

May 2018
Food Regulation Standing Committee

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

For purposes of targeted consultation only

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

Invitation to make a submission

The Food Regulation Standing Committee (FRSC) is inviting submissions from identified stakeholders, including industry, public health and consumer organisations, which express a view on pregnancy warning labels on packaged alcoholic beverages.

Information provided in response to the consultation questions in this paper will be used to prepare a Decision Regulation Impact Statement (RIS) in which FRSC will identify a preferred policy option for pregnancy warning labels on packaged alcoholic beverages to recommend to the Australia and New Zealand Ministerial Forum on Food Regulation in late 2018.

Please provide your submissions by 14 June 2018. Electronic submissions from both Australia and New Zealand stakeholders are preferred and should be sent to the e-mail address below:

Title: Submission in relation to pregnancy warning labels on packaged alcoholic beverages

Email to: FoodRegulationSecretariat@health.gov.au

OR mail to:

Food Regulation Secretariat
C/- MDP707, GPO Box 9848
Canberra ACT 2601

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Executive Summary

This policy options targeted consultation paper (also known as a consultation Regulation Impact Statement (CRIS)) has been prepared at the request of the Australia and New Zealand Ministerial Forum on Food Regulation (the Forum) to support consideration of regulatory and non-regulatory options for pregnancy warning labels on packaged alcoholic beverages.

The consultation paper has been prepared in accordance with COAG best practice regulation requirements, and includes the following sections:

- a statement of the problem – explaining the need for government action;
- a statement of the objectives of any intervention;
- a statement of the possible options to address the problem; and
- an impact analysis of the options.

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 can be difficult to diagnose and therefore robust prevalence estimates of FASD are not available for Australia or New Zealand.

Government advice is that pregnant women not consume any alcohol. Pregnancy warning labels are recommended to communicate this advice to pregnant women and their support network, as part of a broader suite of activities (including targeted interventions) that aim to prevent FASD. Pregnancy warning labels on packaged alcoholic beverages also may support the establishment of cultural norms in relation to pregnant women not drinking alcohol.

Australia and New Zealand currently implement pregnancy warning labels on packaged alcoholic beverages on a voluntary basis. Two evaluations of the voluntary labelling 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, there are some product categories where coverage remains a concern. The evaluations also identified issues such as inconsistent warning labels being used, and some consumer misunderstanding of the messaging on the labels. These implementation issues have prompted consideration of possible regulatory and non-regulatory approaches to pregnancy warning labels on packaged alcoholic beverages to ensure good coverage of the pregnancy warning labels, and pregnancy warning labels that are consistent with the government advice and understood by the target audience.

This paper presents voluntary approaches (three variations) and a mandatory option to that may support high coverage of pregnancy warning labels on packaged alcoholic beverages and messaging on these warning labels (picture or words) that is understood by the target audience and consistent with government advice. The paper also considers the benefits that could be achieved from the proposed policy options, and the potential costs associated with each option.

Stakeholder feedback is sought in key areas to ensure that the information presented in this paper is correct and to attempt to fill gaps in evidence that exists. The information provided in response to the consultation questions, and the information provided in this paper, will be used to prepare a Decision Regulation Impact Statement (DRIS) to identify a preferred policy option for pregnancy warning labels on packaged alcoholic beverages to recommend to the Forum. If information of sufficient quality and volume can be obtained from through targeted consultation, it may be possible to undertake a more quantitative impact analysis of the proposed options for this document.

Introduction

Purpose of this paper

This policy options paper has been prepared at the request of the Australia and New Zealand Ministerial Forum on Food Regulation (the Forum) to support consideration of regulatory and non-regulatory options for pregnancy warning labels on packaged alcoholic beverages in Australia and New Zealand. Questions for stakeholders are provided at the end of each section. In providing responses to the consultation questions, stakeholders are asked to provide evidence and references to support their statements.

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 Bodies¹, and responses to the questions will be used to develop a Decision Regulatory Impact Statement (DRIS) with a preferred option to recommend to the Forum.

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))² 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 25³ 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.*

¹ Council of Australian Governments (COAG) 2007. '[Best Practice Regulation: A Guide for Ministerial Councils and National Standard Setting Bodies](#)'.

² The Forum is made up of Ministers responsible for food regulation from the Australian Federal Government; New Zealand; and Australian states and territories.

³ 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.

In December 2011, in its response to the report on the Labelling Logic Review of Food Labelling Law and Policy 2011, 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. The FoFR considered the results in 2014 and 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 (RTD) 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 these both 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 alcohol beverage types. The results of the second evaluation of the pregnancy warning labelling initiative for Australia and New Zealand are available at <http://www.health.gov.au/internet/fr/publishing.nsf/Content/pregnancy-warnings-alcohol-labels>

In November 2017, the Forum noted the results of the second evaluations of the uptake of 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 pregnancy⁴.

⁴ 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

Alcohol is a regular part of many people's diets in Australia and New Zealand⁵. It is also a potent teratogen—a toxic substance that can inhibit the healthy development of the fetus. Some will not survive the exposure. As levels of alcohol consumption increase, so does the risk of miscarriage and stillbirth⁶. Babies exposed to alcohol during pregnancy are also more likely to be born prematurely and may enter the world with permanent damage to their brain and other critical organs, functions and structures⁷. 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*⁸ by the National Medical Health and Research Council (NHMRC) 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.

The *Australian Guidelines to Reduce Health Risks from Drinking Alcohol* recommend that not drinking is the safest option for women who are planning a pregnancy, pregnant, or breastfeeding. In New Zealand, women who could be pregnant, are pregnant, or are trying to get pregnant are advised to stop drinking alcohol⁹. Women who are breastfeeding are also advised to avoid consumption of alcohol¹⁰.

Pregnancy warning labels on packaged alcoholic beverages were recommended to raise awareness about the risks of consuming alcohol while pregnant, as part of a range of measures to address Fetal Alcohol Spectrum Disorder (FASD), in both Australia and New Zealand.

1.1 About FASD

FASD is an umbrella term describing the range of physical, cognitive, behavioural and neurodevelopmental disabilities that can result from alcohol exposure during pregnancy. Prenatal alcohol exposure is the only cause of FASD and the leading cause

⁵ 36 percent of Australians aged 14 and over and 58 percent of New Zealanders (52 percent of women) aged 15 and over drink at least weekly. Source: Australian Institute of Health and Welfare 2017.

⁶ [‘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

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

⁸ Bailey BA and Sokol RJ 2011. [‘Prenatal Alcohol Exposure and Miscarriage, Stillbirth, Preterm Delivery and Sudden Infant Death Syndrome’](#). *Alcohol Research Health* 34(1): 86–91.

