

**17 February 2020**  
**[113-20]**

Approval report – Proposal P1050

## Pregnancy warning labels on alcoholic beverages

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Food Standards Australia New Zealand (FSANZ) has assessed a proposal to consider a mandatory pregnancy warning label on packaged alcoholic beverages.

On 4 October 2019, FSANZ sought [submissions](#) on a draft variation and published an associated report. FSANZ received 137 (including seven late) submissions.

After having regard to the submissions received and the relevant matters as set out in this report, FSANZ approved the draft variation on 31 January 2020. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 17 February 2020.

This Report is provided pursuant to paragraph 63(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

# Table of contents

## Contents

<b>EXECUTIVE SUMMARY .....</b>	<b>4</b>
<b>1 INTRODUCTION .....</b>	<b>7</b>
1.1 THE PROPOSAL .....	7
1.2 REASONS FOR PREPARING PROPOSAL P1050 .....	7
1.3 PROCEDURE FOR ASSESSMENT .....	8
1.4 SCOPE OF THE PROPOSAL .....	8
1.5 DECISION .....	8
<b>2 BACKGROUND .....</b>	<b>9</b>
2.1 HISTORY OF THE POLICY CONSIDERATIONS.....	9
2.2 PREVIOUS CONSIDERATION OF PREGNANCY WARNING LABELS .....	10
2.3 ALCOHOL CONSUMPTION GUIDELINES IN AUSTRALIA AND NEW ZEALAND .....	11
2.4 CURRENT TRENDS IN ALCOHOL CONSUMPTION DURING PREGNANCY .....	12
2.5 BROADER PUBLIC HEALTH INITIATIVES TO SUPPORT FASD REDUCTION .....	12
2.5.1 <i>New Zealand</i> .....	12
2.5.2 <i>Australia</i> .....	13
2.6 RELEVANT LABELLING REQUIREMENTS IN THE CODE .....	14
2.7 PREGNANCY WARNING LABELS IN OTHER COUNTRIES.....	14
2.7.1 <i>Countries with mandatory or voluntary pregnancy warning labels</i> .....	14
2.7.2 <i>Codex discussions about labelling of alcoholic beverages</i> .....	15
2.8 INTERNATIONAL TRADE AGREEMENTS .....	15
2.9 AUSTRALIA AND NEW ZEALAND WINE EXPORTS .....	17
<b>3 SUMMARY OF THE FINDINGS.....</b>	<b>17</b>
3.1 ISSUES RAISED IN SUBMISSIONS.....	17
3.1.1 <i>Public consultation</i> .....	17
3.1.2 <i>WTO notification</i> .....	42
3.2 EVIDENCE SUMMARY .....	46
3.2.1 <i>Literature review on the effectiveness of warning labels</i> .....	46
3.2.2 <i>Consumer testing of warning statements</i> .....	47
3.2.3 <i>Labelling as part of a suite of measures</i> .....	47
3.3 RISK MANAGEMENT .....	48
3.3.1 <i>Pregnancy warning label overall approach</i> .....	48
3.3.2 <i>Pictogram</i> .....	50
3.3.3 <i>Warning statement</i> .....	50
3.3.4 <i>Signal words</i> .....	52
3.3.5 <i>Warning label size and font type</i> .....	53
3.3.6 <i>Location and label orientation</i> .....	57
3.3.7 <i>Colour and contrast</i> .....	58
3.3.8 <i>Summary of decision for pregnancy warning label design</i> .....	60
3.3.9 <i>Beverages to display the pregnancy warning label</i> .....	60
3.3.10 <i>Application to different types of sales</i> .....	61
3.3.11 <i>Application to different types of packages</i> .....	63
3.3.12 <i>Summary of amendments to draft variation provided in CFS</i> .....	64
3.4 RISK COMMUNICATION .....	65
3.4.1 <i>Public consultation</i> .....	65
3.4.2 <i>Targeted stakeholder consultations</i> .....	65
3.4.3 <i>World Trade Organization (WTO) consultation</i> .....	65
3.5 FSANZ ACT ASSESSMENT REQUIREMENTS .....	65
3.5.1 <i>Section 59</i> .....	65
3.5.2 <i>Subsection 18(1)</i> .....	76

3.5.3	<i>Subsection 18(2) considerations</i> .....	77
3.5.4	<i>Decision Regulation Impact Statement</i> .....	77
3.5.5	<i>Joint Food Standards Treaty Between Australia and New Zealand</i> .....	78
<b>4</b>	<b>TRANSITIONAL ARRANGEMENTS</b> .....	<b>78</b>
4.1	DECISION .....	78
4.2	RATIONALE FOR DECISION.....	78
<b>5</b>	<b>IMPLEMENTATION</b> .....	<b>79</b>
5.1	EDUCATION .....	79
<b>6</b>	<b>MONITORING AND EVALUATION</b> .....	<b>80</b>
<b>7</b>	<b>REFERENCES</b> .....	<b>80</b>
	ATTACHMENT A – APPROVED DRAFT VARIATIONS TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE.....	86
	ATTACHMENT B – EXPLANATORY STATEMENT .....	92
	ATTACHMENT C – DRAFT VARIATIONS TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE (CALL FOR SUBMISSIONS).....	98
	ATTACHMENT D – PREGNANCY WARNING LABELS IN OTHER COUNTRIES .....	105
	ATTACHMENT E – THE TBT AGREEMENT .....	113
	ATTACHMENT F – GUIDANCE FOR DESIGN LABELLING ELEMENTS AND CODE REQUIREMENTS RELEVANT TO ALCOHOLIC BEVERAGES... .....	125
	ATTACHMENT G – NEW ZEALAND AND AUSTRALIAN LEGISLATION AND GUIDANCE INCLUDING ALCOHOLIC BEVERAGE DEFINITIONS... .....	127
	ATTACHMENT H – SUPPORTING INFORMATION FOR THE CONSIDERATION OF COSTS AND BENEFITS.....	128

## Supporting documents

The [following documents](#) which informed the assessment of this proposal are available on the FSANZ website:

- SD1      Pregnancy warning labels on packaged alcohol: A review of recent literature.
- SD2      Alcohol warning label survey report. Prepared by Roy Morgan Research for FSANZ. 20 September 2019.
- SD3      Addendum to Alcohol warning survey report by Roy Morgan Research. Prepared by FSANZ. January 2020.

## Executive summary

The Australian and New Zealand governments advise women not to consume alcohol during pregnancy. Exposure of the fetus to alcohol can cause a range of physical, cognitive, behavioural and neurodevelopmental disabilities, collectively known as Fetal Alcohol Spectrum Disorder (FASD). FASD is preventable by avoiding alcohol consumption during pregnancy. However, available data show that approximately 25% of women in Australia and 20% of women in New Zealand continue to consume alcohol while pregnant.

In Australia and New Zealand, FASD is listed as a priority in the National Alcohol Strategy 2019-2028 and the National Drug Policy 2015-2020, respectively. Actions aimed at FASD prevention, diagnosis and management, support and evidence are in place in both countries and include such initiatives as public education campaigns about the risks of drinking alcohol during pregnancy and FASD, health promotion resources, training packages for health professionals, tools for alcohol screening and intervention guidelines.

Evidence demonstrates pregnancy warning labels on packaged alcoholic beverages can raise awareness of the risks of drinking alcohol during pregnancy and prompt discussion of these risks. Evidence from alcohol warnings and tobacco warning labels confirms that the label as part of a suite of measures can contribute to behaviour change. Therefore, when combined with other public health initiatives, pregnancy warning labels can contribute to increased awareness of the risks of drinking alcohol while pregnant and encourage behaviour change. It can also contribute to the development of social norms to support this behaviour change. These will ultimately reduce the prevalence and/or severity of FASD.

Since 2011, the alcohol industry has implemented a voluntary pregnancy warning labelling scheme. However, following evaluation of the voluntary scheme in 2014 and 2017, the Australia and New Zealand Ministerial Forum on Food Regulation (the Forum) noted that while industry uptake and implementation of the pregnancy warning label on alcohol products had increased over time, there continued to be low uptake in some product categories. Following consideration of policy options, the Forum agreed that, *based on the evidence, a mandatory labelling standard for pregnancy warning labels on packaged alcoholic beverages should be developed and should include a pictogram and relevant warning statement.*

In October 2018, Forum ministers requested Food Standards Australia New Zealand (FSANZ) consider mandatory pregnancy warning labelling on packaged alcoholic beverages. Ministers provided FSANZ with a Decision Regulation Impact Statement as policy advice. In response, FSANZ prepared Proposal P1050.

In accordance with the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act), when proposing a change to the Australia New Zealand Food Standard Code (the Code), FSANZ must undertake its own assessment based on best available scientific evidence and having regard to a number of matters. FSANZ's primary statutory objective when developing or reviewing food regulatory measures is the protection of public health and safety.

