

**October 2018**

**Food Regulation Standing Committee  
Decision Regulation Impact Statement:**

***Pregnancy warning labels on packaged  
alcoholic beverages***

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# Executive Summary

## *Introduction*

This Decision Regulation Impact Statement (DRIS) has been prepared to provide a recommendation to the Australia and New Zealand Ministerial Forum on Food Regulation (the Forum) in regard to regulatory and non-regulatory options for pregnancy warning labels on packaged alcoholic beverages.

This DRIS is based on existing data and evidence and information provided by stakeholders through a targeted consultation process undertaken in May and June 2018.

The DRIS has been prepared in accordance with Council of Australian Government (COAG) best practice regulation requirements.

## *Statement of the problem*

Government advice is that pregnant women not consume any alcohol. If a pregnant woman consumes alcohol (of any type), it can cause damage to the developing fetus. Babies exposed to alcohol during pregnancy are more likely to be born prematurely and may be born with permanent damage to their brain and other critical organs, functions and structures.

Fetal Alcohol Spectrum Disorder (FASD) is an umbrella term describing the range of physical, cognitive, behavioural and neurodevelopmental disabilities that can result from alcohol exposure during pregnancy. FASD is a life-long disability which significantly impacts individuals, families and the wider community. People with FASD have greater education, health and mental health needs, are more likely to have problems gaining employment and working independently, and are at an increased risk of breaking the law. The cost of FASD is borne by Governments in sectors including health, education and criminal justice. Individuals and families are affected through lost productivity, morbidity and premature mortality. **FASD is completely preventable by avoiding alcohol consumption during pregnancy.**

Accurately reporting incidence, prevalence and burden of FASD in Australia and New Zealand is difficult due to data limitations. Conservative estimates are that FASD affects 1-2% of the population in Australia and New Zealand. However, these estimates are considered to be underestimated, especially considering that Australia and New Zealand have higher rates of drinking during pregnancy compared to countries such as the United States and Canada where 1-5% of children have FASD. If international estimates are applied to Australia and New Zealand, accounting for the higher rate of alcohol consumption in these countries, a more reasonable estimate is 5% (potential range of 2%-9%) and 3% (potential range 1%-6%) of babies are born with FASD each year in Australia and New Zealand. These are population-wide estimates and do not reflect FASD rates in high-risk groups such as Indigenous populations which are likely to be higher. For example, a study in Fitzroy Crossing Valley in the Kimberley region of Western Australia reported that 19% of participating children had FASD - one of the highest rates of diagnosis of FASD worldwide.

The cost of FASD in Australia and New Zealand has not been comprehensively measured, but if international data are applied to the Australian and New Zealand context, this paper estimates that a plausible incidence rate of FASD of 5% could cost the Australian community around AUD \$1.18 billion a year while a plausible incidence rate of 3% could cost the New Zealand community around NZD \$170 million year. This is equivalent to AUD \$75,661 per new case of FASD in Australia and NZD \$95,978 per new case of FASD in New Zealand.

### ***Pregnancy warning labels on packaged alcoholic beverages***

Australia and New Zealand currently implement pregnancy warning labels on packaged alcoholic beverages on a voluntary basis. Internationally, pregnancy warning labels on packaged alcoholic beverages are mandatory in 28 countries.

Pregnancy warning labels on packaged alcoholic beverages can raise awareness and prompt discussions about the risks of consuming alcohol during pregnancy. Pregnancy warning labels may also support the establishment of cultural norms in relation to pregnant women not drinking alcohol. However, pregnancy warning labels, as an isolated intervention, have not been found to change behaviours in relation to alcohol consumption during pregnancy. It is widely recognised that pregnancy warning labels need to be complemented by broader activities and targeted interventions that aim to promote behaviour change, reduce the proportion of women who drink alcohol during pregnancy and ultimately prevent FASD.

### ***Concerns with the current labelling system***

Two evaluations of the voluntary pregnancy warning label initiative have been undertaken in Australia and New Zealand, demonstrating an increase in the coverage of the pregnancy warning labels between 2013/2014 and 2016/2017. However, coverage of pregnancy warning labels remains a concern; in Australia 48% of products carry a pregnancy warning label. In New Zealand, data are not available on the coverage of pregnancy warning labels across the entire market of packaged alcoholic beverages, however, the majority of products that make up the leading market share do display pregnancy warning labels. The evaluations also identified issues such as inconsistent warning labels being used, and some consumer misunderstanding of the messaging on the labels.

The alcohol industry is generally of the view that the current voluntary labelling scheme is working well, although some industry groups have expressed frustration that despite their strong efforts in voluntarily introducing pregnancy warning labels on their products, there are other producers who have not done so.

Other stakeholders such as public health groups, academics, consumer groups and Governments in Australia and New Zealand have concerns about the current voluntary pregnancy warning label scheme including concerns about label coverage and consumer understanding, size and placement of pregnancy warning labels and concerns that some pregnancy warning labels are accompanied by contradictory information such as the message '*enjoy in moderation*' which confuses the advice that pregnant women should not drink alcohol. Concerns have also been raised that some of the labels which the alcohol industry considers to be pregnancy warning labels do not provide any information about the advice that pregnant women should not drink alcohol, but rather advise consumers to go to a website for information, which few

consumers actually will do. Other concerns have been raised that the current system of voluntary pregnancy warning labels on packaged alcoholic beverages does not follow best-practice governance and regulation and lacks transparency and accountability.

### ***Proposed options***

Voluntary and mandatory options were assessed and evaluated to determine if they could address the current concerns with pregnancy warning labels and achieve high coverage of pregnancy warning labels on packaged alcoholic beverages and convey messaging that is understood by the target audiences and consistent with government advice.

The options considered were:

#### **Voluntary**

*1a- status quo-* Industry discretion is permitted in whether to apply pregnancy warning labels, and which labelling to apply. For producers that choose to adopt pregnancy warning labels they may use designs by DrinkWise or Cheers (alcohol industry funded organisations), or any other label design.

*1b- industry self-regulated-* The alcohol industry or Food Standards Australia New Zealand (FSANZ) develops a code of practice that alcohol producers voluntarily sign up to. The code of practice would require signatories to commit to presenting pregnancy warning labels on all the packaged alcoholic beverages they produce. The code of practice would outline how the pregnancy warning labels would be presented to ensure that the message is clear, consistent with government recommendations, and understood by the target audience(s).

The industry group that leads the code of practice would be responsible for administering and enforcing the code of practice, encouraging alcohol producers to become signatories, monitoring signatories' compliance with the code of practice, working with signatories that are not complying with the code of practice to improve their labelling, and publishing reports on the number of signatories and compliance with the code of practice. Sanctions for signatories to the code of practice who are non-compliant would be determined by industry.

The large majority of the alcohol industry supported this option and considered that it offered the greatest net benefit. This view was justified on the basis that the industry self-regulated option would minimise labelling costs, maintain flexibility, provide the opportunity to continue the current work on voluntary pregnancy warning labels and utilise existing infrastructure.

*1c- government style guide-* Voluntary labelling scheme with evidence based style guide that producers who choose to display pregnancy warning labels should follow. The style guide would be developed by Government with input from public health groups and industry. Pictures and wording in the style guide would be the one shown to be most effective.

Government would monitor compliance with the style guide. Alcohol producers can choose to follow the Government style guide, but industry would not have to sign up to a code or pledge to follow the style guide.

Few stakeholders supported this option and some industry groups considered that it would duplicate existing work undertaken by groups such as *DrinkWise* and was therefore redundant.

### **Mandatory**

2 mandated through the Australia New Zealand Food Standards Code- Pregnancy warning labels mandated through the Australia New Zealand Food Standards Code and enforced by the existing food enforcement authorities. As with other mandatory requirements in the Australia New Zealand Food Standards Code the requirements for pregnancy warning labels would apply to domestic and imported alcoholic beverages and there would be penalties for non-compliance.

The majority of non-industry submissions (i.e. Government, public health, academics etc.) supported this option. This was based on the view it was the only option that could increase coverage, particularly in the sectors of the alcohol industry that had resisted the voluntary labelling. These groups considered that the mandatory option offered the greatest net benefit as the costs of label changes were considerably less than the impact of FASD on society.

### ***Impacts of the proposed options and likely net benefits***

The proposed options were assessed in terms of their pros and cons, costs, risks and uncertainties, and potential to achieve pregnancy warning labels with the highest coverage, consistency and consumer understanding (relative to the status quo).

### **Costs to the industry**

To address the concerns with the current pregnancy warning labels in the market, some producers will have to change their labels under each of the proposed options. The proportion of producers that would need to change their labels is not known as it would depend on the extent to which pregnancy warning labels required under the industry code of practice/ Government style guide/ Australia New Zealand Food Standards Code differ to those currently used.

There are also additional costs to industry associated with some of the options, for example, there is a cost associated with establishing and administering the industry code of conduct. Some options also introduce savings to the industry- some industry groups undertake considerable efforts and expense in promoting uptake of the voluntary pregnancy warning labels, and this work and expense would not be required under the mandatory approach.

The costings for the proposed options in Australia are presented below, with three scenarios modelled to account for the unknown proportion of producers that would need to change their labels to address current concerns with pregnancy warning labels. Each scenario models costs for all of the packaged alcoholic beverages on the market in Australia, including both domestic and imported products.

**Business compliance costs associated with each option for Australia (AUD)**

Scenario	Industry self-regulated (1b)	Government style guide (1c)	Mandatory (2)
1	\$7.2m (average) \$0- \$99.7m (range)	\$7.2m (average) \$0- \$99.7m (range)	\$7.2m (average) \$0- \$99.7m (range)
2	\$6.6m (average) \$0-\$91.3 m (range)	\$6.6m (average) \$0-\$91.3 m (range)	\$6.6m (average) \$0-\$91.3 m (range)
3	\$13.9m (average) \$0- \$191.0m (range)	\$13.9m (average) \$0- \$191.0m (range)	\$13.9m (average) \$0- \$191.0m (range)
Other business compliance costs	\$0.31m (annual) \$0- 0.024m (one-off).		
Savings			0.020m (annual)
Notes	Annual cost for industry to self-regulate and one-off cost to establish industry code of practice. No cost if FSANZ develops the code of practice.	Costs of developing the style guide and monitoring and reporting on compliance with the style guide borne by Government.	Industry savings associated with not having to promote adoption of the voluntary scheme.

Scenarios modelled:

1. Label change costs to businesses not currently displaying a pregnancy warning label (21,020 SKUs<sup>1</sup>)
2. Label change costs to businesses if products currently displaying warning labels need to change their labels to comply (up to 19,249 SKUs)
3. Maximum cost required to achieve 100% coverage (40,269 SKUs)

The business compliance costs associated with each option under Scenario 3 are estimated to be similar for New Zealand. However it is acknowledged that for New Zealand this will be a conservative (highest) estimate given that the actual number of SKUs in the market is likely to be lower.

It is relevant to note that the upper costings reflect the cost of immediate label changes with minimal transition periods. These costs can be mitigated through transition periods and stock-in trade exemptions to reduce the burden on industry.

### **Extent to which the options can ensure pregnancy warning labels with high coverage, consistency with government advice and consumer understanding**

The proposed options were assessed to consider the extent to which they can ensure pregnancy warning labels on packaged alcoholic beverages with high coverage, consistency with government advice and consumer understanding. An analysis of the options against these variables is presented on the next page.

<sup>1</sup> A stock keeping unit (SKU) is a product identification code.

**Extent that each option can achieve pregnancy warning labels with high coverage, consistency with government advice and consumer understanding**

Option	Coverage	Consistency	Consumer understanding
1b	No power to encourage industry to become signatories to the proposed code of practice. Unlikely to encourage producers who have not adopted the current voluntary labelling to change their practices.	<p>Potential for consistency with government advice and consistency amongst signatories to the code of practice. The level of consistency that could be achieved across the entire market depends on coverage that can be achieved.</p> <p>May result in some producers using the existing labels and signatories using revised labels. Industry considered this option offered flexibility in how pregnancy warning labels could be presented.</p>	<p>Potential to improve consumer understanding as some industry groups have stated they are open to revising the current pregnancy warning labels to improve consumer understanding.</p> <p>However, there is no power to encourage industry to change their labels and the cost of label changes may deter them from doing so.</p>
1c	Limited- low support from the alcohol industry for this option suggests that there is a high risk the Government style guide would not be widely adopted by the alcohol industry. Some industry groups see this option as a duplication of the existing scheme and therefore redundant.	<p>The concept of a Government developed style guide can achieve consistency with Government advice and consistency amongst labels that are following the style guide.</p> <p>However, low support for this option from the alcohol industry indicates that the style guide is unlikely to be widely adopted by the alcohol industry and therefore this option has little potential to improve consistency. May result in some producers following the style guide and others using the existing labels.</p>	<p>The concept has potential to support consumer understanding. Governments can work with behaviour change and communication experts to identify the characteristics of the most effective pregnancy warning labels and detail these in the style guide.</p> <p>However, low support for this option from the alcohol industry indicates that the style guide is unlikely to be widely adopted by the alcohol industry and therefore this option has little potential to improve consumer understanding.</p>
2	High - As pregnancy warning labels would be mandatory with penalties for non-compliance. This option offers power to ensure that producers adopt pregnancy warning labels and can reach producers that have not adopted voluntary labels. The level of uncertainty associated with this option is low.	This option ensures that pregnancy warning labels are consistent with government recommendations, and other pregnancy warning labels in the market as the requirements for the pregnancy warning labels would be set out in the Australia New Zealand Food Standards Code.	High potential to support consumer understanding. FSANZ can work with behaviour change and communication experts to identify the most effective pregnancy warning labels and detail the requirements for effective labels in the Australia New Zealand Food Standards Code



## Net benefit

Analysis of the likely impact of the labelling changes was undertaken by determining what proportion of cases of FASD in Australia would need to be prevented to offset the cost of labelling changes under the three scenarios modelled (the loss of revenue to industry and governments resulting from a reduction in the consumption of alcohol have been ignored).

Scenario	Potential cost of labelling changes in one year (AUD)	FASD cases that would need to be prevented to offset this cost (at 5% FASD incidence rate and AUD \$75,662 per new case of FASD)
<i>Average costings (includes transition period for label changes)</i>		
1	7.2 million	0.62% (96 cases)
2	6.6 million	0.56% (88 cases)
3	13.9 million	1.18.% (183 cases)
<i>Upper costings (no transition period for label changes)</i>		
1	\$99.7 million	8.47% (1,318cases)
2	\$91.3 million	7.76% (1,207 cases)
3	\$191.0 million	16.23% (2,524 cases)

Based on the estimated incidence rate for FASD in Australia of 5%, this suggests 1.18% of FASD cases (183 cases) would need to be prevented in one year to offset the costs associated with adopting mandatory labelling.

However the cost of FASD depends on the severity of FASD, and international studies suggest heavy drinkers are least likely to be affected by mandatory labelling. As exposure to alcohol during pregnancy is directly related to the severity of FASD, although the precise relationship is not well known, a more conservative approach is to consider the number of mild cases of FASD that may need to be avoided in order to offset the increased cost to business.

Estimates of the annual health-related cost of mild cases of FASD from the Canadian study on which the health-related costs included above are based, updated to 2018, range from AUD \$7,499 to AUD \$20,962, with an average of AUD \$13,785. (As mild cases of FASD are unlikely to result in impacts on the cost of the prison and juvenile justice system, these costs have been ignored.) As every case avoided would save these costs over each year of an individual's life, the proposal would only need to avoid 13 cases of mild FASD a year in Australia to result in a net benefit over 20 years.

Based on the estimated incidence rate for FASD in New Zealand of 3% (1,783 cases per year) and the costs per new case of FASD of NZD \$95,977.55, 8.8% of the cases would need to be prevented in one year to recover the costs of labelling changes in New Zealand (based on average label costs and Scenario 3). However given that the average costs of labelling changes are based on a conservative (highest) estimate of the number of SKUs in the market, the percentage of cases that would need to be prevented is likely to be lower.

It is also important to note that the cost of labelling changes would be borne by the alcohol industry once, while the savings to the community from prevention of FASD

would occur each year for every case of FASD prevented when a women chooses not to drink alcohol while pregnant.

Even with the upper costings for label changes, the cost of FASD is still far greater than the cost of labelling changes. As transition periods and stock-in-trade exemptions can be included in the implementation of the preferred option, these higher costings are implausible and would not represent the business compliance costs.

### ***Recommended option***

Taking everything into account, it is recommended that the option that provides the greatest net benefit is **Option 2 mandatory**.

While pregnancy warning labels, in isolation, will not prevent women drinking alcohol while pregnant, they may help to reduce alcohol related harm when part of a broader package of measures. As the cost effectiveness analysis above suggests, the level of harm avoided needed to offset the costs of mandatory labelling is very low (around 0.5 per cent of new cases of FASD each year).

Other measures the Australian Government is introducing to address FASD include the development and dissemination of a FASD diagnostic tool, the development of a FASD register to complement the diagnostic tool, funding to improve data collection of maternal alcohol consumption in pregnancy, and funding for a suite of FASD prevention programs.

New Zealand's *Taking Action on Foetal Alcohol Spectrum Disorder: 2016-2019 Action Plan* aims to create a more effective, equitable and collaborative approach to FASD and has four focus areas: prevention; early identification and assessment; support for affected people and their families; and improving New Zealand's FASD evidence base. The prevention area of the New Zealand Action Plan includes developing and disseminating clear, unambiguous, and consistent messages to increase the community's awareness of the risks of drinking during pregnancy.

The current voluntary approach has seen the dissemination of pregnancy warning labels on a wide range of packaged alcohol. In New Zealand in 2016, 87% of beer, 100% of cider and 82% of straight and 88% of ready-to-drink spirits that represented 90-100% of market share per volume were reported to display some type of pregnancy warning labels. In Australia in 2016-17, 48% of all packaged alcoholic beverages available for sale displayed some type of pregnancy warning label. Ready-to-drink (RTD) beverages, most commonly consumed by young women, had the highest coverage of warning labels (66.5%). Labelling coverage on wine- the most common type of alcoholic beverage consumed by women in Australia and New Zealand aged over 25 years- was mixed, from 56% for red wine priced under AUD \$20 per bottle to 40% for red wine priced over AUD \$20 a bottle. Craft beer recorded the lowest coverage, with 19% of those products displaying a pregnancy warning label in 2016-17.

A continuation of the current voluntary approach may see an increase in the coverage of labelling. However, it is not likely to capture all packaged alcoholic beverages in the near future. Nor would a continuation of the voluntary approach ensure labelling is clear to consumers and consistent with current government advice. There are too

many uncertainties and risks with the voluntary approaches to recommend that pregnancy warning labels on packaged alcoholic beverages continue on a voluntary basis.

A mandatory approach is the only option that can ensure that pregnancy warning labels are applied across all packaged alcoholic beverages (i.e. all types of packaged alcoholic beverages and domestic and imported products), in a manner that is likely to be understood by the target audience, and consistent with government advice. It is also the only option that provides for enforcement by the existing food enforcement authorities. Transition periods and stock-in-trade exemptions could be introduced to minimise the impact on industry as much as possible.

Mandatory pregnancy warning labels recognises the significance of FASD and its impact on individuals, families and the community. Alcohol consumption during pregnancy affects a third-party (the unborn child) and regulation is necessary to help protect this vulnerable group.

Mandatory warning labelling for packaged alcoholic beverages is consistent with mandatory pregnancy warning/advisory labels that are required under the Australia New Zealand Food Standards Code for products such as formulated caffeinated beverages and formulated supplementary sports foods. It is also consistent with labelling requirements for other products that are harmful to the developing fetus such as tobacco.

The effectiveness of labelling in changing consumer behaviour varies across products; however governments' approach to improving the information available to consumers is a key policy lever. It is expected that despite the uncertainty around how many FASD cases mandatory labelling will prevent, and to what extent, the change in both occurrence and level of drinking in pregnant women will outweigh the cost of moving to mandatory labelling.

This approach, in conjunction with other measures being funded by the Australian and New Zealand governments, is considered the approach most likely to shift the cultural norm by reminding pregnant women and their partners, friends and families of the hazards of drinking while pregnant. It is therefore the approach most likely to result in a reduction in the incidence and severity of FASD.

### ***Implementation***

It is recommended that the Forum request that FSANZ develop a mandatory labelling standard for pregnancy warning labels on packaged alcoholic beverages.

In implementing the preferred option it is recommended FSANZ give consideration to including a **two to three year transition period** to minimise impacts on industry in introducing mandatory pregnancy warning labels.

It is recommended that FSANZ give consideration to stock-in-trade exemptions so that products that have already been packaged and labelled prior to the end of the transition period would not have to change their label.

### **Label design**

Pregnancy warning labels should include both a pictogram and warning message. It is recommended that FSANZ give consideration to pregnancy warning labels that are evidence based and proven to resonate with and be understood by the target audience(s). Evidence suggests that effective pregnancy warning labels:

- Combine a pictogram with a warning message for maximum impact (however, a pictogram is considered more effective than a single health warning message);
- Include text that is readable and possibly the same size as all other information on the product label;
- Use short warning messages, and words such as “WARNING” or “HEALTH WARNING” to indicate it is a warning label;
- Are separated from other information on the label (for example, placed in boxes with borders and away from messages such as ‘*enjoy in moderation*’); and
- Use contrasting colours. Should not use the colour green as this can cause consumer confusion. Use of the colour red receives the most attention and is readily associated as being a warning.

### ***Monitoring and evaluation***

It is recommended that future monitoring and evaluation be undertaken after a suitable period of time to monitor the implementation of pregnancy warning labels and determine whether the desired outcome has been achieved.

Initial evaluations (two and five years after the transition period ends) should measure the implementation of the pregnancy warning labels (e.g. coverage, consistency, size of labels), and impact of the pregnancy warning labels (e.g. understanding and recall of pregnancy warning labels and awareness of the advice that pregnant women should not drink alcohol).

Ongoing monitoring activities are recommended to evaluate the outcome of the pregnancy warning labels and broader work on the prevention of FASD. Monitoring in this area should include:

- proportion of women who drink alcohol while pregnant. These data can be collected through surveys such as the Australian National Drug Strategy Household Survey; and
- incidence and prevalence of FASD. While these data has not previously been available for Australia and New Zealand, the new Australian FASD Register and Australian FASD Diagnostic Tool will provide valuable data in this area.
- New Zealand should also give priority to building capacity to collect data on these topics.

# Introduction

## *Purpose of this paper*

This Decision Regulation Impact Statement (DRIS) has been prepared to provide a recommendation to the Australia and New Zealand Ministerial Forum on Food Regulation (the Forum) on the preferred option for progressing pregnancy warning labels on packaged alcoholic beverages in Australia and New Zealand.

The scope of this paper is limited to pregnancy warning labels on packaged alcoholic beverages. Unpackaged alcohol (e.g. a glass of wine served at a restaurant) is out of scope.

This paper is based on the Council of Australian Governments (COAG) Best Practice Regulation: A Guide for Ministerial Councils and National Standard Setting Bodies<sup>2</sup>.

## *Background*

New Zealand and Australia share a joint system for food labelling. In 2009, the Legislative and Governance Forum on Food Regulation (FoFR) (now Australia and New Zealand Ministerial Forum on Food Regulation (the Forum))<sup>3</sup> agreed to a comprehensive independent review of food labelling law and policy. An expert panel, chaired by Dr Neal Blewett AC, undertook the review and the panel's final report, Labelling Logic: Review of Food Labelling Law and Policy (Labelling Logic) was publically released in January 2011.

Recommendation 25<sup>4</sup> of the Labelling Logic Report was that: *a suitably worded warning message about the risks of consuming alcohol while pregnant be mandated on individual containers of alcoholic beverages and at the point of sale for unpackaged alcoholic beverages, as support for ongoing broader community education.*

In December 2011, in its response to Labelling Logic, FoFR provided the alcohol industry with a two-year period, commencing December 2011, to adopt the voluntary initiative to place pregnancy health labels on packaged alcohol products, before regulating such a change. Pregnancy warning labels are currently being implemented by industry on a voluntary basis.

An initial evaluation of the voluntary labelling initiative to place pregnancy health warnings on alcohol products was undertaken in Australia at the end of the two-year period to December 2013, as measured by market coverage, visibility, consistency of message with National Health and Medical Research Council (NHMRC) Australian guidelines and consumer awareness. A similar evaluation was also undertaken in New Zealand in 2014. In 2014 the FoFR considered the result of these evaluations and

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<sup>2</sup> Council of Australian Governments (COAG) 2007. '[Best Practice Regulation: A Guide for Ministerial Councils and National Standard Setting Bodies](#)'.

<sup>3</sup> The Forum is made up of Ministers responsible for food regulation from the Australia Federal Government; New Zealand; and Australian states and territories.

<sup>4</sup> It is relevant to note that recommendation 26 of the Labelling Logic report was that: *the energy content be displayed on the labels of all alcoholic beverages consistent with the requirements for other food products.* Policy work on recommendation 26: energy labelling on alcohol is also currently being progressed in parallel to recommendation 25. However it is acknowledged that these are being undertaken as separate processes. Please refer to the [food regulation website](#) for more information on consultations for recommendation 26.

determined that the overall percentage of products with a pregnancy health warning label was encouraging. However, there was concern with the low uptake in the mixed alcoholic beverages or ready-to-drink category. Ministers agreed to continue to work with industry to ensure increased uptake, particularly with companies where the uptake is lower, and agreed to extend the existing trial on voluntary uptake of pregnancy health warnings on alcohol product labels, and to undertake a review in two years.

A second evaluation was undertaken in Australia and in New Zealand in late 2016/2017, and both of these evaluations considered uptake and consumer awareness of the industry's voluntary measures. The second evaluation reported that, overall, adoption and implementation of the pregnancy health warnings labels have increased over time. However, there continued to be some product categories where adoption of the warning labels was lower, in particular, for the premium or craft beer category in Australia. In New Zealand the warnings were on a majority of packaged products, although there was still variation in uptake among different alcoholic beverage types. The results of the second evaluation of the pregnancy warning labelling initiative for Australia and New Zealand are available online at [Second Evaluation of Pregnancy Warning Labels](#).

In November 2017, the Forum noted the results of the second evaluation of the pregnancy warning labels and requested the development of a policy options consultation paper to consider issues including mandatory versus voluntary application; most appropriate pictogram, and most appropriate and easy to understand message to discourage drinking during pregnancy<sup>5</sup>.

In May 2018, the Forum approved a targeted Consultation Regulation Impact Statement (CRIS) on pregnancy warning labels on packaged alcoholic beverages, and approved for a six week consultation process. The consultation process operated from 3 May 2018 to 14 June 2018. The CRIS and information provided through the targeted stakeholder consultation process have been drawn upon to prepare this DRIS.

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<sup>5</sup> New Zealand's Health Promotion Agency has a current application to Food Standards Australia New Zealand to require a health advisory label on alcoholic beverage containers advising of the risks of consuming alcohol when planning to become pregnant and during pregnancy. The application was made in 2006 by the Health Promotion Agency's predecessor organisation, the Alcohol Advisory Council of New Zealand. The application was paused pending consideration of the recommendation of the Labelling Review and the subsequent decisions on the voluntary initiative.

# 1. Statement of the problem

## 1.1 Current recommendations relating to alcohol consumption in pregnancy

Alcohol is a regular part of many people's diets in Australia and New Zealand<sup>6</sup>. It is also a potent teratogen—a toxic substance that can inhibit the healthy development of the fetus. As a pregnant woman's levels of alcohol consumption increase, so does the risk of miscarriage and stillbirth<sup>7</sup>. Babies exposed to alcohol during pregnancy are also more likely to be born prematurely and may be born with permanent damage to their brain and other critical organs, functions and structures<sup>8</sup>. These effects can have a profound effect on a person's life, and increase the likelihood of negative outcomes for them, their family and wider society. These outcomes are preventable.

The *Australian Guidelines to Reduce Health Risks from Drinking Alcohol*<sup>9</sup> by the NHMRC report that maternal alcohol consumption can harm the developing fetus or breastfeeding baby and recommend that for women who are planning a pregnancy, pregnant, or breastfeeding, not drinking is the safest option. The guidelines report that the risk of harm to the developing fetus is highest when there is high, frequent maternal alcohol intake and likely to be low if a woman has consumed only small amounts of alcohol (such as one or two drinks per week) before she knew she was pregnant or during pregnancy. However, the risk of harm depends on a wide range of individual factors and it is therefore not possible to establish a safe limit on the amount of alcohol that can be consumed while pregnant.

One to two hours after maternal alcohol ingestion, fetal blood alcohol concentrations (BACs) reach levels nearly equivalent to maternal levels. Alcohol elimination from the fetus relies on the mother's metabolic capacity. Metabolic capacity among pregnant women varies considerably, which may help explain how similar amounts of alcohol consumption during pregnancy results in different outcomes for the fetus<sup>10</sup>.

In New Zealand, women who could be pregnant, are pregnant, or are trying to get pregnant are advised to stop drinking alcohol<sup>11</sup>. Women who are breastfeeding are also advised to avoid consumption of alcohol<sup>12</sup>.

## 1.2 Current trends in alcohol consumption during pregnancy

It is difficult to accurately estimate the proportion of women who drink alcohol while pregnant. This is related to factors such as women not knowing exactly when they

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<sup>6</sup> 36% of Australians aged 14 and over and 58% of New Zealanders (52% of women) aged 15 and over drink at least weekly. Source: 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 and Ministry of Health 2015. [‘Alcohol Use 2012/13: New Zealand Health Survey’](#). Wellington: Ministry of Health

<sup>7</sup> For a summary of the research, see Bailey, B.A.Sokol,R.J. 2011. [‘Prenatal Alcohol Exposure and Miscarriage, Stillbirth, Preterm Delivery and Sudden Infant Death Syndrome’](#). *Alcohol Research Health*, 34(1): 86–91.

<sup>8</sup> Bailey, B.A., Sokol, R.J. 2011. [‘Prenatal Alcohol Exposure and Miscarriage, Stillbirth, Preterm Delivery and Sudden Infant Death Syndrome’](#). *Alcohol Research Health* 34(1): 86–91.

<sup>9</sup> National Health and Medical Research Council (NHMRC) 2009. [‘Australian Guidelines to Reduce health risks from Drinking Alcohol’](#). Canberra, Australian Government.