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

¹⁰ New Zealand Health Promotion Agency [‘Low-risk alcohol drinking advice’](#)

¹⁰ New Zealand Ministry of Health. 2016. [‘Alcohol: pregnancy and babies’](#).

of preventable brain damage¹¹. 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 heart¹². 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.

A clinical diagnosis of FASD requires evidence of prenatal alcohol exposure and severe impairment in three or more domains of central nervous system structure or function. A diagnosis can be divided into one of two sub-categories:

1. FASD with three sentinel facial features
2. FASD with less than three sentinel facial features

Not everyone who has been affected by alcohol exposure in utero will meet the diagnostic criteria for FASD. There is no typical FASD profile. However, common issues may include: 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.

Issues for people with FASD and their families tend to increase as the child ages. 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 suicide¹³.

1.2 Alcohol consumption during pregnancy

Australia - 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 trimester¹⁴. According to the Australian Institute of Health and Welfare (AIHW)¹⁵, the proportion of pregnant women abstaining from alcohol rose slightly between 2010

¹¹ 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.

¹² Popova S et. al. 2016. '[Comorbidity of fetal alcohol spectrum disorder: a systematic review and meta-analysis](#)'. *The Lancet*. Published Online.

¹³ New Zealand Ministry of Health. 2015. '[Taking Action on Fetal Alcohol Spectrum Disorder \(FASD\): A discussion document](#)'. Wellington: Ministry of Health.

¹⁴ O'Keeffe, L., Kearney, P., McCarthy, F. 2015. '[Prevalence and predictors of alcohol use during pregnancy: findings from international multicentre cohort studies](#)'. *BMJ Open*.

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

and 2013 (from 49% to 53%), but this increase was not statistically significant. More than half (56%) of pregnant women reported that they consumed alcohol before they knew they were pregnant and about 1 in 4 (26%) of these women continued to drink, even after they knew they were pregnant. About 3 in 4 (78%) pregnant women who consumed alcohol while pregnant drank monthly or less, and 17% drank 2–4 times a month. Most (96%) 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 spirits¹⁶. This information is relevant as pre-pregnancy drinking is associated with drinking during pregnancy (see Section 1.3).

New Zealand - New Zealand does not currently routinely collect data on drinking during pregnancy, however the findings of a range of recent studies¹⁷ suggest around one in two New Zealand women consume alcohol while pregnant, with around one in ten drinking at high risk levels¹⁸. 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 trimester¹⁹.

In the largest New Zealand survey to date 71% of women reported drinking alcohol at some level before being aware of their pregnancy, 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 percent continued to drink at a lower volume before stopping;
- 11 percent continued at the same volume before stopping;
- 5 percent drifted in and out of drinking;
- 5 percent were drinking four or more drinks a week and initially reduced this before reverting back to original drinking patterns; and
- 2 percent maintained a high volume of drinking throughout the pregnancy.

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

¹⁶ 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.

¹⁷ 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.

¹⁸ 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.

¹⁹ O'Keeffe, L., Kearney, P., McCarthy, F. 2015. '[Prevalence and predictors of alcohol use during pregnancy: findings from international multicentre cohort studies](#)'. *BMJ Open*.

rates of drinking and hazardous drinking²⁰ dropped slightly among women overall, rates of hazardous drinking increased for Māori and Pacific women²¹.

Like Australia, New Zealand does not have data available on the types of alcoholic beverages consumed by pregnancy women. The New Zealand Health Promotion Agency, as part of its statutory function, regularly researches and reports on alcohol use in New Zealand. Its 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 RTDs (41%)^{22,23}. Women in all other age groups, including age 25 to 44 years, most commonly reported drinking wine.

1.3 Factors related to drinking during pregnancy

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

A review by the Australian Institute of Family Studies (AIFS)²⁴ 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 pregnancy²⁵.

Research commissioned by the New Zealand Health Promotion Agency²⁶ also identified the above factors being associated with drinking when pregnant, but noted that women drinking at high-risk levels after the first trimester are more likely than

²⁰ Defined as having an AUDIT score of ≥ 8 .

²¹ New Zealand Ministry of Health. 2018. '[Annual Data Explorer 2016/17: New Zealand Health Survey](#)' Wellington. Ministry of Health.

²² New Zealand Ministry of Health. 2015. '[Alcohol Use 2012/13: New Zealand Health Survey](#)' Wellington. Ministry of Health.

²³ New Zealand Health Promotion Agency. 2016. '[Types of alcohol consumed by adults on last occasion: 2014/15 ABAS](#)' Wellington. Health Promotion Agency.

²⁴ McLean S. McDougall S. 2014. '[Fetal alcohol spectrum disorders Current issues in awareness, prevention and intervention](#)' Australian Institute of Family Studies. Australian Government.

²⁵ McLean S. McDougall S. 2014. '[Fetal alcohol spectrum disorders Current issues in awareness, prevention and intervention](#)' Australian Institute of Family Studies. Australian Government.

²⁶ Research New Zealand. 2014. '[Drinking alcohol during pregnancy: A literature review](#)'. Wellington. New Zealand Health Promotion Agency.

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 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 Pacific²⁷ women).

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 to drink during pregnancy but at lower levels²⁸.

1.4 Prevalence and impact of FASD

Measuring the 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 can be subtle and difficult to diagnose (or misdiagnosed), clinicians may not have the capacity to diagnose FASD.

Australia - There is no national data on the prevalence or burden of FASD in Australia, as children have not been routinely screened for FASD in infancy or childhood (however, a FASD Diagnostic Tool is now available, and a FASD register is being progressed). It has been suggested that as many as 2% of all Australian babies may be born with some form of FASD²⁹.

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 Indigenous population³⁰. 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 Project³¹, 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 29 out of the 108 participating children were diagnosed with a form of FASD. This is a prevalence of 26.8% (268 per 1,000) and approximately 1 in 4 children having a diagnosis on the FASD spectrum.

²⁷ 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.

²⁸ 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

²⁹ McLean S, McDougall S. 2014. '[Fetal alcohol spectrum disorders Current issues in awareness, prevention and intervention](#)'. Australian Institute of Family Studies. Australian Government.

³⁰ Burns L, Breen C, Bower C et al., O' Leary C, Elliott EJ 2013. '[Counting fetal alcohol spectrum disorder in Australia: the evidence and the challenges](#)'. *Drug and Alcohol Review*;32(5):461–467

³¹ 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.

The above figures are likely to underestimate national 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.

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 prevalence trends over time, which has been long acknowledged as a gap that needs to be addressed.