For this proposal, FSANZ has undertaken an assessment having regard to best available scientific evidence, relevant policy advice, stakeholder views, and costs and benefits. Specifically, FSANZ has:

- conducted a systematic search and reviewed the literature on the evidence about the effectiveness of warning labels on packaged alcoholic beverages to inform warning label design
- commissioned an online survey to test four warning statements to inform the wording of a warning statement appropriate for Australia and New Zealand populations

- released a public Call for Submissions (CFS) between October 4 – 27 October 2019, following two rounds of targeted consultation
- made a notification to the World Trade Organization (WTO) in accordance with the WTO Technical Barriers to Trade (TBT) Agreement
- considered costs and benefits that may arise from the pregnancy warning label in line with relevant requirements under the FSANZ Act, and included updated information on costs provided by industry.

In response to the CFS, FSANZ received 137 (including seven late) submissions. Seven submissions were received in response to the WTO notification.

Following assessment, FSANZ approved an amendment to the Code to require the following pregnancy warning label (incorporating pictogram and wording) on packaged alcoholic beverages with more than 1.15% alcohol by volume for retail sale (or sold as suitable for retail sale without any further processing, packaging or labelling):



A minimum label size is specified for different beverage volumes and types of packages. For packaged alcoholic beverages with a volume of 200 ml or less the pictogram only is required.

During its assessment, FSANZ liaised with the National Health and Medical Research Council regarding the review of Australia's guidelines to reduce health risks from drinking alcohol and considers the warning statement is consistent with the evidence base and the draft guideline about alcohol consumption during pregnancy.

Based on FSANZ's assessment, a benefit is expected beyond the status quo because the mandated pregnancy warning label:

- integrates design elements that evidence shows will increase the attention a warning will receive
- includes a statement that combines elements from the three best performing statements in the consumer testing, which were all shown to score significantly better than the statement used in the voluntary scheme
- has prescribed design elements that will ensure a high level of consistency and coverage in the warning label across packaged alcoholic beverages providing women of childbearing age with consistent information both at the point of purchase and consumption
- supports public health messages as part of a broader suite of measures aimed at raising awareness of the risks of drinking alcohol during pregnancy and encouraging behaviour change.

The updated consideration of costs and benefits concludes relatively few annual cases of FASD need to be avoided or reduced in severity to justify industry costs of incorporating the warning label. There are large human and financial benefits to the community from avoiding or mitigating new FASD cases.

In making its decision, FSANZ also had regard to Australia and New Zealand Government obligations under international trade agreements and remains satisfied the measure and its requirements are consistent with those agreements.

From the date of gazettal of the variation to the Code, there is a two year transition period for implementation of the mandatory pregnancy warning label. Alignment of transitional arrangements for any other mandatory changes to alcoholic beverage labels will be considered in the future.

# 1 Introduction

## 1.1 The Proposal

Proposal P1050 – Pregnancy warning labels on alcoholic beverages was prepared to consider changing the Australia New Zealand Food Standards Code (the Code) to require a pregnancy warning label on packaged alcoholic beverages.

In accordance with the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) when considering a proposal to change the Code, FSANZ must undertake its own assessment based on best available scientific evidence and having regard to a number of matters as set out in this report. FSANZ's primary statutory objective when developing or reviewing food regulatory measures is the protection of public health and safety.

## 1.2 Reasons for preparing Proposal P1050

Drinking alcohol during pregnancy is associated with various types of harm to the unborn child that can be seen in infants, children and adults. These harms may include physical, cognitive, behavioural and neurodevelopmental disabilities with possible life-long implications. Fetal Alcohol Spectrum Disorder (FASD) is an umbrella term used to describe the range of possible harms. FASD is preventable by avoiding alcohol consumption during pregnancy (National Health and Medical Research Council, 2009).

In Australia and New Zealand public health messages are that pregnant women should not consume alcohol. However, available data show that approximately 25% of women in Australia and 20% of women in New Zealand continue to consume alcohol while pregnant (Australian Institute of Health and Welfare (AIHW), 2017; Ministry of Health, 2015).

Government policy considerations have identified that, as part of a broader suite of measures, pregnancy warning labels on alcoholic beverages can reinforce public health messages, help raise awareness of the risks of drinking alcohol during pregnancy, prompt discussions and support the establishment of cultural norms (Food Regulation Standing Committee, 2018). FSANZ's evidence review supports this (refer to section 3.2; Wilkinson et al., (2009)) and Supporting Document 1 (SD1)). Further to this, evidence from alcohol warnings and tobacco warning labels confirms the label as part of a suite of measures can contribute to behaviour change (refer to section 3.2.3). Both Australia (Department of Health, 2019a) and New Zealand (Ministry of Health, 2018a) have action plans aimed at educating consumers about the risks of drinking alcohol during pregnancy and FASD.

Since 2011, the alcohol industry has implemented a voluntary pregnancy warning labelling scheme. However, following evaluation of the voluntary scheme in 2014 and 2017, the Australia and New Zealand Ministerial Forum on Food Regulation (the Forum) agreed that, *based on the evidence, a mandatory labelling standard for pregnancy warning labels on packaged alcoholic beverages should be developed and should include a pictogram and relevant warning statement*. The Forum therefore asked FSANZ to consider mandatory pregnancy warning labelling on packaged alcoholic beverages as a priority and that the work be completed expeditiously (Australia and New Zealand Ministerial Forum on Food Regulation, 2018).

In making this request the Forum provided FSANZ with a Decision Regulation Impact Statement (DRIS) (Food Regulation Standing Committee, 2018) as policy advice. Consistent with the FSANZ Act, this policy advice was one relevant matter amongst others that FSANZ had regard to in its assessment of this proposal. The DRIS states (page 50) that *the **primary objective** of pregnancy warning labels on packaged alcoholic beverages is to provide a clear and easy to understand trigger to remind pregnant women, at both the point of sale and the potential point of consumption, to not drink alcohol. A **secondary objective** of pregnancy warning labels on packaged alcoholic beverages is to provide information to the community about the need for pregnant women to not drink alcohol.*

Therefore, the objective of pregnancy warning labels is, in conjunction with other public health initiatives, the protection of public health and safety by reducing the prevalence and/or severity of FASD.

In response to the Forum's request, FSANZ commenced this proposal in November 2018.

### **1.3 Procedure for assessment**

The proposal was assessed under the General Procedure of the FSANZ Act.

### **1.4 Scope of the proposal**

P1050 considers the requirement for a warning label about the risks of drinking alcohol during pregnancy on packaged alcoholic beverages for sale in Australia and New Zealand. Imported alcoholic beverages are therefore in scope.

P1050 excludes re-examination of the evidence related to the impact of alcohol exposure on the fetus as the scientific evidence base for this has been recently reviewed by the National Health and Medical Research Council (refer to section 2.3 below). Reference to breastfeeding in the warning label is out of scope. The proposal's focus is on packaged alcoholic beverages. As such it excludes consideration of the display of signage in licensed premises and the like.

### **1.5 Decision**

The draft variation as proposed following assessment was approved with amendments. The variation takes effect on gazettal. The approved draft variation, as varied after consideration of submissions, is at Attachment A.

The related explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

The draft variation on which submissions were sought is at Attachment C. The main amendments to the draft variation following consideration of submissions are summarised in section 3.3.12. These include amendments to the wording of the warning statement, the colour to be used in the warning label (red rather than specifically Pantone 485) and editorial amendments to reduce the complexity and improve the clarity of the drafting.



# 2 Background

## 2.1 History of the policy considerations

In response to recommendation 25<sup>1</sup> from *Labelling Logic: Review of Food Labelling Law and Policy* (Labelling Review) (Blewett et al., 2011), the then Legislative and Governance Forum on Food Regulation<sup>2</sup> provided the alcohol industry with a two year period, commencing December 2011, to voluntarily place pregnancy warning labels on alcoholic beverages, before regulating such a change.

Since December 2011, pregnancy warning labels have been included on packaged alcoholic beverages on a voluntary basis in both 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 for alcohol manufacturers to use on their products. The logos provide various options that include the statement *It's safest not to drink while pregnant* and a pictogram featuring a silhouetted pregnant woman holding a wine glass enclosed within a circle with a diagonal strikethrough. The organisation's website is also included in some options. Figure 1 provides examples of the various voluntary logos.



**Figure 1: Voluntary pregnancy warning labels as developed by DrinkWise (left) and Cheers (right)**

In 2014, ministers considered the first evaluation of voluntary labelling in Australia and New Zealand (Siggins Miller, 2014; Ministry for Primary Industries, 2014) and subsequently decided to allow another two years for industry to increase uptake of voluntary labelling.

<sup>1</sup> Recommendation 25 states: *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.*

<sup>2</sup> Now the Australia and New Zealand Ministerial Forum on Food Regulation (the Forum)

In 2017, ministers considered a second evaluation (Siggins Miller, 2017; Ministry for Primary Industries, 2017a, 2017b) and noted that while industry uptake of the pregnancy warning label had increased over time, there continued to be low uptake in some product categories. The Forum therefore asked for a policy options paper to consider mandatory versus voluntary/non-regulatory approaches, and the most appropriate pictogram and easy to understand message to discourage drinking during pregnancy (Australia and New Zealand Ministerial Forum on Food Regulation, 2017).

A Consultation Regulation Impact Statement was prepared by the Food Regulation Standing Committee (FRSC) and targeted consultation undertaken in May and June 2018. Following consideration of stakeholder comments a DRIS was prepared.

