alcohol and pregnancy in Australia. These labels are the “DrinkWise labels” which are provided by the alcohol industry-controlled and funded organisation DrinkWise.¹³

The research clearly demonstrates that the current labelling scheme is suboptimal and that improvements could be made by introducing a mandatory best-practice, consumer-tested warning label. Some of the key issues with the current labels and labelling scheme are as follows.

The warning label is too small and indistinct to attract attention

The current pregnancy warning label is often too small and indistinct to sufficiently attract attention, negating its perception as a warning.¹⁴ Please see evidence outlined in questions 8-11. Despite the evidence, the alcohol industry has not voluntarily increased the size and prominence of the label.

Linking to a website instead of including text is not effective

The DrinkWise labels refer consumers to the DrinkWise website for further information. The evidence suggests the vast majority of consumers do not visit the website to get more information:

- A 2015 survey of 561 Australians assessed consumer awareness of the ‘Get the facts’ logo on alcohol labels which directs consumers to the DrinkWise website, as well as their use of that website. The researchers found that no participants (spontaneously) recalled the ‘Get the facts’ logo, and only 7.3 per cent of respondents had visited the website. The study concluded that “it appears that current warning labels fail to effectively transmit health messages to the general public”.¹⁵
- Research into consumer understanding of the DrinkWise labels was undertaken by Deakin University in 2018. Some participants stated that the warning messages did not encourage them to seek further information about alcohol misuse, including from the DrinkWise web address. For example, one participant said: “*I feel [the web address] is not that direct because no one will go – no one after reading it will go and actually get the facts*” (male, Group 6).¹⁶

These findings are supported by research from overseas. Focus groups and a representative survey of 1,783 consumers in England in 2016-17 by The Royal Society of Public Health (UK) found that using labels to direct consumers to further health information online was of limited utility compared to presenting information on the label itself due to the “conscious and proactive decision needed by each individual to access this information”.¹⁷ This is consistent with other evidence which shows that the inclusion of text on the label itself is more effective. This evidence is outlined in questions 9-11.

Alcohol industry websites are not trusted sources of health information

The alcohol industry is not an independent, trusted or legitimate source of health information.

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”.¹⁸

The objective of alcohol manufacturers is to sell more alcohol. It is unacceptable for public health information to be provided by organisations that are in direct pecuniary conflict of interest with consumers receiving and acting upon that information. Furthermore, those organisations are currently permitted to provide the information in any format they wish, or to not provide it at all if they prefer.

Given a permissive environment, some alcohol manufacturers choose to direct consumers to international branded websites such as Diageo’s [DrinkIQ](#) and [BTBT.com.au](#) (Beer the Beautiful Truth) to find information about drinking ‘responsibly’. These websites are primarily designed to promote alcohol consumption and brand loyalty. They cannot be considered as legitimate sources of consumer health information. Without a mandated, government developed label there is nothing to prevent alcohol companies in Australia continuing to prioritise brand loyalty over consumers’ health.

In Australia, doctors are required to disclose pecuniary conflicts of interest to patients before providing health advice. If a conflict of interest is deemed to exist, doctors may be required to withdraw from their involvement in a particular activity or divest of their financial interest before providing further advice.¹⁹ These same standards on conflict of interest should apply to other types of health advice given in Australia, especially advice about irreversible harm to unborn babies.

Only an independent and mandatory scheme administered by FSANZ, a trusted regulatory body, can overcome the significant conflict of interest (that alcohol producers ultimately want to sell more alcohol) which has thus far prevented the alcohol industry from implementing an effective and consistent warning label.

Messages have not been informed by consumer testing with all population cohorts

The 2012 Parliamentary Inquiry on FASD conducted an evidence session in Fitzroy Crossing. One of the things this highlighted was that the current pictogram had been misunderstood by some women to mean that you could not get pregnant while drinking alcohol. One participant said:

“The first time I have ever seen [the warning label] was when a group of us were sharing a bottle of wine and we passed it around to see the label, to see what it means. It looks like it has a line through a pregnant lady. So it looks like if you drink this bottle of wine, you cannot get pregnant. It needs to be passed around more broadly so people can give you some feedback about what it is that we see when we look at that, so it is meaningful outside of Canberra.”²⁰

This highlights the need for any health warning message to be tested widely with consumers. It also underlines the need to have a pictogram accompanied by text to avoid misunderstanding of the label.

Further results from consumer testing of the DrinkWise labels are outlined under question 12.

Some products use other countries labelling regimes

It is inappropriate and inconsistent to use other countries consumer information and health warning labels instead of the Australian label. Research shows that consistency of a health warning label is crucial to its impact. This situation also demonstrates that under a voluntary scheme there is a lack of control over what messages Australian and New Zealand consumers are exposed to.

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

FARE is not aware of any such evaluation.

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.

The consultation paper does not identify the specific challenges associated with the alcohol industry's conflict of interest – that alcohol producers ultimately want to sell more alcohol. None of the voluntary or self-regulatory options will achieve the objectives of pregnancy warning labels due to this conflict of interest.

Only an independent and mandatory scheme administered by FSANZ, a trusted regulatory body, can overcome the significant conflict of interest which has thus far prevented the alcohol industry from implementing an effective and consistent warning label.

DrinkWise (or a similar industry funded/controlled body) is not an appropriate organisation to implement a voluntary scheme. This is because they do not perceive their labels as warnings; they refer to them as 'consumer information messages' only.²¹ This conflict of interest and lack of consideration demonstrates that a voluntary scheme cannot be appropriately led by industry. Research into consumer understanding of the DrinkWise labels undertaken by Deakin University in 2018 demonstrates that this attitude is transmitted to the consumer; participants' impressions were that the intention of the DrinkWise labels was to simply advise about harm associated with alcohol use, rather than to deter consumption.²²

Due to this conflict of interest, the alcohol industry, or industry-funded/controlled bodies such as DrinkWise, are also not appropriate organisations to monitor compliance or conduct evaluations of the labelling scheme.

Eminent researchers in paediatric health wrote to the Chair of DrinkWise Australia in July 2011 to express concern about the inadequacy of their consumer information messages. They outlined evidence-based and consumer-tested resources and information that could be used as an alternative. As far as FARE can ascertain, no changes were made to the DrinkWise messages as a result.

The Australian Government Guide to Regulation advises that a self-regulatory approach is a good option where 'the market is likely to move towards an optimal outcome by itself' and '...should be approached carefully where previous attempts to achieve compliance or penalise non-compliance have failed.'²³ This indicates that a voluntary or self-regulatory approach is not appropriate to achieve the objectives set out on page 17 of the consultation paper.