There are also difficulties in assessing the financial burden of FASD in the community and no data are available for Australia on the financial impact of FASD. Estimates of the financial burden of FASD in the United States of America and Canada report a significant financial burden on individuals, families and society, however, due to differences in methodology there is a considerable variation in the total cost estimates³².

New Zealand - New Zealand is in the process of conducting an incidence study but at present there are no New Zealand data on the prevalence of FASD. It is not routinely screened for and most clinicians currently lack the capacity to diagnose it, although there is work underway to address this. The New Zealand Ministry of Health currently accepts a prevalence rate of 1% of the population as a solid conservative estimate³³, but notes that alcohol consumption during pregnancy appears to be higher in New Zealand than in North America³⁴, 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 born each year³⁵.

Quantifying the financial impacts of FASD and the wider community is complicated, but it is likely that FASD is costly to both the New Zealand Government and to wider society. Estimates of the annual cost to the New Zealand Government per person with FASD vary, but a very conservative estimate would be NZ\$15,000^{36,37}. Assuming

³² Popova, S, Stade B, Bekmuradov D, Lange S, Rehm J 2011. [‘What do we know about the economic impact of Fetal Alcohol Spectrum Disorder? A systematic literature review’](#), *Alcohol and Alcoholism*; 46 (4): 490–497.

³³ 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.

³⁴ May PA, Gossage JP. 2001. [‘Estimating the prevalence of fetal alcohol syndrome: a summary’](#). *Alcohol Research & Health*; 25(3): 159–167.

³⁵ Refer to the [New Zealand Ministry of Health’s discussion document on FASD](#) for further reading.

³⁶ 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.

46,000 people have FASD, this suggests an annual cost of *at least* \$690 million. On top of that, estimates of productivity loss to New Zealand due to morbidity and premature mortality from FASD range from NZ\$49 million to NZ\$200 million per year³⁸.

1.5 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. Evidence suggests that pregnancy warning labels on packaged alcohol may increase awareness advice that women should not drink alcohol when pregnant, but that the increased awareness does not necessarily translate to behavioural changes. 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. This includes information at point of sale, i.e. sales at on-licences to help inform and educate consumers. A range of other activities are currently in place in Australia and New Zealand to prevent and manage FASD.

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 (www.fasdhub.org.au). 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 Australian Capital Territory based Pregnant Pause project to a national reach;
- Funding for the Australian Institute of Health and Welfare 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.

³⁷ 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

³⁸ Based on 2013 data. Easton B (et.al.).2016. '[Productivity losses associated with Fetal Alcohol Spectrum Disorder in New Zealand](#)'. *NZMJ* ; 129:1440.

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. 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 development of a ten year FASD Strategic Action Plan 2018-2028 (the Strategic Action Plan), previously the FASD Strategy, is also being developed and is expected to be finalised in 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'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 FASD³⁹. 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.

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 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

³⁹ FASD Working Group 2016. '[Taking Action on Fetal Alcohol Spectrum Disorder: 2016–2019: An action plan](#)'. Wellington: Ministry of Health.

products serve as a “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 New Zealand young women of not to drinking alcohol if they could be or are pregnant.

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 above, the proportion of pregnant women in Australia abstaining from alcohol rose slightly between 2010 and 2013 (from 49% to 53%), but this increase was not statistically significant. It is not possible to attribute this change to any specific activity⁴⁰. Trend data are not available for New Zealand.

This section considered the prevalence of pregnant women drinking alcohol when pregnant, and the prevalence and burden of FASD in the Australia and New Zealand communities.

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

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

2. Objectives

The Overarching Strategic Statement for the Food Regulatory System recognises that food and beverage labelling policy is complex, and to support decision making in the area of food and beverage labelling, the aims of the food regulatory system have been translated into the following risk-based issues hierarchy:

1. Food safety
2. Preventive health
3. Consumer values

Preventive health issues include the indirect, long term impacts on health, such as prevention of FASD. Providing information on the label to encourage consumers to understand and act on the advice not to drink alcohol while pregnant is in line with the second priority in the hierarchy.

⁴⁰ Australian Institute of Health and Welfare. 2016. ‘[Australia's Health 2016](#)’. Australia’s health series no. 15. Cat. no. AUS 199. Canberra: AIHW.

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. FASD is prevented if women choose not to drink alcohol when pregnant and pregnancy warning labels complement broader FASD prevention initiatives.

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 when pregnant. Providing this information on the label of alcoholic beverages may communicate the need for pregnant women 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 when pregnant^{41, 42, 43, 44}.

Pregnancy warning labels can be considered to be effective⁴⁵ if they:

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

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 and believed/trusted by the target audiences.

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 RTD 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 to establish cultural norms and inform pregnant women's support networks of the advice for pregnant women not to drink alcohol.

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 'its safest not to drink while pregnant' using messages or pictograms (see examples below). DrinkWise has

⁴¹ Healthy Child Manitoba. *'Alcohol, pregnancy and partner support'*

⁴² McLean S. McDougall S. 2014. *'Fetal alcohol spectrum disorders Current issues in awareness, prevention and intervention'* Australian Institute of Family Studies. Australian Government.

⁴³ Holland, K., McCallum, K., Blood, R.W. 2015. *'Conversations about alcohol and pregnancy'*. Canberra: Foundation for Alcohol Research and Education.

⁴⁴ 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.

⁴⁵ Wilkinson, et al. 2009. *Alcohol Warning Labels: Evidence of impact on alcohol consumption amongst women of childbearing age.*

developed a manual and label templates for use by industry members to guide consistent labelling.



Due to the difficulties in estimating the prevalence of FASD (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 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 prevalence of FASD (if this could be measured) to the voluntary pregnancy warning labelling initiative alone.

International evidence indicates that pregnancy warning labels can raise awareness of the risks of drinking during pregnancy⁴⁶. 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 surveyed⁴⁷.

However, as a stand-alone prevention measure pregnancy warning labels have not demonstrated a meaningful impact on the drinking behaviour of pregnant women^{48, 49}. The need to use a range of complementary interventions is not unexpected given the complex nature of public health problems such as this.

⁴⁶ International Alliance for Responsible Drinking (IARD) 2017. [‘Policy review: Health warning labels’](#). Washington.

⁴⁷ Dumas A, Toutain S Hill C and Simmat-Durand S, 2018. [‘Warning about drinking during pregnancy: lessons from the French experience’](#), *Reproductive Health*, 15: 20.

⁴⁸ International Alliance for Responsible Drinking (IARD) 2017. [‘Policy review: Health warning labels’](#). Washington.