<sup>10</sup> Burd, L., Dropps, K. 2012. [‘Prenatal alcohol exposure, blood alcohol concentrations and alcohol elimination rates for the mother, fetus and newborn’](#). *Journal of Perinatal Medicine*, 32(9):652-9. doi: 10.1038/jp.

<sup>11</sup> New Zealand Health Promotion Agency. [‘Low-risk alcohol drinking advice’](#)

<sup>12</sup> New Zealand Ministry of Health. 2016. [‘Alcohol: pregnancy and babies’](#)

became pregnant, and the nature of self-reported data, where both reporting and recall biases may exist<sup>13</sup>.

In the targeted consultation, stakeholders were asked about the current estimates on the proportion of women in Australia and New Zealand that drink alcohol when pregnant and provide any additional data. Responses from stakeholders have been incorporated into the discussion below.

Australia- Australia has one of the highest rates of alcohol consumption during pregnancy in the world<sup>14</sup>. According to the Australian Institute of Health and Welfare (AIHW)<sup>15</sup>, between 2007 and 2016, the proportion of women consuming alcohol during pregnancy declined and the proportion abstaining increased from 40% to 56%, more recent trends show no significant difference in the proportion of women abstaining from alcohol between 2013 and 2016.

AIHW note that most pregnant women tend to change their drinking behaviour once they find out they are pregnant. In 2016, around half (49%) of pregnant women reported that they consumed alcohol before they knew they were pregnant, a decline from 56% in 2013. About 1 in 4 of these women continued to drink alcohol after they knew they were pregnant. This rate was stable between 2013 and 2016. Of those women who consumed alcohol when pregnant, 81% drank alcohol monthly or less, and 16.2% of these women drank 2–4 times a month. Most (97%) usually consumed 1–2 standard drinks on that drinking occasion.

The AIHW did not collect data on what type of alcoholic beverage pregnant women consumed. However, when examining population consumption of alcoholic beverages in the wider population, wine is the most commonly consumed beverage amongst Australian females, with the exception of 12-17 year olds and 18-24 year olds who are most likely to report consuming pre-mixed spirits<sup>16</sup>. This information is relevant as pre-pregnancy drinking is associated with drinking during pregnancy (see page 11).

The Australian Bureau of Statistics 2014-15 National Aboriginal and Torres Strait Islander Social Survey (latest available) reports the proportion of Aboriginal and Torres Strait Islander children aged 0–3 years with a birth mother who drank alcohol during pregnancy halved between 2008 and 2014–15 (from 20% to 10%). While there have been decreases in maternal alcohol consumption in both non-remote and remote areas over this period, most of the overall improvement is due to a significant decrease in non-remote areas (from 20% in 2008 to 9% in 2014–15). The change in remote areas over this period was not statistically significant.

The ABS did not collect data on the amount of alcohol consumed by Aboriginal and Torres Strait Islander women while pregnant. It is known that while Aboriginal and

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<sup>13</sup> O’Keeffe, L., Kearney, P., McCarthy, F. 2015. ‘[Prevalence and predictors of alcohol use during pregnancy: findings from international multicentre cohort studies](#)’. *BMJ Open*, 5:e006323. doi: 10.1136/bmjopen-2014-006323.

<sup>14</sup> Popova, S., et al. 2017. ‘[Estimation of national, regional, and global prevalence of alcohol use during pregnancy and fetal alcohol syndrome: a systematic review and meta-analysis](#)’. *The Lancet*, 5(3): e290–e299.

<sup>15</sup> Australian Institute of Health and Welfare (AIHW). 2017. ‘[National Drug Strategy Household Survey 2016: detailed findings](#)’. Drug Statistics series no. 31. Cat. no. PHE 214. Canberra: AIHW.

<sup>16</sup> Australian Institute of Health and Welfare (AIHW). 2017. ‘[National Drug Strategy Household Survey 2016: detailed findings](#)’. Drug Statistics series no. 31. Cat. no. PHE 214. Canberra: AIHW.



Torres Strait Islander people generally drink less than non-Indigenous people, those who do drink are more likely to drink at hazardous levels<sup>17</sup>.

As Australia's leading statistics agencies, this report has drawn on the AIHW and ABS estimates. However, it is noted that other studies have been undertaken to examine the proportion of women drinking when pregnant. For example:

- In a study conducted between 2004 and 2011, 38% of Australian women surveyed reported drinking in the first trimester; falling to 7% after the first trimester<sup>18</sup>.
- A prospective study of 1570 women recruited in Melbourne between 2011 and 2012 reported that 41.3% of women did not drink during pregnancy, 27% drank in first trimester only; most of whom stopped once they realised they were pregnant (87%). Almost a third of women continued to drink alcohol at some level throughout pregnancy (27%), around half of whom never drank more than at low or moderate levels.
- A cohort study<sup>19</sup> of 1331 pregnant women recruited between 2008 and 2013 from antenatal clinics of three metropolitan public hospitals in New South Wales and Western Australia found that alcohol use during pregnancy was reported by 65.7% of women. In the first 6 weeks of Trimester 1, consumption at binge and heavy levels was the most common pattern, with 27.3% and 23.1% of drinkers (16.5% and 14.0% of total sample) falling into these categories respectively. Alcohol consumption occurred at lower levels in the latter half of Trimester 1, with 72.3% of women abstaining from alcohol completely and the majority of women who did drink alcohol doing so only at low levels. This pattern remained consistent across Trimester 2 and Trimester 3, with 68.8% and 69.3% of women abstaining from alcohol at these stages, respectively.
- A 2018 survey by the Foundation for Alcohol Research and Education (FARE)<sup>20</sup> reported three quarters (78%) of women who drank alcohol prior to becoming pregnant said that they stopped drinking alcohol altogether during pregnancy, 17% that they restricted it to special occasions, and the remaining 5% either reduced their consumption slightly, drank the same amount or said that they increased their alcohol consumption when they were pregnant.
- A study undertaken with caregivers in remote Western Australia (95% were Aboriginal) reported that 55% of caregivers reported alcohol use in pregnancy; 88% reported first trimester drinking and 53% drinking in all trimesters. Of the 60 women interviewed who drank alcohol during pregnancy, 12% drank daily/almost daily, 33% drank 2-3 times per week; 71% drank  $\geq 10$  standard drinks on a typical occasion; 95% drank at risky or high-risk levels<sup>21</sup>. The most common drinking pattern was consumption of  $\geq 10$  standard drinks either 2-4 times per month (27%) or 2-3 times per week (27%)<sup>22</sup>.

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<sup>17</sup> Australian Bureau of Statistics (ABS). 2015. '[Australian Aboriginal and Torres Strait Islander Health Survey: Nutrition Results - Food and Nutrients, 2012-13](#)'. 4727.0.55.005. Canberra. Australian Government.

<sup>18</sup> O'Keeffe, L., Kearney, P., McCarthy, F. 2015. '[Prevalence and predictors of alcohol use during pregnancy: findings from international multicentre cohort studies](#)'. *BMJ Open*, 5:e006323. doi: 10.1136/bmjopen-2014-006323.

<sup>19</sup> McCormack, C., Hutchison, D., Burns, L., Mattick, R., et al. 2018. '[Maternal and partner prenatal alcohol use and infant cognitive development](#)'. *Drug and Alcohol Dependence*, 185; 330-338.

<sup>20</sup> Foundation for Alcohol Research and Education (FARE). 2018. '[Annual Alcohol Poll 2018- Attitudes & Behaviours](#)'. FARE, Canberra.

<sup>21</sup> based on the Alcohol Use Disorders Identification Test consumption subset (AUDIT-C) tool  $\geq 4$

<sup>22</sup> Fitzpatrick JP, Latimer J, Ferreira ML, et al. 2015 '[Prevalence and patterns of alcohol use in pregnancy in remote western Australian communities: the Lililwan project](#)'. *Drug and Alcohol Review*; 34(3): 329-339.

New Zealand - New Zealand does not currently routinely collect data on drinking during pregnancy; however the findings of a range of recent studies<sup>23</sup> suggest around one in two New Zealand women consume alcohol while pregnant, with around one in ten drinking at high risk levels<sup>24</sup>. In a study conducted between 2004 and 2011, 56% of New Zealand women surveyed reported drinking during pregnancy, 53% reported drinking in the first trimester; falling to 12% after the first trimester<sup>25</sup>. An international systematic review and meta-analysis of alcohol use during pregnancy reported that the proportion of women in New Zealand who drink alcohol during pregnancy was between 25-35%<sup>26</sup>.

In the largest New Zealand survey to date<sup>27,28</sup> (cohort of 6822 pregnant women) 71% of women reported drinking alcohol at some level before being aware of their pregnancy in prenatal interviews conducted in 2009-2010, dropping to 23% once women became aware of their pregnancy and to 13% after the first trimester. While overall most women who were drinking stopped as soon as they found out they were pregnant:

- 5% continued to drink at a lower volume before stopping;
- 11% continued at the same volume before stopping;
- 5% drifted in and out of drinking;
- 5% were drinking four or more drinks a week and initially reduced this before reverting back to original drinking patterns; and
- 2% maintained a high volume of drinking throughout the pregnancy.

Some stakeholders considered that these figures are likely to be an underestimation based on the levels of hazardous alcohol consumption among women of childbearing age combined with high numbers of unplanned pregnancies (up to 40% of pregnancies<sup>29</sup>) in New Zealand.

New Zealand currently lacks the data to show changes in drinking patterns during pregnancy over time. Given the association between pre-pregnancy drinking and drinking during pregnancy it is worth noting that between 2015/16 and 2016/17 while rates of drinking and hazardous drinking<sup>30</sup> dropped slightly among women overall,

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<sup>23</sup> This is the (rough) average of the findings of the three latest pieces of local research: 19% ([Ministry of Health 2015](#)), drawing on a small cohort of pregnant women (565); 56% ([O'Keeffe et al 2015](#)), using a larger cohort (2600), but the cohort only included first-time mothers and those who hadn't had a miscarriage so is likely to underestimate prevalence; and 71% ([Superu 2015](#)), the largest cohort (6800), but the questions asked merged pre-pregnancy consumption and consumption before pregnancy awareness, meaning this may overestimate prevalence. In addition a small recent yet to be published New Zealand study ([Parackal et al 2017](#)) supports these estimates.

<sup>24</sup> This is based on any episode of binge drinking (four or more standard drinks) at any stage in pregnancy. We don't have sufficient data to say how many women would fall into this category based on number of drinks a week.

<sup>25</sup> O'Keeffe, L., Kearney, P., McCarthy, F. 2015. ['Prevalence and predictors of alcohol use during pregnancy: findings from international multicentre cohort studies'](#). *BMJ Open*, 5:e006323. doi: 10.1136/bmjopen-2014-006323.

<sup>26</sup> Popova, S., et al. 2017. ['Estimation of national, regional, and global prevalence of alcohol use during pregnancy and fetal alcohol syndrome: a systematic review and meta-analysis'](#). *The Lancet*, 5(3): e290–e299.

<sup>27</sup> Social Policy Evaluation and Research Unit (Superu). 2015. ['Patterns and Dynamics of Alcohol Consumption During Pregnancy in a Recent New Zealand Cohort of Expectant Mothers'](#). Wellington.

<sup>28</sup> Rossen, F., et al. 2018. [Alcohol consumption in New Zealand women before and during pregnancy: findings from the Growing Up in New Zealand Study](#). *NZMJ* 131;1479:24-34.

<sup>29</sup> Morton, S.M.B., Atatoa Carr, P.E., Bandara, D.K., et al. 2010. ['Growing Up in New Zealand: A longitudinal study of New Zealand children and their families. Report 1: Before we are born'](#). Auckland.

<sup>30</sup> Defined as having an AUDIT score of ≥8.

rates of hazardous drinking increased for Māori and Pacific women<sup>31</sup>. The drinking habits of New Zealand women also appear to vary more than those of men, with there being some clusters of young females that are heavy consumers of alcoholic beverages compared with other population groups<sup>32</sup>.

Like Australia, New Zealand does not have data available on the types of alcoholic beverages consumed by pregnant women. The New Zealand Health Promotion Agency's annual *Attitudes and Behaviour towards Alcohol Survey* (ABAS) provides information on the self-reported types of alcoholic beverages consumed on the last drinking occasion. Combined data from the 2013/14, 2014/15, 2015/16 ABAS show the most common type of drink consumed on the last occasion by young women aged 18 to 24 years was spirits (52%), followed by ready-to-drinks (41%)<sup>33,34</sup>. Women in all other age groups, including age 25 to 44 years, most commonly reported drinking wine.

### **Factors related to drinking during pregnancy**

It is difficult to analyse the factors that affect consumption of alcohol during pregnancy, as not all studies distinguish between drinking alcohol before a women knew she was pregnant, and after knowing she was pregnant.

A review by the Australian Institute of Family Studies (AIFS)<sup>35</sup> reported that following factors have been associated with alcohol consumption during pregnancy:

- pre-pregnancy and current rates of alcohol use (both higher quantity and frequency);
- socio-economic advantage and family income: higher income tends to be associated with increased alcohol consumption pre-pregnancy and during pregnancy;
- being an older woman with higher educational attainment;
- smoking during pregnancy; and
- a history of abuse or exposure to violence.

Intention to consume alcohol in pregnancy has also been associated with alcohol use in past pregnancy, the belief that pregnant women should be able to drink alcohol, intention to smoke during pregnancy, and holding a neutral or positive attitude towards alcohol use during pregnancy<sup>36</sup>.

A study of women attending antenatal clinics at public hospitals in Melbourne between July 2011 and July 2012 reported that when compared to women who abstained from alcohol when pregnant; those who drank in the first trimester only

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<sup>31</sup> New Zealand Ministry of Health. 2018. '[Annual Data Explorer 2016/17: New Zealand Health Survey](#)' Wellington. Ministry of Health.

<sup>32</sup> Wall, M., and Casswell, S. 2017. '[Drinker Types, Harm, and Policy-Related Variables: Results from the 2011 International Alcohol Control Study in New Zealand](#)'. *Alcohol Clinical and Experimental Research*, 41(5):1044-1053.

<sup>33</sup> New Zealand Ministry of Health. 2015. '[Alcohol Use 2012/13: New Zealand Health Survey](#)'. Wellington. Ministry of Health.

<sup>34</sup> New Zealand Health Promotion Agency. 2016. '[Types of alcohol consumed by adults on last occasion: 2014/15 ABAS](#)'. Wellington. Health Promotion Agency.

<sup>35</sup> McLean S., McDougall S. 2014. '[Fetal alcohol spectrum disorders Current issues in awareness, prevention and intervention](#)'. Australian Institute of Family Studies. Australian Government.

<sup>36</sup> McLean S., McDougall S. 2014. '[Fetal alcohol spectrum disorders Current issues in awareness, prevention and intervention](#)'. Australian Institute of Family Studies. Australian Government.

were more likely to have an unplanned pregnancy and not feel the effects of alcohol quickly. When compared with abstainers and to women who only drank in trimester one, those who drank throughout pregnancy tended to be in their early to mid-thirties, smoke, have a higher income and educational attainment<sup>37</sup>.

Another Australian study<sup>38</sup> also found that compared to women who abstained, women who drank alcohol during pregnancy were more likely to have an unplanned pregnancy, completed university, use tobacco and illicit substances, have a higher socioeconomic status, be born in Australia or another primarily English speaking country, and have spoken English as their first language.

Research commissioned by the New Zealand Health Promotion Agency<sup>39</sup> also identified the above factors as being associated with drinking when pregnant, but noted that women drinking at high-risk levels after the first trimester are more likely than other pregnant women to be younger, have an unplanned pregnancy, have lower levels of education, be single parents, and smoke or use recreational drugs.

Recent New Zealand research<sup>40</sup> found that alcohol consumption during pregnancy was strongly associated with drinking patterns prior to awareness of pregnancy and ethnicity (Māori and European women were more likely to drink than Asian or Pacific women<sup>41,42</sup>). Higher levels of alcohol consumption during pregnancy (4+ drinks a week) was more common among younger women, Māori women, women with no secondary qualification, smokers and women whose pregnancy was unplanned. Older women, European women and women from socio-economically advantaged backgrounds were more likely than other women to drink during pregnancy but at lower levels.

### ***1.3 Impact of alcohol consumption during pregnancy***

Alcohol consumption during pregnancy has been found to be a risk factor for fetal mortality, stillbirth and infant and child mortality. Although alcohol consumption during pregnancy affects multiple organ systems of the fetus, it is especially harmful to the central nervous system<sup>43</sup>. Heavy alcohol consumption during pregnancy increases the risks of babies that are low birthweight, preterm and small for gestational age<sup>44</sup>.

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<sup>37</sup> Muggli, E. et al. 2016. [“Did you ever drink more?” A detailed description of pregnant women’s drinking patterns](#). *BMC Public Health* 16:683

<sup>38</sup> McCormack, C., et al. 2018. [‘Maternal and partner prenatal alcohol use and infant cognitive development’](#). *Drug and Alcohol Dependence*, 185: 330-338.

<sup>39</sup> Research New Zealand. 2014. [‘Drinking alcohol during pregnancy: A literature review’](#). Wellington. New Zealand Health Promotion Agency.

<sup>40</sup> Social Policy Evaluation and Research Unit (Superu) 2015. [‘Patterns and Dynamics of Alcohol Consumption During Pregnancy in a Recent New Zealand Cohort of Expectant Mothers’](#). Wellington.

<sup>41</sup> Other New Zealand research has found that Tongan and Samoan women are less likely to drink during pregnancy than those of other Pacific ethnicities ([Ministry of Health, 2009](#)) and [Parackal et al \(2006 and 2013\)](#) found that Pacific women were one of the groups who were more likely to drink and to binge drink in the pre-pregnancy recognition period.

<sup>42</sup> Rossen, F., et al. 2018. [Alcohol consumption in New Zealand women before and during pregnancy: findings from the Growing Up in New Zealand Study](#). *NZMJ* 131;1479:24-34.

<sup>43</sup> Burd, L., et al. 2012. [‘Prenatal alcohol exposure, blood alcohol concentrations and alcohol elimination rates for the mother, fetus and newborn’](#). *Journal of Perinatology*, 32: 652–659

<sup>44</sup> Patra, J., et al. 2011. [‘Dose-response relationship between alcohol consumption before and during pregnancy and the risks of low birthweight, preterm birth and small for gestational age \(SGA\)-a systematic review and meta-analyses’](#). *British Journal of Obstetrics and Gynaecology*, 118(12):1411-21. doi: 10.1111/j.1471-0528.2011.03050.x. Epub.

Fetal Alcohol Spectrum Disorder (FASD) is an umbrella term describing the range of physical, cognitive, behavioural and neurodevelopmental disabilities in the fetus that can result from alcohol exposure during pregnancy. Prenatal alcohol exposure is the only cause of FASD and the leading cause of preventable brain damage<sup>45</sup>. All drinks that contain alcohol (e.g. beer, wine or spirits) can harm the unborn baby and it is not possible to attribute FASD to any particular type or form of alcoholic beverage.

Fetal exposure to alcohol can lead to permanent damage to the brain and other critical organs, functions and structures. Some of these effects will include visible abnormalities: damage to the body, major organs and skeleton. Common physical issues include those relating to malformations of the eye, ear, spine and heart<sup>46</sup>. However, some of the most serious damage will be 'hidden', in the brain. FASD is often characterised by communication, behavioural and sensory issues and can exist alongside or be mistaken for other conditions. These issues will manifest themselves at different points along the developmental trajectory and may not be obvious until an important developmental milestone is delayed or not achieved. This may not be recognised as relating to alcohol exposure or any resulting brain damage.

Not everyone who has been affected by alcohol exposure in utero will meet the diagnostic criteria for FASD. There is no typical FASD profile.

FASD is a life-long condition, and individuals with FASD who have severe cognitive and behavioural disabilities are likely to have shorter, more difficult lives. People with FASD may be affected by intellectual and developmental disabilities, attention deficits, poor social understanding, hyperactivity, learning disabilities, poor coordination and planning, poor muscle tone, working memory deficits, receptive language deficits, executive functioning deficits (e.g. difficulty organising and planning), and the difficulty learning from the consequences of behaviour.

People born with FASD are at an increased risk of child abuse and neglect, poor educational outcomes, developing mental health and substance abuse issues, coming into contact with the justice system, benefit dependence and premature mortality – including through suicide<sup>47</sup>. An international literature review reported that 17% of children in the “child-care system” (e.g. orphanage, foster care, child welfare system) had FASD<sup>48</sup>.

Families affected by FASD are likely to experience increased stress<sup>49</sup> (which affects people's mental and physical health and can lead to family breakdown), and report damage to relationships with friends and wider family, decreased levels of social

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<sup>45</sup> O'Leary, C. M., & Bower, C. 2012. '[Guidelines for pregnancy: What's an acceptable risk, and how is the evidence \(finally\) shaping up?](#)'. *Drug and Alcohol Review*, 31:170-183.

<sup>46</sup> Popova, S. et al. 2016. '[Comorbidity of fetal alcohol spectrum disorder: a systematic review and meta-analysis](#)'. *The Lancet*, 387(10022): 978-987.

<sup>47</sup> New Zealand Ministry of Health. 2015. '[Taking Action on Fetal Alcohol Spectrum Disorder \(FASD\): A discussion document](#)'. Wellington: Ministry of Health.

<sup>48</sup> Lange, S., et al. 2013. '[Prevalence of Fetal Alcohol Spectrum Disorders in child care setting: A meta-analysis](#)'. *Pediatrics* 132(4).

<sup>49</sup> Watson, S.L., et al. 2013. '[Autism spectrum disorder and Fetal Alcohol Spectrum Disorder. Part II: A qualitative comparison of parenting stress](#)'. *Journal of Intellectual and Developmental Disability*, 38(2):105-113.



connection and support, and increased costs while the family's earning potential often decreases<sup>50</sup>.

An Australian House of Representatives Standing Committee on Social Policy and Legal Affairs Inquiry into the prevention, diagnosis and management of FASD heard that 90% of children with FASD will have mental health problems, 80% will remain unemployed, 60% will come into aggravated contact with the law and less than 10% will be able to work independently by the age of 21<sup>51</sup>.

A Canadian study<sup>52</sup> published in 2016 reported that people with Fetal Alcohol Syndrome (FAS- a severe form of FASD) have a life expectancy at birth of only 34 years. The leading causes of death for people with FAS were "external causes" (44%), which include suicide (15%), accidents (14%), poisoning by illegal drugs or alcohol (7%), and other external causes (7%). Other common causes of death were diseases of the nervous and respiratory systems (8% each), diseases of the digestive system (7%), congenital malformations (7%), mental and behavioural disorders (4%), and diseases of the circulatory system (4%).

### **Prevalence, incidence and burden of FASD**

Measuring the incidence, prevalence and burden of FASD in a population is complex, and available data are not necessarily comparable between Australia and New Zealand, or even within these countries due to different methodologies used. As FASD refers to a wide spectrum of impacts, and low-level impacts of exposure to alcohol during pregnancy may be subtle, FASD may be difficult to diagnose (or be misdiagnosed) by non-specialised clinicians<sup>53</sup>.

In the targeted consultation, stakeholders were asked whether the current estimates on the prevalence and burden of FASD in Australia and New Zealand were appropriate. Responses from stakeholders have been incorporated into the discussion below.

Australia - There is no national data on the incidence, prevalence or burden of FASD in Australia, as children have not been routinely screened for FASD in infancy or childhood. Current strategies to address this gap in evidence include the Australian FASD Diagnostic Tool, which became nationally available in May 2016, and the development of the FASD Australian Register, which complements the Australian Diagnostic Tool. These will play a significant part in improving the ability of Australia to monitor incidence and prevalence trends over time, which has been long acknowledged as a gap that needs to be addressed.

It has been suggested that as many as 2% of all Australian babies may be born with some form of FASD<sup>54</sup>. Data from states and territories have estimated rates at 0.01 to 1.7 per 1000 births in the total population and 0.15 to 4.70 per 1000 births for the

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<sup>50</sup> Based on conversations with families affected by FASD as part of the development of the '[NZ FASD Action Plan](#)'.

<sup>51</sup> House of Representative Committees. 2012. '[Inquiry into Fetal Alcohol Spectrum Report: FASD: The Hidden Harm-Inquiry into the prevention, diagnosis and management of Fetal Alcohol Spectrum Disorders](#)'.

<sup>52</sup> Thanh, N.X. and Jonsson, E. 2016, '[Life Expectancy of People with Fetal Alcohol Syndrome](#)', *J. Popul Ther Pharmacol.* 23(1): e53-e59.

<sup>53</sup> Select Committee on Action to Prevent Foetal alcohol Spectrum Disorder. 2015. '[The Preventable Disability Report](#)'. Northern Territory.

<sup>54</sup> McLean, S., McDougall, S. 2014. '[Fetal alcohol spectrum disorders Current issues in awareness, prevention and intervention](#)'. Australian Institute of Family Studies. Australian Government.

Indigenous population<sup>55,56</sup>. These rates are estimated to be even higher in high-risk Indigenous populations with high rates of prenatal alcohol exposure as evidenced through the Lililwan Project, a community driven project to determine the prevalence of FASD among children born in 2002 and 2003 in the Fitzroy Crossing Valley in the Kimberley region of Western Australia. A total of 21 of the 108 participating children were diagnosed as having FASD<sup>57</sup>, which is a rate of 194.4 per 1,000 children - one of the highest rates of diagnosis of FASD worldwide. These researchers also determined the prevalence of Fetal Alcohol Syndrome (FAS- a severe form of FASD)<sup>58</sup> in this group of children, and reported that 13 of the 108 had this condition, which is a prevalence rate of 120 per 1,000 children.

There are also reports that the prevalence of FASD is increasing over time<sup>59,60</sup> related to improved identification and reporting of the condition.

The above figures are likely to underestimate national incidence and prevalence given the historical limitations in data collection for FASD in Australia, but still reflect a significant need to implement prevention measures to address this issue. Submissions from stakeholders noted that current estimates of the incidence and prevalence of FASD in Australia are likely to be underestimated. This was justified by the observation that countries such as Canada and the United States of America have a higher recorded prevalence of Fetal Alcohol Syndrome<sup>61</sup> (FAS- a severe form of FASD) and FASD<sup>62</sup> than Australia, however Australia has a much higher rate of alcohol consumption among pregnant women than Canada and the United States of America<sup>63</sup>.

New Zealand- New Zealand is in the process of conducting an incidence study but at present there are no New Zealand data on the incidence or prevalence of FASD. It is not routinely screened for and some clinicians may lack the capacity to diagnose it, although there is work underway to address this. The New Zealand Ministry of Health currently accepts a incidence and prevalence rate of 1% of the population as a solid conservative estimate<sup>64</sup>, but notes that alcohol consumption during pregnancy appears

<sup>55</sup> Burns, L., et al. 2013. '[Counting fetal alcohol spectrum disorder in Australia: the evidence and the challenges](#)'. *Drug and Alcohol Review*;32(5):461–467

<sup>56</sup> Mutch RC et al.2015. '[Fetal alcohol spectrum disorders: Notifications to the Western Australian Register of Developmental Anomalies](#)'. *Journal of Paediatrics and Child Health*, 51:433-436.

<sup>57</sup> Fitzpatrick, J.P. et al. 2017. '[Prevalence and profile of Neurodevelopment and Fetal Alcohol Spectrum Disorder \(FASD\) amongst Australian Aboriginal children living in remote communities](#)'. *Research Development Disability*, 65:114-126.

<sup>58</sup> Fitzpatrick J, et al. 2015. '[Prevalence of fetal alcohol syndrome in a population-based sample of children living in remote Australia: the Lililwan Project](#)'. *Journal of Paediatrics and Child Health*; 51(4): 450–457.

<sup>59</sup> Elliott EJ et al. 2008. '[Fetal Alcohol Syndrome: a prospective national surveillance study](#)'. *Archives Diseases in Childhood*, 93:732-737.

<sup>60</sup> Mutch RC et al. 2015. '[Fetal alcohol spectrum disorders: Notifications to the Western Australian Register of Developmental Anomalies](#)'. *Journal of Paediatrics and Child Health*, 51:433-436.

<sup>61</sup> Popova, S., et al. 2017. '[Estimation of national, regional, and global prevalence of alcohol use during pregnancy and fetal alcohol syndrome: a systematic review and meta-analysis](#)'. *The Lancet*, 5(3): e290–e299.

<sup>62</sup> Popova, S., Lange, S., Chudley, A. E., Reynolds, J. N., Rehm, J. 2018. '[World Health Organization International Study on the Prevalence of Fetal Alcohol Spectrum Disorder \(FASD\)](#)'. Centre for Addiction and Mental Health, Canada

<sup>63</sup> Popova, S., et al. 2017. '[Estimation of national, regional, and global prevalence of alcohol use during pregnancy and fetal alcohol syndrome: a systematic review and meta-analysis](#)'. *The Lancet*, 5(3): e290–e299.

<sup>64</sup> International research has produced a range of estimates of FASD prevalence. Some studies have estimated that prevalence rates in the USA and Western Europe could be between 2% and 5% of the general population (see [May et al. 2009](#)), although others have produced much lower estimates (see [Ospina and Dennett 2013](#) for a summary). Although the wide range of estimates makes it difficult to know with certainty what the prevalence is likely to be, a widely used figure is 1%. We have therefore also assumed a figure of 1% in line with overseas practice.

to be higher in New Zealand than in North America<sup>65</sup>, where most of the prevalence research has come from. If 1% of the New Zealand population was affected by FASD that would equate to 46,000 people, with an additional 570 cases of FASD born each year<sup>66</sup>.

Some New Zealand stakeholders agreed that it is reasonable to base an estimate on international data due to lack of data from New Zealand but many considered that applying average international prevalence rates is likely to underestimate the prevalence in New Zealand due to differences in drinking patterns between countries. Similar to comments from Australian submissions, stakeholders cited a recent study in Canada<sup>67</sup> where the estimated prevalence of FASD in school children was 2-3% and noted that New Zealand has a higher prevalence of drinking alcohol following pregnancy recognition in New Zealand (23%<sup>68</sup>), when compared to Canada (10%<sup>69</sup>).

### **Cost of FASD to the community**

Quantifying the financial impacts of FASD to community is complicated<sup>70</sup>. A 2011 systematic literature review<sup>71</sup> which sought to assess the economic impact of FASD in different countries concluded that the literature on the economic burden of FASD is scarce. It reported that there are a limited number of studies from Canada and the United States, and data from the rest of the world are absent.