The DRIS included a problem statement with supporting information, a summary of the evaluations of the voluntary labelling initiative, an analysis of regulatory and non-regulatory options including costs and benefits, a summary of evidence related to effective label design, an outline of activities included in Australia and New Zealand FASD Action Plans, and a discussion of implementation issues. The DRIS concluded mandatory labelling provides the greatest net benefit to the community (Food Regulation Standing Committee, 2018).

## **2.2 Previous consideration of pregnancy warning labels**

FSANZ has received two applications seeking to have warning labels on alcoholic beverages about the risks of drinking alcohol during pregnancy and one application for a more generic warning about alcohol.

In 1996, the then National Food Authority (now FSANZ) received Application A306 – Health warning on alcoholic beverages, from the National Council of Women, Launceston Branch. This application requested a warning about the possible risk of birth defects from alcohol consumption during pregnancy be included on labels of alcoholic beverages. Submissions were received in response to the Information Summary released in June 1996. However, the application was subsequently withdrawn at the end of that year due to an impending review of the Australian alcohol guidelines.

The second application (Application A576 – Labelling of Alcoholic Beverages with a Pregnancy Health Advisory Label) was submitted in February 2006 by the then Alcohol Advisory Council of New Zealand<sup>3</sup> (Alcohol Advisory Council of New Zealand, 2006). Application A576 seeks to require a health advisory label on alcoholic beverages advising of the risks of consuming alcohol when planning to become pregnant and during pregnancy. An Initial Assessment of Application A576 was released for public comment in December 2007. FSANZ commissioned two reviews to inform the assessment: a review on the effectiveness of labelling in relation to pregnancy advisory statements (Wilkinson et al., 2009), and a study comparing the cost-effectiveness of mandatory labelling with other strategies to reduce alcohol consumption amongst pregnant women and ultimately FASD (Health Technology Analysts, 2010). In response to a request from the applicant, the FSANZ Board agreed to defer assessment due to its overlap with Recommendation 25 from the Labelling Review. FSANZ will discuss Application A576 with the applicant once the assessment process for P1050 is completed.

In 1998 the then Australia New Zealand Food Authority<sup>4</sup> (ANZFA) received an application (A359) from the Society Without Alcoholic Trauma requesting an amendment to the Code to require all alcoholic beverages be labelled with the statement *This product contains alcohol. Alcohol is a dangerous drug.*

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<sup>3</sup> Now the Health Promotion Agency

<sup>4</sup> Now FSANZ

Following assessment, it was rejected for a number of reasons including that *Scientific evidence for the effectiveness of warning statements on alcoholic beverages shows that while warning labels may increase awareness, the increased awareness does not necessarily lead to the desired behavioural changes in at risk groups. In fact, there is considerable scientific evidence that warning statements may result in an increase in the undesirable behaviour in 'at risk' groups.*<sup>5</sup>

In the context of P1050, FSANZ considers this finding is not applicable. In P1050, the warning is not a generic warning as was proposed in A359, but rather one targeted to one specific issue and audience. Reactance behaviour is typically associated with young men and heavier drinkers and may also occur where warning labels include graphic pictures (Ringold, 2002; Monk et al., 2017). Based on the best available evidence, FSANZ's assessment is that a pregnancy warning label as part of a suite of measures can contribute to behaviour change (refer to section 3.2.3).

## **2.3 Alcohol consumption guidelines in Australia and New Zealand**

Based on scientific evidence, public health advice from government in both Australia (Department of Health, 2019b, 2019c) and New Zealand (Ministry of Health, 2018b; Health Promotion Agency, 2019a) is that pregnant women not consume alcohol.

The National Health and Medical Research Council published *The Australian Guidelines to Reduce Health Risks from Drinking Alcohol* in 2009 (NHMRC, 2009). The purpose of the guidelines is to provide the *evidence base for future policies and community materials on reducing the health risks that arise from drinking alcohol* and to *communicate evidence concerning these risks to the Australian community to allow individuals to make informed decisions regarding the amount of alcohol that they choose to drink*. Guideline 4A states maternal alcohol consumption can harm the developing fetus and: *For women who are pregnant or planning a pregnancy, not drinking is the safest option*. The report provides a summary of the evidence which indicates the risk of birth defects is likely to be highest when there is high, frequent maternal alcohol consumption and lowest when alcohol consumption is low (for example, one or two drinks per week). There is no known safe level of alcohol consumption. It is noted that the level of risk to the individual fetus is also influenced by maternal and fetal characteristics and therefore is hard to predict.

The Australian Department of Health has developed education materials for the general public based on the guidelines (Department of Health, 2019b, 2019c). The main message is: *the safest option is to not drink alcohol at all. Even a small amount of alcohol can harm an unborn baby's development and may have lifelong effects*. Further messaging includes that there is no known safe amount of alcohol and no known safe time to drink alcohol during pregnancy. The Department of Health also encourages women who drank alcohol before they knew they were pregnant to talk with a health professional.

A review of the 2009 Australian guidelines commenced in 2017 (NHMRC, 2019a). The review included an evaluation of the evidence on the health effects of alcohol consumption including the effects of consumption during pregnancy. The NHMRC released draft revised guidelines on 16 December 2019 for public comment for the period until 24 February 2020 (NHMRC, 2019b). It is anticipated the final revised guidelines will be published in 2020. The draft guideline relevant to pregnancy is *to reduce the risk of harm to their unborn child, women who are pregnant or planning a pregnancy should not drink alcohol*.

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<sup>5</sup> The Full Assessment Report and Statement of Reasons for the rejection are available at [Application A359 - Labelling of alcoholic beverages with a warning statement](#)

This guideline is based on the evidence relating to potential harms to a developing fetus, indicating there is no known safe level of alcohol consumption during pregnancy. While the risk of harm to the developing fetus is increased by a higher consumption of alcohol by the mother, the draft guidelines take a precautionary approach, recommending women not consume alcohol during pregnancy.

The New Zealand government's advice is: *Stop drinking alcohol if you could be pregnant, are pregnant or are trying to get pregnant. There is no known safe level of alcohol consumption during pregnancy.* Supporting information is similar to that provided in Australia. Given there is no known safe level of alcohol consumption during pregnancy, pregnant women are advised to drink no alcohol (Ministry of Health, 2018b; Health Promotion Agency, 2019a, 2019b; Ministry of Health and Health Promotion Agency, 2018).

## **2.4 Current trends in alcohol consumption during pregnancy**

Available data indicate some women consume alcohol during pregnancy in both Australia and New Zealand.

According to the Australian Institute of Health and Welfare (AIHW, 2017), between 2007 and 2016 the proportion of women consuming alcohol during pregnancy declined. However, the AIHW also reports that in 2016, nearly 50% of women reported having consumed alcohol at some stage during their pregnancy, with about 25% continuing to drink after they knew they were pregnant. Of those women who consumed alcohol when pregnant, 81% drank alcohol monthly or less, and 16.2% of these women drank 2–4 times a month. Most (97%) usually consumed 1–2 standard drinks on a single occasion (AIHW, 2017).

The New Zealand Ministry of Health reports that in 2012/13 approximately one in five women who were pregnant in the preceding 12 months drank alcohol at some point during their most recent pregnancy (Ministry of Health, 2015).

## **2.5 Broader public health initiatives to support FASD reduction**

### **2.5.1 New Zealand**

#### **2.5.1.1 National Drug Policy 2015 to 2020**

New Zealand's *National Drug Policy 2015 to 2020* sets out the government's approach to alcohol and other drug (AOD) issues. The policy aims to minimise alcohol and other drug harm, and promote and protect health and wellbeing (Inter-Agency Committee on Drugs (IACD), 2015). In line with Priority area 2 of this policy, *Shifting thinking and behaviour*, the Government committed to publication of a FASD Action Plan (IACD, 2015).

New Zealand's *Taking Action on Fetal Alcohol Spectrum Disorder: 2016-2019 Action Plan* was launched in August 2016 and aims to create a more effective, equitable and collaborative approach to FASD (Ministry of Health, 2018a). The Action Plan focusses on four priorities: prevention; early identification; support and evidence and includes 10 action areas (Ministry of Health, 2018c). Action area two is to develop and disseminate clear, unambiguous and consistent messages to increase the whole community's awareness of the risks of drinking alcohol during pregnancy, including FASD (Ministry of Health, 2018c).

The Ministry of Health website provides a summary of progress for each of the action areas (Ministry of Health, 2018d).

The Health Promotion Agency also provides a number of public health initiatives, primarily focussed on prevention of FASD<sup>6</sup>. These include:

- development of an online training package on supporting alcohol-free pregnancies, for midwives
- delivery of a multi-year *Don't know? Don't Drink* public education campaign which builds awareness amongst young women that alcohol should not be consumed if they could be or are pregnant
- redevelopment of pregnancy alcohol screening and brief intervention guidelines for health professionals
- support for the uptake of primary care tools that encourage best practice alcohol screening and support for women in early pregnancy
- an online toolkit which includes a summary of evidence and access to print and online health promotion resources, and
- delivery of a broader alcohol harm reduction programme which supports women to drink less or not to drink, through effective policies and evidence based approaches to reduce drinking.