⁴⁹ Thomas G, Gonneau, G, Poole, N and Cook, J, 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) 91-93.

The second evaluation of the voluntary pregnancy warning labels on packaged alcohol in Australia and New Zealand reported that adoption of the voluntary labels has increased. However, some implementation issues were noted, as detailed below.

2.1 Coverage

Australia - In 2016-2017, 48% of all packaged alcoholic beverages available for sale displayed some type of pregnancy warning label. The table below presents the coverage of pregnancy warning labels on packaged alcoholic beverages by market, comparing coverage between the 2013 and 2016/17 evaluations. 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, ranging from 55-56% for wine priced over \$20 per bottle to 40% for red wine priced under \$20 a bottle. Craft beer recorded the lowest coverage, with 19% of those products displaying a pregnancy warning label in 2016-17.

Table 1: Proportion of products with pregnancy health warning by market

Product Group	Any Pregnancy health warning (n/N, %)		
	Previous (2013)	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	
Total	1,155/3,020 (38.2%)	1728/3612 (47.8%)	9.6%

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 > \$20 and cider markets, there is evidence that those brands with greater market share are more likely to have a pregnancy warning label. The table below provides information on the proportion of products with a pregnancy health warning by market.

Table 2: Proportion of products with pregnancy health warning by market

Market	Previous (2013)		Sample Brand SK U		Current (2016/2017)	
	Unadjusted %	Adjusted %			Unadjusted %	Adjusted ¹ % (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%)
Total	110 (59.8%)	-	141	962	724 (75.3%)	-

New Zealand - in 2016, 87% of beer, 100% of cider and 82% of straight and 88% of RTD 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 3 below.

Table 3: Respondents' market share and percentage of products reported to carry a pregnancy warning label in the quantitative industry survey (2016)

Category of alcohol	Percentage of market share (by volume) covered by responses	Percentage of products 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 (RTD)	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.

The current voluntary uptake of pregnancy warning labels may be related to industry awareness of current monitoring and evaluation activities. If monitoring were to cease, it is possible that adoption of the voluntary labels may reduce. 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.

In surveys with the alcohol industry conducted in New Zealand in 2014 and 2016, 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).

Improving voluntary approaches, or introducing mandatory pregnancy warning labelling, would help to achieve high coverage across all types of packaged alcoholic beverages. However, only mandatory options are likely to be able to ensure that pregnancy warning labels are not pushed off the label of packaged alcoholic beverages by other labelling such as gluten free or recycling symbols.

2.2 Consistency

The second Australian evaluation of the pregnancy warning labelling initiative also revealed areas of inconsistent messaging and some consumer confusion in the interpretation of the messaging. The Australian evaluation reported that there was a high level of compliance with the NHMRC guideline for alcohol consumption in pregnancy. The DrinkWise text is in line with the current Australian guideline for alcohol consumption in pregnancy, but not New Zealand's as the New Zealand guidance does not include the 'safest option' statement⁵⁰.

The field survey conducted in New Zealand 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. 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 United States of America 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.

The second evaluation of the Australian pregnancy warning label initiative reported that both industry and public health sectors support a minimum standard set by government for consistent content, size, and placement to be applied to the pregnancy health warning labels.

⁵⁰ New Zealand Health Promotion Agency '[Alcohol & pregnancy - what you need to know](#)'

Government action could address the issue of variation in labelling, either through a mandatory approach or voluntary style guide set by government. Alternatively, organisations such as DrinkWise and Cheers could take action to better encourage consistent use of labelling amongst industry through industry self-regulation.

2.3 Consumer awareness and understanding

The 2014 and 2017 evaluations of the Australian Government's current 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 shows that few consumers recall 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 pregnant⁵¹.

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 a minority of people (e.g. some respondents considered that the DrinkWise text meant that you can drink while pregnant, but it's safer not to; others considered that using a green colour in the pictogram and text was confusing and suggested that it was okay to drink when pregnant). Mandatory labelling, or improving the current voluntary approaches could also ensure that the most effective colours, wording and pictures are used in pregnancy warning labels.

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

Consultation question 4: This section also identified that coverage, consistency and consumers misunderstanding are reasons for possible regulatory or non-regulatory actions in relation to pregnancy warning labels on alcoholic beverages.

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

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

⁵¹ Rout, J. Hannan, T. 2016. '[Consumer awareness and understanding of alcohol pregnancy warning labels.](#)' Wellington: Health Promotion Agency.

3. Statement of options

As outlined in section 1.5, a range of non-regulatory FASD prevention strategies are currently being implemented in Australia and New Zealand. These include targeted interventions, provision of resources for health practitioners and educational campaigns. A range of complementary initiatives is required to support FASD prevention, and no one initiative is sufficient in isolation. Targeted interventions are important and focus on women who are at high risk of drinking when pregnant; however, information also needs to be distributed across the community about the need for women to not drink alcohol when pregnant to create a supportive environment and establish cultural norms.

While there are many channels that can communicate the need for pregnant women to avoid drinking alcohol when pregnant, providing this information on the label of a packaged alcoholic beverage provides a unique opportunity to communicate with the target audience(s) to reinforce the message to not drink alcohol when pregnant at the point of purchase and/or potential point of consumption of packaged alcoholic beverages. Therefore this section presents labelling options for providing information about the need for pregnant women to not drink alcohol on packaged alcoholic beverages.

Two main labelling options are under consideration⁵²: mandatory pregnancy warning labels, and continuation of voluntary labelling (with three variations of voluntary labelling proposed).

It is relevant to note that internationally, mandatory pregnancy warning labels on alcohol have not been adopted widely and voluntary approaches are more common. There are no agreed international labelling standards for alcohol related matters. The second Australian evaluation of the voluntary pregnancy warning labels on alcoholic beverages reported that between 2009 and 2014, the number of countries with pregnancy health labelling of alcohol products increased from 6 to 33. Of the 33 countries with pregnancy health warning labels, 29 are implementing these labels voluntarily. South Africa, the Russian Federation and the United States are the only countries with both mandatory health warning labels and prescribed pregnancy health warning labels on alcoholic beverages. France also has a mandatory pregnancy warning label (but no other mandatory health warnings). Twenty five of the 29 countries with voluntary pregnancy labelling initiatives currently use the red pregnant lady pictogram mandated in France.

Table 4 compares voluntary and mandatory options for pregnancy warning label on packaged alcoholic beverages in Australia and New Zealand. With any option chosen, continued monitoring and evaluation will be important to monitor the use of pregnancy warning labels and related consumer knowledge, attitudes and behaviours.

⁵² 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.

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 and 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 skills⁵³.