Warning labels should be developed by Food Standards Australia New Zealand (FSANZ), with advice from relevant experts free of commercial interests, and should be informed by consumer testing research. The alcohol industry spends hundreds of millions of dollars each year promoting its products, with much of this promotion having a clear appeal to young people and to women of child-bearing age. Due to the nature of their promotional material they should not be responsible for developing health warning labels targeted at that same cohort. The alcohol industry has a vested interest in limiting the impact of warning labels. FARE recognises that the alcohol industry does have a role in implementing a proper labelling system, but industry involvement should be limited and clearly defined, and should not extend to the development of health warning messages or the design of labels.

This position is supported by the World Health Organization (WHO). WHO has stated in the clearest possible terms, that alcohol policy development should be free from industry influence. In 2013, Dr Margaret Chan, then Director General of the WHO, stated that "In WHO's view, the alcohol industry has no role in formulating policies, which must be protected from distortion by commercial or vested interests".²⁴

FARE does not support options 1a, 1b, or 1c. Although FARE's position is that a voluntary scheme will not be effective in this instance, due to the inherent industry conflict of interest, specific points on each of the options are outlined below.

Option 1a: Voluntary - status quo

Additional risks of maintaining the status quo are that, without incentive or requirement, the following are unlikely to change:

- That fewer than half of all products (48 per cent) will have pregnancy warning labels (the status quo). The situation may in fact get worse.
- The lack of prominence given to the labels, for example Tinawi et al (2018) found that the average size of the pictogram on alcohol products in New Zealand was 6.7mm in diameter, and the average height of the pregnancy text warning was 1.6mm.²⁵
- The limited use of text and pictogram together. A 2017 review of the voluntary pregnancy warning labels scheme found that only 0.5 per cent of alcohol products displayed both pictogram and text together²⁶, despite consumer testing showing that the two in combination are more effective.²⁷

CASE STUDY 1

Alcohol health warning labels in the UK: An example of a government intervention in a voluntary industry scheme which did not result in a change to the status quo

In 1998, the UK Government first addressed alcohol labelling through self-regulation. It was agreed between the government and the alcohol industry that all alcohol products would state clear standard drink information on their labels.

Following inadequate implementation of this agreement by the alcohol industry, the Government intervened in 2007. They secured a voluntary agreement with the alcohol industry which introduced an expectation for the majority (at least 50 per cent) of labels to carry the Government's sensible drinking message (SDM) and the alcohol unit content by the end of 2008. The Government set out for industry five key elements of an ideal label and a sample of an ideal label. The Government also specifically encouraged the alcohol industry to include the Government's preferred pregnancy statement or logo.²⁸

A large-scale independent review was subsequently commissioned by the Department of Health in 2008 to "determine the extent to which the Government's alcohol labelling agreement with industry was being followed".

The 2008 independent review found very poor compliance with the Government recommended label (all figures are adjusted for market share):

- Only 2.2 per cent used the Government's preferred pregnancy warning text and 13.1 per cent the pregnancy logo (total showing any pregnancy information was 17.9 per cent).
- Only 2.6 per cent displayed the agreed sensible drinking guidelines.
- Only 1.2 per cent of the total printable area was devoted to unit and health information (on average)²⁹.

Further independent monitoring in 2009 found that, contrary to the Government's 50 per cent target, only 14.5 per cent (adjusted for market share) had 'acceptable' content of all five elements of the Government's recommended label.³⁰

Option 1b: Voluntary - self-regulated by industry

There are many drawbacks and risks of continuing with a voluntary scheme. Risks that have not been identified include:

- A code of practice developed by the alcohol industry would be unlikely to be ambitious enough to stimulate change to the status quo, and indeed might be designed to maintain the status quo. Meanwhile, the impression that something is being done would lock us into further years of inaction.
- Government and civil society organisations would have no input into the design of the code of practice.
- DrinkWise and similar organisations have proven themselves to be untrustworthy in delivering accurate messages about health risks.³¹ Encouraging greater use of an industry-developed message could be counter-productive to the objective of stopping pregnant women from drinking.

- Evidence on the ineffectiveness of the current system may not be considered and acted upon in developing the code of practice.

CASE STUDY 2

Alcohol Beverages Advertising Code (ABAC): An example of an ineffective self-regulatory scheme

The ineffectiveness of self-regulation by the alcohol industry can be demonstrated in the Australian context, using the Alcohol Beverages Advertising Code (ABAC) as an example. A formal review of the alcohol industry's self-regulation of advertising, carried out in 2003 by the National Committee for Review on Alcohol Advertising (NCRAA), found substantial flaws in the ABAC. The review found that many complaints were not investigated in a timely manner, some complaints were not investigated at all and very few complaints were upheld. Despite amendments to the ABAC it still has substantial limitations in its application.³²

CASE STUDY 3

Alcohol health warning labels in the UK: An example of the alcohol industry choosing a less impactful label under a voluntary scheme

In 2017 the Royal Society for Public Health (UK) and the Portman Group (an alcohol industry body) agreed to collaborate on the issue of alcohol labelling. They jointly commissioned research with the aim of shaping what best-practice alcohol labelling would look like in the future. Although the research was completed, the partnership broke down because it “proved too difficult to reach a consensus position between the agenda of public health and that of industry”.³³

The Royal Society for Public Health and the Portman Group both subsequently published guidelines for a recommended label. The Royal Society for Public Health report was based on the jointly commissioned research; the Portman Group guidelines do not make reference to the jointly commissioned research.³⁴

The Royal Society for Public Health recommended a best practice label inspired by the “need to give consumers the information that is most necessary to raising awareness, [...] and that has demonstrable potential to positively influence behaviour”.³⁵ Their mocked-up best practice label is as follows:



In contrast, the Portman Group's guidelines were considered to have taken a step backwards by removing the Government's recommended low-risk alcohol guidelines as a required element. Their mocked-up label “presenting the minimum elements” is as follows:

CONTENT FOR PACKAGING



Example label presenting the minimum elements on-pack with active signpost to Drinkaware.co.uk.

This experience from the UK is a cautionary tale of how the alcohol industry's interests diverge from public health interests and that of the community. It illustrates the risk that under a voluntary scheme the alcohol industry will not opt to use the most effective, evidence-based label.