## **2.5.2 Australia**

### **2.5.2.1 National Alcohol Strategy**

The National Alcohol Strategy 2019-2028 provides a framework to prevent and reduce alcohol-related harm in Australia, highlighting possible actions at the local, state or territory and national levels (Department of Health, 2019d). The National Alcohol Strategy refers to FASD under priority area three: facilitating access to treatment, information and support services.

### **2.5.2.2 FASD Strategic Action Plan**

In 2018, the Australian Government launched the *National Fetal Alcohol Spectrum Disorder (FASD) Strategic Action Plan 2018-2028* (Department of Health, 2018a). The Strategic Action Plan aims to reduce the incidence and impact of FASD in Australia and to improve the quality of life for people living with FASD. The plan identifies four national priority areas including prevention, diagnosis, support and management. A key objective under prevention is to increase community knowledge and awareness about the harms and consequences of drinking during pregnancy or when planning a pregnancy (Department of Health, 2019a).

The Australian Government has committed \$7.2 million in funding towards these priorities (Department of Health, 2019e).

### **2.5.2.3 Other initiatives**

The National FASD Hub Australia (the Hub) is a one-stop-shop for current, evidence-based information, tools and resources, for both consumers and health professionals (FASD Hub Australia, 2019a). The Hub is funded by the Australian government and serves as a repository for information on FASD including assessment and diagnosis, prevention and management of FASD, and provides links to international research and resources (FASD Hub Australia, 2019b).

A number of other supports are also available for health professionals for the diagnosis and management of FASD. The *Women Want to Know* initiative encourages health professionals to routinely discuss alcohol and pregnancy with women and to provide advice that is consistent with the NHMRC guidelines (Department of Health, 2019f).

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<sup>6</sup> Health Promotion Agency, personal communication, 20 December 2019

The Pregnant Pause initiative was developed by the Foundation for Alcohol Research and Education which encourages Australians to go alcohol-free during their pregnancy or the pregnancy of their partner, family member, friend or loved one (Foundation for Alcohol Research and Education, 2018).

## 2.6 Relevant labelling requirements in the Code

Specific labelling requirements for alcoholic beverages are mostly included in Standard 2.7.1 – Labelling of alcoholic beverages and food containing alcohol. A statement of alcohol content is required on food (including an alcoholic beverage) that contains more than 1.15% alcohol by volume (ABV); an alcoholic beverage that contains 1.15% or less ABV; or a beverage that contains no less than 0.5% ABV but no more than 1.15% ABV (section 2.7.1—3).

A statement of the number of standard drinks contained in food for sale that is capable of being consumed as a beverage and contains more than 0.5% ABV must also be included on the label (section 2.7.1—4).

An alcoholic beverage which contains more than 1.15% ABV must not be represented as a low alcohol beverage (section 2.7.1—5).

The general legibility requirements in the Code apply to mandatory labelling information on alcoholic beverages. Any words required to be on the label must be in English and any required word, statement, expression or design must be legible and prominent so as to contrast distinctly with the background of the label (section 1.2.1—24 of Standard 1.2.1 – Requirements to have labels or otherwise provide information).

The term *warning statement* is defined in the Code (section 1.1.2—2 of Standard 1.1.2 – Definitions used throughout the Code) and means a statement about a particular aspect of the food that is required to be expressed in specific wording as set out in the Code. Warning statements are required to be written in a size of type<sup>7</sup> of at least 1.5 mm for a small package<sup>8</sup> and of at least 3 mm for all other sized packages (section 1.2.1—25).

## 2.7 Pregnancy warning labels in other countries

### 2.7.1 Countries with mandatory or voluntary pregnancy warning labels

Internationally, there is no consistency in the requirements for health warning labels on alcoholic beverages nor with format and/or wording of these labels. Information about requirements for pregnancy warning labels in other countries is provided at Attachment D.

Based on information provided by the International Alliance for Responsible Drinking as at December 2019 (IARD, 2019a), of 38 countries which mandate health warnings about the risk of drinking alcohol on alcoholic beverage containers and/or statements about alcohol being prohibited for sale to those under 18 years, 11 countries have legal requirements for a pregnancy warning label (refer to Attachment D).

In France, labels of beverages with more than 1.2% ABV must include either the text *Consumption of alcohol beverages during pregnancy, even in small amounts, can have serious consequences for the child's health* OR a pictogram to that effect. Lithuania, Mexico,

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<sup>7</sup> Size of type means the measurement from the base to the top of a letter or numeral (section 1.1.2—2).

<sup>8</sup> Small package means a package with a surface area of less than 100 cm<sup>2</sup> (section 1.1.2—2)

Moldova and Turkey mandate the use of the French pictogram, with some design variation in Moldova. Requirements in other countries for aspects of label design such as colour and size along with specifications of the beverages required to display the pregnancy warning label are summarised at Attachment D.

While the Irish *Public Health (Alcohol) Act 2018* (Government of Ireland, 2018) confers power on the Minister for Health to provide for the labelling of alcohol products including a warning about the risks of drinking alcohol during pregnancy, regulations to implement provisions in the Act are yet to be approved by the European Commission. Therefore a pregnancy warning label is not yet implemented in Ireland.

Both Japan and the United Kingdom have voluntary labelling initiatives about the risks of drinking alcohol during pregnancy. Additionally, some alcoholic beverage producers have policies to voluntarily include pregnancy warning labels on containers (IARD, 2019b).

Information on requirements for pregnancy warning labels in other countries is also available from the 2018 Global Status Report on Alcohol and Health (World Health Organization (WHO), 2018a, 2018b). In that report it is stated 27 countries have a legal requirement for a pregnancy health warning label, however details of the requirements are not available (refer to Attachment D).

### **2.7.2 Codex discussions about labelling of alcoholic beverages**

Codex Alimentarius has no specific guidelines for the labelling of alcoholic beverages. However, at the 44<sup>th</sup> meeting of the Codex Committee on Food Labelling (CCFL) in October 2017, a paper on alcoholic beverage labelling prepared by the WHO was discussed (Codex Alimentarius, 2017). The WHO proposed CCFL do new work to develop guidance on labelling of alcoholic beverages, covering a definition of alcoholic beverages, product information, health warnings, restrictions on information and packaging presenting risks to health and restrictions on nutrition labelling and health claims. It was agreed a discussion paper on alcoholic beverage labelling would be prepared for the May 2019 CCFL meeting for the purpose of deciding whether new work on alcoholic beverage labelling will proceed. At that meeting delegates expressed a wide range of views, with some supporting and others not supporting future work (Codex Alimentarius, 2019). It was agreed comments on the paper would be sought via a Circular Letter and a further discussion paper be prepared for the next session in October 2020.

## **2.8 International trade agreements**

Australia and New Zealand are members of the World Trade Organization (WTO) and therefore are legally obliged to follow the rules of WTO trade related agreements. The General Agreement on Tariffs and Trade (GATT), and in particular, the Technical Barriers to Trade (TBT) Agreement is relevant to the pregnancy warning label. This Agreement is further discussed in sections 3.1.2, 3.4.3, and at Attachment E.

Australia and New Zealand are also parties to a number of bilateral and multilateral free trade agreements (FTAs), which relevantly include obligations similar to the GATT and the TBT Agreement. The general purpose of the relevant obligations in these WTO Agreements and the FTAs is to protect against technical regulations that create unnecessary barriers to trade.

Proposal P1050 has been prepared taking all these international trade obligations into account.

Some of the FTAs also include clauses that deal specifically with the labelling of alcoholic beverages, particularly wine and distilled spirits. For example, Australia and New Zealand are parties to the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP). Chapter 8 of the CPTPP includes Annex 8-A: Wine and Distilled Spirits. Section 10 of Annex 8-A states that if a party requires a wine label to include information other than the product name, country of origin, net contents or alcohol content, the party shall permit the supplier to provide the information on a supplementary label fixed to the wine container after importation but before offering the product for sale and may require that the supplier fix the supplementary label before release from customs. Section 5 of Annex 8-A sets out similar permissions for distilled spirits.

This means that a pregnancy warning label required in Australia and New Zealand must be able to be affixed as a supplementary label on imported wines and distilled spirits. The proposed amendment to the Code, and the Code more generally, does not prevent the use of supplementary labels.

Further, FSANZ understands that mandatory labelling requirements do not necessarily need to be met before products are released from customs in both Australia and New Zealand, but must be met before products are offered for sale.

Similarly, other FTAs may include additional considerations. For example the Korea-Australia FTA includes that where legitimate objectives (in accordance with the TBT Agreement) are not compromised a Party shall endeavour to accept non-permanent or detachable labels or accompanying documentation in place of labelling attached to the product. On this matter, FSANZ had regard to the fact that the pregnancy warning label is intended to protect human health by raising awareness about the risks of drinking alcohol while pregnant. It is therefore important that women of childbearing age are provided with consistent information both at the point of purchase and consumption. Allowing non-permanent or a detachable label, or accompanying documentation runs the risk of the information being separate, or separated, from the packaged alcoholic beverage. In this case, the information would not be available and, consequently, the label would not achieve its intended purpose.