The 'smoking harms unborn babies' warning (with picture) has undergone market testing⁵⁴ 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 women would not cause direct harm to an unborn child (unlike exposing a pregnant women to the effects of second-hand smoke), and therefore such strict warning labels are not being proposed for alcohol products.

⁵³ Wilkinson, et al. 2009. [Alcohol Warning Labels: Evidence of impact on alcohol consumption amongst women of childbearing age.](#)

⁵⁴ 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.

The AIHW⁵⁵ reports that rates of smoking during pregnancy have declined in Australia. However, it is well recognised 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 action⁵⁶, including, in addition to labelling tobacco products with graphic health warnings, staged excise increases on tobacco products, education programs; national tobacco campaigns; plain packaging 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.

⁵⁵ Australian Institute of Health and Welfare (AIHW) 2016. [‘Australia’s Health 2016’](#). Australia’s health series no. 15. Cat. no. AUS 199. Canberra: AIHW.

⁵⁶ Australian Government Department of Health, 2017. [Tobacco Control Timeline](#)

Table 4: Policy options for pregnancy warning labels on packaged alcoholic beverages

Policy option	Description	Examples	Pros	Cons	Risks
Option 1a) Voluntary Status quo	Industry discretion is permitted in which labelling to apply to products, with one option to use the DrinkWise or Cheers label designs, or any other label design.	Current situation. DrinkWise and Cheers could also increase efforts in promoting the uptake, and use of consistent warning labels amongst industry groups.	Overall use of these labels is currently relatively high; however some sectors need further encouragement to adopt the labels. Minimal cost to industry, as many products are already using the labels. The policy is consistent with international arrangements where companies have signed up to voluntary labelling commitments.	While using the DrinkWise and Cheers labels supports a level of consistency in labelling, it does not fully overcome the variation in labelling styles and wording that has been observed. This can lead to consumer confusion and misinterpretation. The DrinkWise text also promotes a message that the 'safest option' is not to drink alcohol which is not consistent with New Zealand Government guidelines, and research shows the message can be misinterpreted by some consumers. Certain groups (such as craft and premium beer producers in Australia) may continue to not use the pregnancy warning labels.	Changes to alcohol labelling elements (e.g. potential energy content labelling, or labelling introduced by industry in response to consumer demand e.g. 'gluten free' or recycling messages) could compete for space with pregnancy warning labels and may reduce the uptake of the voluntary pregnancy labels. Current situation where some products do not display the pregnancy warning labels may continue. It is possible that current momentum to adopt voluntary labelling may not be sustained. Current high level of voluntary uptake may be related to industry awareness of current monitoring and evaluation activities.

For purposes of targeted consultation only

DO NOT CIRCULATE

Policy option	Description	Examples	Pros	Cons	Risks
Option 1 b) Voluntary industry self-regulated	<p>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.</p> <p>The industry group(s) could develop a code of practice that alcohol producers voluntarily sign up to. Alternatively, Food Standards Australia New Zealand (FSANZ) may also develop a code of practice, as part of its functions.</p> <p>The code of practice would require signatories</p>	<p>Responsible Children’s Marketing Initiative (RCMI) and the Quick Service Restaurant Initiative for Responsible Advertising and Marketing to Children (QSRI) from the Australian Food and Grocery Council (AFGC)⁵⁷.</p> <p>AFGC manages the RCMI and QSRI in line with the Australian Competition and Consumer Commission’s Guidelines for developing effective voluntary industry codes on 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.</p> <p>In New Zealand the Advertising Standards Authority⁵⁸ has a Code for Advertising and Promotion</p>	<p>As above.</p> <p>Limited work for Government in applying and enforcing the scheme.</p> <p>Industry may be more proactive in placing warnings on packaging.</p> <p>Reputational benefit to manufacturers who become signatories to the code of practice.</p>	<p>As above.</p> <p>Government role is limited in ensuring effective and consistent labelling.</p> <p>Messages that may not be consistent with Government guidelines may continue to be used.</p> <p>Current situation where some products do not display the pregnancy warning labels may continue.</p> <p>Unless New Zealand and Australian industry agree on this approach, it is not a completely joint system for labelling.</p>	<p>As above</p> <p>Not all industry groups or companies may elect to be signatories to such an agreement.</p>

⁵⁷ Australian Food and Grocery Council ‘[Advertising to Children](#)’

⁵⁸ Advertising Standards Authority ‘[Code for Advertising and Promotion of Alcohol](#)’

Policy option	Description	Examples	Pros	Cons	Risks
	<p>to commit to presenting pregnancy warning labels on all the packaged alcoholic beverages that they produce. The code of practice would outline the how the pregnancy warning labels would be presented to ensure that the message is clear, consistent with government recommendations, and understood by the target audiences. The code of practice may also encourage signatories to provide other health information on product labels.</p> <p>The industry group that leads the code of practice would be responsible for administering and enforcing the code of practice, encouraging alcohol producers to</p>	<p>of Alcohol, which requires all alcohol advertising and promotion to adhere to the principles and guidelines contained in the Code. The Association of New Zealand Advertisers⁵⁹ is responsible for administering the advertising industry's voluntary system of pre-vetting all alcohol advertisements.</p> <p>Another example is the European Beer Pledge⁶⁰, where members of an association representing European brewers has committed to taking action to improve consumer information by providing, among others, the nutrition information on beers.</p>			

⁵⁹ [Association of New Zealand Advertisers](#)

⁶⁰ The Brewers of Europe. [European Beer Pledge](#)

Policy option	Description	Examples	Pros	Cons	Risks
	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.				
Option 1c) Voluntary with Government style guide	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 could be tested to ensure effective messaging and reduce consumer misunderstanding. 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	Health Star Rating (HSR) - 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. Food manufacturers and retailers are responsible for the correct and accurate use of the HSR system. The HSR system Style Guide and Guide for Industry on Using the HSR calculator provides guidance for the application of the HSR	Supports consistent labelling and effective messaging. Can align with international voluntary agreements and allows flexibility for any future changes in international guidelines, research and evidence. The second Australian evaluation reported that both industry and public health sectors support a minimum standard set by government for consistent content, size, and placement to be	Cost to industry to change current labels. No regulatory approach to encourage adoption of more consistent, clearer and effective labelling. As it is not mandatory, it would not prohibit other warning labelling being used. Current situation where some products do not display the pregnancy warning labels may continue.	As above.