Option 1c: Voluntary – with government style guide

The main risk has been identified which is that companies may not elect to be signatories to the agreement. This is a very substantial risk, which involves all the development work of the mandatory option but potentially without the results. It does not matter if the warnings are effective if they do not appear on products and are not seen by consumers.

This current level of coverage (which is itself inadequate) has been reached under circumstances where there is a threat of government regulation and monitoring and evaluation activities occurring. There is a substantial risk that this level of coverage would decline once these activities cease. In addition, two parliamentary inquiries have found that voluntary implementation by the alcohol industry is inadequate.³⁶

Again, the Alcohol Beverages Advertising Code (ABAC) is a pertinent example here. There are many alcohol companies that are not signatories to the code. Even for those [companies that are signatories](#), there are no financial sanctions for non-compliance.

Alcohol manufacturers already change their labels frequently, and therefore FARE disagrees that 'cost to industry to change current labels' should be considered a disadvantage of option 1c.

CASE STUDY 4

Health Star Rating System: An example of a government-developed voluntary scheme with selective uptake

The Health Star Rating System was established in 2014. It is a front-of-pack labelling system that rates the overall nutritional profile of packaged food and assigns it a rating from ½ a star to 5 stars. It is being implemented from June 2014 on a voluntary basis by the food industry over the following five years, with a review of progress after two years and a formal review at five years.

The two-year review report states that there were 2,031 products displaying the Health Star Rating. This represents 14.4 per cent of total eligible products. In the two-year report, a trend was identified that the uptake of the scheme was higher for products which rated highly on the scale (> 3.5 stars) than for products which rated lower on the scale (< 3.5 stars).³⁷

The George Institute for Global Health conducted a review of the Health Star Rating system in 2018 and found that only 7.5 per cent of products in the sample displayed the label. The review also found that food manufacturers were more likely to put Health Stars on foods that scored towards the higher end of the five-star scale, rather than on more unhealthy products.³⁸

Option 2: Mandatory – with government developed label

Only an independent and mandatory scheme administered by FSANZ, a trusted regulatory body, will achieve the primary objective as outlined in the consultation paper – 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”.

Option 2 is also the only option that can deliver against the secondary objectives outlined in the consultation paper – to “provide information to the community about the need for pregnant women to not drink alcohol when pregnant”.

Option 2 is the only option that can deliver an effective warning in accordance with the definition of effective pregnancy warning label that is outlined in the consultation paper:

“Pregnancy warning labels can be considered to be effective if they:

1. attract the attention of pregnant women and their support network;
2. convey a clear, easy to understand message;
3. are recalled by consumers;
4. influence consumer judgement of product hazards; and
5. influence behaviour of pregnant women and/or their support network.”³⁹

This is because option 2 is the only option that can provide the coverage, consistency, prominence, and comprehension required for the warning label to be effective.

Australian alcohol producers have demonstrated that they are able to apply mandatory warning labels when exporting their products to countries which have a mandatory requirement, such as France and the USA. Meanwhile, in Australia in 2016-17, fewer than half (48 per cent) of all packaged alcoholic beverages available for sale displayed some type of pregnancy warning label.⁴⁰

The mandatory scheme should include specifications as to the size, location, shape and placement of the warning label. At present the Standard Drinks Labels mandated by FSANZ do not cover these elements. Given that pregnancy warning labels in Australia and New Zealand have been found deficient in noticeability⁴¹, it is crucial that the spatial elements of the government label are also mandated.

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.

An independent and mandatory scheme administered by FSANZ, a trusted regulatory body, is the only policy option that can deliver both the primary and secondary objectives as outlined in the consultation paper.

The voluntary labelling scheme has been operating for more than six years and has not been effective at communicating a clear message that pregnant women should not drink alcohol.^{42,43,44,45} Furthermore, it has only achieved 48 per cent coverage of all alcohol products. Considering the significant conflict of interest of the alcohol industry, nothing short of an independent mandatory scheme with a consumer-tested label will ensure the implementation of an effective and consistent warning label.

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.

Option 2 (mandatory) is the only policy option that can deliver both the primary and secondary objectives as outlined on p17 of the consultation paper.

Specific points are highlighted below on each of the elements identified in question 7.

Coverage

Australian and New Zealand alcohol producers have demonstrated that they can apply mandatory warning labels in countries where it is a requirement (including France and the USA) but they are not doing it in Australia and New Zealand. It follows logically that they are not doing it here because it is optional; only a mandatory scheme will significantly improve the coverage.

- Meanwhile, in Australia in 2016-17, fewer than half (48 per cent) of all packaged alcoholic beverages available for sale displayed some type of pregnancy warning label.⁴⁶
- In surveys with the alcohol industry conducted in New Zealand in 2014 and 2016, one of the main reasons given for not adopting the voluntary pregnancy warning labels was that they only comply with mandatory labelling requirements, and therefore would not provide the pregnancy warning messaging unless it became mandatory.⁴⁷
- Some overseas alcohol brands apply the Australian pregnancy warning labels when they export products to Australia.
- A study conducted on a sample of UK alcohol labels found that, under a voluntary labelling regime, about one-third of the alcohol producers did not include any health warning messages on their labels. Those that did apply warning messages manipulated the message meaning, size and legibility in their favour.⁴⁸

Consistency with government recommendations

Research shows that consistency of warning labels combined with the application of a mandatory warning scheme increases awareness and aids effectiveness. For instance:

- Recent research conducted on consumer understanding of the DrinkWise pregnancy warning label (explored further in questions 8-12).⁴⁹
- Research looking at the impact of the mandatory alcohol labelling scheme in the US.⁵⁰

Evaluations of the effectiveness of tobacco warning labels have further supported the evidence regarding the use of a consistent font and size of text, colour, placement and orientation of the label.⁵¹

Consistency is unlikely to be achieved through a voluntary scheme where alcohol producers can choose between the current message (requiring no action) and a new and improved stronger message.

While option 1c provides for a government style guide, there is no policy lever to ensure that it is used by alcohol producers. The government-recommended message is likely to be significantly more effective than the current pregnancy warning labels being used by industry, thereby increasing the possibility that its use will be avoided by industry as much as possible.

Therefore, only option 2 (mandatory) is likely to result in consistent use of a government recommended message.

Comprehension by the target audience

Recent research conducted on consumer understanding of the DrinkWise pregnancy warning label shows that the current message is not fully understood, and leaves room for interpretation as to whether alcohol consumption

during pregnancy is safe. In particular, the text needs to be updated in order to be comprehended by the target audience (and consistently used alongside the pictogram).⁵² This evidence is discussed further in questions 8-12.