Finally, Australia and New Zealand are members of the World Wine Trade Group (WWTG) along with Argentina, Canada, Chile, Georgia, South America and the USA. The group developed a Labelling Agreement in 2007 which enables exporters to sell wine into WWTG markets without having to redesign all of their labels for each individual market. Under the Labelling Agreement, the WWTG members have agreed to a *single field of vision* approach to wine labelling, whereby four key common items of information (country of origin, product name, net contents, and alcohol content) are deemed to comply with domestic labelling requirements if they are presented together in any single field of vision on the container. If the common mandatory information is presented outside of a single field of vision, the information has to comply with the requirements of the importing country.

National mandatory information, such as the pregnancy warning label, may also be required by an importing country. Article 10 of the Labelling Agreement states that although an importing country may not restrict the placement of national mandatory information, an importing country may require two or more items of national mandatory information to appear in the same field of vision as each other (World Wine Trade Group, 2019).

Importantly, Article 5.4 of the Labelling Agreement also makes clear that *Nothing in this Agreement shall in any way prevent a Party from taking measures for the protection of human health and safety, provided such measures are in accordance with the provisions of the World Trade Organization (WTO) Agreement (as defined)*. As such, Australia and New Zealand may mandate pregnancy warning labels that comply with the WTO agreements.



## 2.9 Australia and New Zealand wine exports

While there are broad requirements in both Australia and New Zealand for wine exported from either country to comply with domestic labelling requirements, provisions in the *Wine Australia Regulations 2018* and the *New Zealand Wine Act 2003* mean that a mandatory warning label in Australia and New Zealand is unlikely to be a barrier for exported product.

Section 14(3) of the *Wine Australia Regulations 2018*<sup>9</sup> states:

*The Authority may approve the grape product if the Authority is satisfied that:*

*(a) either:*

*(i) the grape product complies with the Australia New Zealand Food Standards Code; or*

*(ii) the ways in which the product does not comply will not compromise the reputation of Australian grape products; and*

*(b) the grape product is sound and merchantable; and*

*(c) the description and presentation of the grape product is appropriate having regard to requirements of the Act, other Australian laws and the laws of other countries.*

Therefore it appears that a mandatory pregnancy warning label in Australia would not be a barrier for wine exports provided an export wine without a warning label (that would be required in the Code) is not considered to *compromise the reputation of Australian grape products*.

Section 14(2A) of the *New Zealand Wine Act 2003*<sup>10</sup> states that labelling requirements in a New Zealand standard do not apply where they conflict with a labelling requirement for an export market. Therefore, a mandatory warning label in the Code will not affect labelling of wine products exported from New Zealand where the export market requires a different pregnancy warning label.

## 3 Summary of the findings

### 3.1 Issues raised in submissions

#### 3.1.1 Public consultation

FSANZ sought public comment via a Call for Submissions (CFS) on the proposed draft variations to the Code from 4 to 27 October 2019. A total of 137 (including seven late) submissions were received: 83 from industry, 33 from public health, 15 from Government, and 6 from academics/consumer groups. The relevant documents and submissions received are published on the FSANZ website at [P1050 – Pregnancy warning labels on alcoholic beverages](#).

In general, the introduction of a mandatory pregnancy warning label was broadly supported by submitters, however, stakeholder groups had divergent views on the proposed approach to warning label design and implementation.

Most industry submitters did not support a prescriptive approach to label design, raising issues with several of the proposed label design elements and indicating a strong preference for mandating the current voluntary scheme. Industry submitters also raised issues about the process FSANZ undertook in considering this proposal, the evidence base and the

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<sup>9</sup> Refer to [Wine Australia Regulations 2018](#)

<sup>10</sup> Refer to [New Zealand Wine Act 2003](#)

consideration of costs and benefits.

Public health submitters generally supported the proposed label design and the evidence base used to support the proposed approach. However, some of these submitters preferred larger text and increased label size; prescribing the location of the label; and a shorter transition period of 12 months. Government submitters in general supported the level of prescription proposed. However, one noted specific aspects for which the level of prescription could be more than necessary, for example the exact colour red and font type.

Stakeholder groups had mixed views regarding label size requirements based on different alcoholic beverage volumes, the wording of the warning statement, and the alcohol content of the beverages required to display the warning label.

Table 1 summarises the issues raised in submissions to the CFS and provides FSANZ's response.

**Table 1: Summary of issues raised in submissions to the CFS and FSANZ response**

Note: Column 2 of Table 1 indicates the stakeholder groups which raised the issue. However, the issues raised are not necessarily the representative view of all submitters in a stakeholder group.

Issue	Stakeholder group	FSANZ response
<b>Mandatory labelling approach</b>		
<p>Lack of evidence that warning labels change behaviour, or that the proposed mandatory label will achieve more or provide additional net benefit to the existing voluntary label (DrinkWise scheme).</p> <p>The DRIS and CFS assume behaviour change results from labelling and that FASD cases are avoided, but says label alone does not influence behaviour.</p>	Industry	<p>Pregnancy warning labels on packaged alcoholic beverages can raise awareness of the risks of drinking alcohol during pregnancy and prompt discussion of these risks (SD1, Wilkinson et al., 2009). Evidence from alcohol warnings and tobacco warning labels confirms the label as part of a suite of measures can contribute to behaviour change (refer to section 3.2.3). Therefore, when combined with other public health initiatives, pregnancy warning labels can contribute to increased awareness of the risks of drinking alcohol while pregnant and encourage behaviour change. It can also contribute to the development of social norms to support this behaviour change. These will ultimately reduce the prevalence and/or severity of FASD.</p> <p>The warning label has been designed based on the best available evidence, with consideration given to labelling elements that serve to attract attention and enhance understanding (refer to section 3.3). FSANZ's literature review (SD1), together with outcomes from consumer testing (SD2), indicate the pregnancy warning label, with specific design elements, is likely to better convey public health advice not to drink alcohol during pregnancy and attract consumer attention to a greater extent than the warning labels used in the voluntary initiative.</p>
Support mandatory implementation of the DrinkWise label or a label similar to the existing voluntary label, which accompanied by awareness raising materials and public campaigns, would have far less cost for industry.	Industry	<p>Based on consumer testing, FSANZ determined <i>It's safest not to drink while pregnant</i> statement (the current voluntary DrinkWise message) does not convey public health advice as well as the other warning statements tested (refer to section 3.2.2). Evidence also suggests the pictogram alone (as often used voluntarily) may not challenge some beliefs about the risks of drinking alcohol during pregnancy. The inclusion of the consequences of drinking alcohol during pregnancy in a statement may also enhance label effectiveness (SD1).</p> <p>The combination of the pictogram, signal words and warning statement in the prescribed pregnancy warning label (rather than the pictogram alone) is based on the findings of the literature review (SD1) which confirmed multiple design elements can be used in varying combinations to enhance the noticeability and understanding of the warning label.</p>

Issue	Stakeholder group	FSANZ response
		Results of the second evaluation of the existing voluntary scheme (refer to section 2.1) found adoption of the voluntary pregnancy warning label continued to be low in some product categories. Where the voluntary label had been adopted, there was variation in type, colour, size and design of the warning labels. As discussed in sections 1.2 and 2.4, despite existing measures to inform pregnant women not to consume alcohol, the available data indicate 20% of women in New Zealand and 25% of women in Australia, continue to do so.
<b>FSANZ process</b>		
<p>Reliance on the DRIS and FSANZ Act requirements:</p> <ul style="list-style-type: none"> <li>FSANZ has not fulfilled its FSANZ Act responsibilities. In the absence of a formal Policy Guideline, FSANZ relied on the DRIS in substitution for the performance of its own functions under the Act. FSANZ has failed to take a full view of the evidence or weigh all of the relevant considerations appropriately.</li> <li>Over-reliance on DRIS and Ministerial Forum Communiqué. Misapplied significance given status of policy guidelines/Ministerial direction status.</li> </ul>	Industry	<p>FSANZ has made its own assessment and decision in accordance with the FSANZ Act. FSANZ was not bound by the policy advice issued by the Forum.</p> <p>FSANZ undertook an independent assessment of the adequacy or otherwise of the DRIS and acted to address gaps that were identified with its analysis of the evidence on which it relied. As noted in section 3.5.1.1, the Office of Best Practice Regulation (OBPR) was satisfied the necessary range of potential regulatory change had been considered through the DRIS and exempted FSANZ from the need to undertake a formal Regulation Impact Statement. Specifically FSANZ has:</p> <ul style="list-style-type: none"> <li>systematically searched and reviewed relevant evidence to inform the design and content of the pregnancy warning label</li> <li>undertaken a survey with representative samples in Australia and New Zealand to test women of childbearing age's response to, and understanding of, several text options for the warning label</li> <li>obtained external independent peer review of the literature review and survey report, and included additional information as suggested by peer reviewers (SD1, SD2, SD3)</li> <li>reviewed and extended the economic analysis in the DRIS, including checking primary data sources and incorporating new evidence on label costs from stakeholders</li> <li>considered all new risk assessment and risk management work undertaken</li> <li>reconsidered the value of a number of key variables (such as additional colours and different printing methods) in light of a more defined warning label design and additional evidence</li> <li>undertaken updated calculations using the new variables across three scenarios to extend the consideration of costs and benefits</li> <li>considered all submissions received to the CFS and WTO notification.</li> </ul>
FSANZ adopted the design labelling elements recommended in the DRIS despite the evidence in FSANZ's	Industry	As noted above, FSANZ made its own independent assessment and was not bound by the policy advice in the DRIS. FSANZ uses the best available scientific evidence to inform its standards development. FSANZ undertook a systematic search to identify relevant