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DO NOT CIRCULATE

Policy option	Description	Examples	Pros	Cons	Risks
	follow the style guide.	system on food packages. The Style Guide allows the HSR system to be implemented consistently.	applied to the pregnancy health warning labels.		
Option 2: Mandatory	<p>Mandated through the Australia New Zealand Food Standards Code. The prescribed warning label would be the one shown to be most effective (see section 4) and may include a warning pictogram, or text or both.</p> <p>If this were to be introduced, it would be more efficient and cost-effective to do so at the same time as any other changes to alcohol labelling.</p> <p>Transition period included to allow time for industry to adopt new regulations and reduce costs associated with labelling changes.</p>	<p>Other elements of alcohol labels are regulated under Parts 1.2 and 2.7 of the Code, including:</p> <ul style="list-style-type: none"> • alcohol by volume • standard drink labelling • specific representations about alcoholic beverages (e.g. low alcohol) • nutrition information requirements (when a claim is made regarding energy, carbohydrate or gluten). 	<p>Mandatory labelling could overcome the identified barriers to pregnancy warning labels, and maintain or increase current levels of labelling coverage.</p> <p>The second Australian evaluation reported that both industry and public health sectors support a minimum standard set by government for consistent content, size, and placement to be applied to the pregnancy health warning labels.</p> <p>All consumers of alcohol will be provided with consistent, understandable messages about not drinking alcohol during pregnancy. If this translates to behaviour change, women choosing</p>	<p>Cost to industry for compliance. In particular, the Australian evaluation noted that, for 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.</p> <p>Increased workload for regulators.</p> <p>Does not acknowledge strong industry efforts to introduce pregnancy labelling voluntarily.</p> <p>Even with mandatory labelling, 100% compliance may not be achieved if a robust compliance scheme was not also introduced.</p>	<p>Any new mandatory labelling requirements may have trade implications. However, there are clear public health reasons for having this labelling, and some countries (such as France) have mandated pregnancy warning labels and pictogram. There could also be allowances made for other countries messaging, e.g. if there is a mandatory warning message in another country, then this is acceptable for the Australia/NZ market.</p> <p>If a mandatory standard is made, the time taken to develop the standard and put it into place may mean that the voluntary efforts disappear in the interim.</p>

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Policy option	Description	Examples	Pros	Cons	Risks
			<p>not to drink alcohol during pregnancy prevents FASD.</p> <p>More consistent labelling and greater coverage of pregnancy warning labels, including in product categories that are currently identified as having limited use of the voluntary labelling.</p> <p>Reduces the possibility that use of pregnancy warning labels will decrease over time, or be ‘pushed-off’ labels by other labelling initiatives.</p> <p>Many producers are already voluntarily meeting the costs of providing these warnings (assumes no change to current wording and pictogram warning labels).</p>		

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Consultation question 6: This section has identified potential regulatory and non-regulatory options to progress pregnancy labelling on alcoholic beverages and address the implementation issues identified through the Australia and New Zealand evaluations of the current voluntary labelling scheme.

- a) Are there additional pros, cons, and risks associated with these options that have not been identified?
- b) Are there other potential options that could be implemented, and if so, what are the pros, cons and risks associated with these alternate approaches?

Please provide evidence to support your response.

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

4. Ensuring the message is understood

As outlined in Section 2.3, the Australian and New Zealand evaluation reports noted variation in the wording and colours used for pregnancy warning labels, and some instances where the pregnancy warning messages were misunderstood, with the misbelief that it is acceptable to drink when pregnant. In addition, the DrinkWise text is inconsistent with the New Zealand Government guidelines about drinking during pregnancy.

The Forum requested consideration of the most appropriate pictogram and most easy to understand message to discourage drinking during pregnancy. Once the most appropriate pictogram and message are identified, they could be adopted in all of the regulatory options proposed above. However, Government has more opportunity to ensure these are applied with the government developed style guide or mandatory options.

4.1. Pictogram

The Australian evaluation 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.

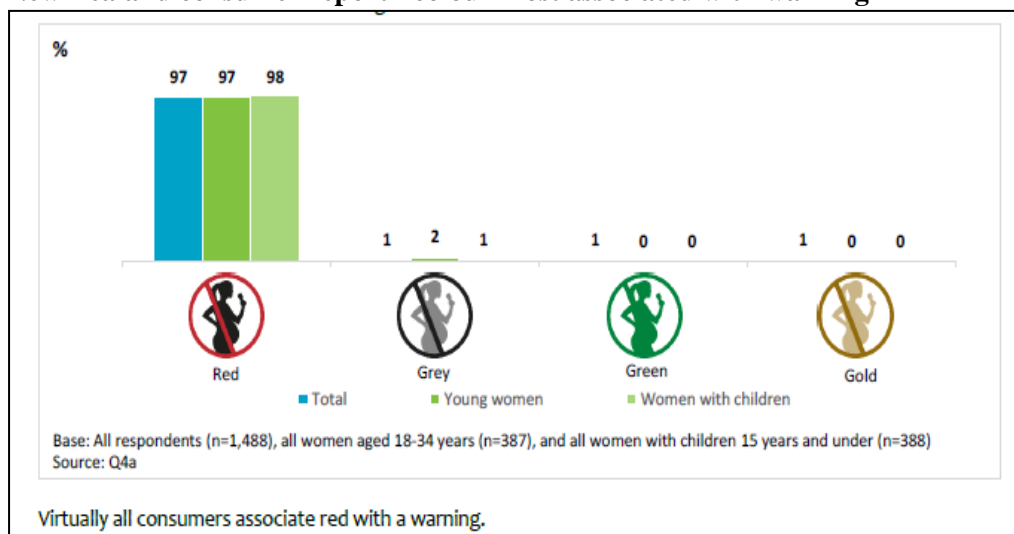


Pictogram colour and contrast - The DrinkWise pictogram uses green colouring; however, the evaluations identified confusion associated with the green colour where some people considered that this meant it was acceptable to drink when pregnancy.

A red pregnancy warning pictogram is commonly used internationally, with France mandating this image be displayed on the labels of alcoholic beverages, and 25 of the 29 countries that have voluntary pregnancy warning labels also using the red pictogram (refer to section 6.12 of the Australian evaluation report).

Consumer understanding of the pictogram colours was tested in the New Zealand consumer research, 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 overleaf 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.

New Zealand consumer report - colour most associated with warning⁶¹



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.

One option could be to prescribe the colour of the pictogram (e.g. red lines with black image). Another option is to require contrasting colours are used and explore the use of other contrasting colours on a pictogram, bearing in mind that there may need to be some flexibility given the range of colouring on packaging.

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 above) show a picture of a pregnant woman holding a beer glass. The variation of the types of glasses/drinks shown in the pictogram was not captured in the Australian or New Zealand evaluations. Further information would be required to determine how the different images impact on understanding of the warning message.