As outlined above, due to the significant conflict of interest, a new and improved warning message of sufficient ambition is only likely to come from a government or civil society source. Once this message is developed, it is very unlikely to be implemented without a mandatory framework.

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.

FARE supports the use of a pictogram, but only in combination with (revised) text. This position is supported by research commissioned by FARE in early 2018 (Hall & Partners). Any final design options should be comprehensively tested and evaluated.

Hall & Partners investigated consumer understanding and interpretation of the two most commonly used consumer information message labels for alcohol and pregnancy (by DrinkWise), in order to explore whether there might be potential to enhance their effectiveness.

This research consisted of eight focus group discussions with key target groups: four with women who are pregnant or trying to conceive and four with key influencers (two with partners of women who were pregnant or trying to conceive and two with female peers). Each group comprised between six and eight participants.

Overall, in addition to always being displayed next to (revised) text, Hall & Partners (2018) recommended the following changes to the current pictogram, as relevant to question 8:

“Enhance the visual impact of the label, for example by:

- increasing the size of the warning on the product/label
- using a contrasting colour, ideally red to signify danger
- using bold text
- using borders and/or white space to help the warning stand out from other information
- locating the warning next to commonly viewed information, such as the number of standard drinks.”⁵³

FARE is indifferent on whether the pictogram features a woman holding a beer glass or a wine glass. It may be warranted to change the image of the pictogram dependent on the product that it is featured on.

In terms of the specific parts of this question, FARE’s position is outlined below:

Size

- The Hall & Partners (2018) research demonstrated that the current pictogram is too small to effectively attract attention.
- Hall & Partners (2018) recommended that if the size was increased, the pictogram has the potential to draw the attention of the consumer.
- Recently published research by Tinawi et al (2018) into the effectiveness of warning labels in New Zealand found that the average size of the pictogram on alcohol products in New Zealand was 6.7mm in diameter. The researchers found that “pregnancy-related pictograms occupied between an average of 0.13 per cent (wine) and 0.21 per cent (ready-to-drink) of the available surface area of the alcoholic beverage container (i.e. less than 1/400th of the available space)”.⁵⁴
- Research into consumer understanding of the DrinkWise labels was undertaken by Deakin University in 2018. Most participants commented on the small size of the 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. 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).⁵⁵*
- FARE’s position is that the warning labels should be mandated to occupy a specific percentage of the container’s surface, determined by the size of the container, product label size, and noticeability. A minimum size of font and label should be specified to ensure visibility.

Colour

- The colour green has consistently been found inappropriate by:
 - Hall & Partners (2018)⁵⁶
 - Siggins Miller's evaluations of the voluntary labelling scheme in 2014⁵⁷ and 2017⁵⁸
 - Research undertaken by Rout & Hannan (2016) on consumer awareness and understanding of the alcohol pregnancy warning labels⁵⁹
- The colour red is considered the most appropriate colour for the prohibition symbol (this encompasses the circle and the line through the circle) as it is commonly used to convey danger/warnings. This was a finding of the Hall & Partners (2018) research.

Contrast

- Hall & Partners (2018) found that pregnancy warning labels need to have:
 - greater contrast to the background
 - greater distinctiveness from surrounding information.

The labels tended to get lost among other information on the label, especially in examples where the text/pictogram is the same colour as other parts of the label.

Position

Hall & Partners recommended locating the warning next to commonly viewed information, such as the number of standard drinks.⁶⁰

A WHO (2017) report on alcohol labelling and a report by Sambrook Research International (2009) prepared for the European Commission, make very similar recommendations for effective health warning labels about using large bold print, high contrast, colour and borders, and the importance of size.^{61,62}

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.

FARE's position is that the use of warning text is supported but that the current wording is not supported. The Hall & Partners (2018) research found that the text reinforces the view that some alcohol consumption in pregnancy is okay, and that while no alcohol consumption is one course of action available to women during pregnancy other options that include alcohol consumption are equally valid.

Similarly, research commissioned in 2016 by the Health Promotion Agency (HPA) on consumers' understanding of alcohol health warning labels, including the commonly used DrinkWise pictogram and text, found that unprompted, 14 per cent of young women (aged 18-34 years) thought that the DrinkWise text meant that you could drink alcohol when pregnant.

After prompting:

- Only 56 per cent of people thought that the DrinkWise text portrayed the message that you shouldn't drink any alcohol while pregnant.
- Only 49 per cent of people thought that the DrinkWise text portrayed a link between pregnant women drinking alcohol and harm to an unborn child.

In addition:

- 38 per cent of people said that the DrinkWise text made them think that drinking a little alcohol while pregnant would be okay.

These findings tell us that the DrinkWise text is not sufficiently informing consumers of the danger of drinking alcohol when pregnant, and in some cases is misleading women to think that some alcohol is safe to consume while pregnant.

The Hall & Partners (2018) research found the main problematic aspect was the use of the term 'safest'. This "conveyed to these participants that pregnant women should 'ideally' avoid alcohol, rather than providing a clear direction to abstain". It was noted by participants that it would be 'safest' for everyone to avoid alcohol, indicating that this text failed to convey the heightened risk and serious consequences that are specific to pregnancy. Participants interpreted the text warning as follows:

- *"Gentle advice that it's not a good idea to take the risk to drink" (Pregnant/ trying to conceive, aged 25-45, higher education)*
- *"Very weak advice" (Male partner, aged 25-45, higher education)*
- *"It is safest not to drive and it is safest not to leave the house, but you are not going to do that" (Female peer, aged 18-29, lower education)*
- *"[The text conveys] it's not harmful if you have a drink every now and then" (Male partner, aged 25-45, higher education)*
- *"It says we're advising you against it, but you could still drink pretty much" (Pregnant/ trying to conceive, aged 25-45, lower education)*
- *"It makes me think that some level of drinking is actually OK" (Male partner, aged 20-45, lower education)⁶³*

Hall & Partners (2018) concluded that the "current warning text may reinforce a belief that low-level alcohol consumption in pregnancy poses negligible risk of harm".

Although the wording 'it is safest not to drink when pregnant' is in line with current National Health and Medical Research Council's (NHMRC) *Australian Guidelines to Reduce Health Risks from Drinking Alcohol* (Alcohol Guidelines). The Alcohol Guidelines (developed in 2009) are in the process of being updated. Research into consumers' understanding and interpretation of the wording of the guidelines will feed into the evidence review

process. It is likely that the statement around alcohol and pregnancy will be strengthened to make it clearer to consumers that no amount of alcohol is safe during pregnancy. However, a decision about making alcohol pregnancy warning labels mandatory, should not wait for the Alcohol Guidelines review process to be completed; decisions can be made and messages tested externally to this review.