Issue	Stakeholder group	FSANZ response
literature review being weak, irrelevant or non-existent. Design is dictated by the DRIS rather than adherence to existing design principles embodied in the Code.		<p>evidence to inform the design and content of the pregnancy warning label (refer to section 3.2.1). The evidence was independently assessed by FSANZ and limitations in the evidence were noted in the literature review at SD1. FSANZ also undertook a survey with representative samples in Australia and New Zealand to test women of childbearing age's response to, and understanding of, several text options for the warning label (refer to section 3.2.2). Both the survey report and literature review have been reviewed by external independent academics with experience in the behavioural sciences.</p> <p>FSANZ's approach to the label design was based on the best available evidence regarding elements that serve to attract attention and enhance understanding (refer to section 3.2.1). FSANZ also considered submitter comments and other relevant matters, such as the range of beverage volumes and package sizes available in the market with varying label space, to ensure a pragmatic approach while not undermining label effectiveness (refer to rationale for decisions in section 3.3).</p>
The proposal is an example of <i>Explicit Government Regulation</i> set out in the Australian Government Guide to Regulation. Other less burdensome regulatory options could be considered while maintaining a mandatory system, including <i>Co-Regulation</i> and <i>Quasi-Regulation</i> .	Industry	Potential quasi-regulation and co-regulation options were considered and rejected for reasons discussed in section 3.5.1.2.
<p>FSANZ's consultation process:</p> <ul style="list-style-type: none"> <li>Limited opportunity to participate in targeted stakeholder consultation; this should have been broadened.</li> <li>Three week public consultation is insufficient and inconsistent with OBPR guidelines. Limited opportunity to consider and provide response, including provision of data and examples.</li> <li>Expeditious consideration of P1050 should not be at the expense of genuine stakeholder engagement.</li> </ul>	Industry	<p>FSANZ is satisfied public consultation in this case was appropriate, consistent with the FSANZ Act and provided stakeholders with a reasonable opportunity to provide input.</p> <p>This proposal was preceded by public consultation and input which informed the DRIS. Additionally, before issuing the CFS, FSANZ undertook significant targeted stakeholder consultation in early and mid-2019 (refer to section 3.4.2). This informed FSANZ's assessment and the preparation and content of the draft variation proposed in the CFS. Key stakeholders were also given advance notice of the release of the proposal for public consultation.</p> <p>FSANZ also made a notification to the WTO in accordance with Australia and New Zealand's obligations under the WTO TBT Agreement.</p>
Finalising the proposal prior to revision	Industry	FSANZ has had regard to the draft guidelines released by the NHMRC in December 2019.

Issue	Stakeholder group	FSANZ response
of NHMRC guidelines currently underway, risks the warning statement being inconsistent with revised guidelines, potentially causing confusion among the target audience and wider population.		The prescribed warning statement (refer to section 3.3.3) is consistent with public health advice provided by both the Australian and New Zealand Governments, including the draft NHMRC guidelines, on consumption of alcohol during pregnancy. The statement is also consistent with the evidence base regarding risks associated with consumption of alcohol during pregnancy.
The proposed labelling is not used in the New Zealand Health Promotion Agency initiative <i>Don't know, don't Drink</i> . This is at odds with the need for consistency of label information.	Industry	The pregnancy warning label required by the approved draft variation (refer to Attachment A) is consistent with public health advice provided by both the Australian and New Zealand Governments on consumption of alcohol during pregnancy. As indicated in a recent publication, the New Zealand Health Promotion Agency supports and promotes the advice of the New Zealand Government (Health Promotion Agency, 2019b).
Peer review of FSANZ's literature review and consumer testing: <ul style="list-style-type: none"> <li>• The peer review of literature review was not completed before public consultation.</li> <li>• Independent peer-review of consumer testing is needed.</li> </ul>	Industry Public health	Peer review of evidence documents prior to their public release was not possible in this instance. Both the literature review and survey report have been reviewed by external independent academics. The literature review at SD1 has been revised to include suggestions arising from its peer review. The addendum at SD3 to the survey report (SD2) contains additional information the peer reviewer suggested be included with the report.
<b>Literature review</b>		
The lack of evidence to support elements of the warning label should be identified, rather than draw comparisons between pregnancy warning labels and warning labels for other conditions. Health warnings and pregnancy warnings are not comparable as they illicit a different response from the reader.	Industry	FSANZ undertook a systematic search to identify relevant evidence to inform the design and content of the pregnancy warning label. This included evidence from the broader warning literature when considering aspects of warning label design (e.g. size, colour, location, pictorials, and signal words) which is appropriate for fundamental human perceptual processes. FSANZ also reviewed available evidence on the pictogram which was specific to the pregnancy warning label. FSANZ undertook a consumer survey to inform the text of the warning statement, which was also specific to pregnancy.
Unclear how the evidence was synthesised and how findings from the literature review informed decisions (e.g. review showed larger warning labels with larger font size are more effective, however this is not reflected in the proposed label).	Public health Consumer	FSANZ's approach to the label design was based on the best available evidence regarding elements that serve to attract attention and enhance understanding. FSANZ also considered other relevant matters, including submitter comments, to ensure a pragmatic approach while not undermining label effectiveness. The rationale for the decisions made in respect of each label element is provided section 3.3.

Issue	Stakeholder group	FSANZ response
<b>Consumer testing</b>		
<p>Consumer testing of the full label:</p> <ul style="list-style-type: none"> <li>Consumer testing the whole label (including colours and pictogram) should have been undertaken noting lack of evidence in these areas.</li> <li>Not all elements of the warning label were tested. Pre-empted label elements without consumer testing.</li> </ul>	Public health Industry	<p>Given the existing evidence base relating to design labelling elements such as colours, signal words and the pictogram (SD1 and sections 3.3.2, 3.3.4 and 3.3.7), FSANZ decided not to consumer test all elements of the label. The focus of the consumer testing was on the warning statement to be used in the label (refer to section 3.2.2).</p>
<p>Consumer testing with Māori:</p> <ul style="list-style-type: none"> <li>Consumer testing of label with Māori groups is necessary before the proposal is finalised.</li> <li>The pictogram should be consumer tested with Māori.</li> </ul>	Public health	<p>Māori were included in the New Zealand survey sample, and results from Māori/Pacific participants are included in Appendix B of the survey report (SD2).</p> <p>As noted above, given the existing evidence base relating to the pictogram, FSANZ decided not to consumer test this component of the label.</p>
<p>Concern that Indigenous groups in Australia were not included in the consumer testing process, as these communities are disproportionately affected by FASD.</p>	Public health	<p>FSANZ held a teleconference with two Australian Indigenous stakeholder representatives in July 2019. FSANZ sought their views on key aspects including warning label design (excluding statement wording as consumer testing had not been completed) and implementation (refer to section 3.4.2). FSANZ did not attain an adequate sample of Aboriginal and Torres Strait Islander people to report them as a separate group in consumer testing (see SD3).</p>
<p>Does not support consumer testing process. Reasons included:</p> <ul style="list-style-type: none"> <li>By not testing DrinkWise labels (which have good recognition and recall), FSANZ had no baseline model from which to assess costs and benefits associated with adopting a more prescriptive and costly label.</li> <li>Does not support the consumer testing process as an indication of behaviour change.</li> </ul>	Industry	<p>As previously noted, FSANZ determined the current voluntary DrinkWise message (<i>It's safest not to drink while pregnant</i>) does not convey public health advice as well as the other warning statements tested (refer to section 3.2.2). Evidence also suggests the pictogram alone may not challenge some beliefs about the risks of drinking alcohol during pregnancy. The combination of the pictogram with wording (rather than the pictogram alone) is based on the literature review findings (SD1) which confirmed multiple design elements can be used in varying combinations to enhance the noticeability and understanding of the warning label.</p> <p>FSANZ expects a benefit from the mandated pregnancy warning label beyond the status quo for the reasons listed in section 3.5.1.1, noting the pregnancy warning label is part of a broader suite of measures aimed to raise awareness of the risks of drinking alcohol during pregnancy. Evidence from alcohol warnings (Pettigrew et al., 2016) and tobacco warning labels (Wilkinson et al., 2009) confirms the label as part of a suite of measures can</p>