The evidence that is available indicates FASD is likely to be very costly to both the Australian and New Zealand Governments and to wider society.

Existing estimates of the economic impact of FASD demonstrate significant cost implications on the individual, the family and society. For example, an analysis<sup>72</sup> of studies from Canada, the United States and New Zealand to estimate that direct costs of FASD (health care, criminal justice, education, other services) in the total population ranged from CAD \$762 million to \$10.5 billion annually. Indirect costs from lost productivity due to morbidity/ premature mortality from FASD ranged from CAD \$46.8 million to \$2.4 billion annually. Criminal justice system costs contributed most to the total financial burden of FASD (CAD \$395 million to \$7.2 billion) followed by loss of productivity (CAD \$46.8 million to \$2.4 billion). Costs of health care accounted for CAD \$7 to \$265 million. This work has only been published as a conference abstract and further information on this analysis is not yet available.

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<sup>65</sup> May, P.A., Gossage, J.P. 2001. '[Estimating the prevalence of fetal alcohol syndrome: a summary](#)'. *Alcohol Research & Health*; 25(3): 159–167.

<sup>66</sup> Refer to the '[New Zealand Ministry of Health's discussion document on FASD](#)' for further reading.

<sup>67</sup> Popova, S. et al. 2018. '[World Health Organization International Study on the Prevalence of Fetal Alcohol Spectrum Disorder \(FASD\)](#)'. Centre for Addiction and Mental Health, Canada.

<sup>68</sup> Social Policy Evaluation and Research Unit (Superu). 2015. '[Patterns and Dynamics of Alcohol Consumption During Pregnancy in a Recent New Zealand Cohort of Expectant Mothers](#)'. Wellington.

<sup>69</sup> Popova, S. et al. 2018. '[World Health Organization International Study on the Prevalence of Fetal Alcohol Spectrum Disorder \(FASD\)](#)'. Centre for Addiction and Mental Health, Canada.

<sup>70</sup> Popova, S. et al. 2012 '[A model for estimating the economic impact of fetal alcohol spectrum disorder](#)'. *J Popul Ther Clin Pharmacol*, 19(1): e51-e65

<sup>71</sup> Popova, S., et al. 2011. '[What do we know about the economic impact of fetal alcohol spectrum disorder? A systematic literature review](#)'. *Alcohol*, 46(4):490-7.

<sup>72</sup> Andersson, E., Elliott, E. 2018. '[Economic Costs of Fetal Alcohol Spectrum Disorder \(FASD\)](#)'. *Journal of Paediatrics and Child Health*, 54(S2):7.



A Canadian study<sup>73</sup> reported that the total direct health care cost of acute care, psychiatric care, day surgery, and emergency department services associated with Fetal Alcohol Syndrome (FAS- a type of FASD) in Canada in 2008–2009, was about CAD \$6.7 million . Another Canadian study estimated that a FASD evaluation requires 32 to 47 hours for one individual to be screened, referred, admitted, and diagnosed with an FASD diagnosis, which results in a total cost of CAD \$3,110 to \$4,570 per person. The total cost of FASD diagnostic services in Canada ranges from \$3.6 to CAD \$5.2 million (lower estimate), up to CAD \$5.0 to \$7.3 million (upper estimate) per year<sup>74</sup>.

Canadian research also reports that people with FASD are approximately 19 times more likely to be incarcerated than those who do not have FASD<sup>75</sup>. In 2011/12, approximately CAD \$17.5 million was calculated for the cost of corrections amongst youth and over \$356.2 million of those adults with FASD<sup>76</sup>.

The New Zealand Government<sup>77</sup> makes a very conservative estimate for per person costs of FASD to be NZD\$15,000<sup>78,79</sup>. This figure is based on international cost estimates and does not include lifetime costs as a result of primary and secondary consequences of FASD including behavioural issues, mental health issues, learning disabilities, alternative education, substance abuse, access to specialist support, legal help, unemployment and lower productivity, and the cost of lost opportunities. Assuming 46,000 people in New Zealand have FASD, this suggests an annual cost of *at least* NZD \$690 million. On top of that, estimates of productivity loss to New Zealand due to morbidity and premature mortality from FASD range from NZD \$49million to NZD\$200 million per year<sup>80</sup>.

Researchers are currently working to estimate the economic burden of FASD in Australia<sup>81</sup>; however these results are not yet available.

A number of submissions in the targeted consultation cited the economic analysis undertaken by Health Technology Analysts<sup>82</sup> for FSANZ which reported that FASD (at an incidence rate of 1% of all births) would conservatively be costing Australian

<sup>73</sup> Popova S. et al.2012. '[Health care burden and cost associated with fetal alcohol syndrome: Based on official Canadian data](#)'. *PLoS One*, 7(8): e43024. doi.org/10.1371/journal.pone.0043024.

<sup>74</sup> Popova, S. et al. 2013. '[Cost of Fetal Alcohol Spectrum Disorder Diagnosis in Canada](#)' *PLoS One*, 8(4): e60434. <https://doi.org/10.1371/journal.pone.0060434>.

<sup>75</sup> Popova, S., et al. 2011. '[Fetal Alcohol Spectrum Disorder prevalence estimates in correctional systems: A systematic literature review](#)'. *Canadian Journal of Public Health*, 102(5): 336-340.

<sup>76</sup> Popova, S. et al. 2015. '[Cost attributable to Fetal Alcohol Spectrum Disorder in the Canadian correctional system](#)'. *International Journal of Law and Psychiatry*, 41:76-81.

<sup>77</sup> Ministry of Health, New Zealand Government, 2015. '[Taking Action on Fetal Alcohol Spectrum Disorder \(FASD\) A Discussion Document](#)'

<sup>78</sup> Suebwongpat. et al. 2009. '[Fetal Alcohol Spectrum Disorders \(FASD\): Exploratory economic analysis of a hypothetical national prevention programme](#)'. HSAC Report 2(4). Christchurch and Sydney: Health Services Assessment Collaboration. Estimated the annual cost per case in New Zealand to be NZD\$16,333. This uses 2008 dollars and focused solely on costs to Government but excluded significant sources of cost such as justice sector expenditure.

<sup>79</sup> Suebwongpat, et al. 2009. '[Fetal Alcohol Spectrum Disorders \(FASD\): Exploratory economic analysis of a hypothetical national prevention programme](#)'. HSAC Report 2(4). Christchurch and Sydney: Health Services Assessment Collaboration.

<sup>80</sup> Based on 2013 data. Easton B et.al.2016. '[Productivity losses associated with Fetal Alcohol Spectrum Disorder in New Zealand](#)'. *NZMJ*, 129:1440.

<sup>81</sup> Telethon Kids Institute 2018. '[Estimating the Economic Burden of FASD in Australia](#)

<sup>82</sup> Health Technology Analysts. 2010. '[Fetal alcohol spectrum disorder \(FASD\) Exploratory economic analysis of different prevention strategies in Australia and New Zealand](#)'. Food Standards Australia New Zealand.

and New Zealand taxpayers an extra AUD \$66 million and NZD \$16 million per annum respectively in 2009 dollars. The costings from this report were based on Canadian costings and adjusted for Australia and New Zealand by applying an internationally accepted FASD incidence of 1% of live births to the birth rates in these countries and relevant exchange rates. This equates to AUD\$32,584 per case of FASD, and NZD \$35,267 per new case of FASD (in 2009 prices) or AUD \$39,494 and NZD \$40,437 in 2018 prices (adjusted using March 2018 Consumer Price Index-latest available).

The costings by Health Technology Analysts include direct costs to the healthcare system and other relevant government agencies and direct costs to industry, as well as indirect costs such as productivity loss, and out-of-pocket expenses to individuals and their families. The productivity loss in these estimates related to parents' lost work time due to caring for their child with disabilities, however, productivity losses from children with disabilities were not captured. The Health Technology Analysts costings also do not include costs to the legal and justice system. These costs reflect the cost of new cases of FASD, and do not reflect existing costs associated with people with the condition. Therefore the Health Technology Analysts' estimates are likely to be underestimates of the true cost of FASD to society in Australia and New Zealand.

## Modelled incidence and costings for FASD

As outlined above, incidence of FASD has been reported to be 2% for Australia and 1% for New Zealand, however many stakeholders consider this to be an underestimate.

To address the data limitations in regard to the incidence and cost of FASD in the Australian and New Zealand communities, a hypothetical scenario has been modelled to create a plausible estimate of the incidence of FASD in Australia and New Zealand. This exercise also seeks to address different reporting and methodological approaches to measuring the incidence, prevalence and impact of FASD in Australia and New Zealand by using a consistent methodology. This modelling exercise is necessary to facilitate the cost-benefit analysis that is undertaken later in this document.

These incidence rates estimated in this section are for the overall population, and are not specific to high risk populations such as Indigenous communities.

### *Modelled estimate of the incidence of FASD*

Reducing the proportion of women who drink alcohol during pregnancy, or the amount of alcohol consumed by women during pregnancy, will reduce the incidence or severity of FASD.

Due to the nature of FASD, the condition is generally not identified at birth, but rather identified as the child develops and the developmental impacts of the FASD (such as impairment in motor skills, language, memory or social skills<sup>83</sup>) become apparent<sup>84</sup>. Therefore, there is limited data available on the incidence rate<sup>85</sup> of FASD at birth and most of the literature reports on the prevalence<sup>86</sup> of FASD in children.

This paper assumes that the prevalence of FASD in children is equivalent to the incidence rate of FASD at birth. This is reasonable considering that FASD develops during fetal development and cannot be developed at other points in life, and assuming that all babies born with FASD live into childhood.

Most of the data and research on the prevalence of FASD in children is from the United States and Canada. Based on in-person assessments of school children, the United States Centres of Disease Control reports the prevalence of FASD in school children in United States could be between 1% and 5%<sup>87</sup>. A Canadian study<sup>88</sup>, also based on in-person assessments of school children, estimated the prevalence of FASD in Canadian children is between 2% and 3%, which the authors still considered an underestimate.

The rate of drinking during pregnancy is considerably higher in Australia and New Zealand compared to the United States and Canada as reported by a systematic

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<sup>83</sup> Bower et al., 2016. [Australian Guide to the diagnosis of FASD](#)

<sup>84</sup> Note the Australian FASD Diagnostic Instrument is designed for use with children aged 6 years.

<sup>85</sup> The incidence rate is the number of new cases per population at risk in a given time period.

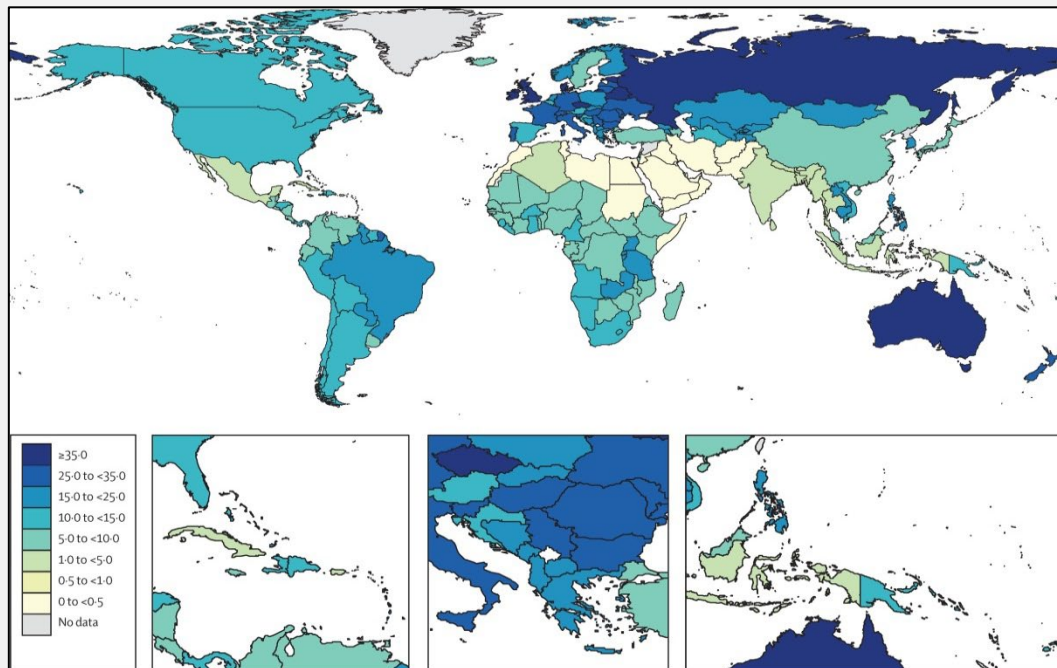
<sup>86</sup> The prevalence rate is the proportion of persons in a population who have a particular disease or attribute at a specified point in time or over a specified period of time.

<sup>87</sup> Centres for Disease Control and Prevention, 2018 '[Fetal Alcohol Spectrum Disorders](#)'

<sup>88</sup> Popova, S., Lange, S., Chudley, A. E., Reynolds, J. N., Rehm, J. 2018. '[World Health Organization International Study on the Prevalence of Fetal Alcohol Spectrum Disorder \(FASD\)](#)'. Centre for Addiction and Mental Health, Canada.

literature review published in *The Lancet* (the most prestigious health and medical journal).

**Figure 1.1 Global prevalence (%) of alcohol use (any amount) during pregnancy among the general population in 2012**



According to this publication, Australia's rate of alcohol consumption in pregnancy is more than three times that of the United States<sup>89</sup> and Canada. An upper estimate of 9% incidence of FASD in Australia is therefore derived by tripling the United States estimate of 1-5% of school children with FASD (i.e. 3-15%), and taking the mid-point of this figure: 9%.

Using the conservative current estimated Australian FASD incidence rate of 2%, a plausible incidence estimate for FASD in Australia is between 2% to 9%. **The mid-point of these estimates is 5% which has been used as the plausible incidence estimate for FASD in Australia.** This would be reasonable considering international prevalence estimates for FASD in school children<sup>90</sup> are 4%–7% in Croatia, 4%–5% in Italy and 6%–21% in South Africa and Australia's rate of alcohol consumption in pregnancy is still higher than these countries<sup>91</sup>.

For New Zealand, alcohol consumption during pregnancy is about double that of Canada and the United States. Using the same reasoning as the Australian modelling, the United States prevalence of FASD in children (1-5%) was doubled (2-10%) and the mid-point of this range (6%) was taken as the upper FASD incidence estimate for New Zealand.

<sup>89</sup> Popova, S., et al. 2017. '[Estimation of national, regional, and global prevalence of alcohol use during pregnancy and fetal alcohol syndrome: a systematic review and meta-analysis](#)'. *The Lancet*, 5(3): e290–e299.

<sup>90</sup> Popova, S., Lange, S., Chudley, A. E., Reynolds, J. N., Rehm, J. 2018. '[World Health Organization International Study on the Prevalence of Fetal Alcohol Spectrum Disorder \(FASD\)](#)'. Centre for Addiction and Mental Health, Canada.

<sup>91</sup> Factors such as a volume of alcohol consumed and a women's health and metabolism also affect whether the FASD will occur.

Using the conservative current estimate that 1% of people in New Zealand have FASD, it can be estimated that the incidence of FASD in New Zealand is between 1% to 6%. **The mid-point of these estimates is 3% which has been used as the plausible incidence estimate for FASD in New Zealand.** This would also seem reasonable, even conservative, noting that alcohol consumption during pregnancy in New Zealand is similar to Italy and higher than Croatia and South Africa.

#### *Modelled financial impact of FASD*

Tables 1.1 and 1.2 below apply the Health Technology Analysts estimated costs per case of FASD to the range of estimated FASD incidence rates for Australia and New Zealand.

The Health Technology Analysts report was used for this costing exercise as it provided estimates of the cost per case of FASD and no other appropriate cost estimates reported in this way were identified. The cost per case of FASD allows for modelling of the cost of FASD at different hypothetical incidence rates. The Health Technology Analysts work was commissioned for initial work on pregnancy warning labels on packaged alcoholic beverages and was widely cited by stakeholders in submissions to the consultation.

Using incidence rather than prevalence in this modelling exercise means that these cost estimates only reflect the cost of new cases of FASD in the population, and do not reflect the costs of existing cases. Incidence was considered to be a more appropriate measure rather than prevalence as most of the FASD prevalence studies have been undertaken in children and the life-expectancy of people with FASD may be lower than that of the general population. Age-specific prevalence data for FASD is not available and it is therefore unknown whether the prevalence of FASD in children applies across the broader population.

**Table 1.1- Estimated yearly cost of new cases of FASD in Australia**

<b>FASD incidence rate (per live births)</b>	<b>Estimated number of FASD cases (based on 311,104 births in 2016<sup>92</sup>)</b>	<b>Yearly cost of new cases of FASD in that year (based on AUD \$39,494 per case of FASD)</b>
2%	6,222	\$245.73 million
5%	15,555	\$614.33 million
9%	27,999	\$1.11 billion

<sup>92</sup> Australian Bureau of Statistics (ABS). 2017. [Births, Australia-2016](#). 3301.0. Canberra. Australian Government.

**Table 1.2 Estimated yearly cost of new cases of FASD in New Zealand**

FASD incidence rate (per live births)	Births in 2016 (based on 59,430 births in 2016 <sup>93</sup> )	Yearly cost of new cases of FASD in that year (based on NZD \$40,437 per case of FASD)
1%	594	\$24.03 million
3%	1,783	\$72.10 million
6%	3,566	\$144.19million

One of the major limitations of the Health Technology Analysts costings is that it does not include costs to the legal and justice system, which according to other research<sup>94</sup> contributes the most to the total burden of FASD. A recently published study Australian found that 36% of young people in Banksia juvenile detention centre located in Western Australia had FASD<sup>95</sup>. However no data are available on the prevalence of FASD in the broader correctional system in Australia. Therefore, international data was used to estimate the costs of FASD in the Australia and New Zealand justice sector.

A systematic literature review study undertaken in 2012 reported that between 10.9% and 22.3% of youth in custodial correction systems in Canada have FASD. For adults, prevalence of FASD in the correctional system was estimated to be 9.9%. The literature review also identified one study from the United States on the prevalence of FASD in the correctional system but concluded this study was affected by data limitations.

The AIHW reports there were 964 young people in detention on an average night in the June quarter 2017<sup>96</sup>. The ABS reports that there are 41,202 adults in corrective services custody at 30 June 2017<sup>97</sup>. If the Canadian estimates of FASD prevalence in the correctional system are applied to the Australian context, there could be between 105 and 215 youth with FASD in the detention and 4,079 adults in the correctional system with FASD. The cost of putting one person in prison for a year was \$109,500 AUD<sup>98</sup> in 2015 (\$132,720 in 2018 dollars). If this cost is applied to the predicted population of FASD in the prison system this cost could be \$541.4 million in one year for adults and between \$13.9 million and \$28.5 million per year for youth (mid-point \$21.2 million). This does not capture other costs to the justice system such as policing and court costs.

For New Zealand the cost of putting one person in prison for a year was AUD \$80,000<sup>99</sup> in 2015 (NZD \$90,912, equivalent to NZD \$93,962 in 2018). In March 2018 there were 10,645 adult prisoners in New Zealand<sup>100</sup>. If the Canadian prevalence estimates are applied to this population, it is estimated that 1,054 prisoners

<sup>93</sup> Stats New Zealand. [Stats New Zealand Infoshare](#). New Zealand Government.

<sup>94</sup> Andersson, E., Elliott, E. 2018. 'Economic Costs of Fetal Alcohol Spectrum Disorder (FASD)'. *Journal of Paediatrics and Child Health*, 54(S2):7.

<sup>95</sup> Bower, C. et al. 2018. 'Fetal alcohol spectrum disorder and youth justice: a prevalence study among young people sentenced to detention in Western Australia'. *BMJ Open*, 2018; 8.

<sup>96</sup> Australian Institute of Health and Welfare (AIHW). 2016. 'Youth detention population in Australia 2017'. Bulletin no. 143. Cat. no. AUS 220. Canberra: AIHW.

<sup>97</sup> Australian Bureau of Statistics (ABS). 2017, *Prisoners in Australia, 2017*. 4517.0. Canberra. Australian Government.

<sup>98</sup> Brushnell, A. 2017. 'Australia's Criminal Justice Costs: An international Comparison'. Institute of Public Affairs Research.

<sup>99</sup> Brushnell, A. 2017. 'Australia's Criminal Justice Costs: An international Comparison'. Institute of Public Affairs Research.

<sup>100</sup> New Zealand Government Department of Corrections 2018. *Prison facts and statistics - March 2018*



in New Zealand would have FASD, which would cost NZD \$99.02 million per year. Youth detention numbers for New Zealand were not available.

Table 1.3 provides the combined annual costs of new cases of FASD based on the costs from Health Technology Analysts and the prison costs of FASD. The costings still do not capture the costs of existing cases of FASD in the community; however, data limitations in relation to age-specific prevalence estimates of FASD limit the opportunity to predict these costs. It is noted that these costings are considerably less than New Zealand Government costings described above due to different methodologies<sup>101</sup>.

**Table 1.3 Combined yearly FASD cost estimates**

Cost	Australia (\$AUD)	New Zealand (\$NZD)
Cost of new cases of FASD in one year (based on mid-point estimate from Tables 1.1 and 1.2)	\$614.33 million	\$172.10 million
Yearly costs to the prison and youth detention system	\$562.6 million	\$99.02 million
<b>Combined annual cost</b>	<b>\$1.18 billion</b>	<b>\$171.12 million</b>

Based on this modelling, a plausible central case that this paper will use in subsequent cost-benefit analyses is that the annual incidence of FASD is 5% and 3% in Australia and New Zealand respectively which is costing the Australian and New Zealand communities **AUD \$1.18 billion and NZD \$171.12 million per year**. This is equivalent to AUD \$75,662 per case of FASD for Australia (at a 5% incidence rate) and NZD \$95,978 per case of FASD in New Zealand (at a 3% incidence rate).

However the cost of FASD depends on the severity of FASD, and international studies suggest heavy drinkers are least likely to be affected by mandatory labelling<sup>102</sup>. As exposure to alcohol during pregnancy is directly related to the severity of FASD, although the precise relationship is not well known, a more conservative approach is to consider the average cost of mild cases of FASD.

Estimates of the annual health-related cost of mild cases of FASD from the Canadian study<sup>103</sup> on which the health-related costs included above are based, updated to 2018, range from AUS\$7,499 to AUS\$20,962, with an average of \$13,785. (As mild cases of FASD are unlikely to result in impacts on the cost of the prison and juvenile justice system, these costs would be ignored.)

<sup>101</sup> New Zealand Government costings are based on applying a 1% prevalence estimate to the total New Zealand population

<sup>102</sup> Health Technology Analysts. 2010. '[Fetal alcohol spectrum disorder \(FASD\) Exploratory economic analysis of different prevention strategies in Australia and New Zealand](#)'. Food Standards Australia New Zealand.

<sup>103</sup> Stade B, et al.. 2009. [The burden of prenatal exposure to alcohol: REVISED measurement of cost](#). *Canadian Journal of Clinical Pharmacology*. 16(1): 91-102

### ***1.4 Labelling approaches to raise awareness about the recommendations for women not to drink when pregnant***

A range of complementary measures are required to raise awareness of the risks associated with drinking alcohol when pregnant, and ultimately prevent FASD. No one initiative is sufficient in isolation. This is not unexpected given the complex nature of public health problems such as this.

Targeted interventions are important and focus on women who are at high risk of drinking when pregnant; however, population wide initiatives are also needed to distribute information about the need for women to not drink alcohol when pregnant across the community, create supportive environments and establish cultural norms. Appendix 1 describes the current actions that are being undertaken to prevent FASD in Australia and New Zealand.

Pregnancy warning labels on packaged alcoholic beverages are an important part of the suite of measures that aim to raise awareness of the risks associated with drinking alcohol when pregnant. While health care providers and other targeted communication channels play an important role in communicating the recommendations that women should not drink alcohol when pregnant, pregnancy warning labels provide a unique opportunity to communicate this message at the potential point of purchase or consumption of alcoholic beverages. The warning labels also provide an opportunity to communicate with broader community that would not receive these targeted communication messages (including women planning a pregnancy and partners and family of women who are pregnant or planning a pregnancy).

Internationally, pregnancy warning labels are displayed on alcoholic beverages on either a voluntary or mandatory basis. Preliminary results from the 2016 World Health Organization (WHO) global survey on alcohol and health<sup>104</sup> report that 28 countries have a legal requirement for a pregnancy warning label on alcoholic beverages. Countries with mandated pregnancy health warning labels include France, Republic of Korea, Lithuania, Mexico, South Africa, Turkey, the Russian Federation and the United States<sup>105</sup>. There are no agreed international labelling standards for alcohol related matters.

International evidence reports that health warning labels on alcoholic beverages improve knowledge, raise awareness<sup>106</sup> and prompt discussion of the harmful health consequences of alcohol<sup>107</sup>. It is recognised that health warning labels on alcohol, as an isolated intervention, do not lead to behaviour change<sup>108,109</sup>.

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<sup>104</sup> Rekve, D. 2017 '[An update from the World Health Organization with a focus on labelling](#)'. World Health Organization.

<sup>105</sup> International Alliance for Responsible Drinking. 2018. '[Health Warning Labeling Requirements](#)'. United States and United Kingdom.

<sup>106</sup> Stockwell, T. 2006. '[A Review Of Research Into The Impacts Of Alcohol Warning Labels On Attitudes And Behaviour](#)'. Centre for Addictions Research of BC University of Victoria, British Columbia, Canada.

<sup>107</sup> World Health Organization. 2017. '[Alcohol labelling – A discussion document on policy options](#)'. Regional Office for Europe.

<sup>108</sup> <sup>108</sup> Stockwell, T. 2006. '[A Review Of Research Into The Impacts Of Alcohol Warning Labels On Attitudes And Behaviour](#)'. Centre for Addictions Research of BC University of Victoria, British Columbia, Canada.

<sup>109</sup> Wilkinson, C., Room, R., 2009. '[Warnings on alcohol containers and advertisements: international experience and evidence on effects](#)' *Drug Alcohol Rev*, 28(4):426-35. doi: 10.1111/j.1465-3362.2009.00055.x.



In regard to pregnancy warning labels specifically, international evidence indicates that these can raise awareness of the risks of drinking alcohol during pregnancy<sup>110</sup>. An evaluation of women's awareness of pregnancy warning labels in France five years after the introduction of mandatory pregnancy warning labels found that pregnancy warning labels had been noticed by 66.1% of women and 77.3% of drinkers. Of those who had noticed the warning, 98.6% thought that it suggested abstinence; daily drinking during pregnancy and binge drinking were both considered harmful by nine women out of ten surveyed<sup>111</sup>. In the United States, pregnant women who saw the warning labels on alcoholic beverages were more likely to discuss the issue of alcohol and pregnancy and a “dose–response” effect was found where the more types of information the respondents had seen (on adverts at point of sale, in magazines and on containers), the more likely they were to have discussed the issue<sup>112</sup>.

A review of the potential impact of pregnancy warning labels on alcoholic beverages undertaken for FSANZ in 2009 by leading Australian population health academics<sup>113</sup> reported:

- Within a two- to three-year period, the majority of women drinkers will have noticed the warnings;
- Younger women and heavier drinkers may be more likely to notice the warnings;
- Of those who notice the labels, approximately 50% will be able to recall the message (this will vary depending on the content of the message);
- There is likely to be an increase in the number of conversations that people will engage in on the risks of alcohol use during pregnancy message topics; and,
- It is less clear whether any behaviour change will occur. However, it is possible that:
  - If labels are complemented by point of sale, posters and other message sources, people *may* report a reduction in the consumption or their intentions to drink during pregnancy.

A 2005 survey<sup>114</sup> of non-pregnant women aged 16–40 years in New Zealand (n=1084) reported that 53% of respondents gave a high rating for a warning label as a source of information on alcohol consumption in pregnancy. A further 17% gave a medium rating and about 30% gave a low rating for a warning label on alcohol containers as a source of information.

Responses to the targeted consultation from the alcohol industry, public health, Governments and others (i.e. academics) offered a similar view that the value in pregnancy warning labels is in their role in communicating and raising awareness of

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<sup>110</sup> International Alliance for Responsible Drinking (IARD). 2017. [‘Policy review: Health warning labels’](#). Washington.

<sup>111</sup> Dumas, A., Toutain, S., Hill, C., Simmat-Durand, S. 2018. [‘Warning about drinking during pregnancy: lessons from the French experience’](#). *Reproductive Health*, 15: 20.

<sup>112</sup> World Health organization. 2017. [‘Alcohol labelling – A discussion document on policy options’](#). Regional Office for Europe.

<sup>113</sup> Wilkinson, C., et al. 2009. [‘Report 2-Alcohol Warning Labels: Evidence of impact on alcohol consumption amongst women of childbearing age’](#). National Drug Research Institute (Curtin University of Technology). Prepared for Food Standards Australia New Zealand (FSANZ).

<sup>114</sup> Paracka, S. M., et al. 2010. [‘Warning labels on alcohol containers as a source of information on alcohol consumption in pregnancy among New Zealand women’](#). *International Journal of Drug Policy*, Vol 21 (4): 302–5.

the advice that pregnant women should not drink alcohol, and a that multifactorial approach is required to facilitate behaviour change<sup>115</sup>. Responses from the public health sector also commented on the important role that pregnancy warning labels play in raising awareness in the broader community about the advice that pregnant women should not drink alcohol and the unique opportunity to communicate the advice for pregnant women not to drink alcohol at the potential point of purchase or consumption. Public health submissions also saw pregnancy warning labels as a preventive health initiative and others saw value in pregnancy warning labels in their ability to signal that alcohol is no ordinary commodity and the need to treat alcohol differently. Some public health sector submissions considered the community had a right to know alcohol was dangerous for pregnant women and that providing this information on alcohol labels was in line with consumer laws.

### ***1.5 Pregnancy warning labels in Australia and New Zealand***

Since December 2011, pregnancy warning labels have been presented on packaged alcoholic beverages on a voluntary basis in Australia and New Zealand.