Other key observations about the text included:

- Text warnings were considered to be more thought-provoking and emotionally resonant if they focused on the consequences of drinking while pregnant.
- For some participants, the relevance of the messages was increased when it referred to low levels of consumption. For others, some of the stronger messages which implied definite harm from low consumption were rejected due to the strength of existing beliefs that some alcohol is okay.
- Using direct language such as ‘your’ baby was considered to be more impactful.
- Use of the term ‘warning’ was considered to be helpful in attracting attention and signalling severity.

Overall, Hall & Partners (2018) recommended the following changes to the current warning label, as relevant to question 9:

“Use a pictogram and warning text together, with the pictogram serving primarily to attract attention and visually convey the instruction ‘do not drink while pregnant’, and the warning text providing additional, thought-provoking, information. For example, by:

- Directly referring to low levels of alcohol consumption, to begin to challenge the idea that small quantities of alcohol are unlikely to be harmful during pregnancy.
- Clearly explaining the potential consequences of alcohol consumption during pregnancy in a way that is considered believable and credible, particularly in the context of low levels of alcohol consumption (among the examples tested ‘harm’ was generally considered more relatable/believable than ‘birth defects’).
- Avoiding language that implies low levels of alcohol consumption in pregnancy will (definitively) result in negative consequences, as this reduced the credibility of the message and may result in rejection of it
- Using personalised language, to increase the relevance and emotional resonance of the message (e.g. ‘unborn baby’ rather than ‘fetus’ and ‘your’ unborn baby, rather than ‘unborn babies’).
- Including a ‘signal word’, such as ‘warning’, to draw attention to the label and to indicate the serious risk posed by the product.”⁶⁴

Other consumers

As much as possible the message needs to be tailored to, and tested with, various consumers to ascertain their understanding and comprehension of the labelling. This should include women who are pregnant or planning pregnancy but also other consumers. This reflects the fact that pregnant women’s perception of risk from alcohol consumption during pregnancy is affected by those around her and are important in enabling her to go alcohol-free and remain alcohol-free throughout her pregnancy.

Process

New text should be developed by behaviour change experts and tested with the target audience and those around the target audience that influence them, in order to ensure that it is properly understood and comprehended.

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.

Overall, Hall & Partners (2018) recommended the following changes to the current warning label, as relevant to question 10:

“Enhance the visual impact of the label, for example by:

- increasing the size of the warning on the product/label
- using a contrasting colour, ideally red to signify danger
- using bold text
- using borders and/or white space to help the warning stand out from other information
- locating the warning next to commonly viewed information, such as the number of standard drinks.”⁶⁵

In terms of the specific parts of question 10, FARE’s position is outlined below:

Size

- Recent research by Tinawi et al (2018) into the effectiveness of warning labels in New Zealand found that the average height of the text warning was 1.6mm.⁶⁶
- Research into consumer understanding of the DrinkWise labels was undertaken by Deakin University in 2018. Most participants commented on the small size of the 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.⁶⁷
- FARE’s position is that the warning labels should be mandated to occupy a specific percentage of the container’s surface, determined by the size of the container, product label size, and noticeability. A minimum size of font and label should be specified to ensure visibility.

Colour

- The colour green has consistently been found inappropriate by:
 - Hall & Partners (2018)⁶⁸
 - Siggins Miller’s evaluations of the voluntary labelling scheme in 2014⁶⁹ and 2017⁷⁰
 - Research undertaken by Rout & Hannan (2016) on consumer awareness and understanding of the alcohol pregnancy warning labels.⁷¹
- The colour red is considered the most appropriate colour for the prohibition symbol as it is commonly used to convey danger/warnings. This was a finding of the Hall & Partners (2018) research.

Contrast

- Hall & Partners (2018) found that pregnancy warning labels need to have:
 - greater contrast to the background
 - greater distinctiveness from surrounding information.
- The research found that the labels tended to get lost among other information on the label, especially in examples where the text/pictogram is the same colour as other parts of the label.

Position

- Hall & Partners (2018) recommended locating the warning next to commonly viewed information, such as the number of standard drinks.⁷²

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

Hall & Partners (2018) found that participants were in agreement that a pictogram should be combined with supporting text in order to maximise the effectiveness of the message.

In addition to the evidence provided by the Hall & Partners report, there are added benefits from warning labels comprising of both text and symbol. This combination will ensure that the health warning messages reach a broad audience and are understood by consumers with a range of literacy levels and consumers that come from culturally and linguistically diverse backgrounds.

Overall, Hall & Partners (2018) recommended the following changes to the current warning label, as relevant to this question:

“Use a pictogram and warning text together, with the pictogram serving primarily to attract attention and visually convey the instruction ‘do not drink while pregnant’, and the warning text providing additional, thought-provoking, information.”

Earlier research concluded that the pictogram does not convey unintended messages, but its impact and clarity is best enhanced by adding text.⁷³

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?

Yes, there are four research studies FARE is aware of that have investigated the understanding and interpretation of the DrinkWise pictogram and/ or text. These are summarised below.

1. Hall & Partners (2018)

As previously outlined, in early 2018 FARE commissioned research to provide independent evidence on consumer understanding of the DrinkWise pregnancy-related messaging on alcohol products.

Hall & Partners (2018) investigated consumer understanding and interpretation of the two most commonly used consumer information message labels for alcohol and pregnancy (by DrinkWise) to explore whether there might be potential to enhance their effectiveness.

Focus groups were undertaken with:

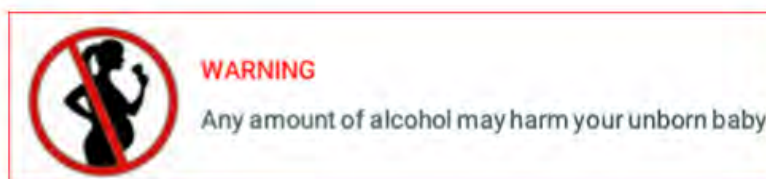
- women who were pregnant or planning pregnancy
- their male partners
- their female peers.