Additional considerations for the pictogram would also include size, borders and proportions of the pictogram as well as its placement on the alcohol label.

4.2 Text

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. However, the ‘safest not to’ part of the DrinkWise text is not consistent

⁶¹ Rout, J. Hannan, T. 2016. ‘[Consumer awareness and understanding of alcohol pregnancy warning labels](#)’. Wellington: Health Promotion Agency.

with the New Zealand alcohol guidelines and has been misinterpreted by some consumers as allowing some leeway in the consumption of alcohol when pregnant.

The New Zealand consumer research on awareness and understanding of pregnancy warning labels undertaken to inform the second evaluation on pregnancy warning labels tested the pictogram, the DrinkWise text and an alternative text “*Don’t drink pregnant*” which is not currently used in New Zealand.

In the New Zealand consumer research 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 respondents (including 14% of young women) 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).

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.

To determine the most effective pregnancy warning text, it is suggested that the messages such as “*Don’t drink pregnant*” could undergo further consumer testing, particularly for Australian consumers. Other options for consumer testing (in both Australia and New Zealand) could include looking to 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*” or a variation on the US statement.

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.

As noted in the section above on the pictogram, other considerations for any text warning message include colour, size, contrast, borders, and position and placement of any wording message.

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

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

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

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

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

5. Impact analysis (Costs and Benefits)

A RIS should provide an analysis of the costs and benefits of the feasible options, including the groups in the community that would be affected by each option and the economic, social and environmental impacts on them. This section discusses the predicted costs and benefits of the options identified above.

Each of the proposed options would benefit the population through reminding pregnant women and their support networks that women should not drink alcohol when pregnant. This is one initiative which as part of a wider suite of initiatives supports FASD prevention. 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. Prevention of FASD would result in a significant improvement in the quality of life of those who would otherwise be affected.

Preventing FASD would also have benefits for families. Families affected by FASD are likely to experience increased stress⁶² (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 connection and support, and increased costs while the family's earning potential often decreases⁶³. Siblings of people who would otherwise have FASD are also likely to benefit from increased attention and opportunities.

According to Canadian studies, people with FASD are approximately 19 times more likely to be arrested than those who do not have FASD with increasing costs to the adult and juvenile systems. In 2011/12, approximately \$17.5 million Canadian dollars was calculated for the cost of corrections amongst youth and over \$356.2million of those adults with FASD⁶⁴. Preventing FASD would also reduce costs to the community associated with crime and the juvenile and adult systems.

⁶² Watson SL, Hayes SA, Coons KD and Radford Paz E. 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.

⁶³ based on conversations with families affected by FASD as part of the development of the [NZ FASD Action Plan](#).

⁶⁴ Popova, S., Lange, S., Burd, L., Rehm, J. 2015. '[Cost attributable to Fetal Alcohol Spectrum Disorder in the Canadian correctional system](#)' *International Journal of Law and Psychiatry*; 41:76-81.

For the community, reduced prevalence of FASD would reduce burden on healthcare and social support systems, the education system and care and protection systems. It would also have economic and productivity benefits through increased participation in the labour force.

However, it is difficult to quantify these potential benefits in financial terms given the difficulties in measuring the impact of FASD on the Australian and New Zealand community.

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 disproportionate impact on indigenous communities.

While there are many benefits to the community and individuals associated with each case of FASD prevented, it is recognised 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 FASD⁶⁵.

However, with pregnancy warning labels on alcoholic beverages being just one of a suite of initiatives aimed at reducing FASD and with the objective of pregnancy warning labels being to provide a clear and easy to understand trigger to remind pregnant women and their support network that pregnant women should not drink alcohol, an appropriate measure of effectiveness for the label would be change in awareness and understanding of the message by that target audience. The effects of other initiatives combined with the pregnancy warning labels on alcoholic beverages could in turn affect drinking behaviour in the target audience and ultimately prevalence of FASD.

Because pregnancy warning labels need to be accompanied by broader FASD prevention initiatives, challenges and uncertainties are introduced in estimating the net benefits each of the different regulatory and non-regulatory options proposed in this paper. Uncertainty is also introduced in the estimates of the net benefits due to the lack of data on the prevalence of FASD in Australia and New Zealand and its burden on individuals and the community.

Evidence suggests that each of the proposed options will contribute to raising awareness amongst the target audiences about the need for pregnant women to not drink alcohol. It is assumed that the option that ensures the highest coverage of warning labels across all types of alcoholic beverages and that the pregnancy warning labels are most clearly understood by the target audiences and consistent with Government recommendations is likely to best meet this objective. However, there is a lack of evidence to support this assumption.

⁶⁵ International Alliance for Responsible Drinking (IARD) 2017. [‘Policy review: Health warning labels’](#). Washington.

As outlined in Table 4, there are risks that the voluntary options (option 1a, 1b and 1c) would not achieve high rates of coverage (and therefore not reach the two target audiences) due to their voluntary nature and because use of the labels being at the discretion of the alcohol industry. There are also risks that other elements of the alcohol label may compete for space on the alcohol label, and ‘push off’ the pregnancy warning labels.

The status quo (Option 1a) has achieved reasonably high coverage across packaged alcoholic beverages, when analysed by market share (see Section 2 of this document). However there are noted concerns with the warning labels’ consistency with each other, and with government advice in relation to drinking alcohol when pregnant. There are also noted issues with comprehension of the messaging by some audiences.

An industry code of practice (Option 1b) or Government style guide (Option 1c) may support achieving labelling that is consistent with Government guidelines and consistent with each other, and labels that can be understood by the target audience, but it is not known whether these options still can ensure high coverage and reach the target audiences. The option that is likely to achieve the highest coverage and consistency is the mandatory approach (Option 2). Option 2 would also ensure that the message that is best understood by the target audiences is used on packaged alcohol. In determining the option with the highest net benefit, these potential outcomes must be balanced against the costs of the regulatory option, and take into account the uncertainties in the evidence.

5.1 Business compliance costs

In preparing a DRIS, the costs or savings associated with complying with each regulatory option need to be determined. Assuming that individuals and community organisations would not bear the cost of complying with the proposed labelling options, this section will focus on the cost to businesses associated with complying with each regulatory approach.

The second Australian evaluation of the pregnancy warning labels on alcoholic beverages involved an alcohol industry survey and reported that the average cost for introducing the voluntary labelling was AUD\$338.76 per Stock Keeping Unit (SKU). A breakdown of these costs is provided in Table 5. 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. However, the Australian evaluation report did not compare costs for small and large producers.