Not-for-profit organisations established and funded by the alcohol industry, DrinkWise in Australia, and Cheers in New Zealand, have developed a series of logos that alcohol producers can use on their product labels which communicate the message '*it's safest not to drink while pregnant*' using written messages or pictograms (see Figure 1.2 below, noting that these images have been enlarged and combined and do not necessarily reflect the way they are used on alcoholic beverage labels). DrinkWise has developed a manual and label templates for use by industry to guide consistent labelling, which it recently redesigned to further improve clarity (revised logos were made available to the alcohol industry in late 2016).

It is relevant to note that some of the images in the DrinkWise suite of pregnancy warning labels do not provide a pictogram or warning message, and instead direct interested consumers to the DrinkWise website.

In response to the targeted consultation process, some public health sector submissions raised concerns that the current voluntary pregnancy warning labels scheme was not developed through a transparent process and there was no consumer testing undertaken in developing the current suite of voluntary pregnancy warning labels.

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<sup>115</sup> Stockwell, T. 2006. '[\*A Review Of Research Into The Impacts Of Alcohol Warning Labels On Attitudes And Behaviour\*](#)'. Centre for Addictions Research of BC University of Victoria, British Columbia, Canada.

Figure 1.2 Examples of pregnancy warning labels in Australia and New Zealand



Due to the limitations in the available data on the incidence and prevalence of FASD in Australia and New Zealand (discussed above), it is not possible to determine whether the voluntary initiative to place pregnancy warning labels on packaged alcoholic beverages has resulted in changes to the incidence or prevalence of FASD in Australia or New Zealand. A range of complementary initiatives are in place to support FASD prevention, and it would be difficult to attribute any changes in the incidence or prevalence of FASD (if this could be measured) to the voluntary pregnancy warning labelling initiative alone. Submissions to the consultation process agreed with this statement.

While Australia has seen a reduction in the proportion of pregnant women who drink alcohol, it is also not possible to attribute this to one single initiative. Some submissions from the Australian alcohol industry cited a March 2018 online survey conducted by DrinkWise which found that 16% of those who had seen the DrinkWise pregnancy warning labels reduced their alcohol intake and 20% had shared the information with others. Characteristics of survey respondents were not reported and it was therefore not possible to determine whether those who had reduced their

alcohol intake in response to the pregnancy warning labels were pregnant women or those planning a pregnancy. In contrast, other submissions to the targeted consultation process cited literature<sup>116</sup> where young Australians reported that the DrinkWise pregnancy warning labels would not encourage them to drink less alcohol per session or drink less frequently or encourage them to discuss the information with others (this research is discussed in more detail on page 38).

### **Characteristics of effective pregnancy warning labels**

A report prepared by leading Australian public health academics from the National Drug Research Institute (Curtin University of Technology), in collaboration with West Australian Drug and Alcohol Office, National Drug and Alcohol Research Centre (University of New South Wales) and Public Health Advocacy Institute. (Curtin University of Technology) reported that pregnancy warning labels can be considered to be effective<sup>117</sup> if they:

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

For pregnancy warning labels to be effective, coverage of the labelling needs to be high, the warning labels need to be consistent with government recommendations and be seen and understood, believed and trusted by the target audiences.

### **Concerns regarding the current pregnancy warning labels in Australia and New Zealand**

The second evaluation of the voluntary pregnancy warning labels on packaged alcohol undertaken in 2016/17 in Australia (by Siggins Miller)<sup>118</sup> and New Zealand (by the Ministry for Primary Industries)<sup>119</sup> reported that adoption of the voluntary labels has increased. However, some concerns were noted in relation to coverage, consistency and consumer understanding.

The targeted stakeholder consultation about pregnancy warning labels on alcohol also identified further concerns raised by Government and public health organisations in relation to confusing information next to the pregnancy warning labels, the requirement for consumers to visit a website for more information, and poor governance and potential conflicts of interest associated with the current voluntary pregnancy warning labels.

More detail on these concerns is provided in the discussion below.

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<sup>116</sup> Coomber, K. Hayley, A. Miller P.G. 2017. '[Unconvincing and ineffective: Young adult responses to current Australian alcohol product warnings](#)'. *Australian Journal of Psychology*, 70( 2): 131-138.

<sup>117</sup> Wilkinson, C., et al. 2009. '[Report 2-Alcohol Warning Labels: Evidence of impact on alcohol consumption amongst women of childbearing age](#)'. National Drug Research Institute (Curtin University of Technology). Prepared for Food Standards Australia New Zealand (FSANZ).

<sup>118</sup> Siggins Miller. 2017. '[Second evaluation of the voluntary labelling initiative to place pregnancy health warnings on alcohol products](#)'.

<sup>119</sup> Ministry for Primary Industries. 2017. '[Overview report: voluntary pregnancy warning labelling on alcohol products in New Zealand](#)'.

Some of the responses to the targeted consultation from the Australian and New Zealand alcohol industry were of the view that the current voluntary scheme is working well and there are no concerns with its implementation. Other submissions from the alcohol industry raised concerns that not all industry sectors had adopted the voluntary labelling.

### **Coverage**

Australia - In 2016-2017, 48% of all packaged alcoholic beverages available for sale displayed some type of pregnancy warning label. Table 1.4 below presents the coverage of pregnancy warning labels on packaged alcoholic beverages by product group, comparing coverage between the 2013 and 2016/17 evaluations. Ready-to-drink (RTD) beverages had the highest coverage of the warning labels - these beverages are mostly commonly consumed by young women in Australia and New Zealand.

Labelling coverage on wine- the most common type of alcoholic beverage consumed by women in Australia and New Zealand aged over 25 years- was mixed, from 56% for red wine priced under AUD \$20 per bottle to 40% for red wine priced over AUD \$20 a bottle. Craft beer recorded the lowest coverage, with 19% of those products displaying a pregnancy warning label in 2016-17.

**Table 1.4 Proportion of products with pregnancy warning labels by market in Australia**

Product Group	Any pregnancy warning (n/N, %) Previous (2013)	Any pregnancy warning (n/N, %) Current (2016/2017)	Difference
Dark Spirits	116/353 (32.9%)	201/334 (60.2%)	27.3%
White Spirits	63/168 (37.5%)	157/285 (55.1%)	17.6%
RTD	36/162 (22.2%)	218/328 (66.5%)	44.3%
Cider	43/122 (35.3%)	107/298 (35.9%)	0.6%
Int. Beer	43/153 (28.1%)	174/344 (50.6%)	22.5%
Prem/Craft Beer	36/226 (15.9%)	66/340 (19.4%)	3.5%
Full Beer	28/75 (37.3%)	83/214 (38.8%)	1.5%
Mid/light Beer	14/42 (33.3%)	42/121 (34.7%)	1.4%
Red Wine < \$ 20	237/421 (56.3%)	203/361 (56.2%)	-0.1%
Red Wine > \$20	160/472 (33.9%)	131/327 (40.1%)	6.2%
White Wine < \$ 20	198/410 (48.3%)	187/335 (55.8%)	7.5%
White Wine > \$20	161/382 (42.2%)	159/325 (48.9%)	6.7%
Missing	20/34 (58.8%)	0	
<b>Total</b>	<b>1,155/3,020 (38.2%)</b>	<b>1728/3612 (47.8%)</b>	<b>9.6%</b>

The Australian evaluation also analysed the data by market share. Of those products that represent ~75% of the alcohol market, between 51.9% and 97.6% have a pregnancy health warning of some type depending on the product market. After adjusting for market share of each brand, between 39.5% and 100% of those products that represent 75% of the alcohol market carried a pregnancy warning label. Apart from the white wine > AUD \$20 and cider markets, there is evidence that those brands with greater market share are more likely to have a pregnancy warning label. Table 1.5 below provides information on the proportion of products with a pregnancy health warning by product group (adjusted for market share) in Australia.

**Table 1.5 Proportion of products with pregnancy warning labels (adjusted for market share) in Australia**

Product group	Previous (2013)		Current (2016/2017)			
	Unadjusted %	Adjusted %	Sample Brand	Sample SKU	Unadjusted %	Adjusted % (range)
Spirits	18 (37.5%)	46.0%	38	196	149 (76.0%)	79.5% (35.7% - 96.3%)
Wine	71 (73.2%)	78.2%	78	287	209 (72.8%)	-
Red Wine < \$20	-	-	15	76	62 (81.6%)	86.7% (64.0% - 92.7%)
Red Wine > \$20	-	-	29	93	67 (72%)	75.9% (54.2% - 83.7%)
White Wine < \$20	-	-	12	41	40 (97.6%)	99.0% (95.9% - 99.0%)
White Wine > \$20	-	-	22	77	40 (51.9%)	46.6% (39.5% - 61.4%)
Beer	14 (66.7%)	81.3%	12	95	85 (89.5%)	96.0% (80.5% - 100%)
RTD	3 (23.1%)	24.5%	8	63	48 (76.2%)	82.6% (54.0% - 93.7%)
Cider	4 (80.0%)	79.9%	5	34	24 (70.6%)	38.8% (27.4% - 53.9%)
<b>Total</b>	<b>110 (59.8%)</b>	<b>-</b>	<b>141</b>	<b>962</b>	<b>724 (75.3%)</b>	<b>-</b>

In response to the targeted consultation, DrinkWise reported that its work in encouraging industry to adopt the updated logos had resulted in an additional 156 producers downloading the logos for use over the past four months, however, it did

not report whether the producers that downloaded the logos had applied them to their products.

The Winemakers' Federation of Australia reported that it conducted an evaluation of the uptake of the voluntary pregnancy warning label initiative at the end of 2016. The evaluation examined all Australian produced wines, across cask and bottle packaging types, in the top 75% market share sold in Australian outlets. The evaluation found that 90% of Australian produced stock keeping units (SKUs<sup>120</sup>) in that category carried a version of the DrinkWise pregnancy warning label. A total of 426 Australian produced SKUs were examined. The Winemakers' Federation reported that of the 10% of Australian SKUs not carrying a warning pregnancy label, 3% were from one company, which is now progressively adopting the warning message across its entire range. The Winemakers' Federation evaluation did not include vintages prior to 2012, as that pre-dates the voluntary initiative (introduced in Australia in 2011/12). The Winemakers' Federation did not report on what types of DrinkWise pregnancy warning labels were being displayed on these products (e.g. pictogram, warning text or weblink).

Some of the Australian alcohol industry submissions and DrinkWise commented that they are actively working to encourage voluntary uptake of the pregnancy warning labels in their sector, and other areas such as with retailers. One alcohol industry submission expressed disappointment and frustration that after six years of the voluntary pregnancy warning label scheme, there were sectors of the alcohol industry that still had not adopted the voluntary labels.

*New Zealand* - In 2016, 87% of beer, 100% of cider and 82% of straight and 88% of ready-to-drink spirits that represented 90-100% of market share per volume were reported to display some type of pregnancy warning labels. 92% of wine representing 58% of the market share per volume was reported to display some type of pregnancy warning label- See Table 1.6. The New Zealand evaluation did not report on the proportion of SKUs that had a pregnancy warning label.

In response to the targeted consultation, some New Zealand industry stakeholders confirmed that they provide 'How-to' labelling guides, including a recommendation to display a 'pregnancy advisory message'.

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<sup>120</sup> A stock keeping unit (SKU) is a product identification code.

**Table 1.6 Respondents' market share and percentage of products per volume reported to carry a pregnancy warning label in the quantitative industry survey (New Zealand 2016)**

Category of alcohol	Percentage of market share (by volume) covered by responses	Percentage of products (market share by volume) that were reported to carry some form of warning
Beer	approx. 90%	87%
Cider	99.7%	100%
Wine	68%	92%*
Spirits (straight)	95%	82%
Spirits (ready-to-drink)	95%	88%

\* Results include wine produced by the five largest producers that represent 58% of the wine market. An additional 10% of the market was covered by the further 22 responses but it was not possible to determine the percentage of these products carrying a warning.

In response to the targeted consultation, Spirits New Zealand reported that across its members in April 2018, the average uptake for pregnancy warning labels for spirits is 96% and for ready-to-drink beverages is 98%. This compares to 81% and 83% respectively in November 2017. The submission did not report on the types of pregnancy warning labels being used by this industry sector.

### **Factors affecting current coverage**

The current voluntary uptake of pregnancy warning labels may be related to industry awareness of current monitoring and evaluation activities and potential regulation should high coverage not be achieved. If monitoring were to cease, it is possible that adoption of the voluntary labels may reduce. However, some industry responses to the targeted consultation disagreed with this view and considered that current momentum in voluntary pregnancy warning labelling would be sustained regardless of Government monitoring.

Other changes to alcohol labelling (e.g. energy labelling, or other labelling introduced by industry in response to consumer demand e.g. 'gluten free' or recycling messages) could compete for space with pregnancy warning labels, which may also reduce the uptake of the voluntary pregnancy labels. However one industry submission disagreed and considered that other labelling would not impact on the voluntary label adoption.

In surveys with the alcohol industry conducted in New Zealand in 2014 and 2016<sup>121</sup>, the main reasons given for not adopting the voluntary pregnancy warning labels were:

- only comply with mandatory labelling requirements, and therefore would not provide the pregnancy warning messaging unless it became mandatory;
- one industry body does not endorse the pregnancy warning labels;
- it is well known that alcohol should not be consumed when pregnant; and
- using up old stock (labelled prior to introduction of voluntary pregnancy warning labels).

Another factor impacting industry uptake of the voluntary labelling is the lack of perceived benefit to adopt the pregnancy warning labels. One industry submission to the targeted consultation reported that more producers would adopt the voluntary labels if they saw value in pregnancy warning labelling. The submitter considered that at this stage the benefits of the voluntary labels are not apparent. This submitter also

<sup>121</sup> Ministry for Primary Industries. 2017. '[Overview report: voluntary pregnancy warning labelling on alcohol products in New Zealand](#)'.



reported that producers are discouraged from adopting the labelling because the Australian labels and guidance are out of step with international efforts.

### Consistency

Using the DrinkWise and Cheers labels supports a level of consistency in labelling, however the second Australian evaluation of the pregnancy warning labelling initiative also revealed areas of inconsistent messaging.

The field survey conducted as part of the second New Zealand evaluation showed a lot of variation in the type of pregnancy warning messages found on product labels. This is not unexpected due to the voluntary nature of the initiative, but it does mean it is not consistent with the expectation of the New Zealand Government's FASD Action Plan, which is to disseminate clear, unambiguous and consistent messages.

The pictogram was the most common pregnancy warning label used in Australia and New Zealand: 76% of the products sampled in Australia carried the pictogram by itself and over half of the New Zealand products surveyed carried the pictogram.

Of the 24.1% of labels in Australia that used a text warning label, 90.6% of these were consistent with the NHMRC recommendation that it is safest not to drink alcohol while pregnant.

The DrinkWise text: *"It's safest not to drink while pregnant"* was the most commonly used pregnancy warning text in Australia and New Zealand. Three other warning texts were also sighted in the New Zealand field survey: a variation of the DrinkWise text: *"It is safest not to drink <brand name> while pregnant"*; the US mandated warning: *"According to the Surgeon General women should not drink alcoholic beverages during pregnancy because of the risk of birth defects"*; and *"Avoid alcohol during pregnancy"*.

Variation in the type, colour and size of messaging was observed, both for text and pictogram warning text in Australia and New Zealand.

**Figure 1.2- Examples of label variation observed in the New Zealand evaluation**



## Consumer understanding

The 2014 and 2017 Australian evaluations of the voluntary labelling initiative to place pregnancy health warnings on alcohol products showed there was a significant increase in unprompted consumer awareness of health messages or campaigns about not drinking while pregnant, from 62% to 71%.

The major sources of these messages appear to be healthcare professionals or informational posters and pamphlets and other mass mediated educational materials. Without prompting, fewer than 12% of people who were aware of the health messages about drinking while pregnant nominated a label on an alcohol product as the source of information.

The 2016 New Zealand research into consumer awareness reported that few consumers recalled the current pregnancy warning labels without visual prompting, but overall, most of those respondents who recall the warning labels when prompted have a clear understanding that they mean to not drink alcohol while pregnant or possibly pregnant<sup>122</sup>.

However, in the Australian evaluation and New Zealand consumer research, some of the words and colours currently used for pregnancy warning labels were misinterpreted by some people. For example, 38% of consumers (total n=1,488) in the New Zealand research<sup>123</sup> reported the text '*it's safest not to drink while pregnant*' would make them think that drinking some alcohol while pregnant would be okay. Similar findings were reported in the Australian evaluation. The Australian evaluation<sup>124</sup> also reported that 2.6% of respondents (total n=5,622) considered that using a green colour in the pictogram was confusing and suggests that alcohol could be consumed during pregnancy.

In the targeted consultation, DrinkWise reported that it had redesigned its pregnancy warning labels to further improve clarity, and these were made available to the alcohol industry in late 2016. It is unclear whether these redesigned pregnancy warning labels were subject to consumer testing prior to being made available to the industry. DrinkWise considered that the revised pregnancy warning labels would not have been implemented across the majority of products and packaging during the time of the fieldwork for the Australian evaluation.

DrinkWise also reported that the updated DrinkWise Style Guide prescribes that charcoal must be the prominent colour applied to the labels, unless the use of a producer's prominent colour palette is more cost effective. DrinkWise assumed that there are very few products applying a green pictogram as a proportion of the products available, but acknowledged that it does not have data to confirm this assumption.

DrinkWise provided brief results from consumer research on its suite of pregnancy warning labels in March 2018, which include the pregnancy warning pictogram, the

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<sup>122</sup> Rout, J., Hannan, T. 2016. '[Consumer awareness and understanding of alcohol pregnancy warning labels](#).' Wellington: Health Promotion Agency.

<sup>123</sup> Rout, J., Hannan, T. 2016. '[Consumer awareness and understanding of alcohol pregnancy warning labels](#).' Wellington: Health Promotion Agency.

<sup>124</sup> Siggins Miller. 2017. '[Second evaluation of the voluntary labelling initiative to place pregnancy health warnings on alcohol products](#)'.

message ‘*It’s safest not to drink while pregnant*’ and a box that only says ‘*Get the Facts: DrinkWise.org.au*’ with no reference to pregnancy (the DrinkWise suite of pregnancy warning labels is presented at Figure 1.2).

This research involved a three-minute online survey (four questions) with 301 Australian adults aged 18 years and over. DrinkWise reported that this was a nationally-representative sample of those who had purchased packaged alcohol in the previous 12 months. It reported that:

- 74% of those aged 18-40 years who had purchased packaged alcohol in the previous 12 months had seen the DrinkWise pregnancy labels (highest in the 18-24 year age group at 89%);
- the majority (75%) of those surveyed understood the image and the message that ‘It’s safest not to drink while pregnant’;
- 67% thought the labels provided useful information; and
- 41% of the those who had seen the labels reported that they had done something different as a result of seeing this information on alcohol products and packaging, including:
  - sharing the information with others (20%)
  - reducing their consumption (16%)

Public health submissions to the targeted consultation raised concern over whether evaluations of the pregnancy warning labels undertaken by industry or industry-funded organisations like DrinkWise were reliable and not subject to bias or conflict of interest. They noted that industry reports do not undergo the academic publication process such as peer-review and therefore should be treated with caution.

Another piece of literature<sup>125</sup> cited in the responses to the targeted consultation reported quite different results to those reported by DrinkWise. In focus groups of Victorian university students aged 18-25 most participants had never noticed the DrinkWise pregnancy warning labels on alcohol packages before. These young Australians reported that the DrinkWise pregnancy warning labels would not encourage them to drink less alcohol per session or drink less frequently or encourage them to discuss the information with others and that the overall quality of the messages conveyed by the alcohol warning labels was poor. Some reported that the labels did not encourage them to seek further information on the harms of alcohol, including from the DrinkWise website. This study also reported that those who were familiar with alcohol product warnings indicated that the most memorable warning was the pictogram and that some participants considered the pregnancy warning labels to be vague, uninformative and irrelevant to them.

The Foundation for Alcohol Research and Education (FARE) also provided a report from its research<sup>126</sup> on the effectiveness of the current pregnancy warning labels, including their ability to attract attention, be recalled and the potential impact on consumer attitudes, beliefs and behaviours. Research was undertaken with eight focus groups (comprising six to eight participants): four focus groups were with women who were pregnant or trying to conceive, and the other four focus groups were with

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<sup>125</sup> Coomber, K., et al. 2017. ‘[Unconvincing and ineffective: Young adult responses to current Australian alcohol product warnings](#)’. *Australian Journal of Psychology*, 70( 2): 131-138.

<sup>126</sup> Hall & Partners. 2018. ‘[Understanding of consumer information messaging on alcohol products: Focus group testing report](#)’. Foundation for Alcohol Research and Education, Canberra.

key influences such as partners of women who were pregnant or trying to conceive or female peers. Focus groups were held in February and March 2018.

The FARE research reported that focus group participants considered that it has become common knowledge that women should avoid consuming alcohol during pregnancy and, as a result, this has become the social norm. Nevertheless, participants were aware of conflicting advice and anecdotal evidence which led some to believe that consuming ‘small amounts’ of alcohol ‘occasionally’ during pregnancy is unlikely to cause harm. Given their awareness of the advice to avoid alcohol during pregnancy, they did not actively seek out information about pregnancy on alcohol products. Participants also observed that the messaging tended to get lost among other information on the label, especially in examples where the text/pictogram colour blends in with the rest of the label.

FARE reported that the current pictogram was understood to convey the message ‘do not drink alcohol when pregnant’, and mainly served to remind and reinforce what participants already knew. The research found that the pictogram did not appear to communicate the consequences of consuming alcohol during pregnancy and had no discernible impact on the belief held by some that occasionally consuming small quantities of alcohol during pregnancy is unlikely to harm the developing baby.

The FARE research also examined understanding of the text – ‘*it’s safest not to drink while pregnant*’ – which participants interpreted as meaning pregnant women should ‘ideally’ avoid alcohol, rather than providing a clear direction to abstain.

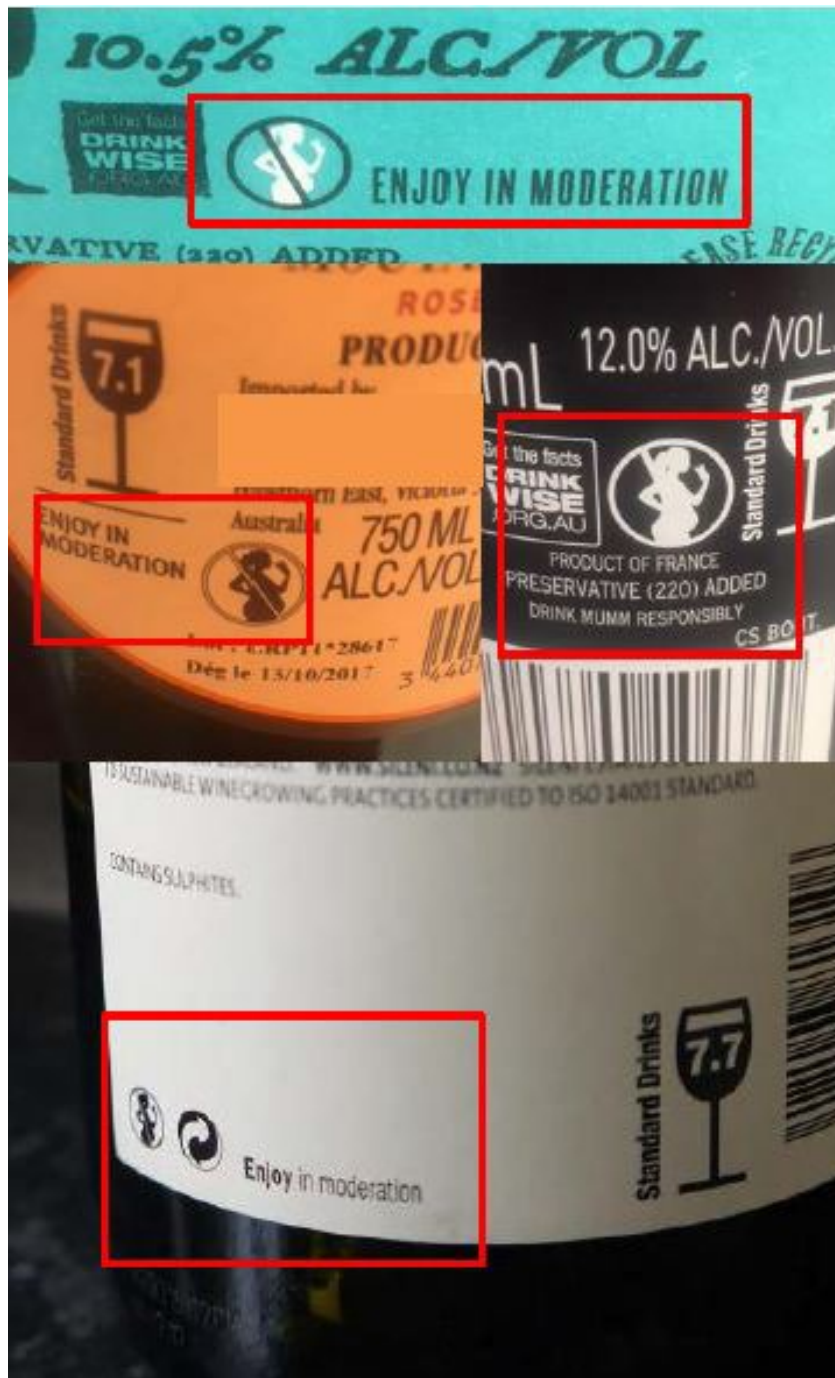
No New Zealand submissions to the targeted consultation provided additional evaluations on consumer understanding of the current pregnancy warning labels.

### **Conflicting label information**

Eighteen submissions (most of which were from the public health sector) raised concerns with the co-location of the pregnancy warning labels with messages such as ‘*Cheers*’, ‘*Enjoy Responsibly*’ ‘*Drink Responsibly*’ and ‘*Enjoy in moderation*’. No evidence was provided on the proportion of products that display these messages next to the pregnancy warning labels. Concerns were raised that these contradictory messages can cause confusion about the recommendations for pregnant women to not drink alcohol and are ambiguous.

One submission raised concern about a product where the pregnancy warning label pictogram is beside an arrow pointing to the words ‘*Drink in moderation*’. A photo of this product is presented in Figure 1.3 together with some other examples of this practice.

**Figure 1.3- Examples of contradictory information next to the pregnancy warning label**



### Information accessibility- requirement to visit a website for more information

Sixteen submissions (most of which were from the public health sector) also raised concerns about the pregnancy warning labels not providing direct information about advice that pregnant women not consume alcohol, but rather advising consumers to 'Get the Facts' and directing to websites such as 'DrinkWise.org.au' and 'Cheers.org.nz'. These submitters considered that the 'Get the facts', DrinkWise logo and DrinkWise website were not pregnancy warning labels, and do not inform consumers of the risks associated with alcohol use during pregnancy.

While no current data was provided on how commonly the 'DrinkWise.org.au' and 'Cheers.org.nz' websites were displayed on alcohol packages, an audit<sup>127</sup> commissioned by the FARE reported that the most commonly observed pregnancy warning label in 2013 was 'Get the facts DrinkWise.org.au' logo used in conjunction with the pregnancy silhouette.

Figure 1.4- Enlargement of the 'Get the Facts' pregnancy warning label



Submissions cited the New Zealand evaluation of pregnancy warning labels by Colmar Brunton<sup>128</sup> in New Zealand which involved an online survey of 1,488 consumers in 2016. In this study, 39% of survey respondents considered that adding the *Cheers.org.nz* website address would make the label less clear. This survey also reported that 28% of consumers are aware of the website *Cheers.org.nz* (although this is higher among young women at 41%).

Some submissions reported that there is no information about drinking alcohol during pregnancy on the DrinkWise website homepage, however, at the time of writing this document (July/August 2018) this appeared to have changed as 'Effects of Alcohol and Pregnancy' is one of the first links that displays on the DrinkWise home page. However, this is not the case on the New Zealand Cheers website where there is no immediately available information on pregnancy and alcohol (website observed in July/August 2018).

Submissions noted a 2015 study<sup>129</sup> in Australia of 561 adults aged 18-45 which reported that 25% of respondents recognised the 'Get the Facts' logo, however, only 7% of respondents had visited the DrinkWise website. Of those who had visited the DrinkWise website, 80% had done so after seeing the 'Get the Facts' logo, and the remaining 20% had visited the website for other reasons. Females were significantly less likely than males to have visited the DrinkWise website.

<sup>127</sup> Ipsos Social Research Institute. 2013. '[FARE Alcohol Label Audit 2013](#)'. Foundation for Alcohol Research and Education, Canberra.

<sup>128</sup> Rout, J. Hannan, T. 2016. '[Consumer awareness and understanding of alcohol pregnancy warning labels](#).' Wellington: Health Promotion Agency.

<sup>129</sup> Coomber, K., et al. 2015. '[Do consumers 'Get the facts'? A survey of alcohol warning label recognition in Australia](#).' *BMC Public Health*, 15: 816. ' *BMC Public Health*, 15: 816.



Submissions also cited the results of focus groups<sup>130</sup> with Victorian university students aged 18-25 where some students didn't realise that the '*DrinkWise.org.au*' as a web address and there were mixed views about the web address' salience. Some participants<sup>131</sup> in this focus group also reported that they were unlikely to visit the website for more information.

One submission from the public health sector cited a report<sup>132</sup> from the Royal Society of Public Health in the UK which reported that consumers are unlikely to visit websites on alcohol labels for health information and that presenting information on the label itself is preferable due to the conscious and proactive decision required for individuals to access information from the website.

This is a concern as the requirement for consumers to visit these websites is not consistent with the unique role that pregnancy warning labels can play in providing information at the potential point of purchase or consumption of alcoholic beverages, and requires at least one additional step for consumers to access this information (first step to visit the website, and the second step may be to search the website for the relevant information).

Public health and Government submitters also raised concerns about the potential conflict of interest associated with directing consumers to alcohol industry funded organisations' websites for health advice. Submitters cited a survey<sup>133</sup> of 467 Australian adults in 2016 where one-third (37%) of those who had heard of DrinkWise were aware that it was an alcohol industry funded organisation, while 84% believed the organisation receives Government funding. Respondents who incorrectly believed DrinkWise receives Government funding were significantly more likely to hold a favourable perception of the organisation's credibility, trustworthiness and respectability than those who did not believe it receives government funding (75.9% vs. 58.3%;  $p=0.032$ ). Similarly, focus groups<sup>134</sup> with 40 young Australians (aged 18-25 years) also reported that participants had rarely heard of DrinkWise and none were aware that it was an alcohol industry funded organisation. Participants familiar with the name 'DrinkWise' believed it to be an Australian government organisation. The researchers noted that by associating the DrinkWise organisation with the authority of the Australian government, consumers may be less likely to question the information offered on the DrinkWise website, or the intended effectiveness of the warning message designs.