It was considered important to broaden the scope beyond the key target audience of women who were pregnant or trying to conceive, as their beliefs are likely to be influenced by close friends and family, with partners and/or female peers likely to be influencers and likely to be present if/when they consume alcohol. In addition, women's beliefs about alcohol use during pregnancy will be influenced by information they are exposed to before they fall pregnant, so it was also useful to include the perspectives of women who were not currently pregnant (i.e. female peers and women trying to conceive).

Key findings of the research are that:

- The current pictogram is understood by consumers but does not challenge existing beliefs.
- The accompanying text was considered to be weak and ambiguous. For some, it reinforced the belief that small amounts of alcohol during pregnancy was okay.
- The pictogram and (revised) text should be used in combination in order to maximise the effectiveness of the message.
- The warning messages need to be larger and have greater contrast to the background.
- Use of the signal word 'warning' was considered to be helpful in attracting attention and signalling severity.
- Red was considered the most appropriate colour for the prohibition symbol as it is commonly used to convey danger/warnings.
- Other examples of pictograms and text were viewed by participants and considered to be more emotionally resonant than the current label. Text warnings were considered to be more thought-provoking and emotionally resonant if they focused on the consequences of drinking while pregnant, i.e. harm to the unborn child.

Following the focus groups conducted by Hall & Partners (2018), they recommended a warning label which is included below. This is for illustrative purposes as it has not been tested with the target population.



2. Deakin University (2018)

Another research study into consumer understanding of the DrinkWise labels was undertaken by Deakin University in 2018. It investigated young adult (aged 18-25) drinkers' perceptions of DrinkWise consumer messages on Australian alcohol products. The researchers investigated a range of DrinkWise messages, including pregnancy-related messages. The majority of the participants were categorised as risky drinkers.

The study found that young adult drinkers perceive current alcohol warnings to lack meaning and impact. After being shown examples of current labels, young adult consumers said that the current labelling situation represented a lack of sincere effort from the alcohol industry to reduce harm. A range of comments from participants are included below:

- *"I just feel like they're made to not stand out, to be as invisible as possible" (male, Group 6)*
- *"...they've specifically tried to make it [the warning] sort of blend in with the rest of the label. Like with the Carlton Draught it's sort of that reddy colour and then like the yellow one, whatever that's called, then it's, like, yellow. So, you pretty much just see it as one image and not the distinct thing you should be drawn to" (female, Group 5)*
- *"It took me a while to find it actually. I couldn't even find it [on the bottle images]. Like, what am I looking at?" (female, Group 5)*
- *"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)*
- *"It just looks like it's information on the drink or ingredients or whatever" (female, Group 1)*

Participants reported that the pregnancy warning messages were framed as suggestions or recommendations rather than direct statements persuading against alcohol misuse. Participants noted the warnings conveyed the sentiment that consuming alcohol while pregnant was "...not that big of a deal" (female, Group 5). One female (Group 1) suggested the message regarding avoiding alcohol while pregnant was "almost like an option", while a male described the pregnancy warning label as "a mild suggestion" (Group 2). Another participant said:

"I think technically [the warnings] don't even say that drinking while pregnant is a bad thing, or you should not do it – it just says 'it's safest not to'" (male, Group 3)

This study suggests that current Australian alcohol warnings represent regulatory failure and are not conveying information about alcohol use to consumers. The researchers concluded that the development and implementation of new, larger mandatory alcohol product warnings using images and targeted messages is recommended.⁷⁴

3. Health Promotion Agency (2016)

In 2016, The Health Promotion Agency (HPA) commissioned Colmar Brunton to undertake an independent online survey of consumers' understanding of alcohol health warning labels, including the commonly used DrinkWise pictogram and text. An online survey was conducted with 1,488 consumers.

The researchers concluded that consumers want warning labels to convey a clearer link between drinking while pregnant and the harm to the unborn child.

Unprompted, 14 per cent of young women thought that the DrinkWise text meant that you could drink alcohol when pregnant.

After prompting:

- Only 56 per cent of people thought that the DrinkWise text portrayed the message that you shouldn't drink any alcohol while pregnant.

- Only 49 per cent of people thought that the DrinkWise text portrayed a link between pregnant women drinking alcohol and harm to an unborn child.

In addition:

- 38 per cent of people said that the DrinkWise text made them think that drinking a little alcohol while pregnant would be okay.
- 39 per cent of people said that adding the cheers.org.nz website address would create confusion and make the label less clear.

These findings tell us that the DrinkWise text is not sufficiently informing consumers of the danger of drinking alcohol when pregnant, and in some cases is misleading women to think that it is safe to drink while pregnant.⁷⁵

4. Galaxy Research (2011)

In 2011, FARE commissioned Galaxy Research to undertake independent consumer testing of the DrinkWise alcohol labels in comparison to a best practice alcohol label developed by FARE. Galaxy Research conducted focus group testing, and an online questionnaire which was completed by 504 people (adjusted to create a representative sample of the adult population in Australia).

Throughout the questionnaire, the labels were not attributed to FARE or DrinkWise. The labels were also rotated so that individuals were randomly assigned to be presented FARE or DrinkWise labels as the first set of labels for different question items.

Following the collection of data, the results were weighted by age, gender and region to reflect the latest Australian Bureau of Statistics (ABS) population estimates. Occasional, moderate and regular drinkers were included in the sample.

The FARE pregnancy warning was designed to incorporate best practice features of effective health warning messages. Below left is an example of the FARE label as viewed by participants in situ on the bottle, and below right is the label up close:



People were shown the DrinkWise and the FARE pregnancy warning labels applied to alcohol products. People were then asked to select which warning label would be most likely to:

- raise awareness of the harm that can result from drinking alcohol during pregnancy
- prompt conversations about the risk of drinking alcohol during pregnancy
- stop women from drinking alcohol while pregnant.

The findings are summarised in the table below which illustrates the proportion of people who selected the FARE pregnancy label and those that selected the DrinkWise pregnancy label as being most likely to raise awareness, prompt conversations and stop women from drinking alcohol. These findings tell us that pregnancy warning labels have the capacity to both raise awareness and change behaviour if they are redesigned in accordance with best practice principles of health warning labels.⁷⁶

	FARE pregnancy label (%)	DrinkWise pregnancy label (%)
Raise awareness	86	14
Prompt conversations	84	16
Prevent drinking during pregnancy	85	15

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

No amount of alcohol during pregnancy is safe.⁷⁷

Alcohol is a teratogen – a substance that can harm an unborn baby. As outlined in the consultation paper, other teratogens are either:

- completely banned from use in products which are designed to be consumed by people
- illegal
- only used when there is no better alternative, under medical supervision
- carry a warning label on the packaging.⁷⁸

FASD is the leading cause of preventable developmental disability in Australia. It is essential that consumers are fully informed of the risks of consuming alcohol in order to protect the health and future of the unborn child.