Table 5: Estimated costs per cost item per SKU

Cost item	Average estimated cost per labelled SKU	Range of estimated total cost per labelled SKU
Cost Item Breakdown		
Redesign and approval of artwork	\$95.66	\$0.00 - \$1,132
Production of new print plates	\$210.85	\$0.00 - \$3,397
Administration Costs	\$67.16	\$0.00 - \$1,000
Additional Costs	\$7.31	\$0.00 - \$126
Total Cost	\$338.76	\$0.00 - \$4,665

The Australian Evaluation report estimated that there are 21,557 active SKUs, with 47.8% (10,304) of these carrying a pregnancy warning label. Therefore, the total cost to industry in Australia for labelling the SKUs available for sale in 2017 was estimated to be AUD \$3.5 million. In a sensitivity analysis, the proportion of SKUs that carry a pregnancy health warning from those products that comprise the top 75% of Australian market leading products was used instead; the resultant cost to industry in Australia was estimated as AUD\$5.5 million.

In the Australian evaluation, some manufacturers reported that there were no costs associated with labelling changes as they were able to include the new labels into an otherwise scheduled change in the product label.

The Australian evaluation also 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. However, a reputational benefit from being associated with the promotion of responsible consumption of alcohol was seen to be a non-monetary benefit.

Based on the above, the following costs to businesses could be expected from each of the regulatory options under consideration. The cost estimates presented in this section are for Australia only, as the costing for label changes was not estimated in New Zealand.

5.1.2 Status quo - minimal costs for industry that have already adopted the voluntary pregnancy labelling with an average of AUD\$340 per SKU for products that choose to adopt the voluntary labelling.

5.1.3 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 manufactures that would need to change their practices to adopt the new style guide.

Assuming that all products that currently display the pregnancy warning labels choose to adopt the voluntary style guide, and need to change their labels, the cost to business is estimated to be \$3.5 million AUD for the label changes (based on \$340 per SKU with 10,304 SKUs currently adopting the voluntary warning labels).

However, given the voluntary nature of this approach, labelling changes could occur with other updates to labels to reduce the impact.

5.1.4 Voluntary, industry self-regulated - as above, the cost for adopting this approach would depend on the degree to which the industry code would differ from the status quo and the proportion of manufactures that would need to change their practices to adopt the industry code. There would also be an additional cost on the industry peak body that would self-regulate this code of practice. This would be an ongoing cost.

Assuming that all products that are currently adopting the voluntary labelling decide to become a signatory to the industry code and need to change their label to comply with the pictogram and text proposed at 3.1, this cost would be \$3.5 million AUD (based on \$340 per SKU with 10,304 SKUs currently adopting the warning labels).

As identified above, the voluntary nature of this approach allows for labelling changes to be incorporated with other label changes, to reduce the financial burden.

5.1.5 Mandatory through the Code - the cost for adopting this approach would depend on the degree to which the requirements under the Code would differ from the status quo and the proportion of manufactures that would need to change their practices to adopt Code. Given the high number of manufactures that are already voluntary adopting the pregnancy warning labels, the impact on industry for mandating the labels may be limited to those who have not adopted the voluntary scheme.

If only the products that are not currently displaying the pregnancy warning labels are required to adopt the labelling, the cost to business would be \$3.8 million AUD (based on 11,217 SKUs not displaying the labelling, and a cost of \$340 per SKU for the labelling change).

However, given the variation in text and pictograms observed in the market, it is likely that some businesses would need to change their labelling to comply with the Code. In the worst case scenario, if all products need to be re-labelled, the estimated cost to businesses for adopting new pregnancy warning labels would equate to \$7.3 million AUD (based on a total of 21,557 SKUs and cost of \$340 per SKU).

It is recognised that there could be costs to smaller producers industry arising from a regulatory option. The issue of regulatory design will be considered in more detail in the DRIS with transition periods and stock in trade exemptions considered to appropriately minimise a large proportion of costs to producers, including smaller producers. An attempt will also be made where possible to differentiate costs of large and small producers.

IMPACT

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

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

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

COST

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

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

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

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

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

Consultation question 21: To better predict the proportion of products that would need to change their label to comply with any proposed change, information on the type of pictogram and text currently used is required. The Australian and New Zealand evaluation reports provided information on the proportion of products currently using the pregnancy warning pictogram, and text, or both. However, the evaluation reports did not examine the proportion of products using different colours in the pictogram, or different images (e.g. pregnant woman holding a wine glass or beer glass).

Do you have evidence of the proportion of alcohol products that are currently using the red pictogram, and what proportion of products are using an alternate pictogram (e.g. green)? Do you have evidence on the proportion of alcohol products that are currently using the beer glass pictogram, or the wine glass pictogram? Please specify which country (Australia or New Zealand) your evidence is based on.

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

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

Consultation question 24: If you identified an alternate policy option in question 6(b), please provide estimates of the cost to industry associated with this approach.

6. Preferred option

Determining the best approach for progressing pregnancy warning labels on alcohol will consider the factors including the effectiveness of labelling approaches, potential benefits, costs, risks and impacts of the options under consideration, and the level of uncertainty associated with these.

Following stakeholder consultation on the options identified in this paper, a Decision RIS will be developed that will identify the option which is likely to have with the highest net benefit.

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

7. Implementation and review

Implementation approaches would depend on the nature of the preferred option. More detail on the implementation approach would be provided in the final RIS document.

Whichever option is pursued, the Australian and New Zealand Governments will continue to work closely with industry and organisations such as DrinkWise and Cheers and with the peak industry bodies, to monitor and review the use, uptake and awareness of pregnancy warning labels and to ensure all actions from Australia and New Zealand's FASD Strategies and Action Plans are implemented. New products and also consumer knowledge, attitudes and behaviours will be particularly monitored.

The voluntary labelling initiative has been evaluated twice in Australia using evidence based analysis by an external consultant and further empirical evaluation can be commissioned by this consultant for whichever approach is chosen. In New Zealand, two evaluations on uptake were undertaken by the Ministry for Primary Industries with help from industry peak bodies, with consumer research commissioned by the Health Promotion Agency informing the 2016 evaluation. Any future monitoring in New Zealand would need to be considered by the relevant agencies.

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 impact of the preferred

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option (together with other concurrent initiatives) on the prevalence of FASD in the population. Future drug and alcohol consumption surveys, such as the National Drug Strategy Household Survey in Australia, can provide data on the prevalence of women drinking alcohol during pregnancy, which may also inform evaluations about whether the selected option has reduced the proportion of women that drink when pregnant (but noting that it is not possible to attribute changes in FASD prevalence, or the proportion of pregnant women drinking to pregnancy warning labels alone).