If consumers are directed to a website, public health sector submissions considered this should be a government website.

## Placement and size of pregnancy warning labels

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<sup>130</sup> Coomber, K., et al. 2017. '[Unconvincing and ineffective: Young adult responses to current Australian alcohol product warnings](#)'. *Australian Journal of Psychology*, 70(2): 131-138.

<sup>131</sup> The research article did not indicate whether this was a minority or majority of participants who expressed this view.

<sup>132</sup> Royal Society for Public Health (RSPH). 2018. '[Labelling the Point: Towards better alcohol health information](#)'. RSPH, London.

<sup>133</sup> Brennan, E., et al. 2017, '[Public awareness and misunderstanding about DrinkWise Australia: a cross-sectional survey of Australian adults](#)', *Australian and New Zealand Journal of Public Health*, 41( 4): 352-357

<sup>134</sup> Coomber, K. et al. 2017. '[Unconvincing and ineffective: Young adult responses to current Australian alcohol product warnings](#)'. *Australian Journal of Psychology*, 70(2):131-138.



Some public health organisations raised concerns about the placement and size of the current pregnancy warning labels, and whether labels on the back would be noticed by consumers. The 2016/2017 Siggins Miller evaluation<sup>135</sup> found that 65.1% of pregnancy labels on the Australian alcohol packages surveyed were on the back of the product, 20.6% on the side and only 1.6% were on the front (total n= 3,612). The 2017 New Zealand evaluation<sup>136</sup> reported that when used, the pregnancy warning label was predominantly on the back of the packaging with some individual beer packages having it on the side and some on the bottom of a box or pack (percentages were not given, total n= 307).

Public health submitters also raised concerns about the size and legibility of the current pregnancy warning labels. Submissions cited a survey<sup>137</sup> conducted in New Zealand of 59 local and imported beers, wines and ready-to-drink alcoholic beverage containers in 2016/2017 which reported that 80% of products surveyed carried a pregnancy-related warning label, however, on average, pregnancy-related pictograms occupied between 0.13% (wine) and 0.21% (ready-to-drink) of the available surface area of the alcoholic beverage container. The average height of text in the warning labels was 1.6mm. It is important to note that the sampling methods were not randomised and the study sample was small and not representative of products on the market. Furthermore, pictogram size was compared to the total container surface area not the label surface area and therefore does not fairly represent the space available for the pictogram.

Some submissions also cited research with focus groups<sup>138</sup> of young Australians where participants considered that the pregnancy warning labels were small relative to the other label information and difficult to notice due to being placed on the back of the package.

However, submissions from industry noted the Siggins Miller evaluation<sup>139</sup> of pregnancy warning labels compared pregnancy warning labels against FSANZ legibility requirements (total n= 3,612). The majority of pregnancy health labels across all product types were assessed as standard or above in terms of both legibility (93%) and prominence (90%). When legibility was disaggregated by particular product categories, low legibility was observed most commonly amongst international beers (15.5% with low legibility), premium/craft beers (23.8%) and mid-light beer (16.7%). Low prominence was most commonly observed in ready-to-drink beverages (26.1% with low prominence), cider (22.4%) and international beer (24.1%).

One Australian alcohol industry submission to the targeted consultation reported that the DrinkWise pictogram is large and many producers in its sector consider the pictogram takes up too much room on a label. This submission suggested that consideration should be given to reducing the size of the recommended pictogram.

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<sup>135</sup> Siggins Miller. 2017. '[Second evaluation of the voluntary labelling initiative to place pregnancy health warnings on alcohol products](#)'.

<sup>136</sup> Ministry for Primary Industries. 2017. '[Overview report: voluntary pregnancy warning labelling on alcohol products in New Zealand](#)'.

<sup>137</sup> Tinawi, G., et al. 2018. '[Highly deficient alcohol health warning labels in a high-income country with a voluntary system](#)'. *Drug and Alcohol review*, 37(5). 616-626.

<sup>138</sup> Coomber, K., et al. 2017. '[Unconvincing and ineffective: Young adult responses to current Australian alcohol product warnings](#)'. *Australian Journal of Psychology*, 70(2): 131-138.

<sup>139</sup> Siggins Miller. 2017. '[Second evaluation of the voluntary labelling initiative to place pregnancy health warnings on alcohol products](#)'.

The FARE commissioned research<sup>140</sup> reported that focus group participants considered that the current pregnancy warning labels were too small to effectively attract attention.

It should be noted that placement of the pregnancy warning label on the back of the alcohol package is in line with other important food labelling elements, such as allergen declarations and warning labels for pregnant women in regard to caffeinated beverages.

### **Governance of current voluntary labelling initiative**

Public health and Government sector submissions to the targeted consultation raised concerns about the governance of the voluntary pregnancy warning labelling scheme and potential conflicts of interest associated with alcohol industry funded groups Cheers and DrinkWise administering the scheme.

Some submissions cited literature which reported that organisations such as Cheers and DrinkWise promote the interests of the alcohol industry<sup>141</sup>, and that the alcohol industry may mislead the public in relation to health risks of alcohol<sup>142</sup> to justify their concerns associated with DrinkWise and Cheers administering the current voluntary labelling scheme.

Some public health sector submissions cited the Australian Government Guide to Regulation<sup>143</sup> which advises “*self-regulation is a good option where the consequences of market failure are low and the market is likely to move towards an optimal outcome by itself*” and another section of the Australian Government Guide to Regulation which states that “*self-regulation is not a viable option if an industry has no incentive to comply with its own rules*”. Submitters considered that pregnancy warning labels did not meet these requirements, the consequences of market failure can be very serious (i.e. the serious nature of FASD), and the current voluntary labelling scheme has no incentive for the alcohol industry to comply, with no industry sanctions for non-compliance.

One submission argued that the current voluntary scheme does not meet key elements of best practice regulation such as a transparency, regular internal and external monitoring and accountability. An example of a best-practice regulation is set out in the Australian Competition and Consumer Commission (ACCC) *Guidelines for developing effective voluntary industry codes of conduct*<sup>144</sup> which provides guidance on developing an industry Code of Conduct (including through stakeholder consultation), establishing complaints handling mechanisms independent reviews, sanctions for non-compliance, establishing performance indicators, monitoring, accountability and

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<sup>140</sup> Hall & Partners. 2018. ‘[Understanding of consumer information messaging on alcohol products: Focus group testing report](#)’. Foundation for Alcohol Research and Education (FARE), Canberra.

<sup>141</sup> Miller, P.G., et al. 2011. ‘[Vested interests in addiction research and policy. Alcohol industry use of social aspect public relations organizations against preventative health measures](#)’. *Addiction*, 106(9):1560-7.

<sup>142</sup> Peticrew, M., et al. 2017. ‘[How alcohol industry organisations mislead the public about alcohol and cancer](#)’. *Drug and Alcohol Review*, 37(3): 293-303.

<sup>143</sup> Australian Government. 2014. ‘[The Australian Government Guide to Regulation](#)’. Department of the Prime Minister and Cabinet, Commonwealth of Australia, Page 20.

<sup>144</sup> Australian Competition & Consumer Commission (ACCC). 2011. ‘[Guidelines for developing effective voluntary industry codes of conduct](#)’. Commonwealth of Australia.

reviewing. This submitter considered that the current voluntary scheme does not contain the key elements of best-practice industry self-regulation.

## 2. Objectives

Under the *Overarching Strategic Statement for the Food Regulatory System*, the aims of the food regulatory system are to:

- Protect the health and safety of consumers by reducing risks related to food;
- Enable consumers to make informed choices about food by ensuring that they have sufficient information and by preventing them from being misled;
- Support public health objectives by promoting healthy food choices, maintaining and enhancing the nutritional qualities of food and responding to specific public health issues; and
- Enable a strong sustainable food industry to assist in achieving diverse, affordable food supply and general economic benefit.

Providing information on the label of alcoholic beverages about the Government advice that pregnant women should not drink alcohol is in line with the first and second objectives of the Food Regulatory System.

The **primary objective** of pregnancy warning labels on packaged alcoholic beverages is to provide a clear and easy to understand trigger to remind pregnant women, at both the point of sale and the potential point of consumption, to not drink alcohol.

A **secondary objective** of pregnancy warning labels on packaged alcoholic beverages is to provide information to the community about the need for pregnant women to not drink alcohol.

The second objective recognises the importance of communicating the advice that pregnant women should not to drink alcohol to partners, friends and family of pregnant women, and women planning a pregnancy. Cultural norms and a supportive network of family and friends are recognised factors that can encourage women not to drink alcohol when pregnant<sup>145,146,147,148</sup>.

To target the primary audience of the pregnancy warning labels, it is important that pregnancy warning labels are present on the packages of alcoholic drinks most commonly consumed by women of child bearing age in Australia and New Zealand – wine, spirits and ready-to-drink spirits. However, as all types of alcoholic beverages are equally harmful, the warning labels should appear on all types of alcoholic beverages. Furthermore, as the secondary audience for these warning labels is the broader community, it is important that pregnancy warning labels appear on all types of alcoholic beverages to help establish cultural norms and inform pregnant women's support networks of the advice for pregnant women not to drink alcohol.

<sup>145</sup> Healthy Child Manitoba. '[Alcohol, pregnancy and partner support](#)'. Manitoba, Canada.

<sup>146</sup> McLean, S., McDougall, S. 2014. '[Fetal alcohol spectrum disorders Current issues in awareness, prevention and intervention](#)'. Australian Institute of Family Studies, Australian Government.

<sup>147</sup> Holland, K., McCallum, K., Blood, R.W. 2015. '[Conversations about alcohol and pregnancy](#)'. Canberra: Foundation for Alcohol Research and Education.

<sup>148</sup> New Zealand Health Promotion Agency. 2016. '[Attitudes to drinking in pregnancy: Attitudes and behaviour towards alcohol survey 2015/16](#)'. Wellington: New Zealand Health Promotion Agency.

### **Case-study: Warning labels on tobacco products.**

Other teratogens (substances that can inhibit the healthy development of the fetus) are either completely banned from use in products which are designed to be consumed by people and/or illegal (e.g. cyhexatin and methamphetamine); only used when there is no better alternative, under medical supervision, and carry a warning label on packaging (e.g. some medications).

Mandatory warning labels are used for tobacco.

The Australian Government has mandatory warning labels for tobacco products under the *Competition and Consumer (Tobacco) Information Standard 2011* (in addition to plain packaging requirements which were introduced under separate legislation).

Smoking when pregnant harms the unborn baby, and one of the health warning statements required on cigarette packages, and most other smoked tobacco products, reads 'smoking harms unborn babies' which is accompanied by a large photograph of a premature baby and explanatory text providing more detailed information on the harm caused by smoking while pregnant.

Cigarette packages are recognised as a prominent source of health information and smokers have reported that warning labels have prompted them to reduce their consumption levels, increase their motivation and likelihood of quitting and increase the likelihood of remaining abstinent following an attempt to quit. It is also relevant to note that there is evidence that, in relation to tobacco products, pictorial messages are superior, no matter how clear the warning text may be. Text-based warnings may be less effective with young people, less educated people and people with poorer reading skills<sup>149</sup>.

The 'smoking harms unborn babies' warning (with picture) has undergone market testing<sup>150</sup> which reported that the warning reminded smokers of the harmful implications of smoking during pregnancy and also prompted thoughts about the harmful effects of second-hand smoke on 'others'. It is acknowledged that this is not directly comparable to pregnancy warning labels on packaged alcoholic beverages, because drinking alcohol near a pregnant woman would not cause direct harm to an unborn child (unlike exposing a pregnant woman to the effects of second-hand smoke), and therefore such graphic warning labels are not being proposed for alcohol products.

The AIHW<sup>151</sup> reports that rates of smoking during pregnancy have declined in Australia. However, it is well recognised that these declines, and declines in smoking across the population, are a result of concerted, sustained, and comprehensive public policy efforts from all levels of government and action<sup>152</sup>, including, in addition to labelling tobacco products with graphic health warnings, staged excise increases on tobacco products; education programs; national tobacco campaigns; plain packaging

<sup>149</sup> Wilkinson, C., et al. 2009. '[Report 2-Alcohol Warning Labels: Evidence of impact on alcohol consumption amongst women of childbearing age](#)'. National Drug Research Institute (Curtin University of Technology). Prepared for Food Standards Australia New Zealand (FSANZ).

<sup>150</sup> GfK Blue Moon. 2011. '[Market Testing of Potential Health Warnings and Information Messages for Tobacco Product Packaging: Phase 2 Front and Back of Pack Graphic Health Warnings Qualitative Formative Research Report](#)'. Prepared for the Department of Health and Ageing, Canberra.

<sup>151</sup> Australian Institute of Health and Welfare (AIHW). 2016. '[Australia's Health 2016](#)'. Australia's health series no. 15. Cat. no. AUS 199. Canberra: AIHW.

<sup>152</sup> Australian Government Department of Health. 2017. '[Tobacco Control Timeline](#)'.

of tobacco products; prohibiting tobacco advertising, promotion and sponsorship; and providing support for smokers to quit, including through nicotine replacement therapies on the Pharmaceutical Benefits Scheme.

In New Zealand, graphic health warnings on cigarettes were mandated in the Smoke-free Environments Regulations 2007, including warnings against smoking whilst pregnant. In March 2018 the Smoke-free Environments (Tobacco Standardised Packaging) Amendment Act 2016 will come into force which includes pictures and warnings including ‘smoking harms your baby before it is born’ and ‘smoking when pregnant harms your baby’.

Whilst lessons can be learnt from the health warnings on tobacco when considering pregnancy warning labels for packaged alcohol, alcohol and tobacco differ in many respects. No level of tobacco consumption is considered low risk for anyone, and the aim of public health initiatives is to encourage people not to commence smoking at all or to quit if they do. While for pregnant women no level of alcohol consumption is safe for the health of the unborn child, for the general public the message is to consume alcohol in moderation.

As is the case for tobacco, for preventing the misuse of alcohol, no single intervention is effective on its own and pregnancy warning labels are part of a range of complementary initiatives that seek to contribute to FASD prevention.

### 3. Statement of options

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, regulatory and non-regulatory options were considered and their effectiveness assessed as to whether they could achieve:

- the highest coverage of pregnancy warning labels across all types of alcoholic beverages;
- pregnancy warning labels that are clearly understood by the target audiences and consistent with Government recommendations.

The options assessed were: status quo, mandatory pregnancy warning labels, and continuation of voluntary pregnancy warning labels- with two variations of voluntary labelling proposed<sup>153</sup>.

The section below discusses each of the options considered and provides feedback from the targeted stakeholder consultation about each option and considers the extent to which each option can achieve the highest coverage, consistency and consumer understanding.

For each of the proposed options, pregnancy warning labels should be based on evidence about the most appropriate and easy to understand pregnancy warning label to discourage drinking alcohol during pregnancy. Some of this evidence is provided in [Appendix 2](#); however, it is recommended that further consumer testing be undertaken to inform the specific details about which pregnancy warning labels would be implemented (i.e. colour, wording, and pictogram)

#### ***3.1 Option 1a- Status quo.***

##### **Description**

Industry discretion is permitted as to whether to apply pregnancy warning labels, and which labelling to apply to products with the option to use the DrinkWise or Cheers label designs, or any other label design. The status quo is described in Section 1.5 of this document.

#### ***3.2 Option 1b- Voluntary industry self-regulated***

##### **Description**

Groups such as DrinkWise or Alcohol Beverages Australia in Australia could introduce a self-regulatory approach for industry to adopt the pregnancy warning labels. In New Zealand, this would likely be the role of industry bodies (who would have to work together), or an overarching group such as Cheers.

The industry group(s) could develop and administer a code of practice that alcohol producers voluntarily sign up to. Alternatively, Food Standards Australia New

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<sup>153</sup> Readers should note that consultation on policy options for recommendation 26 of the Labelling Logic report (energy labelling on alcoholic beverages) is also currently being undertaken in parallel to recommendation 25 (pregnancy warnings on alcohol). However it is acknowledged that these are being undertaken as separate processes. Please refer to the [food regulation website](#) for more information on consultations for recommendation 26.



Zealand (FSANZ) may also develop a code of practice, as part of its functions. Involving FSANZ can help to achieve consistency in regulatory approaches and labelling across Australia and New Zealand.

The code of practice could follow the guidance set out in the ACCC *Guidelines for developing effective voluntary industry codes of conduct*<sup>154</sup>.

The code of practice would require signatories to commit to presenting pregnancy warning labels on all the packaged alcoholic beverages that they produce. The code of practice would outline how the pregnancy warning labels would be presented to ensure that the message is clear, consistent with government recommendations, and understood by the target audience(s) (refer to [Appendix 2](#)). The code of practice may also encourage signatories to provide other health information on product labels.

The industry group that leads the code of practice would be responsible for administering and enforcing the code of practice, encouraging alcohol producers to become signatories, monitoring signatories' compliance with the code of practice, working with signatories that are not complying with the code of practice to improve their labelling, and publishing reports on the number of signatories and compliance with the code of practice. Sanctions for signatories to the code of practice who are non-compliant would be determined by industry.

In response to the targeted consultation, DrinkWise indicated that it would be willing to administer an industry code of practice in relation to pregnancy warning labels on alcohol. However, one Australian alcohol industry submission expressed reservations about how a DrinkWise code of practice would work, how it would be implemented and its ultimate effectiveness. Another Australian alcohol industry submission commented that there needs to be additional work done to identify the correct industry body to oversee the code of practice and that existing bodies may not be appropriate.

New Zealand stakeholders did not indicate an interest in leading an industry code of practice for pregnancy warning labels on alcohol but supported the formation of an industry and government working group to develop a code of practice/guidelines. More than one New Zealand industry submission suggested the New Zealand Advertising Standards Authority could oversee the code of practice.

One Australian alcohol industry submission raised concern over the compliance burden that this option would introduce, which it considered would disproportionately impact on smaller producers. This industry submission considered that the industry self-regulated option offered no additional value to the current system of voluntary pregnancy warning labels.

In response to the targeted consultation, submissions from public health organisations raised concerns about conflicts of interest associated with this option and concerns that this option would preclude Government and public health organisations and relevant independent experts from having a role in designing the scheme and revising pregnancy warning labels. However, some industry submissions reported they were willing to involve Government in this work and draw on Government's expertise.

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<sup>154</sup> Australian Competition & Consumer Commission (ACCC). 2011. '[Guidelines for developing effective voluntary industry codes of conduct](#)'. Commonwealth of Australia.



The experience of the United Kingdom<sup>155</sup> was raised by one public health organisation, where the Royal Society for Public Health attempted to collaborate with the Portman Group (a not-for-profit organization funded by alcohol companies) to undertake research about what best-practice alcohol labelling might look like and develop recommendations that were supported by industry (given that industry would be the ones to implement them). These groups were unable to reach a consensus and eventually published separate and different alcohol labelling guidelines<sup>156</sup>.

### **Current examples of industry self-regulation**

The Responsible Children's Marketing Initiative (RCMI) and the Quick Service Restaurant Initiative for Responsible Advertising and Marketing to Children (QSRI) by the Australian Food and Grocery Council (AFGC)<sup>157</sup>. AFGC manages the RCMI and QSRI in line with the Australian Competition and Consumer Commission's Guidelines for developing effective voluntary industry codes of conduct. This includes regular monitoring of compliance with the initiatives, the effectiveness of the initiatives in achieving their objectives and the commissioning of independent reviews.

Some public health sector submissions raised concerns about the examples of industry self-regulatory models described above and considered them ineffective. They cited research which reported no change in the rate of unhealthy food advertising since the RCMI and QSRI schemes were introduced<sup>158</sup> and that the design and administration of the schemes does not follow best practice self-regulation<sup>159</sup>.

Another example of a self-regulatory model is the New Zealand Advertising Standards Authority Code for Advertising and Promotion of Alcohol<sup>160</sup>, which requires all alcohol advertising and promotion to adhere to the principles and guidelines contained in the Code. The Association of New Zealand Advertisers is responsible for administering the advertising industry's voluntary system of pre-vetting all alcohol advertisements.

Submissions from Australian industry also cited the Beverages Advertising Code (ABAC) as an example of an industry code of practice, which industry considered to be highly effective. However, several submissions from public health stakeholders cited the ABAC as an example of an ineffective self-regulatory approach from the alcohol industry as many alcohol producers are not signatories to the ABAC and the governance arrangements were considered to be subject to conflicts of interest<sup>161</sup>.

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<sup>155</sup> Royal Society for Public Health (RSPH). 2018. '[Labelling the Point: Towards better alcohol health information](#)'. RSPH, London.

<sup>156</sup> Portman Group. 2017. '[Communicating alcohol and health-related information](#)'. Portman Group's Advisory Service, UK.

<sup>157</sup> Australian Food and Grocery Council. '[Advertising to Children](#)'.

<sup>158</sup> Watson, W.L. et al. 2017. '[Advertising to children initiatives have not reduced unhealthy food advertising on Australian television](#)'. *J Public Health (Oxf)* 1;39(4):787-792.

<sup>159</sup> Reeve, B. '[Self-Regulation of food advertising to children: An effective tool for improving the food marketing environment?](#)' *Monash University Law Review* (Vol 42, No 2)

<sup>160</sup> New Zealand Advertising Standards Authority '[Code for Advertising and Promotion of Alcohol](#)'.

<sup>161</sup> Pierce, H., Stafford, J. 2017. '[How to regulate alcohol marketing](#)'. *MJA InSight*, 34/4.

The New Zealand alcohol industry also provided another example of this approach: the *Voluntary Industry Code for RTDs*<sup>162</sup> by the Distilled Spirits Association of New Zealand which governs the production of ready-to-drink (RTD) beverages and limits their alcohol content to a maximum of two standard drinks. The Code also limits caffeine content of ready-to-drink beverages.

Another example is the European Beer Pledge<sup>163</sup>, where members of an association representing European brewers have committed to taking action to improve consumer information by providing, among others, the nutrition information on beers.

### **Extent to which this option can achieve the highest coverage, consistency and consumer understanding**

The majority of submissions from alcohol industry groups to the targeted consultation process considered that this option provided the greatest opportunity to ensure that coverage of the pregnancy warning labels 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 targeted audiences. Some responses from industry considered that this option offered the opportunity to tailor the message to the consumer which would provide the highest comprehension, however this would negate the consistency required. While many industry submissions did not respond to the question about which option is likely to achieve the greatest level of awareness amongst the target audiences about the need for pregnant women to not drink alcohol, those who did considered that this option was the best for raising awareness. This was justified by the view that it would allow continuation and improvements to the current voluntary system and that other options would lose the progress that has been achieved so far. No public health, government or other (e.g. consumer, academics) shared industry's views in this regard. Some public health submissions considered that conflicts of interest would mean that industry would not require strong and meaningful pregnancy warning labels for signatories to the industry code of practice.

Taking everything into account, it is unlikely this option will achieve sufficiently high coverage of the pregnancy warning labels as it offers no power to encourage industry to voluntarily become signatories to the proposed code of practice. The voluntary pregnancy warning labels have been in place since 2011 and the latest evaluation reported that less than 50% of packaged alcohol products display a pregnancy warning label in Australia. An industry code of practice may not encourage producers who have not adopted the voluntary labelling to change their practices. While reputational benefit may be one incentive to become a signatory, one submission from industry considered that consumers place higher value on other industry behaviours such as recycling. The mixed response from the alcohol industry about a suitable organisation to lead the self-regulated code of conduct indicates that there is a risk of internal disagreements within industry which may impact the number of producers that become signatories to the proposed code of practice. In New Zealand industry groups expressed interest in a joint industry government working group to develop the proposed code of practice in New Zealand which could increase the chance of this approach being successfully implemented in New Zealand.

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<sup>162</sup> Distilled Spirits Association of New Zealand. '[Voluntary Industry Code for RTDs](#)'.

<sup>163</sup> The Brewers of Europe. '[European Beer Pledge](#)'.

Some industry submissions stated they are open to revising the current pregnancy warning labels to support improved consumer understanding. In this case, some producers that have currently adopted the voluntary pregnancy warning labels would need to change their labels to improve consumer understanding of the pregnancy warning labels and comply with the proposed industry code of practice, and there is no assurance that they would do so. As a result there is a risk that this option may result in increased variation in the labelling on the market and not overcome the current concerns in relation to consumer misunderstanding, conflicting label information and the need for consumers to visit a website to receive a warning message.

### ***3.3 Option 1c- Voluntary with Government style guide***

#### **Description**

Voluntary labelling with evidence based style guide developed by Government, with input from public health groups and industry. Pictures and wording in the style guide would be the one shown to be most effective (see [Appendix 2](#)) and may include a warning pictogram, or text or both.

Government would monitor compliance with the style guide. Alcohol producers can choose to follow the Government style guide, but industry would not have to sign up to a code or pledge to follow the style guide.

Can align with international voluntary agreements and allows flexibility for any future changes in international guidelines, research and evidence.

Some submissions from industry considered that the Government style guide would duplicate the existing work of organisations such as DrinkWise and suggested that the work put into developing the Government style guide would be redundant.

#### **Current examples of a voluntary approach with a Government style guide**

Health Star Rating (HSR) is a voluntary front of pack nutrition labelling scheme developed by the Australian, state, territory and New Zealand governments in collaboration with industry, public health and consumer groups.

The HSR system style guide and guide for industry on using the HSR calculator provides guidance for the application of the HSR system on food packages. The style guide allows the HSR system to be implemented consistently. Food producers and retailers are responsible for the correct and accurate use of the HSR system.

Some submissions in the targeted consultation raised concerns about the potential effectiveness of a model such as the HSR, as not all of the food industry has adopted the voluntary HSR labelling scheme<sup>164,165</sup>.

Another submission considered that the HSR was not an appropriate example of this option because the HSR can encourage consumers to purchase and consume a product

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<sup>164</sup> Jones, A., Radholm, K., Neal, B. 2018. '[Defining 'Unhealthy': A Systematic Analysis of Alignment between the Australian Dietary Guidelines and the Health Star Rating System](#)'. *Nutrients*, 10(4).

<sup>165</sup> Health Star Rating Advisory Committee. 2017. '[Two year progress review report on the implementation of the Health Star Rating system – June 2014 – June 2016](#)'.

(depending on the rating of the product), whereas pregnancy warning labels discourage consumption. It is noted that products that would receive a low HSR, are less likely to display the HSR on the packaging<sup>166</sup>. The HSR can also encourage industry to reformulate (e.g. develop a product with less sugar or salt) to achieve a better HSR, whereas, there is no safe level of alcohol for pregnant women.

One submission from the public health sector cited a report<sup>167</sup> about the United Kingdom's (UK) alcohol labelling experience. In 2007 the UK Government developed a voluntary agreement with the alcohol industry for health information on alcohol labels, including a pregnancy warning label as agreed by the UK Chief Medical Officers (the statement '*Avoid alcohol if pregnant or trying to conceive*'). However, a 2008 audit of labels revealed that industry generally did not adopt the UK Government's recommended pregnancy warning label and used alternate labels or wording. Other aspects of Government's labelling recommendations were also not widely adopted by industry, and industry tended to alter Government's preferred labels and information. Another publication<sup>168</sup> on US voluntary labelling reported that the objectives of clear, legible health warning labelling were not achieved as just over half (57%) of alcohol products surveyed met best practice with font and logos smaller than would be accepted on other products with health effects.

### **Extent to which this option can achieve the highest coverage, consistency and consumer understanding**

Only one public health and one alcohol industry submission to the targeted consultation process considered that this option provided the greatest opportunity to ensure that coverage of the pregnancy warning labels 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 targeted audiences.

This option has high potential to achieve good consumer understanding and consistency with government recommendations as it provides the opportunity to undertake consumer testing and research to design pregnancy warning label(s) that are best understood by the target audience, drawing on Government and external communication expertise. However, given the limited support from industry on this option based on consultation responses, there is a risk that this option will not achieve high coverage and increase variation in the pregnancy warning labels on the market. As a result this could reduce the opportunity to communicate effectively with the target audience.

Two industry submissions saw this option as unnecessary and redundant. If this view is shared by the broader alcohol industry there is a risk that the style guide may not be widely adopted by industry. This would consequently increase the variation and inconsistency in the pregnancy warning labels on the market as some industry may adopt the style guide, and others maintain the labelling under the status quo. In this scenario, the work to develop the style guide would be redundant and an inefficient use of Government time and funds.

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<sup>166</sup> Health Star Rating Advisory Committee. 2016. '[Two year progress review report on the implementation of the Health Star Rating system – June 2014 – June 2016](#)'.

<sup>167</sup> Eurocare – European Alcohol Policy Alliance. 2009. '[Labelling initiatives: A brief summary of health warning labels on alcoholic beverages](#)'. Belgium.

<sup>168</sup> Petticrew, M., et al. 2016. '[Health information on alcoholic beverage containers: has the alcohol industry's pledge in England to improve labelling been met?](#)' *Addiction*, 2016 Jan;111(1):51-5.

As industry did not support this option, it is unlikely to improve coverage in pregnancy warning labels and engage those sectors in the industry which have not adopted the warning labels.

### **3.4 Option 2- Mandatory**

#### **Description**

Mandated through the Australia New Zealand Food Standards Code. Code requirements apply to domestic and imported products. There would be penalties for non-compliance which would be enforced by the existing food enforcement authorities, i.e. Australian state and territory Governments, the Australian Government Department of Agriculture and Water Resources (for imported foods) and the New Zealand Government. While this would increase enforcement workloads in these Government agencies, they already have systems and expertise to do this as they currently enforce other elements of alcohol labelling required under the Australia New Zealand Food Standards Code. These agencies also work together through the Implementation Sub-Committee for Food Regulation (a FRSC sub-committee) to ensure food standards are implemented and enforced consistently. No Government submissions raised concerns regarding their capacity to enforce the mandatory option.

It is anticipated that consideration would be given to pregnancy warning label designs that have been shown to be most effective (see evidence at [Appendix 2](#)). Transition period and stock-in-trade exemptions could be considered to allow time for industry to adopt new regulations and reduce costs associated with labelling changes.