If pregnancy warning labels were effectively applied on all packaging for alcoholic beverages:

- consumers would be appropriately informed in accordance with Australian Consumer Law
- awareness levels would increase of the harm caused by alcohol during pregnancy⁷⁹
- conversations about the risks of alcohol consumption would be stimulated⁸⁰
- levels of FASD would reduce in the population⁸¹
- other alcohol-related health harm such as stillbirth and low birth weight babies would reduce.⁸²

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

'Option 2: Mandatory' is likely to achieve the highest coverage, comprehension and consistency, and is the only policy option that can deliver both the primary and secondary objectives as outlined on p17 of the consultation paper. Please see answer to question 7 which addresses coverage, comprehension and consistency.

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?

The following answer addresses behaviour change as well as awareness.

Awareness

'Option 2: Mandatory' is the only policy option that can deliver both the primary and secondary objectives as outlined on p17 of the consultation paper. The voluntary labelling scheme has been operating for more than six years and has not been effective at communicating a clear message that pregnant women should not drink alcohol.^{83,84,85,86}

Only an independent and mandatory scheme administered by FSANZ, a trusted regulatory body, can overcome the significant conflict of interest (that alcohol producers ultimately want to sell more alcohol) which has thus far prevented the alcohol industry from implementing an effective and consistent warning label.

Once the parameters of an effective message have been set, this is ultimately an issue of coverage. Under the current voluntary scheme in Australia, in 2016-17 fewer than half (48 per cent) of all packaged alcoholic beverages available for sale displayed some type of pregnancy warning label.⁸⁷ Women will not see, read or comprehend the warning unless it is on the products they are buying and consuming.

It is logical that a greater level of awareness will be achieved at a population level if a greater proportion of the population are exposed to it. Research looking at the introduction of alcohol warning labels in the USA shows that awareness levels of the messages subsequently increased.⁸⁸ Similarly, substantial research has shown high levels of awareness of mandatory tobacco health warnings, and that introduction of stronger tobacco health warning labels results in more warnings being noticed and read. Research has also found that tobacco health warnings have resulted in increased knowledge of the health effects of smoking.⁸⁹

Behaviour change

Although much of the research on alcohol labelling has suggested that the labels do not impact on behaviour change, the research is hampered by the fact that current labels are ineffective in both design and implementation. This has created a catch 22 situation in which it is not possible to demonstrate their effectiveness because they are ineffective.

Experience from tobacco labelling strongly suggests that explicit health warning labels, particularly pictorial labels, can be effective not only in raising awareness but also in influencing behaviour change. At least a quarter of respondents in all four countries in the International Tobacco Control evaluation (the UK, USA, Canada and Australia) reported that these warnings had made them more likely to quit. Such warnings are also thought to have indirectly influenced behaviour change by stimulating peer pressure from non-smokers.⁹⁰

Evidence shows that a similar effect could be achieved through alcohol warning labels. The [Global Drug Survey \(2018\)](#) found that 22.1 per cent of Australians *would* consider drinking less after learning about the risk of cancer from warning labels, and a further 22 per cent *might* consider drinking less. In New Zealand, 22.5 per cent *would* consider drinking less after learning about the risk of cancer from warning labels, and a further 22 per cent *might* consider drinking less.⁹¹

This suggests that almost 1 in 2 drinkers might change their behaviour after learning about long-term health harm from alcohol warning labels. For women aged under 25, the Survey found that one in four would consider drinking less after learning about the risks of cancer from warning labels.

There is evidence that a change in message would increase the likelihood of behavioural change from pregnant women. In 2011, FARE commissioned Galaxy Research to undertake independent consumer testing of the DrinkWise alcohol labels in comparison to a best practice alcohol label developed by FARE. Galaxy Research

conducted focus group testing, and an online questionnaire which was completed by 504 people (adjusted to create a representative sample of the adult population in Australia).

People were shown the DrinkWise and the FARE pregnancy warning labels applied to alcohol products. People were then asked to select which warning label would be most likely to:

- raise awareness of the harm that can result from drinking alcohol during pregnancy
- prompt conversations about the risk of drinking alcohol during pregnancy
- stop women from drinking alcohol while pregnant.

The findings are summarised in the table below which illustrates the proportion of people who selected the FARE pregnancy label and those that selected the DrinkWise pregnancy label as being most likely to raise awareness, prompt conversations and stop women from drinking alcohol:

	FARE pregnancy label (%)	DrinkWise pregnancy label (%)
Raise awareness	86	14
Prompt conversations	84	16
Prevent drinking during pregnancy	85	15

These findings tell us that pregnancy warning labels have the capacity to both raise awareness and change behaviour if they are redesigned in accordance with best practice principles of health warning labels.

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.

'Option 2: Mandatory' is the only policy option that can deliver both the primary and secondary objectives as outlined on p17 of the consultation paper. Any financial costs of implementing a mandatory pregnancy warning label would be far outweighed by the social and health benefits for individuals and the community realised through lower levels of FASD and other alcohol-related harm. Other schemes may incur costs for the industry while proving suboptimal in effecting behavioural change.

The health burden caused by alcohol consumption during pregnancy

The risks from alcohol consumption during pregnancy are associated with:

- a three-fold increase in miscarriage and a six-fold increase in stillbirth⁹²
- premature birth and low birthweight⁹³
- FASD, a lifelong disability.