Issue	Stakeholder group	FSANZ response
		<p>contribute to behaviour change (refer to section 3.2.3).</p> <p>The literature review and consumer testing reports were reviewed by external independent academics with expertise in the behavioural sciences. Refer to section 3.5.1.1 for FSANZ's consideration of costs and benefits.</p>
Consumer testing did not include unprompted responses.	Industry	Unprompted responses to warning label options were collected and reported in the consumer testing report (refer to SD2).
Lower socio-economic groups were under-represented in consumer testing.	Public health	This issue is discussed in the addendum (SD3) to the consumer testing report (SD2).
<b>Pictogram</b>		
<p>Does not support use of the DrinkWise pictogram design. Comments included:</p> <ul style="list-style-type: none"> <li>• Conflict of interest to use label developed and funded by DrinkWise.</li> <li>• DrinkWise label is not effective and using this with new messaging may be confusing.</li> </ul>	Public health	<p>For the reasons stated in this report, FSANZ has decided to mandate a similar pictogram design commonly used in the Australia and New Zealand voluntary labelling initiative (refer to section 3.3.2), noting there are moderate and increasing levels of prompted awareness and understanding of the pictogram (SD1).</p> <p>FSANZ is not aware of there being a conflict of interest in mandating the pictogram already commonly used.</p>
<p>Design of the pictogram:</p> <ul style="list-style-type: none"> <li>• Should reflect a woman saying no to a glass being offered to her.</li> <li>• Will the lady depicted in late stage pregnancy be equally effective for women in both early and late stage pregnancy.</li> <li>• Ponytail adds non-essential detail.</li> <li>• Imagery may have a detrimental effect on pregnant women who currently drink alcohol or have a drinking problem (suggests an alternative be designed using rigorous development methods).</li> </ul>	Public health Industry Academic	<p>Refer to the response above. Additionally:</p> <ul style="list-style-type: none"> <li>• Evidence shows that a woman saying no to a glass in the pictogram with the strikethrough was too complex as it was a double negative; and without the strikethrough the easily recognised 'prohibition/do not' message was lost (SD1).</li> <li>• The pictogram is intended to convey pregnancy generally rather than a specific stage of pregnancy – this would not be achieved by an image of a woman in the early stages of pregnancy.</li> <li>• The ponytail is used in the existing voluntary labelling initiative.</li> <li>• The pictogram reinforces public health advice and messaging not to drink alcohol when pregnant.</li> </ul>
<p>Request wine glass image be reconsidered. Comments included:</p> <ul style="list-style-type: none"> <li>• Applying this image across all beverage types risks the perception</li> </ul>	Public health Government	The wine glass shape is used in the current voluntary labelling initiative and is commonly associated with, or recognised as being, specifically for serving an alcoholic beverage compared to other drinking vessels which may also be associated with non-alcoholic beverages. FSANZ has therefore decided to maintain the approach for the pictogram to



Issue	Stakeholder group	FSANZ response
<p>that it is warning against wine instead of alcohol.</p> <ul style="list-style-type: none"> <li>Relevancy of the wine glass for Indigenous communities (and women who don't drink wine) needs to be considered. Supports further engagement with Indigenous communities on proposed label.</li> </ul>		<p>include the wine glass image. FSANZ has amended the draft variation to specify that the vessel in the pictogram is a wine glass (refer to Attachment A).</p> <p>Refer to response above under Consumer Testing issues regarding engagement with Indigenous communities on the warning label design.</p>
<p>Support the pictogram only and not the full warning label.</p>	<p>Industry</p>	<p>As discussed in section 3.2.1, the literature review confirmed that multiple design elements (including pictorials and signal words) can be used in varying combinations to enhance the noticeability of warning labels. Warnings using signal words and pictorial elements (and other elements such as colour) attract more attention than labels lacking those elements. The use of the statement with the pictogram reinforces the meaning of the pictogram (to not drink alcohol during pregnancy) and explains the consequences of alcohol consumption during pregnancy which may increase the effectiveness of the label (SD1). Evidence also suggests the pictogram alone may not challenge some beliefs about the risks of drinking alcohol during pregnancy (SD1). As noted in section 2.4, 20% of women in New Zealand and 25% of women in Australia continue to drink alcohol while pregnant.</p>
<p><b>Warning statement</b></p>		
<p>Unclear why <i>any amount of alcohol can harm your baby</i> was chosen instead of the <i>lifelong</i> message which performed best in consumer testing.</p>	<p>Public health Government</p>	<p>FSANZ has reconsidered the warning statement and decided to revise the text of the statement to <i>Alcohol can cause lifelong harm to your baby</i>. Refer to further discussion and rationale for this change, including discussion of the consumer testing outcomes, in section 3.3.3.</p>
<p>Suggest <i>any amount of alcohol can cause lifelong harm to your baby</i> or variations to this (including use of terms such as <i>permanently harm</i> or <i>unborn baby</i>) based on consumer testing.</p>	<p>Public health Government Consumer</p>	<p>Refer to the response above.</p> <p>FSANZ notes the suggestion for terms such as <i>permanently</i> or <i>unborn</i>, however has limited its consideration of the warning statement to elements of the statements that were consumer tested.</p>
<p>The words <i>any amount</i> are:</p> <ul style="list-style-type: none"> <li>Inconsistent with proposed exclusion for beverages with less than 1.15% ABV to display the warning label.</li> <li>Scientifically incorrect; inconsistent with current government guidelines and DRIS advice.</li> </ul>	<p>Industry Academic</p>	<p>As noted above, FSANZ has amended the text of the warning statement to <i>Alcohol can cause lifelong harm to your baby</i> (refer to section 3.3.3). The words <i>any amount</i> have been removed in the revised statement.</p>

Issue	Stakeholder group	FSANZ response
The proposed warning label could cause undue stress for women who have consumed alcohol while pregnant.	Industry	The pregnancy warning label is intended to reinforce existing public health advice and messaging not to drink alcohol when pregnant. The warning statement reflects the evidence base regarding the risks associated with consumption of alcohol during pregnancy, and applies six principles for warning statement effectiveness (further discussed in section 3.3.3). FSANZ also notes that broader public health messaging advises if pregnant women who may have consumed alcohol are concerned, they should speak with health professionals (refer to section 2.3).
The term <i>can harm your baby</i> extends beyond concerns relating to pregnancy and implies harm to any child, born or unborn.	Industry	The statement is supported by the pictogram which indicates it is during pregnancy that harm can be caused. The warning label is also supported by other measures in Australia and New Zealand aimed to raise awareness of the risks of drinking alcohol during pregnancy (refer to section 2.5). As noted above, FSANZ has amended the text of the warning statement to <i>Alcohol can cause lifelong harm to your baby</i> . This statement reflects the fact that FASD can cause permanent, lifelong harm to the baby.
Recommend warning statement be in both English and Te Reo Māori.	Public health	The pregnancy warning label is a population-level initiative required on alcoholic beverage labels in both Australia and New Zealand. English is widely spoken and understood across Australia and New Zealand. While a bi-lingual warning statement is not required, there is opportunity for multi-lingual education referencing the label to be a part of public health initiatives.
<i>Any amount of alcohol</i> may be confusing for those with low literacy; recommends testing with these groups.	Public health	As discussed above, FSANZ has revised the statement to <i>Alcohol can cause lifelong harm to your baby</i> .
Recommend warning statement font requirements be further prescribed to be in bold, not italic and not condensed.	Consumer	FSANZ considers it has applied a high level of prescription of font requirements for the warning statement. As discussed in section 3.3.5, a sans-serif typeface is required for the warning statement to restrict the use of fonts which may reduce readability. The statement is required to be in black and in sentence case to provide a distinction to the red capitalised signal words.
<b>Signal words</b>		
Does not support proposed 'HEALTH WARNING'. Comments included: <ul style="list-style-type: none"> <li>• Goes beyond Forum mandate to develop a pregnancy warning and is not well supported by evidence.</li> <li>• No alternatives were used in consumer testing.</li> <li>• Is misleading, inflammatory and may alarm consumers.</li> </ul>	Industry	FSANZ has decided to maintain the signal words 'HEALTH WARNING' as discussed in section 3.3.4, also noting: <ul style="list-style-type: none"> <li>• The Forum requested FSANZ develop a mandatory pregnancy warning label, but did not specify the wording to use for this label. The DRIS recommended using signal words such as 'WARNING' or 'HEALTH WARNING' to indicate it is a warning label.</li> <li>• FSANZ's assessment of the signal words is based on the best available evidence as discussed in section 3.3.4.</li> <li>• Given the existing evidence base relating to signal words (refer to SD1 and section 3.3.4), FSANZ decided not to consumer test this component of the label; the focus of</li> </ul>