One Government and some public health sector submissions noted that mandatory approaches to labelling are recommended for first tier issues under the Australian and New Zealand Food Policy Labelling Conceptual Framework<sup>169</sup>. This framework was designed to guide decision making on government intervention on food labelling issues and first tier issues are those that pose an immediate, acute and direct threat to health. These submissions considered alcohol consumption in pregnancy was a first tier issue due to the severe and direct impacts on the developing fetus if a pregnant woman drinks alcohol.

In response to the targeted consultation, the alcohol industry raised several concerns about the mandatory option, including concerns that it would require them to produce different labels for domestic and export markets. Some considered that this would result in exporting products being cost prohibitive. However, public health sector responses considered that the alcohol industry already do this when exporting to countries with mandatory pregnancy warning labels. This issue was not listed as a 'con' in the section below, as with all options (including the status quo), industry may be required to change labels to meet various requirements of export markets. The benefits of international consistency in pregnancy warning labels are noted.

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<sup>169</sup> Food Standards Australia New Zealand (FSANZ). '[Overarching Strategic Statement for the Food Regulatory System](#)'.

## Current examples of mandatory labelling

Other elements of alcohol labels are regulated under Parts 1.2 '*Labelling and other information requirements*' and 2.7 '*Alcoholic beverages*' of the Australia New Zealand Food Standards Code, including:

- alcohol by volume;
- standard drink labelling;
- specific representations about alcoholic beverages (e.g. low alcohol);
- nutrition information requirements (currently when a claim is made regarding energy, carbohydrate or gluten).

Pregnancy advisory statements are required on formulated caffeinated beverages due to their caffeine content. Standard 2.6.4- *Formulated caffeinated beverages* in the Australia New Zealand Food Standards Code requires an advisory statement to the effect that:

- (a) the food contains caffeine; and
- (b) the food is not recommended for:
  - i. children; or
  - ii. pregnant or lactating women; or
  - iii. individuals sensitive to caffeine.

Standard 2.9.4 '*Formulated Supplementary Sports Foods*' in the Australia New Zealand Food Standards Code also requires a mandatory statement '*Not suitable for children under 15 years of age or pregnant women: Should only be used under medical or dietetic supervision*'.

## Extent to which this option can achieve the highest coverage, consistency and consumer understanding

All public health, government and other (i.e. academics and consumer representatives) considered that this option provided the greatest opportunity to ensure that coverage of the pregnancy warning labels is high across all types of packaged alcoholic beverages; that pregnancy warning labels are consistent with government recommendations and are that they see and understood by the targeted audiences. Public health, government and other submissions also considered that this option offered the greatest opportunity to achieve the greatest level of awareness amongst the target audiences of the need for pregnant women not to drink alcohol and some cited research<sup>170</sup> from the United States where the introduction of mandatory health warning labels on packaged alcohol (including pregnancy warning labels) led to an increase in awareness of the messages that the warning labels contained. No industry submissions shared these views.

Taking everything into account, this option provides the greatest opportunity to achieve the highest coverage of pregnancy warning labels across all alcohol products. There are some alcohol producers that only adopt mandatory elements of alcohol labelling, and this is the only option that will reach these producers. This option also can reach those producers who report that they don't endorse pregnancy warning labels, or that they see no value in adopting the voluntary labelling.

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<sup>170</sup> Stockwell, T. 2006. '[A Review Of Research Into The Impacts Of Alcohol Warning Labels On Attitudes And Behaviour](#)'. Centre for Addictions Research of BC University of Victoria, British Columbia, Canada.



The mandatory option also ensures that pregnancy warning labels are consistent with government recommendations, and other pregnancy warning labels in the Australian and New Zealand market as the requirements for the pregnancy warning labels would be set out in the Australia New Zealand Food Standards Code. It is anticipated that these pregnancy warning label requirements would be based on consumer testing and research on pregnancy warning label(s) that are best understood by the target audience, drawing on Government and external communication expertise.

Coverage and consistency can be ensured because pregnancy warning labels would be mandatory and penalties can be enforced for non-compliance.

### ***3.5 Other possible options***

The targeted consultation asked whether stakeholders could suggest alternate options than those proposed above.

New Zealand industry submitters proposed a variation of option 1b), which would be a continuation of voluntary labelling with improved guidelines, to be developed by an industry/government working group (led by FSANZ). Industry suggested that this option could be applied in New Zealand through utilising the food control system. All food businesses in New Zealand are required to have some kind of documented food control/national plan dealing with safety. An additional ‘insert’ could be developed for the purposes of labelling packaged alcoholic beverages for the relevant producer/importer.

An Australian industry submission suggested that alcohol retailers, especially the major chains, could enter a Memorandum of Understanding with DrinkWise which would require all alcohol products to bear the DrinkWise pregnancy warning pictogram on labels, or not be stocked in their outlets. Implementation details such as this would be considered during the implementation of the preferred option.

These suggestions are largely describing a possible implementation approach for Option 1b, and therefore were not assessed as a separate option.

Some public health stakeholders also suggested price signalling such as taxes and minimum pricing for alcohol, however these were not considered reasonable options to achieve the desired outcome of providing 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.



Some industry groups also commented that regulatory options should target only those producers that are not currently displaying a pregnancy warning label, and considered that regulatory action on producers who have already adopted the pregnancy warning labels was unnecessary and would be a form of ‘punishment’. Given the issues with the current pregnancy warning labels noted in Section 1.5, regulating only those producers that are not currently adopting the pregnancy warning labels was not considered as it would not enable the issues such as consumer misunderstanding, conflicting information and requirement to visit a website to be addressed.

## **4. Impact analysis (Costs and Benefits)**

This section provides an analysis of the impacts of the options under consideration, including their pros and cons, costs and benefits, and economic and social impacts.

### ***4.1 Pros and cons***

Pros and cons of options 1b, 1c and 2 are provided in Table 4.1 below, relative to the status quo.

Stakeholders were asked for their views on the pros and cons of the different options under consideration and these have been incorporated into the document where appropriate. Some of the pros and cons provided were in relation to the other options, rather than the status quo and these comments were only incorporated where possible. In some instances, pros and cons of the different options put forward in the targeted consultation document were rebutted. For example, some public health organisations found it concerning that the consultation document identified trade implications for Australia and New Zealand as an issue associated with mandatory labelling.

**Table 4.1 Pros and cons of the proposed options compared to the status quo**

Option	Pros	Cons
Option 1 b- Voluntary industry self- regulated	<ul style="list-style-type: none"> <li>• Code of practice can provide directions to signatories to address the issues identified in this paper such as consumer misunderstanding of the pregnancy warning labels, contradictory messages and requirement to visit a website.</li> <li>• More transparency in reporting which industry groups are signatories and the extent to which they are meeting the requirements of the code of practice.</li> <li>• Regular monitoring and public reporting by industry on compliance with the Code of Practice.</li> <li>• Opportunity to involve FSANZ in the development of the Code of Practice allows for best practice regulatory design to be introduced.</li> <li>• Most industry groups that submitted to the targeted consultation indicated a preference for a scheme such as this and a willingness to participate.</li> <li>• Consistency in pregnancy warning labels amongst alcohol industry groups that adopt the code of practice.</li> </ul>	<ul style="list-style-type: none"> <li>• Some industry groups (a minority) don't support this option and have raised concerns over the associated reporting and compliance burden.</li> <li>• Cost to industry to change labels to comply with new code of practice.</li> <li>• Cost to an industry body to administer to code of practice, monitor and report on compliance.</li> <li>• Could potentially increase variation in pregnancy warning labels in the market with some industry groups following the status quo, and others adopting the code of practice.</li> </ul>
Option 1c- Voluntary with Government style guide	<ul style="list-style-type: none"> <li>• Opportunity for the style guide to give to directions to industry to address the issues identified in this paper such as consumer misunderstanding and contradictory messages.</li> <li>• Style guide would apply to both Australia and New Zealand and therefore potentially increase consistency in labelling across both countries.</li> </ul>	<ul style="list-style-type: none"> <li>• Cost to industry to change labels to comply with new Government style guide.</li> <li>• Some industry groups don't support this option and see it as duplicative and unnecessary.</li> <li>• May not achieve better coverage or consistency compared to the status quo, as not all industry groups or companies may elect to follow the Government style guide.</li> </ul>

Option	Pros	Cons
	<ul style="list-style-type: none"> <li>• The Siggins Miller<sup>171</sup> evaluation reported that both industry and public health sectors support a minimum standard set by government for consistent content, size, and placement of pregnancy health warning labels.</li> <li>• Opportunity for communication experts, the public and consumer and public health organisations to have input into Government style guide.</li> <li>• Some industry groups (a minority) that submitted to the targeted consultation have indicated support for this option.</li> </ul>	<ul style="list-style-type: none"> <li>• Could potentially increase variation in pregnancy warning labels in the market with some industry groups following the status quo, and others adopting the new style guide.</li> <li>• Cost and workload for Government to develop the style guide.</li> </ul>
Option 2-Mandatory	<ul style="list-style-type: none"> <li>• Opportunity to address the issues identified in this paper such as consumer misunderstanding, contradictory messages and requirement to visit a website.</li> <li>• Level playing field for industry as all industry need to comply with the mandatory requirements.</li> <li>• Open and transparent process for establishing the requirements for pregnancy warning labels.</li> <li>• Consistent with other pregnancy advice on food labels such as formulated caffeinated beverages and formulated supplementary sports foods which require mandatory statements to advise that the products are not recommended/suitable for pregnant women.</li> </ul>	<ul style="list-style-type: none"> <li>• Cost to industry for compliance (the extent of which will depend on how the requirements in the proposed Australia New Zealand Food Standards Code compare to current industry practices).</li> <li>• For producers of smaller packages (e.g. 50ml bottles) it may not be physically possible to accommodate a pregnancy health warning without substantial change to the current package / labelling.</li> <li>• Increased workload for regulators.</li> <li>• Cost and work for Government to introduce mandatory labelling into the Australia New Zealand Food Standards Code.</li> <li>• Would require imported products to comply with the Australia New Zealand Food Standards Code requirements.</li> </ul>

<sup>171</sup> Siggins Miller. 2017. '[Second evaluation of the voluntary labelling initiative to place pregnancy health warnings on alcohol products](#)'.

Option	Pros	Cons
	<ul style="list-style-type: none"> <li>• Consistent with the way other teratogens such as tobacco and some medications are required to carry mandatory warning labels.</li> <li>• The Australia New Zealand Food Standards Code applies to both Australia and New Zealand and therefore would increase consistency in labelling across both countries.</li> <li>• Will reach industry groups that do not display pregnancy warning labels because they are not mandatory and other producers not currently displaying the voluntary labels.</li> <li>• Reduces the possibility that use of pregnancy warning labels will decrease over time, or be ‘pushed-off’ labels by other labelling initiatives.</li> <li>• Some sectors of the alcohol industry spend a lot of time and resources in encouraging producers to adopt voluntary labels. This would not be necessary under a mandatory approach.</li> <li>• Public health stakeholders support the mandatory approach.</li> <li>• Legal sanctions for non-compliance.</li> <li>• Removes conflicts of interest associated with voluntary adoption of a labels.</li> <li>• Recognises the seriousness of FASD.</li> </ul>	<ul style="list-style-type: none"> <li>• Would require notification to the World Trade Organisation. However, there are clear public health reasons for having this labelling, and some countries (such as France) have mandated pregnancy warning labels and/or pictogram.</li> <li>• Timely process to modify Australia New Zealand Food Standards Code in response to future changes in alcohol consumption guidelines, research and evidence.</li> <li>• Does not acknowledge strong efforts by some sectors of the industry to introduce pregnancy labelling voluntarily.</li> <li>• Time taken to develop the standard and put it into place may mean that the voluntary efforts disappear in the interim.</li> </ul>

## 4.2 Business compliance costs

The costs or savings to businesses associated with each option has been determined. As the alcoholic beverage industry is the main group to be impacted by the proposed options, this section focuses on the cost to businesses in this industry associated with complying with each proposed approach.

### Costs of label changes

The second Australian evaluation of the pregnancy warning labels on alcoholic beverages<sup>172</sup> (Siggins Miller report) involved an alcohol industry survey and reported that the average cost for introducing the voluntary labelling was \$338.76 AUD per Stock Keeping Unit (SKU) (equivalent to \$344.44 in 2018 prices). A breakdown of these costs is provided in Table 4.2 (prices have been indexed to 2018 prices using the March 2018 Producer Price Index). It is recognised that costs may be concentrated on smaller producers and the costs of smaller producers may be disproportionately higher than the cost on larger producers. The Siggins Miller report did not compare costs for small and large producers.

Table 4.2 indicates there was a wide variation in the costs associated with introducing the voluntary pregnancy warning labels. For some sectors of the industry, there was no cost because producers were able to incorporate the pregnancy warning labels as part of an otherwise scheduled label change during the four year period industry was given to adopt the voluntary labelling initiative. Industry participants in the Siggins Miller evaluation reported that label changes routinely occur annually and therefore the addition of voluntary pregnancy warning labels was achieved for no additional cost. However, Siggins Miller also reported that costs to some producers were much higher, up to AUD \$4,665 per SKU (\$4,743 in 2018 prices).

**Table 4.2 Estimated costs (AUD) per cost item per SKU<sup>173</sup>**

Cost item	Average estimated cost per labelled SKU	Range of estimated total cost per labelled SKU
Redesign and approval of artwork	\$97.26	\$0.00 - \$1,151
Production of new print plates	\$214.39	\$0.00 - \$3,454
Administration Costs	\$68.29	\$0.00 - \$1,017
Additional Costs	\$7.43	\$0.00 - \$128
Total Cost	\$344.44	\$0.00 - \$4,743

The targeted consultation sought feedback from industry to determine whether the estimated average cost of AUD \$340 (rounded) per SKU was appropriate (this is equivalent to \$344.44 in 2018 prices). Industry submissions indicated that the cost would depend on factors such as colour, number of different colours, size and placement of the warning labels and length of transition periods. This made costing for label changes difficult due to a number of unknown variables.

<sup>172</sup> Siggins Miller. 2017. [‘Second evaluation of the voluntary labelling initiative to place pregnancy health warnings on alcohol products’](#).

<sup>173</sup> Costs from the report have been indexed to 2018 using ABS 6427.0 - Producer Price Indexes, Australia, March 2018.

The Australian wine industry estimated that cost of label changes would range from around AUD \$200 per SKU for a minimal design change (for example, adopting a same colour pictogram under the existing voluntary scheme) to between AUD \$400-\$769 per SKU for a change to introduce a new colourway in a pictogram. The wine industry also reported that this cost is likely to be at the higher end of the range per SKU for smaller winemakers. The wine industry also noted that there are distributional cost impacts of the mandatory option between small and large businesses. Smaller business will still incur up-front or fixed costs, have less ability to pass these costs on to consumers and have smaller profit margins.

A submission from the Australian cider industry reported that the cost of changing a label will depend on the transition period and whether changes can be made as part of normal label redesign. This submission reported that the AUD \$340 per SKU is conservative for smaller producers, and an estimate of AUD \$500 per SKU is considered more appropriate.

Alcohol Beverages Australia noted that costs can range between AUD\$5,000 and AUD \$20,000 per SKU depending on the label design. This was explained by noting that if only one plate change is required (e.g. a single colour change to the bottle) this could be reduced to approximately AUD \$5,000, 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. Typically, the costs (AUD) are estimated to be:

- \$1,500 per label
- \$1,863 per wrap
- \$1,360 per pre-print carton
- \$1,284- \$1,898 per tray and carton

It is relevant to note that pregnancy warning labels may not be required on the outer packaging, and therefore these costs would not apply. This would be considered during implementation.

Another Australian industry submission reported that the estimated average cost of AUD \$340 per SKU was 'grossly underestimated' but did not elaborate further on this statement or provide alternate costings.

Some New Zealand industry stakeholders believed that the potential cost has been vastly underestimated. They acknowledged that cost depends on a variety of factors, but estimated that the cost for alcoholic beverages with a long shelf-life could be up to NZD \$2,000 - \$3,000 (AUD \$1,800-\$2,800) if changes were phased in over a 2-3 year period. If a more immediate change was required, this could cost NZD \$10,000- \$15,000 (AUD \$9,100-\$13,700).

Many public health submissions considered that there would be minimal costs to industry associated with a labelling change, because industry changes their labels regularly, and also change their labels to meet the requirements of export markets.

As the majority of the cost estimates are within the range of estimates reported by Siggins Miller the cost estimates in this paper will be based on the Siggins Miller

estimates, with the average and upper costs reported. The very high cost estimate provided by Australian Beverages Australia (AUD \$20,000 per SKU) was significantly higher than other industry cost estimates provided, and therefore it was not relied upon in the costings. Implementation periods would be incorporated into the preferred option to minimise impact on industry and therefore the costings for immediate label changes provided by New Zealand stakeholders were also not included in this analysis.

#### *Other costs to industry*

The Australian wine industry also reported there are ongoing direct costs of approximately AUD \$20,000 per annum to promote adoption of the voluntary labelling in its sector.

#### *Non-monetary impacts to industry*

The Siggins Miller evaluation identified non-monetary costs in adopting the voluntary pregnancy labelling. These related to reduced label space that can be used for other purposes, or reduced label aesthetics. If labelling requirements are applied uniformly across industry there should be no relative disadvantage experienced by any individual alcohol producer.

In the Siggins Miller report, reputational benefit from being associated with the promotion of responsible consumption of alcohol was seen to be a non-monetary benefit. However, one Australian industry submission to the targeted consultation process disagreed that a reputational benefit was offered to industry from voluntarily adopting pregnancy warning labels, and believed that competing issues may represent greater value in the minds of consumers (for example, environmental practices, origin labelling, ownership of the company and employment practices).

### **Estimates of the number of products affected**

The Siggins Miller report estimated that there are 21,557 active SKUs in Australia, with 47.8% (10,304) of these carrying a pregnancy warning label. This includes domestically produced and imported products.

The targeted consultation asked whether the reported 21,557 active SKUs in the market was an appropriate estimate for Australia. Industry responses considered that this estimate did not capture the products produced by smaller industry producers. The Australian Cider industry estimated that there were an additional 300-500 SKUs in the craft cider sector and the Australian wine industry reported that it had commissioned research which identified more than 30,000 SKUs<sup>174</sup>, with approximately half sold through national retail outlets and half sold direct (cellar door/mail order/websites) and through local/regional outlets. Based on these figures, this cost analysis in this paper will be based on the number of SKUs in the market as set out in Table 4.3 below.

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<sup>174</sup> Winemakers' Federation of Australia. 2013. [\*Wine Industry Report: Expert Report on the Profitability & Dynamics of the Australian Wine Industry\*](#).



**Table 4.3 Estimated number of SKUs in the Australian packaged alcohol market**

<b>Market</b>	<b>Number of active SKU's (reported by Siggins Miller)</b>	<b>With industry estimates incorporated</b>	<b>Proportion with a warning (from Siggins Miller report)</b>
Beer	4,492	4,492	38.8%
Cider	1,022	1,422	35.9%
Wine	11,688	30,000	50.4%
Spirits	2,783	2,783	57.8%
Ready-to-drink	1,572	1,572	66.5%
<b>Total</b>	<b>21,557</b>	<b>40,296</b>	<b>47.8%</b>

Submitters did not report whether these additional SKUs were or were not adopting the current voluntary pregnancy warning labels, and therefore warning label coverage for the sectors reported in the Siggins Miller evaluation was applied to these additional SKUs.

New Zealand stakeholders did not comment in their responses to the targeted consultation whether the estimates of the number of SKUs in the market presented in the targeted consultation document are appropriate for New Zealand.

In responding to a New Zealand consultation on this issue, industry bodies indicated that they do not routinely collect data on SKUs, but they were able to undertake some research, as well as further consult their members. The estimate provided for beer was that there are at least 3,000 SKUs in the market. For wine the estimate reported was 12,000 SKUs sold through supermarkets and liquor stores but excluding sales for example on premise, cellar door, duty free and online. Based on the information reported by the Australian wine industry that half of sales are through national outlets, the total estimate for wine SKUs in the market in New Zealand is taken to be approximately 24,000. For spirits the number of SKUs was estimated by industry to be approximately 1,000 and for ready-to-drink 200 SKUs. No estimate of SKUs in the market were provided for cider.

Based on this additional information provided by the New Zealand industry bodies, the total number of SKUs in the market in New Zealand is somewhere between the number of SKUs reported by Siggins Miller for Australia (21,557) and the Australian industry estimates (40,296). The information provided does not allow for a more precise estimate of the number of SKUs in the market in New Zealand.

It is noted that some products in the market in Australia will be imported from New Zealand and vice versa, and thus included in the number of SKUs available in both markets. Accordingly, the estimated number of SKUs is a conservative estimate and likely to be an upper maximum and thus higher than if only unique SKUs were included.

### **Business compliance costs associated with each option**

The section below uses the label change costs and estimated number of SKUs to predict the monetary costs to business that could be expected to achieve 100% coverage of pregnancy warning labels under the options being considered. The 100% compliance has been costed as this would be the best outcome and meet the objectives of this work by achieving complete coverage of pregnancy warning labels across all alcoholic beverages.

The cost estimates presented in this section are for Australia only.

*1a- Status quo-* The status quo is described in Part 1 of the document. For producers that choose to adopt the voluntary pregnancy warning labels the average cost of label changes would be AUD \$344.44 per SKU. However, producers may change their labels at any point and may incorporate the pregnancy warning labels as part of an otherwise scheduled label change which would result minimum costs.

A plausible cost to the community under the status quo is AUD \$1.18 billion and NZD \$171.12 million per year associated with the impact of FASD (see section 1.3).

*1b- Voluntary- industry self-regulated* - as outlined above, the cost for adopting this approach would depend on the degree to which the pregnancy warning labels under the industry code of practice would differ from the status quo and the proportion of producers that would need to change their labelling to meet the industry code of practice.

Assuming that all producers that are currently adopting the voluntary labelling become signatories to the industry code of practice and do not need to change their product labels to comply, the cost would impact only on signatories that are not currently displaying any pregnancy warning labels on their products. In this case, for 100% coverage to be achieved, average cost to businesses would be AUD \$7.2 million (based on average of AUD \$344.44 per SKU and 21,020 SKUs not currently displaying the current voluntary warning labels). At the higher end of the costings, this would be AUD \$99.7 million (based on \$4,743 per SKU). However, as this is a voluntary approach, it is uncertain whether all of these producers would become signatories and bear these costs.

Given the concerns raised with the current labelling scheme, it is reasonable to expect that the industry code of practice would address these concerns and therefore differ somewhat to the current labelling scheme. Some producers may therefore need to change their labels to comply with the labelling requirements in the proposed industry code of practice. The targeted consultation process asked for information on the types of pregnancy warning labels that are currently in the market in order to get an indication of the proportion of products currently displaying a pregnancy warning label that may need to change their label to improve consumer understanding. However, insufficient information was received to confidently determine how many products may need to change their labels to improve consumer understanding of the pregnancy warning labels. Some industry submissions reported that the pictograms used in their sector were predominantly black and white, while others reported that the pictograms used are the same colours as the overall label colour scheme to save on costs. Other submissions reported that they did not have this type of data for their industry sector.

If all producers that have adopted the current voluntary labelling on their products need to change their labels to comply with the industry code of practice, the average cost to these businesses is estimated to be AUD \$6.6 million for the label changes (based on an average of AUD \$344.44 per SKU with 19,249 SKUs currently adopting the voluntary warning labels). At the higher end of the costings, this would be AUD \$91.3 million (based on AUD \$4,743 per SKU).

If these scenarios are combined, the total cost would be AUD \$13.9 million (average cost) and up to AUD \$191.0 million based on a total of 40,269 SKUs needing to change their label to achieve 100% coverage and adherence to the industry code of practice.

Given the voluntary nature of this approach, labelling changes could occur with other updates to labels to reduce the impact. As noted in the Siggins Miller evaluation, a long transition time for producers to adopt the code of practice could have no cost as new labelling could be incorporated into regular labelling changes.

There would also be additional costs on the industry peak body that would develop the industry code of practice and monitor and enforce it. Development of the code of practice would be an upfront one-off cost (with potential costs associated with future reviews of the code of practice), and the monitoring and enforcement would be an ongoing cost. FSANZ may also develop a code of practice, as part of its functions, which would be at no cost to industry.

In Australia, DrinkWise indicated that it would be willing to take on this role and estimated that it would require one additional full-time resource and additional back office processes, potentially costing AUD \$180,000 per annum. This cost is associated with administering the code of practice across the whole alcoholic beverage industry in Australia.

The Australian wine industry estimated that the annual costs of an industry regulatory body to oversee only the Australian wine industry. This industry estimated the cost of developing the code of practice would be approximately AUD \$250,000 per annum and establishment costs of approximately AUD \$20,000.

Another Australian industry submission estimated that the cost for industry to self-regulate would be less than AUD \$500,000 per year, based on the Australian Alcohol Beverages Advertising Code.

Based on the information provided above, the Australian costing used in this paper will be an average of the three estimates – AUD \$310,000 per year. The one-off cost for establishing the code of practice was estimated to be AUD \$24,000. This costing is based on the Australian wine industry estimate for this work and adjusted to reflect the proportion of total SKUs in the Australian market that are from the wine sector (wine industry estimated this work would cost AUD \$20,000 for its industry and the wine industry makes up 80% of the active SKUs on the Australian market).

There may also be costs to industry associated with promoting adoption of the code of practice to alcohol producers (if they choose to do so). The Australian wine industry reported that it currently spends approximately AUD \$20,000 per annum to promote adoption of the voluntary pregnancy warning labelling in its sector. It could be expected that a similar expense would be required to promote adoption of the code of practice in that industry. However, as this money is already spent by industry under the status quo, it is not an additional cost associated with this option.

*1c- Voluntary with style guide* - the cost for adopting this approach would depend on the degree to which the style guide would differ from the status quo and the

proportion of producers that would need to change their practices to adopt the new style guide.

Consistent with the costs estimated for the industry code of practice, if producers that are currently not displaying a pregnancy warning label were to adopt pregnancy warning labels on their products under the proposed style guide, average cost to industry would be \$7.2 million. At the higher end of the costings, this would be \$99.7 million. However, as this is a voluntary approach, it is uncertain whether all of these producers would adopt the voluntary style guide and bear these costs.

Given the concerns raised with the current labelling scheme, it is reasonable to expect that the Government style guide may differ somewhat to the current labelling scheme. Some producers may need to change their labels to comply with the proposed style guide. Consistent with the costs estimated for the industry code of practice, if all producers that currently display the pregnancy warning labels adopt the voluntary style guide and need to change their labels to comply (worst-case scenario), the average cost to these businesses is estimated to be AUD \$6.6 million for the label. At the higher end of the costings, this would be AUD \$91.3 million (based on AUD \$4,743.26 per SKU).

If these scenarios are combined, the total cost would be AUD \$13.9 million (average cost) and up to AUD \$191.0 million to achieve 100% coverage and compliance with the voluntary style guide.

Given the voluntary nature of this approach, labelling changes could occur with other updates to labels to reduce the impact. As noted in the Siggins Miller evaluation, a long transition time for the new style guide could have no cost as new labelling could be incorporated into regular labelling changes.

There would be no costs to business associated with the development of the government style guide or government monitoring and reporting of compliance with the style guide, as these costs would be borne by Government.

There may also be costs to industry associated with promoting adoption of the voluntary style guide (if they choose to do so). The wine industry reported that it currently spends approximately AUD \$20,000 per annum to promote adoption of the voluntary pregnancy warning labelling in its sector. It could be expected that a similar expense would be required to promote uptake of the Government style guide in that industry. However, as this money is already spent by industry under the status quo, it is not an additional cost associated with this option.

2- Mandatory through the Australia New Zealand Food Standards Code– Like the other options, the cost for adopting this approach would depend on the degree to which the requirements under the Australia New Zealand Food Standards Code would differ from the status quo, and the proportion of producers that would need to change their practices to meet these requirements. The impact on industry for mandating the labels may be limited only to those who have not adopted the voluntary scheme.

Consistent with the costs estimated for the industry code of practice and government style guide, if only the products that are not currently displaying the pregnancy warning labels are required to adopt the labelling, average cost to industry would be

AUD \$7.2 million. At the higher end of the costings, this would be AUD \$99.7 million.

Given the concerns raised with the current labelling scheme, it is likely that some producers would need to change their labelling to comply with the requirements proposed in the Australia New Zealand Food Standards Code. In the worst case scenario, if all products need to be re-labelled, the estimated average cost to businesses for adopting new pregnancy warning labels would equate to \$13.9 million AUD (based on a total of 40,269 SKUs and cost of AUD \$344.44 per SKU). This is the cost of achieving 100% coverage of pregnancy warning labels.

Industry submissions in the targeted consultation raised concerns that this could mean that proactive businesses would face a greater burden of cost, in that they would effectively be paying twice to include a pregnancy warning label on their products.

At the higher end of the costings, this would be AUD \$191.0 million (based on AUD \$4,743.26 per SKU). It is important to note that this upper costing assumes minimal transition period, which is very unlikely. To reduce this cost on industry associated with compliance under the mandatory approach transition periods and stock-in-trade exemptions will be included to minimise a large proportion of costs to producers, including smaller producers.

There would be no costs to business associated with incorporating pregnancy warning labels in the Australia New Zealand Food Standards Code and undertaking monitoring and enforcement, as these costs would be borne by Government.

There would also be a saving to industry associated with the current expenditure on promoting voluntary adoption of pregnancy warning labels. The wine industry reported that it currently spends approximately AUD \$20,000 per annum to promote adoption of the voluntary pregnancy warning labelling in its sector. This work would not be required under a mandatory approach and therefore this represents a saving to the industry.

Table 4.4 below summarises the business compliance costs associated with each option for Australia and the different level of label change that may be required. Under each scenario, business compliance costs associated with option 1b (industry self-regulated) are the highest and lowest with option 2 (mandatory).