FASD is the leading cause of preventable developmental disability in Australia. The majority of children and adults who have FASD live with significant cognitive, behavioural, health and learning difficulties, including problems with memory, attention, cause and effect reasoning, impulsivity, receptive language and adaptive functioning difficulties. These difficulties are lifelong and have a significant impact on behaviour.⁹⁴

In Australia, Aboriginal and Torres Strait Islander communities have been disproportionately affected by FASD and alcohol harm.⁹⁵

The economic and social burden of FASD

An economic analysis conducted by Health Technology Analysts in 2010 stated that, although there are no reliable estimates of the incidence of FASD in Australia or New Zealand, current international estimates are that 1 per cent of all pregnant women deliver a child with FASD. In Australia this translates to 2,599 children per year, while in New Zealand this translates to 581 children per year. The researchers modelled the cost of these cases conservatively as costing Australian and New Zealand taxpayers an extra AU\$66 million and NZ\$16 million per annum respectively. This represents a significant health and economic burden to society in both countries.⁹⁶

Research studies on the economic burden of FASD to healthcare, childcare systems and correctional services demonstrate the substantial economic toll that FASD exerts on public funds. For example, the following studies have found:

- Young people with FASD are 19 times more likely to be incarcerated than young people without FASD in a given year.⁹⁷
- A meta-analysis with data from eight countries found that the overall pooled prevalence of FAS and FASD among children and youth (0-20 years) in the care of a childcare system was six per cent and 16.9 per cent respectively.⁹⁸ 'Childcare system' was deemed to include orphanages, foster care and child welfare systems.
- In Canada, in 2008-09, the estimated total direct healthcare costs of the 33,730 people identified with Fetal Alcohol Syndrome (FAS) was CAD\$6.7 million. In addition, the use of health services by individuals with FAS are likely to be underreported, therefore actual costs are likely to be higher.⁹⁹
- Using the most conservative approach, a 2013 Canadian study found that FASD diagnostic evaluation requires 32 to 47 hours for one individual to be screened, referred, admitted, and diagnosed with a FASD diagnosis, which results in a total cost of CAD\$3,110 to CAD\$4,570 per diagnosis.¹⁰⁰

Cost-effectiveness analysis of mandatory warning labels in Australia and New Zealand

Health Technology Analysts (2010) conducted an economic analysis of various FASD prevention strategies in Australia and New Zealand. They modelled the cost-effectiveness of introducing mandatory alcohol warning labels over a five year period:

- They estimated that the introduction of alcohol warning labels in Australia would avoid 25 to 77 cases of FASD per annum. This scenario was estimated to achieve cost-neutrality when 35 cases of FASD are avoided. If more than 35 cases were avoided, the strategy could be cost-saving.
- In the case of New Zealand, they estimated that the introduction of alcohol warning labels would avoid 5 to 17 cases of FASD per annum. This scenario was estimated to achieve cost-neutrality when 19 cases of FASD are avoided. If more than 19 cases were avoided, the strategy could be cost-saving.¹⁰¹

This research also highlighted the need for alcohol warning labels to be one part of a larger national strategy to reduce alcohol harm in the population.

Cost to industry versus cost to society of a multi-pronged FASD intervention

Health Technology Analysts (2010) also conducted an economic analysis of the potential lost revenue to industry as a consequence of reduced alcohol sales to women who are pregnant. Assuming a prevention program evoked a 29 per cent reduction¹⁰² in alcohol consumption in pregnant women in any one year, this would be associated with losses of AU\$16.6 million in Australia and NZ\$1.0 million in New Zealand to the alcohol industry.

However, if that 29 per cent reduction in maternal alcohol consumption did not occur then in that year there would be 2,599 individuals born with FASD in Australia and 581 born in New Zealand. For these cases, the lifetime costs associated with managing them would then be AU\$498.3 million in Australia and NZ\$159.4 million in New Zealand.

Consequently, these analyses found that the health benefits and costs savings to society of avoiding FASD far outweigh any potential revenue loss to industry.¹⁰³

FARE's position is that the cost of regulatory interventions to reduce harm caused by alcohol consumption during pregnancy is far outweighed by the moral imperative to reduce preventable lifelong disability.

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.

Alcohol companies already change their labels on a frequent basis. In addition, alcohol companies already apply health warning labels to products that are exported to countries with a mandatory warning label requirement, such as France and the USA as an accepted cost of business.

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?

Many alcohol companies already change their labels on a frequent basis. In addition, alcohol companies already apply health warning labels to products that are exported to countries with a mandatory warning label requirement, such as France and the USA. Changes to labelling are part of standard business practice for alcohol producers.

The costs of informing consumers about the harm caused by alcohol consumption during pregnancy are not unreasonable. As noted in FARE's answer to Question 16, according to the Health Technology Analysts (2010) report, the lifetime costs associated with individuals born with FASD (approximately 2,599 each year in Australia and 581 born in New Zealand) is AU\$498.3 million in Australia and NZ\$159.4 million in New Zealand.

Using these figures, over the six years that industry has been implementing their ineffective labelling scheme 15,594 children have been born with FASD in Australia and 3,486 born in New Zealand. The financial costs of this are estimated to be \$2.989 billion in Australia and \$956.4 million in New Zealand. The societal and personal costs to these children, born with a lifelong disability, and their families are even more severe.

Consequently, the health benefits and costs savings to society of avoiding FASD far outweigh any potential revenue loss to industry.¹⁰⁴

FARE's position is that the cost estimates do not need to be adjusted upwards.

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?

There is no evidence to suggest that pregnant women are less likely to order bespoke products than other drinkers. Alcohol is a teratogen, and it is appropriate that producers are subject to regulation.

FARE's position is that there should be no variations to a mandatory requirement as this would create confusion and could be used to justify inaction or delayed compliance. The industry should be provided with 12 months to implement the changes to labelling.

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.

FARE is not aware of any product using a red pictogram unless the other label information is in red.

FARE is not aware of any evidence that outlines the proportion of products that currently use the green pictogram.

FARE is aware that there is considerable inconsistency in the current pregnancy warning label system; this is partly what contributes to its ineffectiveness. This includes the pictogram in black, gold/orange and white.

FARE has no evidence on the proportion of products using the beer glass pictogram or wine glass pictogram.

Unless the outcome of this consultation is that no change is required, all producers will have to update their labels in some fashion. This is as a direct consequence of the lack of standardisation in the current system.

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.

Nil response

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.

FARE does not know whether industry would pass the costs of labelling changes onto the consumer.

If the costs of labelling were passed onto the consumer, this could be considered a positive result, because evidence has consistently shown that increasing the price of alcohol decreases alcohol harm at a population level.^{105,106,107,108}

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.

“Option 2: Mandatory” is the only policy option that can deliver both the primary and secondary objectives as outlined on p17 of the consultation paper.

The voluntary labelling scheme has been in operation for more than six years and has not been effective at communicating a clear message that pregnant women should not drink alcohol.^{109,110,111,112} Only an independent and mandatory scheme administered by FSANZ, a trusted regulatory body, can overcome the significant conflict of interest (that alcohol producers ultimately want to sell more alcohol) which has thus far prevented the alcohol industry from implementing an effective and consistent warning label scheme across all alcohol products.

Consumers have a right to know if they are consuming a product that puts their health and the health of their unborn child at risk. Only a mandatory scheme with a government-developed label will deliver warnings that are seen and understood by consumers.

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