**Table 4.4 Business compliance costs (AUD) associated with each option for Australia**

Scenario	Industry self-regulated (1b)	Government style guide (1c)	Mandatory (2)
1	\$7.2m (average) \$0- \$99.7m (range)	\$7.2m (average) \$0- \$99.7m (range)	\$7.2m (average) \$0- \$99.7m (range)
2	\$6.6m (average) \$0-\$91.3 m (range)	\$6.6m (average) \$0-\$91.3 m (range)	\$6.6m (average) \$0-\$91.3 m (range)
3	\$13.9m (average) \$0- \$191.0m (range)	\$13.9m (average) \$0- \$191.0m (range)	\$13.9m (average) \$0- \$191.0m (range)
Other business compliance costs	\$0.31m (annual) \$0- 0.024m (one-off).		
Savings			0.020m (annual)

Scenario	Industry self-regulated (1b)	Government style guide (1c)	Mandatory (2)
Notes	Annual cost for industry to self-regulate and one-off cost to establish industry code of practice. No cost if FSANZ develops the code of practice.	Costs of developing the style guide and monitoring and reporting on compliance with the style guide borne by Government.	Industry savings associated with not having to promote adoption of the voluntary scheme.

Scenarios modelled:

1. Label change costs to businesses not currently displaying a pregnancy warning label (21,020 SKUs)
2. Label change costs to businesses if products currently displaying warning labels need to change their labels to comply (up to 19,249 SKUs)
3. Maximum cost required to achieve 100% coverage (40,269 SKUs).

The business compliance costs associated with each option under Scenario 3 are estimated to be similar for New Zealand. However it is acknowledged that for New Zealand this will be a conservative (highest) estimate given that the actual number of SKUs in the market is likely to be lower. As the New Zealand evaluation did not report on the proportion of SKUs that were or were not adopting the current voluntary pregnancy warning labels, no comparison can be made for scenarios 1 and 2.

### Costs to consumers

The targeted consultation asked whether industry would pass the costs associated with labelling changes on to consumers. If this were to occur, the costs of label changes (outlined above) may be borne by consumers rather than the alcohol industry.

The Australian industry indicated that it would pass the costs on to consumers unless label changes could be incorporated into scheduled labelling updates. In particular, industry submissions noted that small businesses would be disproportionately impacted by the labelling changes. The cider industry reported that small businesses would need to absorb a greater proportion of the costs to remain competitive, whereas the wine industry reported that small business would need to pass the costs on to consumers as they have the least ability to absorb the cost. The wine industry also called for transition periods to reduce the impact on small business.

New Zealand stakeholders were unable to elaborate on whether industry would pass costs on to the consumer as these depend on many factors, however evidence shows that this chance can be reduced when costs are anticipated<sup>175</sup>. Furthermore, if costs were to increase, this would not have to be a uniform increase across all products<sup>176</sup>.

Whatever the preferred option, efforts will be made to minimise the costs of label changes on business through transition periods and stock-in-trade exemptions. This would also reduce the potential for costs to be passed on to consumers.

## 4.2 Benefits to society

In the targeted consultation, stakeholders acknowledged that it is important people are informed regarding the effect of alcohol during pregnancy, this includes not just pregnant women or women planning to become pregnant but also the broader

<sup>175</sup> Ravn, M.O., et al. 2009. 'Incomplete cost pass-through under deep habits'. *Rev Econ Dyn*,13:317–332.

<sup>176</sup> Ally, A.K., et al. 2014. 'Alcohol tax pass-through across the product and price range: do retailers treat cheap alcohol differently?' *Addiction*, 109:1994–2002.

community. Each of the proposed options would benefit the community through reminding pregnant women and their support networks that women should not drink alcohol when pregnant and assisting to change social norms.

It is recognised by Government and stakeholders that pregnancy warning labels on packaged alcohol products, as a stand-alone measure, have not demonstrated a meaningful impact on the drinking behaviour of pregnant women and therefore, cannot directly prevent FASD<sup>177</sup>. Pregnancy warning labels contribute to raising awareness amongst the target audiences (i.e. pregnant women and others in the community) about the risks of drinking alcohol during pregnancy<sup>178</sup>. The effects of other initiatives combined with the pregnancy warning labels on alcoholic beverages can contribute to changes in social norms and drinking behaviour amongst pregnant women and ultimately prevalence and/or severity of FASD.

If women did not drink alcohol during pregnancy, thousands of cases<sup>179</sup> of FASD in Australia and New Zealand would be prevented. Drinking during pregnancy is also a risk factor for fetal mortality, stillbirth and infant and child mortality<sup>180</sup> and if women do not drink during pregnancy, health and social costs associated with these outcomes can also be avoided.

FASD is a life-long condition, and individuals with FASD who have severe cognitive and behavioural disabilities are likely to have shorter, more difficult lives (see Section 1.3 of this document). Prevention of FASD would result in a significant improvement in the quality of life of those who would have otherwise been affected. Preventing FASD would also have benefits for families and siblings of people who would otherwise have FASD are also likely to benefit from increased attention and opportunities.

For the community, reduced prevalence of FASD has economic and productivity benefits through increased participation in the labour force. It would also reduce burden on healthcare and social support systems, the education system and care and protection systems. The impact of FASD in the justice and legal system is significant and preventing FASD would reduce costs to the community associated with crime and the juvenile and adult corrective systems.

In both Australia and New Zealand, it is likely that a reduction in FASD will contribute to improved outcomes across generations and, if evenly spread, will have a disproportionately greater impact on indigenous communities.

Because pregnancy warning labels need to be accompanied by broader FASD prevention initiatives, challenges and uncertainties are introduced in quantifying the net benefits for each of the different options proposed in this paper. Uncertainty is also introduced in the estimates of the net benefits due to the nature of the data on the

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<sup>177</sup> International Alliance for Responsible Drinking (IARD). 2017. '[Policy review: Health warning labels](#)'. Washington.

<sup>178</sup> International Alliance for Responsible Drinking (IARD). 2017. '[Policy review: Health warning labels](#)'. Washington.

<sup>179</sup> Health Technology Analysts. 2010. '[Fetal alcohol spectrum disorder \(FASD\) Exploratory economic analysis of different prevention strategies in Australia and New Zealand](#)'. Food Standards Australia New Zealand.

<sup>180</sup> B Burd, L., et al. 2012. '[Prenatal alcohol exposure, blood alcohol concentrations and alcohol elimination rates for the mother, fetus and newborn](#)'. *Journal of Perinatology*, 32:652–659.



incidence and prevalence of FASD in Australia and New Zealand and its burden on individuals and the community.

While the societal costs of FASD are difficult to accurately measure, Section 1.3 provided estimates that the economic costs of FASD could be at least AUD \$1.18 billion per year for Australia and NZD \$171.12 million per year for New Zealand. Preventing FASD would save these costs in the Australian and New Zealand communities.

### 4.3 Net benefit

Analysing the likely impacts of the labelling changes has been undertaken by determining what proportion of cases of FASD would need to be prevented to offset the cost of labelling changes (The loss of revenue to industry and governments resulting from a reduction in the consumption of alcohol have been ignored).

The other business costs, such as the cost to industry to administer a code of practice; have not been included in this analysis.

Costs of new cases of FASD combined with costs to the prison and youth detention system have been drawn from the information presented at Section 1.3 of this document.

**Table 4.5 Potential cases of FASD that would need to be prevented to offset costs of pregnancy warning labels for Australia.**

Scenario	Potential cost of labelling changes in one year	FASD cases that would need to be prevented to offset this cost (at 5% FASD incidence rate and AUD \$75,662 per case of FASD)
<i>Average costings (includes transition period for label changes)</i>		
1	7.2 million	0.62% (96 cases)
2	6.6 million	0.56% (88 cases)
3	13.9 million	1.18.% (183 cases)
<i>Upper costings (no transition period for label changes)</i>		
1	\$99.7 million	8.47% (1,318cases)
2	\$91.3 million	7.76% (1,207 cases)
3	\$191.0 million	16.23% (2,524 cases)

Based on the estimated incidence rate for FASD in Australia of 5%, this suggests 1.18% of FASD cases (183 cases) would need to be prevented in one year to offset the costs associated with adopting mandatory labelling.

However the cost of FASD depends on the severity of FASD, and international studies suggest heavy drinkers are least likely to be affected by mandatory labelling. As exposure to alcohol during pregnancy is directly related to the severity of FASD, although the precise relationship is not well known, a more conservative approach is to consider the number of mild cases of FASD that may need to be avoided in order to offset the increased cost to business.

Estimates of the annual health-related cost of mild cases of FASD from the Canadian study<sup>181</sup> on which the health-related costs included above are based, updated to 2018, range from AUS\$7,499 to AUS\$20,962, with an average of \$13,785. (As mild cases of FASD are unlikely to result in impacts on the cost of the prison and juvenile justice system, these costs have been ignored.) As every case avoided would save these costs over each year of an individual's life, the proposal would only need to avoid 13 cases of mild FASD a year to result in a net benefit over 20 years.

As there are no New Zealand data on the proportion of products with pregnancy warning labels, the percentage of FASD cases that would need to be prevented is calculated based on all products requiring a label change (Scenario 3). Based on the estimated incidence rate for FASD in New Zealand of 3% (1,783 cases per year) and the costs per case of FASD of NZD \$95,978,207 (see section 1.3) 8.8% of new cases of FASD would need to be prevented in one year to recover the costs of labelling changes in New Zealand (based on average label costs). However given that the average costs of labelling changes are based on a conservative (highest) estimate of the number of SKUs in the market, the percentage of cases that would need to be prevented is likely to be lower.

The cost of FASD in the community is considerably greater than the cost of label changes, and only a very small proportion of cases of FASD would need to be prevented to offset the labelling costs. The costings for FASD also do not account for fetal mortality, stillbirth and infant and child mortality<sup>182</sup> associated with alcohol consumption during pregnancy. If these could be quantified, they would further increase the costs of alcohol consumption during pregnancy and further offset the costs of label changes for packaged alcohol products.

It is also important to note that the cost of labelling changes would be borne by the alcohol industry once, while the savings to the community from prevention of FASD would occur each year for every case of FASD prevented when a woman chooses not to drink alcohol while pregnant.

Even with the upper costings for label changes, the cost of FASD is still far greater than the cost of labelling changes. As transition periods and stock-in-trade exemptions can be included in the implementation of the preferred option, these higher costings are implausible and would not represent the business compliance costs to be incurred because industry could incorporate relevant labelling changes into their scheduled label updates.

In response to the targeted consultation, the majority of submissions from industry considered that the industry self-regulated option (1b) offered the greatest net benefit, while noting that this option was not the lowest cost to the industry. This view was justified on the basis that the industry self-regulated option would minimise labelling costs and maintain flexibility for industry. The alcohol industry considered the mandatory option would add additional compliance costs and those producers who have already outlaid costs for adopting the voluntary warning labels may have further

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<sup>181</sup> Stade B, et al.. 2009. [The burden of prenatal exposure to alcohol: REVISED measurement of cost](#). *Canadian Journal of Clinical Pharmacology*. 16(1): 91-102

<sup>182</sup> Burd, L., et al. 2012. [‘Prenatal alcohol exposure, blood alcohol concentrations and alcohol elimination rates for the mother, fetus and newborn’](#). *Journal of Perinatology*, 32, 652–659.

costs to comply with the mandatory warning labels. However, given the concerns raised with the current labelling scheme, it is likely that even under the industry self-regulated option some of the producers who have already adopted voluntary pregnancy warning labels would need to revise their labelling to improve consumer understanding of the pregnancy warning labels and absorb the associated costs, or transfer these to consumers.

One industry submission considered that the government style guide (option 1c) offered the greatest net benefit as it would ensure that pregnancy warning labels are evidence based while maintaining flexibility for producers and the choice to not display pregnancy warning labels if there was a valid reason (such as allowing labels to be acceptable in particular export markets). This industry submission also noted that monitoring and compliance costs under this option would be borne by Government which reduced industry costs.

Submissions from public health, government and other sector (e.g. academics, consumer organisations) considered that the mandatory option offered the greatest net benefit. This was justified on the basis that the costs of label changes were considerably less than the impact of FASD on society. These submissions considered that mandatory warning labels were in the best interest of children and the broader society and aligned alcohol with other foods and products that are required to carry mandatory pregnancy warning labels or advisory statements.

## **5. Consultation**

### ***5.1 Consultation process***

A targeted consultation process was undertaken from 3 May to 14 June 2018. The targeted consultation process involved distributing a Consultation Regulation Impact Statement (CRIS) which included 25 consultation questions to 115 stakeholders including the alcohol industry, public health sector, consumer representatives, think tanks, academics and governments from Australia and New Zealand who were invited to make a submission.

The invitation that was sent to stakeholders provided the CRIS and a template with the 25 consultation questions to complete. It was not necessary to answer every question. The consultation invitation email to stakeholders was distributed by the Food Regulation Secretariat and advised stakeholders that submissions should be supported by evidence and that submissions that are not evidence-based, or do not directly answer the questions may not be drawn upon in preparing the preferred policy option for the Forum.

The consultation invitation email also advised that industry peak bodies were expected to consult their members on the consultation questions and provide a single response on behalf of their members. Invited stakeholders were also asked not to forward the consultation invitation outside their organisation and to advise the Food Regulation Secretariat if they were aware that another organisation had not been invited to make a submission but should be included in the targeted consultation. All additional stakeholders that were suggested in response were invited to make a submission.

Over 50 submissions were received from the following stakeholder groups:

- Public Health (32 submissions)
- Industry (13 submissions)
- Government (5 submissions)
- Others (2 submissions)

Eighteen submissions were from New Zealand stakeholders; the rest were Australian.

Submissions to the consultation process were analysed by the New Zealand Ministry for Primary Industries (MPI) and Australian Government Department of Health (Health). The MPI analysed the submissions from New Zealand stakeholders and drafted summaries of the New Zealand stakeholder's views on the consultation questions and provided these to Health for incorporation into this DRIS document. Health analysed the submissions from Australian stakeholders and incorporated the views from Australian stakeholders into this document as well as the input received from the MPI. Health undertook the drafting of the RIS, with MPI reviewing the draft and providing comments.

### **Additional New Zealand consultation**

In light of the limited information provided by New Zealand industry stakeholders in regard to the number of SKUs in the New Zealand market, on Thursday 2 August, New Zealand MPI approached the 5 industry submitters with a follow up to Question No 19 in the CRIS. Question 19 of the CRIS was *'Is the number of active SKUs used in this estimation approximate? What proportion of SKUs is from smaller producers?'* It was clarified that the number of SKUs used in the document were Australian industry SKUs, and the New Zealand industry submitters were then asked *'is the total number of active SKUs comparable to NZ SKUs – if not, how does it differ? Are you able to provide NZ SKU numbers for each category?'* They were given an additional 2 weeks to provide this information.

Four industry bodies responded to the additional consultation providing some estimates of the SKUs in the market in New Zealand.

## **5.2 Overall consultation themes**

The CRIS formed the basis of this document, with sections of the CRIS revised to reflect the evidence received through the consultation process. Responses to the consultation are incorporated in the relevant sections above.

### **Views of the alcohol industry**

The alcohol industry generally supported voluntary self-regulation (option 1b) and offered various ideas about how this could be implemented, including through collaboration with Government. Industry supported this option as it offered flexibility, the opportunity to continue the current work on voluntary pregnancy warning labels and utilise existing infrastructure. Industry considered that industry self-regulation would ensure consistency, a means to monitor industry uptake and reduce cost to regulatory bodies by being independently managed by the industry. It would also allow for tailoring to specific market segments ensuring the warning is both seen and understood.

Industry was not supportive of the mandatory approach as it was considered to impact on potential export opportunities and would burden those producers who had already voluntarily adopted pregnancy warning labels. More than one industry submission considered that the mandatory approach was a ‘punishment’ and did not recognise the efforts of the industry in voluntarily adopting the pregnancy warning labels.

Some industry groups expressed frustration that despite their efforts to promote adoption of the voluntary labels and achieve high coverage in their sector, some producers in the alcohol industry had not cooperated and some industry responses considered that regulatory action should be targeted to those producers that have not adopted the voluntary labelling rather than the entire industry. Some industry submissions also argued that actions to prevent FASD should be targeted at the causal factors and population groups more likely to drink alcohol while pregnant, rather than a blanket approach across the whole alcohol industry. It is relevant to note that targeted interventions in relation to FASD are occurring, and these actions are outlined in [Appendix 1](#).

### **Views of the public health sector, Governments and others**

The majority of non-industry submissions (i.e. Government, public health, academics etc.) considered that the mandatory approach (option 2) was the best option for progressing pregnancy warning labels on alcohol. This was based on the view that sufficiently high coverage had not been achieved after a six year voluntary pregnancy warning label exercise and that a mandatory approach was the only approach that could increase coverage, particularly in the sectors of the alcohol industry that had resisted the voluntary labelling.

These submissions raised various concerns with the current implementation of the voluntary pregnancy warning labels on alcohol and considered that a mandatory approach was the only way to address these. A mandatory pregnancy warning message on the label of alcoholic beverages was also seen as an opportunity for governments to disseminate health messages at the point of sale and point of consumption. These submissions considered that the benefits of improved pregnancy warning labels would far outweigh the cost to industry associated with label changes. Submissions also argued that industry already change their labels to meet the requirements of export markets and can therefore easily change labels for the domestic market.

### **Views on transition periods and exemptions**

Australian and New Zealand industry submissions stated that flexibility would be key to cost-saving for industry and this would be most beneficial for products with a long shelf-life (i.e. vintage wine and spirits) and small producers. Industry reported that the transition period should be long enough to ensure no producer has to reprint labels and that label redesign is undertaken as part of standard business plans. One New Zealand alcohol industry submission noted that its members, who were predominately small to medium enterprises, purchase labels up to 12 months ahead of use. A number of industry submissions stated that two to three years should be sufficient to adopt new labelling. Industry cited the importance of transition periods, particularly for craft producers, who face a disproportionately high cost in complying with regulatory obligations. Without dedicated legal or regulatory resources, it is relatively more difficult for them to identify, understand and implement changes.

These producers also revise and print labels much less frequently than larger producers.

Submissions from Australian and New Zealand public health and consumer organisations believed that there should be no transition period given to industry, or 12 months at the maximum. These submissions highlighted that transition periods could create confusion which may delay action and compliance.

Few stakeholders supported an exemption. The public health sector did not support exemptions on the basis that all alcoholic drinks are potentially dangerous and should be labelled accordingly; exemptions would create consumer confusion and exemptions would reduce the effectiveness of the pregnancy warning labels and not achieve the desired outcome. Industry considered that exemptions would not create a level playing field, undermine the purpose of the labelling scheme and one submission commented that exemptions for boutique producers or small businesses may not be effective as boutique producers can be very popular and may be unlikely to remain a small business for long. The Australian and New Zealand wine industry supported exemptions for existing vintages.

## 6. Evaluation and conclusion

Determining the best option for progressing pregnancy warning labels on alcohol was undertaken by considering the potential effectiveness of the proposed options in achieving the desired outcome, potential impacts and costs to industry, potential impacts and benefits to society and risks. The level of uncertainty associated with each option was also considered.

### 6.1 *Recommended option*

Taking everything into account, it is recommended that the best option to achieve the desired outcome is **Option 2 mandatory**. Given the significant impacts of alcohol consumption during pregnancy, a voluntary approach is not an appropriate approach to address such a serious issue. Alcohol consumption during pregnancy affects a third-party (the unborn child) and regulation is necessary to help protect this vulnerable group.

It is recommended that the Forum request that FSANZ develop a mandatory labelling standard for pregnancy warning labels on packaged alcoholic beverages which include both a pictogram and warning message.

The mandatory approach is the only option that ensures that pregnancy warning labels are applied across all packaged alcoholic beverages in a manner that is understood by the target audiences and consistent with government advice.

It is uncertain whether the voluntary approaches will be able to achieve greater coverage of pregnancy warning labels across the market, and address the concerns raised with the current voluntary system such as consumer misunderstanding, information accessibility (i.e. requirement to visit a website), and conflicting information (e.g. ‘*enjoy in moderation*’ messaging). The mandatory option has the least level of uncertainty.

While the mandatory option will introduce a cost to industry, it is expected that the same cost would be borne by industry under the other voluntary options if industry change their current pregnancy warning labels to address the concerns with status quo. Transition periods and stock-in-trade exemptions could be included in the mandatory option to reduce the impact on industry as much as possible.

The financial and non-financial cost of FASD to the community is significant and far greater than the costs of changes to the labels of alcoholic beverages. A small proportion of cases of FASD need to be prevented to offset the costs of label changes on industry. A mandatory approach offers certainty that high coverage of pregnancy warning labels will be achieved and the warning labels are designed to support consumer understanding and consistency with Government advice. Therefore the mandatory option represents the greatest net benefit to the community.

## 7. Implementation and review

Implementation of the mandatory approach will be undertaken by FSANZ following the legislated processes set out in the *FSANZ Act 1991*.

### 7.1 Label design

It is recommended that FSANZ give consideration to pregnancy warning labels that are evidence based and proven to resonate with and be understood by the target audience(s). FSANZ should draw upon an already strong body of evidence that warnings with pictograms are more effective than text only warnings and that pictograms increase the message's impact and increase accessibility by people with low levels of literacy. Additional information on the evidence about effective pregnancy warning labels is provided at [Appendix 2](#). Based on this evidence it is recommended that FSANZ develop mandatory pregnancy warning labels which include both a pictogram and warning text. FSANZ may wish to give consideration to further consumer research to identify the most appropriate pregnancy pictogram and warning label for the Australian and New Zealand context, taking into account other pregnancy warning labels that are used in overseas markets.

### 7.2 Transition period

In implementing the preferred option it is recommended FSANZ give consideration to including a **two to three year transition period** to minimise impacts on industry in introducing mandatory pregnancy warning labels.

A recent example of food labelling changes which included a transition period is the Country of Origin Food Labelling Information Standard 2016<sup>183</sup> (CoOL Standard) which is administered by the ACCC. The CoOL Standard requires most food suitable for retail sale in Australia to carry country of origin information. The CoOL Standard commenced on 1 July 2016 and included a two year transition period. From 1 July 2018, food to be sold in Australia must be labelled according to the requirements of the Standard. During the transition period, businesses could either continue to label their products according to the existing requirements, or adopt the new labelling requirements of the Standard. The CoOL standard also included stock-in-trade

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<sup>183</sup> Australian Competition & Consumer Commission (ACCC). 2017. '[Country of Origin food labelling](#)'. Commonwealth of Australia.



exemptions where products that are packaged and labelled on or before 30 June 2018 can still be sold without the new labels after that date.

A report prepared for the Food and Drug Administration in the United States reported that, based on interviews with trade associations, products are typically relabelled every 3 to 4 years<sup>184</sup>.

### ***7.3 Exemptions***

It is recommended that FSANZ give consideration to stock-in-trade exemptions so that products that have already been packaged and labelled prior to the end of the transition period would not have to change their label.

Imported products should not be exempted from the mandatory pregnancy warning label requirements. As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade. A WTO notification will be considered as part of FSANZ's standard development process.

### ***7.4. Monitoring and evaluation***

It is recommended that future monitoring and evaluation be undertaken after a suitable period of time to determine whether the desired outcome has been achieved. Monitoring and evaluation could occur during the transition period and repeated 2-3 years after the preferred option becomes operational.

FSANZ and FRSC will consider who is best placed to undertake the monitoring and evaluation. The previous evaluations have been conducted by the New Zealand Ministry for Primary Industries and commissioned by the Australian Government Department of Health. These agencies could again conduct or commission future monitoring and evaluation work or consideration could be given to whether some parts of the monitoring and evaluation work could be commissioned by FSANZ or the Implementation Sub-committee for Food Regulation (which reports to FRSC).

Issues that should be included in monitoring and evaluation of the implementation of the preferred approach are:

#### **Process evaluation- evaluation of the alcohol labels on the market (two and five years after transition period ends)**

Surveys of packaged alcoholic beverages on the market in Australia and New Zealand should be undertaken to examine:

- Coverage of pregnancy warning labels on packaged alcoholic beverages in the market;
- Consistency of pregnancy warning labels across the market and against the requirements set by FSANZ;
- Size of pregnancy warning labels in the market;

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<sup>184</sup> Food and Drug Administration Center for Food Safety and Applied Nutrition. 2012. '[Model to Estimate Costs of Using Labeling as a Risk Reduction Strategy for Consumer Products Regulated by the Food and Drug Administration](#)', U.S. Food and Drug Administration (FDA).

- Presence of other conflicting information near the pregnancy warning label such as the ‘*enjoy responsibly*’ type messages.
- Impact of pregnancy warning labels on other labelling elements (e.g. do other labelling elements need to be reduced in size or removed from the label to make room for a pregnancy warning label).

Sample sizes and sampling methodology should be considered to ensure results can be reported by alcohol sector and domestic producers and imported products.

### **Impact evaluation- evaluation with Australian and New Zealand consumers (two and five years after transition period ends)**

Surveys and/or focus groups could be undertaken with the target audiences including pregnant women, women planning a pregnancy, partners of pregnant women or women planning a pregnancy to examine:

- Understanding and recall of pregnancy warning labels;
- Awareness of the advice that pregnant women should not drink alcohol;
- Attitudes towards pregnancy warning labels;
- Attitudes towards alcohol consumption during pregnancy;
- Whether they have engaged in conversations about the risks of alcohol use during pregnancy; and
- Any unintended consequences associated with pregnancy warning labels such as feelings of guilt or blame on women who have consumed alcohol during pregnancy.

Sample sizes should be appropriate to enable reporting for population sub-groups such as younger women and heavier drinkers.

### **Outcome evaluation- impact on behaviours (ongoing)**

Pregnancy warning labels are part of a broader suite of measures that aim to prevent FASD. The Australian and New Zealand Governments will continue to implement actions from Australia and New Zealand’s FASD Strategies and Action Plans. While it will not be possible to attribute any changes in behaviours or the incidence or prevalence of FASD to pregnancy warning labels alone, the following monitoring and evaluation should also be undertaken.

- Proportion of women who drink alcohol while pregnant, including frequency and amount of alcohol consumed and changes in consumption during the course of the pregnancy. Consideration should also be given to ensuring priority populations (e.g. Aboriginal and Torres Strait Islander and Maori population) are included in monitoring and evaluation work and sufficient sample sizes are collected to enable robust reporting.

Future drug and alcohol consumption surveys, such as the National Drug Strategy Household Survey in Australia can collect this type of data. New Zealand should prioritise collection of data on this topic due to the absence of national data on the prevalence of women that drink alcohol while pregnant in New Zealand.

- Incidence and prevalence of FASD. The Australian Government funded development of the FASD Australian Register (which complements the Australian FASD diagnostic tool released in 2016) will significantly improve Australia's capacity to monitor the incidence and prevalence of FASD in the Australian population. New Zealand should give priority to building capacity to be able to measure and report the incidence and prevalence of FASD.

This will support an assessment of whether the assumptions in this analysis relating to the incidence of FASD are accurate.

#### **Other monitoring and evaluation (ongoing)**

- Monitoring of literature relating to impact and burden of FASD on the Australian and New Zealand communities. Work is ongoing by Non-Government Organisations and academics in this area. For example, researchers at the Telethon Kids Institute are currently working to estimate the economic burden of FASD in Australia<sup>185</sup>. The information provided by this research and other literature will allow an assessment of whether the assumptions used in this analysis, such as cost per case of FASD are reasonable.

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<sup>185</sup> Telethon Kids Institute 2018. [\*Estimating the Economic Burden of FASD in Australia\*](#)

### **Actions to prevent and manage FASD that are already underway**

In response to recommendation 25 in the Labelling Logic Review, the Forum noted that pregnancy warning labels alone will not prevent women drinking alcohol while pregnant. The Forum recognised that when warning labels on packaged alcohol are part of a broader package of measures, they may help to reduce alcohol related harm. A range of other activities are currently in place in Australia and New Zealand to prevent and manage FASD which are described below.

Because of the difficulties in measuring the prevalence of FASD and the lack of time series data, it is not possible to conclude whether these actions have resulted in a reduction in the prevalence in FASD in Australia or New Zealand. However, as noted in Section 1.2, the proportion of women consuming alcohol during pregnancy in Australia<sup>186</sup> declined and the proportion abstaining increased from 40% to 56% between 2007 to 2016. It is not possible to attribute this change to any specific activity. Trend data are not available for New Zealand.

#### ***Australia***

In Australia, the Government committed funding of \$9.2 million over four years (2013-14 to 2016-17) under the FASD Action Plan. The Plan delivered a number of activities including:

- The finalisation and dissemination of the Australian FASD Diagnostic Tool;
- The development of the FASD Australian Register to complement the Australian Diagnostic Tool;
- The development of an online FASD Hub. The Hub provides a central repository for all information on FASD for clinicians, health practitioners, researchers and consumers;
- Establishment of the FASD Technical Network to provide advice on FASD related matters to the Australian Government Department of Health;
- Funding for the Foundation for Alcohol Research and Education to promote and evaluate the What Women Want to Know Project and to expand the ACT based Pregnant Pause project to a national reach;
- Funding for the AIHW to improve data collection of maternal alcohol consumption in pregnancy and develop a screening tool to identify women at risk of alcohol misuse, mental health problems and domestic violence;
- Evaluation of the best practice resource for drug and alcohol dependent women and funding to 13 drug and alcohol treatment services to test the usability of the best practice resource; and
- Funding for NOFASD Australia to provide information services to individuals and families affected by FASD and to deliver a one-off project to raise awareness of FASD, at the grass roots level.

In the 2016 Budget, the Australian Government announced a further \$10.5 million over four years to June 2020 to build on the achievements of the FASD Action Plan.

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<sup>186</sup> Australian Institute of Health and Welfare (AIHW). 2017. '[National Drug Strategy Household Survey 2016: detailed findings](#)'. Drug Statistics series no. 31. Cat. no. PHE 214. Canberra: AIHW.

This measure consists of funding for activities such as online and telephone support for individuals and families affected by FASD and the provision of FASD Diagnostic Services and Models of Care in communities of high need across Australia.

The Australian Government has also provided funding for additional activities including:

- Extension of the What Women Want to Know Project and the Pregnant Pause Campaign
- Continuation of the FASD Hub
- Continuation of the FASD Australian Register
- The dissemination of the FASD Diagnostic Guidelines
- Funding to DrinkWise, contributing to their suite of FASD prevention programs

The Department also provided funding to the NHMRC to review the Australian Drinking Guidelines which currently has a recommendation directly relating to pregnant women and those who are breastfeeding. This is due for completion in 2020.

The development of a ten year FASD Strategic Action Plan 2018-2028 (the Strategic Action Plan), is underway and expected to be finalised in late 2018. The Strategic Action Plan will provide a cohesive, evidence-based strategy that addresses the whole-of-life, whole-of-population and collaborative cross-sectoral approaches required to prevent and support those living with and affected by the disorder.

## ***New Zealand***

New Zealand's *Taking Action on Fetal Alcohol Spectrum Disorder: 2016-2019 Action Plan* was launched in August 2016 and aims to create a more effective, equitable and collaborative approach to FASD<sup>187</sup>. It is a cross-agency commitment designed to build on work already underway across government and the community and has four focus areas: prevention; early identification and assessment; support for affected people and their families; and improving New Zealand's FASD evidence base.

Actions underway as part of the New Zealand Action Plan include:

- Implementing an intensive service for pregnant women with alcohol and drug dependence and high and complex needs in three regions;
- Redeveloping alcohol screening and brief intervention guidelines for primary care professionals;
- Convening a cross-agency clinical network to drive diagnostic and data collecting protocols for New Zealand;
- Co-designing and piloting a training package for frontline professionals across a range of sectors to improve their capacity to prevent and respond effectively to FASD;
- Testing assessment and support pathways for affected children and families, including trialling new interventions;
- Conducting an FASD incidence study within a representative cohort of 8 year olds;
- Investigating the association between alcohol exposure and neurodevelopmental outcomes in a representative cohort of 4 year olds.

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<sup>187</sup> FASD Working Group. 2016. '[Taking Action on Fetal Alcohol Spectrum Disorder: 2016–2019: An action plan](#)'. Wellington, Ministry of Health.

The prevention area of the New Zealand Action Plan includes developing and disseminating clear, unambiguous, and consistent messages to increase the community's awareness of the risks of drinking during pregnancy. The Action Plan references the current voluntary labelling arrangement which encourages industry to voluntarily provide pregnancy warning labels on all packaged alcoholic products, and notes that the trans-Tasman voluntary arrangement will be subject to review. It also notes that Government will work in partnership with industry to ensure that consumers receive clear, unambiguous and consistent messages about the risks of drinking in pregnancy through all channels. Pregnancy warning labels on packaged alcohol products serve as an "on the spot" reminder at point of sale and point of consumption. More detailed messages are able to be provided through other channels.

In addition, the New Zealand Health Promotion Agency is in the third year of delivering an alcohol-free pregnancies public education campaign. The mainly online campaign - '*Don't Know? Don't Drink*' - is focused on young women. It reminds them that alcohol can harm developing babies and if they 'don't know' whether they're pregnant then 'don't drink'. This campaign is also contributing to awareness amongst young New Zealand women that alcohol should not be consumed if they could be or are pregnant.

### Ensuring the message is understood

The Forum requested consideration of the most appropriate pictogram and most easy to understand message to discourage drinking during pregnancy.

#### *Effective label design*

The World Health Organization (WHO) recommends that if pictograms are used on alcohol labels, it is preferable that they are accompanied by a corresponding health information message.<sup>188</sup> It also recommends:

- label should be placed in a standard location on the container;
- size of the label should be determined as a minimum percentage of the size of the container;
- rotating messages should be used, with sufficient vividness and strength to attract consumers;
- text should be clearly separated from other information on the label (for example, placed in boxes with thick borders);
- text should be printed in capital letters and bold type; its size should be the same as for all other information provided on the container;
- text should appear on a contrasting background (for example, red type on white);
- text should be written in the official language(s) of the country in which the product is sold;
- images used should be informational in style and taken from ongoing educational campaigns; and
- public health bodies can usefully advise on the content of messages.

Australian researchers found certain characteristics influence alcohol warning labels' effectiveness, such as font size, colour, spacing, and position of the warning on the front versus the back of the packaging<sup>189</sup>. Research suggests that for alcohol warning labels to be most effective, they should be large enough to be easily noticed and read, appear on the front rather than the side of packaging and be varied frequently to avoid overexposure<sup>190,191</sup>. Warnings printed on the front of alcohol labels are more noticeable than those printed in any other location<sup>192,193</sup>. Warning labels placed on the lower back of a product near other label features such as the barcode and ingredients list reduces the visibility of the warning and obscures the information conveyed<sup>194</sup>.

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<sup>188</sup> World Health Organization. 2017. '[Alcohol labelling – A discussion document on policy options](#)'. Regional Office for Europe.

<sup>189</sup> Wilkinson, C., et al. 2009. '[Report 2-Alcohol Warning Labels: Evidence of impact on alcohol consumption amongst women of childbearing age](#)'. National Drug Research Institute (Curtin University of Technology). Prepared for Food Standards Australia New Zealand (FSANZ).

<sup>190</sup> Jones, S., Gordon, R., 2013. '[Alcohol warning labels: are they effective?](#)' Deebie Institute Prepared for the Australian Healthcare and Hospitals Association (AHHA).

<sup>191</sup> Wilkinson, C., Room, R., 2009. '[Warnings on alcohol containers and advertisements: international experience and evidence on effects](#)' *Drug Alcohol Rev*, 28(4):426-35.

<sup>192</sup> Laughery KR., et al. 1993. '[The noticeability of warnings on alcoholic beverage containers](#)'. *Journal of Public Policy & Marketing*, 12(1): 38-56.

<sup>193</sup> Wilkinson, C., et al. 2009. '[Report 2-Alcohol Warning Labels: Evidence of impact on alcohol consumption amongst women of childbearing age](#)'. National Drug Research Institute (Curtin University of Technology). Prepared for Food Standards Australia New Zealand (FSANZ).

<sup>194</sup> Coomber, K., et al. 2017. '[Unconvincing and ineffective: Young adult responses to current Australian alcohol product warnings](#)'. *Australian Journal of Psychology*, 70( 2): 131-138.



The use of red/black colour enhances attention to health warning messages<sup>195</sup>, with the colour red for the outside and line of the pictogram considered most appropriate as this is commonly used to convey danger or warning<sup>196</sup>. The most effective health text warning messages are simple, clear, direct and related to specific risks and harms<sup>197</sup>.

Learnings from tobacco labelling can also be applied. A report prepared for the European Commission about health warnings for tobacco packages<sup>198</sup> makes very similar recommendations for effective health warning labels as the WHO (2017) report on alcohol labelling, specifically in relation to using large bold print, high contrast, colour and borders, and the importance of size.

There is a strong body of evidence from tobacco control that large warnings with pictures are more effective than text only warning<sup>199,200</sup>, and that pictures increase the message's accessibility by people with low levels of literacy. Research also shows that colour pictures are more effective than black and white pictures<sup>201</sup>.

Further information about the most appropriate pictogram and pregnancy warning message is discussed below.

### ***Most appropriate pictogram***

Pictograms increase the messages accessibility for people with low levels of literacy<sup>202,203</sup>. Evidence shows that compared to text warnings, pictorial health warnings are associated with increased perceptions of the health risks of consuming alcohol and greater intentions to reduce and quit alcohol consumption<sup>204</sup>. Research into tobacco warnings also finds pictures are more effective than text<sup>205</sup>, although evidence suggests both text and images are required for the maximum impact<sup>206,207</sup>.

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<sup>195</sup> Pham, C., et al. 2017. '[Alcohol warning label awareness and attention: a multi-method study](#)'. *Alcohol and Alcoholism* ; 53(1): 39-45.

<sup>196</sup> Hall & Partners. 2018. '[Understanding of consumer information messaging on alcohol products: Focus group testing report](#)'. Foundation for Alcohol Research and Education, Canberra.

<sup>197</sup> Thomas, G., et al. 2014. '[The effectiveness of alcohol warning labels in the prevention of Fetal Alcohol Spectrum Disorder: A brief review](#)'. *International Journal of Alcohol and Drug Research*, 3(1): 91-103.

<sup>198</sup> Sambrook Research International. 2009. '[A review of the science base to support the development of health warnings for tobacco packages](#)'. Prepared for European Commission, Directorate General for Health and Consumers.

<sup>199</sup> Hammond, D. 2011. '[Health warning messages on tobacco products: a review](#)'. *Tobacco Control*, 20(5): 327-37

<sup>200</sup> Houts, P.S., et al. '[The role of pictures in improving health communication: a review of research on attention, comprehension, recall, and adherence](#)'. *Patient Education and Counseling*. 2006, 61(2): 173-190.

<sup>201</sup> Campaign for Tobacco Free Kids. 2018. '[Tobacco health warnings: evidence of effectiveness](#)'.

<sup>202</sup> Campaign for Tobacco Free Kids. 2018. '[Tobacco health warnings: evidence of effectiveness](#)'. Washington, U.S.A.

<sup>203</sup> Houts, P.S., et al. 2006, '[The role of pictures in improving health communication: a review of research on attention, comprehension, recall, and adherence](#)'. *Patient Education and Counseling*. 61(2): 173-190.

<sup>204</sup> Wigg, S., Stafford, L.D. 2016 '[Health warnings on alcoholic beverages: Perceptions of the health risks and intentions towards alcohol consumption](#)'. *PloS One.*, 11(4): e0153027.

<sup>205</sup> Wilkinson, C., et al. 2009. '[Report 2-Alcohol Warning Labels: Evidence of impact on alcohol consumption amongst women of childbearing age](#)'. National Drug Research Institute (Curtin University of Technology). Prepared for Food Standards Australia New Zealand (FSANZ).

<sup>206</sup> Noar, S.M., et al. 2015 '[Pictorial cigarette pack warnings: a meta-analysis of experimental studies](#)'. *Tobacco Control*. 25(3): 341-354.

<sup>207</sup> Tobacco Resource Labelling Centre. 2013. '[Tobacco Labelling Toolkit](#)'. Ontario, Canada.

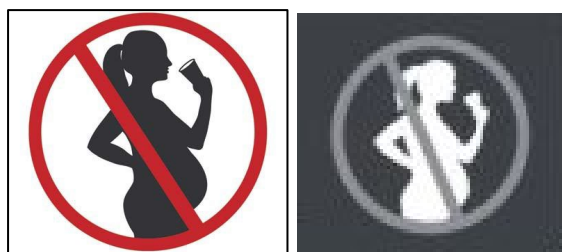
The Australian evaluation<sup>208</sup> reported that the most commonly used pregnancy health warning label is the pictogram by itself, with 76% of products using this image. The New Zealand evaluation also reported that the pictogram was the most commonly sighted pregnancy warning label used, with over half of the pregnancy warning labels for beer, cider, wine and spirits surveyed in the New Zealand field survey using it.

All submissions supported the use of a pictogram. Many stakeholders indicated a preference for a pictogram over a text warning, while others supported a pictogram accompanied by text warnings to explain the reason for abstaining from alcohol. Industry mostly preferred the option to use either the pictogram *or* the text.

### Pictogram image

The DrinkWise and Cheers pictograms show a picture of a pregnant woman holding a wineglass; however other pictogram warning images used internationally (such as the French image shown below) show a picture of a pregnant woman holding a beer glass.

**Figure A.1.1- The Pregnancy warning pictogram from France (left) and DrinkWise (right)**



Further information would be required to determine how the different images impact on understanding of the warning message. Most submissions did not indicate a preference either way for beer versus wine glass in the pictogram. Many suggested that it be consumer tested. Several submissions suggested a beer glass could be misinterpreted to be a glass tumbler containing any beverage and therefore it may be more appropriate to use an image of a pregnant woman holding a wine glass as it is a more identifiable drinking vessel. It was also noted by one stakeholder that wine is the beverage most commonly consumed by women and therefore a wine glass would be more appropriate. One submission suggested it may be warranted to change the image of the pictogram dependent on the product it is featured on – i.e. use a wine glass image on wine labels, and a beer glass on other products.

### Pictogram colour and contrast

The DrinkWise pictogram has used green colouring; however, the Australian and New Zealand evaluations identified confusion associated with the green colour where some people considered that this meant it was acceptable to drink when pregnancy.

A red pregnancy warning pictogram is commonly used internationally; many countries using this image (refer to section 6.12 of the Australian evaluation report)<sup>209</sup>.

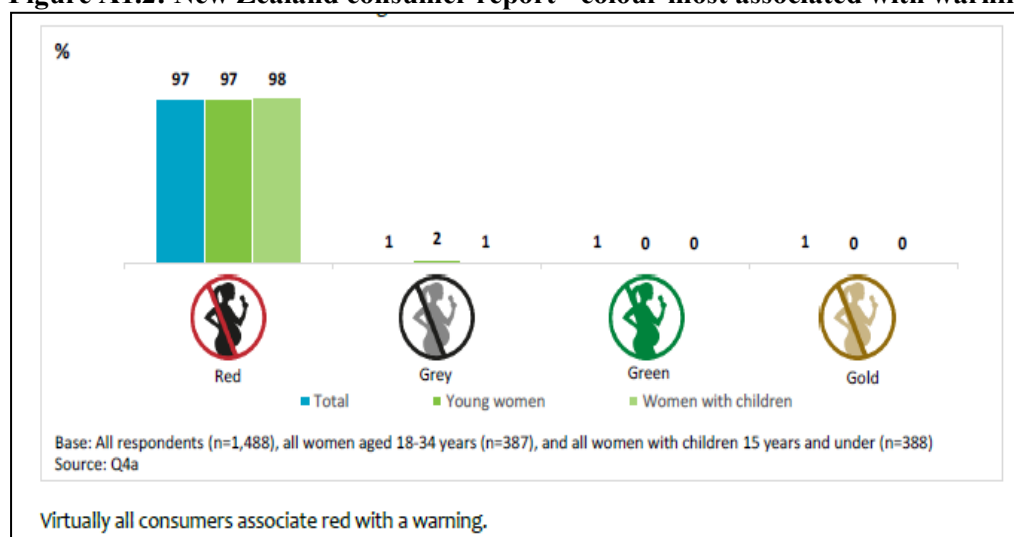
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<sup>208</sup> Siggins Miller. 2017. '[Second evaluation of the voluntary labelling initiative to place pregnancy health warnings on alcohol products](#)'.

<sup>209</sup> Siggins Miller. 2017. '[Second evaluation of the voluntary labelling initiative to place pregnancy health warnings on alcohol products](#)'.

Consumer understanding of the pictogram colours was tested in the New Zealand consumer research<sup>210</sup>, where 97% of women surveyed agreed that the red colour looked most like a warning, and 1% of agreed that a green pictogram looked most like a warning (refer to the graph below which has been extracted from the New Zealand consumer report undertaken to inform the second evaluation of the pregnancy warning labelling initiative). The Australian evaluation report also recommended using a red colour to indicate danger.

**Figure A1.2: New Zealand consumer report - colour most associated with warning**<sup>211</sup>



The red/black pictogram was also the only image used in the New Zealand consumer research which had different colours between the symbol of the woman and the line through and around it. The other pictograms tested had one colour with different tones or were monotone. Observations from the New Zealand field survey were that the pictogram stands out most when contrasting colours are used for the line through the pregnant figure and the figure itself, or if in monotone, the line through the pregnant figure is separated from the figure.

Other evidence suggests enhanced attention (with a 37% increase) to the alcohol pregnancy warning label can be achieved when a red coloured and 50% larger warning label is used on alcohol packaging compared to the current market warning label in grey<sup>212</sup>. Research undertaken on behalf of the Foundation for Alcohol Research and Education (FARE) found red is considered the most appropriate colour for the prohibition symbol (i.e. the circle and line through the circle)<sup>213</sup>.

Public health and consumer submissions strongly favoured the use of red in the pictogram, noting that consumers recognise that red signifies danger. Many suggested the contrast of a black pregnant silhouette with red circle and line. A number of

<sup>210</sup> Rout, J., Hannan, T. 2016. '[Consumer awareness and understanding of alcohol pregnancy warning labels](#)'. Wellington: Health Promotion Agency.

<sup>211</sup> Rout, J., Hannan, T. 2016. '[Consumer awareness and understanding of alcohol pregnancy warning labels](#)'. Wellington: Health Promotion Agency.

<sup>212</sup> Pham, C., et al. 2017. '[Alcohol warning label awareness and attention: a multi-method study](#)'. *Alcohol and Alcoholism* ; 53(1): 39-45.

<sup>213</sup> Hall & Partners. 2018. '[Understanding of consumer information messaging on alcohol products: Focus group testing report](#)'. Foundation for Alcohol Research and Education, Canberra.

submissions recommended consumer testing in order to determine the colour that has the most impact.

Industry submissions noted the challenges and costs associated with introducing an additional colour such as red. Introduction of a two-colour pictogram would be challenging for industry as it could potentially require small volume imported products' labels to undergo changes. Industry noted it is less costly to have flexibility in allowing the pictogram to be displayed in the same colourway as the rest of the label. For example, the vast majority of wine labels (particularly those of smaller producers) have one colourway, usually black or charcoal. The introduction of a new colour has significant additional costs in colour plates (in offset printing) and in printing costs per label.

It was noted by several stakeholders that some producers in the alcohol industry already apply a red pictogram to products that are exported to other countries, such as France, as an accepted cost of business.

### **Pictogram size**

Many public health, consumer group and government submissions asserted that the pictograms are currently too small, and recommended consumer testing to determine the most appropriate size for best visibility. Several submissions suggested that the size of the warning should be a minimum percentage of the container size, as recommended by the WHO<sup>214</sup>. Conversely, some industry submissions stated that the current DrinkWise pictogram takes up too much room on the label and should be smaller.

Additional considerations for the pictogram would include borders and its placement on the alcohol label. See below for more information on these considerations.

### ***Most easy to understand message***

While use of the text warning label is less common than the pictogram, of those products that use a written message, the DrinkWise text: *“It’s safest not to drink while pregnant”* is the most commonly used pregnancy warning text in Australia and New Zealand.

Many submissions supported the use of warning text. Some industry submissions indicated that they support the option of using the text without the pictogram. However, no public health, consumer or government submissions supported this, and many of these stakeholders recommended that it be used in conjunction with a pictogram to explain the risks associated with drinking during pregnancy.

### **Messaging**

Australian alcohol industry submissions strongly preferred the current DrinkWise text, while some New Zealand industry stakeholders suggested the final decision on the imagery and messaging for the labelling be decided on a 'best evidence' basis.

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<sup>214</sup> World Health Organization. 2017. [‘Alcohol labelling – A discussion document on policy options’](#). Regional Office for Europe.

Public health, consumer and government submissions overwhelmingly did not support the current DrinkWise text.

The ‘*safest not to*’ part of the DrinkWise text is not consistent with the New Zealand alcohol guidelines and has been interpreted by some consumers as weak and allowing some leeway in the consumption of alcohol when pregnant<sup>215</sup>. The New Zealand consumer research<sup>216</sup> on awareness and understanding of pregnancy warning labels undertaken to inform the second evaluation on pregnancy warning labels found that unprompted, 14% of young women (aged 18-34 years) thought that the DrinkWise text meant that you could drink alcohol when pregnant.

The New Zealand consumer research tested an alternative text “*Don’t drink pregnant*” which is not currently used in New Zealand and found 80% of respondents considered that the text “*Don’t drink pregnant*” conveyed the general message not to drink when pregnant (compared to 54% for the DrinkWise text). This text was also less likely to be misinterpreted than the DrinkWise text (8% of all respondents misinterpreted the DrinkWise text, compared to 1% for the alternate text). A higher proportion of women reported that the alternate text would make them very unlikely to think that drinking alcohol when pregnant would be okay (39% compared to 31% for the DrinkWise text).

It should be noted that the “*Don’t drink pregnant*” message tested in the New Zealand consumer research was green in colour. The Australian evaluation report noted that the green text was confusing. It is proposed that green colouring should not be used for the text warning label.

The New Zealand consumer research did not recommend the DrinkWise text as an ideal text to accompany a pictogram and recommended more research on possible text options.

Consumer research undertaken on behalf of FARE<sup>217</sup> into alternative warning messages found that:

- use of the word ‘warning’ is effective for attracting attention and signalling gravity;
- the word ‘harm’ tended to be considered more credible than ‘birth defects’;
- the word ‘can’ (compared to ‘may’) reduced participants disputing the message on the basis that small amounts of alcohol would not definitely cause harm; and
- personalising the message by referring to ‘the unborn baby’ rather than ‘fetus’, and to ‘your baby’ rather than ‘babies’, increased the relevance and emotional resonance of the message.

This research recommended a message such as “*Drinking while pregnant can hurt your baby*”

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<sup>215</sup> Hall & Partners. 2018. ‘[Understanding of consumer information messaging on alcohol products: Focus group testing report](#)’. Foundation for Alcohol Research and Education, Canberra.

<sup>216</sup> Rout, J. Hannan, T. 2016. ‘[Consumer awareness and understanding of alcohol pregnancy warning labels](#).’ Wellington: Health Promotion Agency.

<sup>217</sup> Hall & Partners. 2018. ‘[Understanding of consumer information messaging on alcohol products: Focus group testing report](#)’. Foundation for Alcohol Research and Education, Canberra.

Most public health and government submissions suggested consumer testing to determine the most effective message. Some submissions provided alternative text for the warning, such as “*Alcohol harms your unborn baby*” and “*Drinking alcohol during pregnancy can cause birth defects*”. A small number of submissions suggested that the text support the full NHMRC advice by also including statements not to drink when breastfeeding or when planning a pregnancy. Many public health submissions referred to research suggesting that effective messages include a signal word such as “WARNING”<sup>218,219</sup> or “HEALTH WARNING”<sup>220</sup> to indicate it is a warning label. One New Zealand submission asked for consideration of messages written in both English and Te Reo Māori.

### Text colour and contrast

A review of health warnings on alcohol beverages in Europe found that the specific colour used for warnings is less important than the colour combination, and that a strong foreground-background contrast is more effective in drawing attention<sup>221</sup>. The 2017 WHO report recommends that the visual impact of the label can be improved by employing large bold print, high contrast, colour, and borders<sup>222</sup>. Similarly, consumer research in Australia also recommends using bold, legible text, colour that increases noticeability of the label, and a high level of contrast from the surrounding label and background packaging<sup>223</sup>.

Several public health, consumer and government submissions proposed red or bold black text, and some advocated for black text on a yellow background. However, most recommended consumer testing to determine the most appropriate colour and contrast for a text warning label. Industry submissions noted that the introduction of a new colour that is not currently contained within existing label designs will impose significant additional costs, especially to smaller producers.

The need to consider borders and clear space around the message was raised in numerous submissions. Research recommends warning labels should not be obscured by surrounding information and the use of borders ensures the area is large enough to ensure the text can be read<sup>224,225,226</sup>. Up to a certain size, borders appear to increase noticeability of the message they contain<sup>227</sup>. Borders also better allow for contrasting

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<sup>218</sup> Hall & Partners. 2018. ‘[Understanding of consumer information messaging on alcohol products: Focus group testing report](#)’. Foundation for Alcohol Research and Education, Canberra.

<sup>219</sup> Mercer, R., et al. 2013. ‘[Literature review on the impact of label format on consumers’ attention and comprehension for mandated label elements](#)’. Prepared for Food Standards Australia New Zealand (FSANZ).

<sup>220</sup> Victorian Health Promotion Foundation. 2009. ‘[Alcohol health information labels: Report of qualitative research into health information labels on alcoholic beverages](#)’. Carlton South, Australia.

<sup>221</sup> European Commission. 2011. ‘[Health warnings and responsibility messages on alcoholic beverages – a review of practices in Europe](#)’.

<sup>222</sup> World Health Organization. 2017. ‘[Alcohol labelling – A discussion document on policy options](#)’. Regional Office for Europe.

<sup>223</sup> Hall & Partners. 2018. ‘[Understanding of consumer information messaging on alcohol products: Focus group testing report](#)’. Foundation for Alcohol Research and Education, Canberra.

<sup>224</sup> European Commission. 2011. ‘[Health warnings and responsibility messages on alcoholic beverages – a review of practices in Europe](#)’.

<sup>225</sup> Hall & Partners. 2018. ‘[Understanding of consumer information messaging on alcohol products: Focus group testing report](#)’. Foundation for Alcohol Research and Education, Canberra.

<sup>226</sup> World Health Organization. 2017. ‘[Alcohol labelling – A discussion document on policy options](#)’. Regional Office for Europe.

<sup>227</sup> Adams, A.S., Edworthy, J. 1995. ‘[Quantifying and predicting the effects of basic text display variables on the perceived urgency of warning labels: tradeoffs involving font size, border weight and colour](#)’. *Ergonomics*. 38(11): 2221-2237



background colour to be used. Many public health stakeholders requested that these considerations be consumer tested.

## Text size

A number of studies that looked at consumer responses to the current DrinkWise warnings have found that the labels are not noticeable due to the warning being too small<sup>228,229</sup>.

Increasing the size of warnings on food labels has been shown to increase attention<sup>230</sup>. A study that looked at the size of alcohol warnings found increasing the size reduces positive perceptions about alcohol products in general<sup>231</sup> (although note this study used warnings that were 50%, 75% and 90% of the label size).

Numerous public health and government submissions recommended consumer testing to determine the most appropriate size of the text, with several noting the WHO's recommendations to use large print and make the warning a minimum percentage of the container size<sup>232</sup>. Several referred to regulations in South Africa which require that health messages on alcohol products must be on a place specifically devoted to the warning that must cover at least one eighth of the total size of the container label<sup>233</sup>.

Most industry submissions did not comment specifically on the size of the text, although it was noted that the DrinkWise Style Guide prescribes the size of the labels to ensure legibility.

## Location of warning

There is a considerable body of evidence that warning labels are more noticeable and effective when placed on the front of the product<sup>234,235,236,237,238,239</sup>. Many public health, consumer and government submissions advocated that the warning labels should appear on the front label of the alcoholic beverage. However, it was noted by an industry organisation that no other mandatory information is required on the front

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<sup>228</sup> Coomber, K.Hayley, A. Miller P.G. 2017. '[Unconvincing and ineffective: Young adult responses to current Australian alcohol product warnings](#)'. *Australian Journal of Psychology*, 70( 2): 131-138.

<sup>229</sup> Hall & Partners. 2018. '[Understanding of consumer information messaging on alcohol products: Focus group testing report](#)'. Foundation for Alcohol Research and Education, Canberra.

<sup>230</sup> Mercer, R., et al. 2013. '[Literature review on the impact of label format on consumers' attention and comprehension for mandated label elements](#)'. Prepared for Food Standards Australia New Zealand (FSANZ).

<sup>231</sup> Al-Hamdani, M., Smith. S.M. 2016 '[Alcohol warning label perceptions: do warning sizes and plain packaging matter?](#)' *Journal of Studies on Alcohol and Drugs*, 78(1): 79-87.

<sup>232</sup> World Health Organization. 2017. '[Alcohol labelling – A discussion document on policy options](#)'. Regional Office for Europe.

<sup>233</sup> Republic of South Africa. 2014. '[Regulation amendment on container labels of alcoholic beverages](#)'. Trade Policy Monitoring, Beverages, Food and Agricultural Import Regulations and Standards. Pretoria, South Africa.

<sup>234</sup> European Commission. 2011. '[Health warnings and responsibility messages on alcoholic beverages – a review of practices in Europe](#)'.

<sup>235</sup> World Health Organization. 2017. '[Alcohol labelling – A discussion document on policy options](#)'. Regional Office for Europe.

<sup>236</sup> Jones, S., Gordon, R., 2013. '[Alcohol warning labels: are they effective?](#)'. Deeble Institute Prepared for the Australian Healthcare and Hospitals Association (AHHA).

<sup>237</sup> Wilkinson, C., Room, R., 2009. '[Warnings on alcohol containers and advertisements: international experience and evidence on effects](#)' *Drug Alcohol Rev*, 28(4):426-35. doi: 10.1111/j.1465-3362.2009.00055.x.

<sup>238</sup> Laughery KR., et al. 1993. '[The noticeability of warnings on alcoholic beverage containers](#)'. *Journal of Public Policy & Marketing*, 12(1): 38-56.

<sup>239</sup> Coomber, K.Hayley, A. Miller P.G. 2017. '[Unconvincing and ineffective: Young adult responses to current Australian alcohol product warnings](#)'. *Australian Journal of Psychology*, 70(2): 131-138.



labels on alcohol, including elements such as alcohol volume or standard drinks. Industry submissions strongly objected to mandating warnings on the front of the packaging.

Several submissions advised that the warning should not be placed next to contradictory messages such as ‘*enjoy responsibly*’. Others proposed it should be located next to other consumer information such as standard drinks. Some industry submissions noted the need for flexibility with regard to position on the package to place the warning within the available space.

## ***Recommendations***

Consumer understanding of the current warning labels could be improved by increasing the size of the pictogram and text, using contrasting colours and legible fonts, changing the wording of the warning message, and using features such as borders and clear space around the warning to help the warning stand out and be distinctive from surrounding information on the label.

Consumer testing should be undertaken to determine the most appropriate features of the pictogram. It is recommended that testing explores:

- image – beer versus wine glass;
- colour and contrast – black with red prohibition symbol; black with charcoal prohibition symbol (or vice versa); monotone with the line through the pregnant figure separated from the figure (e.g. in charcoal or black); and a range of other contrasting colours;
- size – the minimum size recommended by DrinkWise and Cheers versus various minimum percentages of the label; and
- location – proximity to other information on the label.

The warning text should not be used on its own, but should be used in conjunction with the pictogram to explain *why* women should not drink when pregnant. Consumer testing of the warning text should explore:

- message –
  - current DrinkWise messages;
  - statements mandated internationally, such as in France: “*Consumption of alcoholic beverages during pregnancy, even in small amounts, can have serious consequences for the child's health*”;
  - other statements such as “*Don’t drink pregnant*”; “*Drinking while pregnant can hurt your baby*”; “*Alcohol harms your unborn baby*”; “*Drinking alcohol during pregnancy can cause birth defects*”;
  - statements including message not to drink when planning a pregnancy or when breastfeeding; and
  - use of the word “*WARNING*”, “*HEALTH WARNING*”, or “*GOVERNMENT WARNING*”.
- size – minimum font size
- print – bold typeface versus plain; uppercase versus lower case;
- colour – black, red, charcoal;
- contrast – use of clear space around the message; different text and background combinations (e.g. black text on yellow background; red and black text on white background); and

- border – colour; size; width.

The consumer testing should not be undertaken by industry in order to eliminate any perceptions of conflict of interest or bias. Ideally the warnings to be tested should be developed by communication, behaviour change and health literacy experts. Warnings should be tested with the women of childbearing age, pregnant women and women planning a pregnancy, as well as those who influence their decision not to drink, such as partners and health professionals.