Issue	Stakeholder group	FSANZ response
<ul style="list-style-type: none"> <li>• Generally references everyone's health rather than specific to pregnant women.</li> <li>• Does not align with current Code practice for warning statements.</li> <li>• Pregnant women may not be drawn to it.</li> <li>• Could be used as a precedent by those seeking to demonise alcohol and add other health warnings (e.g. cancer).</li> </ul>		<p>the consumer testing was on the warning statement to be used in the label (refer to section 3.2.2).</p> <ul style="list-style-type: none"> <li>• No evidence has been provided by submitters or identified by FSANZ that suggests the signal words would be inflammatory or would alarm consumers.</li> <li>• FSANZ has not received an application or ministerial request to consider other health warnings for alcoholic beverages (e.g. in relation to cancer). Should FSANZ receive an application/ministerial request, FSANZ would undertake an independent assessment in accordance with the FSANZ Act.</li> </ul>
<p>Recommends 'PREGNANCY WARNING' or 'PREGNANCY ADVICE' instead of 'HEALTH WARNING' as a more targeted and direct way to raise awareness across the community.</p>	Industry	<p>FSANZ considers 'HEALTH WARNING' is more relevant and appropriate than 'PREGNANCY WARNING' or 'ADVICE' – refer to reasons discussed in section 3.3.4.</p>
<p>Has conducted consumer research which showed Australian females primarily selected 'Pregnancy Warning' (72.2%) to 'Health Warning' (24.5%) as the label which best conveys message not drinking is the safest option in pregnancy.</p>	Industry	<p>The details of the survey methodology, questionnaire, sample size, sampling, and analysis were not provided. FSANZ was therefore not able to assess the findings of the survey.</p>
<p>Does not support 'PREGNANCY WARNING' as may imply message is only relevant to pregnant women and not the broader community.</p>	Public Health	<p>FSANZ has decided to maintain the signal words 'HEALTH WARNING' as discussed in section 3.3.4.</p>
<p>Does not support capitals for the signal words as not justified in the research. The literature review states <i>sentences in all capitals can be harder to read than those in sentence case</i>.</p>	Industry	<p>The studies reviewed typically tested the signal words in capitals. Although the literature review suggests sentences in all capitals can be harder to read, the signal words are only two words and not a full sentence. Signal words can operate as a heuristic cue, and are less likely to be read as a sentence. FSANZ has therefore decided to maintain the approach for the signal words to be in capitals to help attract attention, and to provide a visual distinction to the warning statement which is in sentence case.</p>
<p>Questions need for signal words at all noting widespread community understanding women should not drink</p>	Industry	<p>As previously noted, the available data indicate 20% of women in New Zealand and 25% of women in Australia, drink alcohol during pregnancy. Based on the evidence that signal words operate as a heuristic cue and enhance the attention that a warning label receives</p>

Issue	Stakeholder group	FSANZ response
and recognition of existing pictogram.		(SD1), FSANZ has decided to maintain the approach to require signal words (refer to section 3.3.4).
Replace 'HEALTH WARNING' with <i>DRINK RESPONSIBLY</i> . This statement is enough to make a point as it encompasses everyone. We don't need to cast judgement on groups in society.	Industry	<i>Drink Responsibly</i> messaging is already used on alcoholic beverages voluntarily but is not designed as a warning. This messaging would not meet the intended purpose of the pregnancy warning label to reinforce public health advice and messaging not to drink alcohol when pregnant.
<b>Size and font</b>		
<p>Recommend changes to size categories. Comments included:</p> <ul style="list-style-type: none"> <li>• Recommend two categories only: <ul style="list-style-type: none"> <li>- pictogram only on products ≤ 100 ml, and</li> <li>- full sized warning label (as proposed for &gt; 800 ml) on all products &gt;100 ml, noting the literature review suggests larger labels attract more attention.</li> </ul> </li> <li>• Support larger pictogram and label size to increase noticeability: <ul style="list-style-type: none"> <li>- Minimum pictogram size 8 mm – 11 mm.</li> <li>- Minimum warning statement text of 3 mm, consistent with existing Code requirements.</li> </ul> </li> </ul>	Public health Consumer Government Academic	<p>FSANZ has taken a pragmatic approach to the label size requirements, considering a number of factors including the wide range of alcoholic beverage volumes and available label space (refer to section 3.3.5).</p> <p>Having regard to the evidence, FSANZ has prescribed other aspects to enhance the noticeability of the label, including colour and contrast and a distinct border with a minimum clear space outside the border (the latter for the pregnancy warning label with both the pictogram and wording) (refer to sections 3.3.7 and 3.3.5 respectively).</p>
Does not support beverages ≤ 200 ml have the pictogram only, with particular concern about small wine bottles (187 ml) that still contain a high alcohol content.	Public health Consumer	The ≤ 200 ml product size comprises a comparatively small portion of the alcoholic beverage market with generally less available label space due to their smaller size. FSANZ has therefore taken a pragmatic approach to the size requirements, noting the majority of alcoholic beverages for retail sale will be required to display the label with all three elements, i.e. the pictogram, signal words and warning statement (refer to section 3.3.5).
Some industry sought pictogram only on products either ≤ 400 ml or ≤ 500 ml, however, other industry did not support this approach due to inequity between product types e.g. beer and wine (supports ≤ 200 ml pictogram).	Industry	As noted above, the requirement for products ≤ 200 ml to be labelled with the pictogram only is a pragmatic approach. In addition, FSANZ notes industry submitters had differing views on this point. FSANZ has decided not to extend the pictogram only requirement to products with volumes > 200 ml to ensure broader application of the warning label with both the pictogram and wording across the alcoholic beverage sector.

Issue	Stakeholder group	FSANZ response
Does not support proposed size requirements. Suggests use of a smaller label consistent with allergen and standard drinks labelling. Size is excessive, costly and will impact on label design.	Industry	Although the size of allergen declarations is not prescribed in the Code, food-allergic consumers are motivated to look for these specific allergen declarations on food labels. As consumers do not specifically look for warning labels, they must be presented in a way that is likely to attract attention in order to achieve their purpose. Prescribing the size of warning statements is already an approach adopted in the Code (section 1.2.1—25 of the Code). Refer to section 3.5.1 for consideration of costs and benefits.
The overall size of the warning label may result in businesses' deciding to reduce the size of, or remove, existing non-mandatory health information (e.g. <i>drink responsibly</i> ) from their products.	Industry	FSANZ considers the size of the pregnancy warning label is appropriate to achieve the intended objectives of the proposal. Decisions regarding how voluntary labelling such as <i>Drink responsibly</i> is managed within a business, are for individual businesses.
Recommends products available in larger formats, e.g. cask wines, or beers packaged as multiples, have a large label that is sufficiently evident.	Industry	Alcoholic beverages with a volume > 800 ml are required to bear a larger pregnancy warning label than other volume sizes. A larger label is also required on all outer packages (including an outer package containing multiple alcoholic beverages, e.g. 6 pack of beer), except for the outer package of an alcoholic beverage with a volume ≤ 200 ml (the pictogram only is required in this instance) (refer to Tables 3a and 3b). As noted above, FSANZ has prescribed other aspects to enhance the noticeability of the label.
Does not support different size requirements for 750 ml and 1000 ml, as there is little difference in these product sizes. Recommends same label size for 200 ml – 1000 ml, and larger label size only over 1000 ml.	Industry	As discussed in section 3.3.5, evidence shows a larger warning label size relative to other label elements attracts greater attention than smaller warning labels. Noting this, FSANZ has taken a pragmatic approach to label size requirements, acknowledging the range of product volumes available in the market. Given there is typically a larger label space available when volumes are > 800 ml, FSANZ considers the requirement for these products to display a larger label, is appropriate.
A larger health warning would be required for small multipacks than for single containers of large volume, e.g. four-pack of 330 ml beers (1.320 L) requires larger warning label than 1.5 L bottle of spirits or 3 L cask of wine.	Industry	FSANZ has retained the approach to reduce any further complexity and notes that package sizes and label space are highly variable irrespective of beverage volume.
Recommends how minimum font sizes will be measured in either millimetres (mm) or points be specified in the Code, or provided in written guidance.	Consumer	FSANZ has amended the draft variation to specify <i>size of type</i> requirements for the signal words and warning statement in mm (points has been removed) – refer to Attachment A. <i>Size of type</i> is defined in section 1.1.2—2 of the Code as the measurement from the base to the top of a letter or numeral.

Issue	Stakeholder group	FSANZ response
<b>Location and orientation</b>		
<p>Recommend location and orientation are prescribed. Comments included:</p> <ul style="list-style-type: none"> <li>• Prescription important to ensure a prominent location.</li> <li>• Prescribe front-of-pack location.</li> <li>• Prescribe horizontal orientation.</li> <li>• Close proximity to drink responsibly labelling may cause confusion and inconsistent messaging.</li> </ul>	<p>Public health Government Consumer Academic</p>	<p>FSANZ has not prescribed the location to provide flexibility for industry noting the prescribed design labelling elements will enhance noticeability (refer to section 3.3.6).</p> <p>A border around the pregnancy warning label (with the pictogram and wording) with at least 3 mm of clear space outside the border is required, to help achieve separation of the warning label from other label information and to attract attention.</p>
<p>Does not support prescribed 3mm clear space outside the label.</p>	<p>Industry</p>	<p>Refer to the response above regarding the 3mm clear space.</p>
<p>Inconsistent and confusing to have warning label applied anywhere but with other pertinent information in single field of vision (universally accepted practice to have all pertinent information in single field of vision).</p>	<p>Industry</p>	<p>As noted above, not prescribing the location provides flexibility for the warning label to be applied in the most suitable place determined by the food business. This could be in the single field of vision.</p>
<b>Colour and contrast</b>		
<p>Does not support prescription of colour. Comments included:</p> <ul style="list-style-type: none"> <li>• Contrast is more important than colour to ensure noticeability. Would support contrast guidelines.</li> <li>• Recommend flexible label design guidelines similar to DrinkWise or Country of Origin Food Labelling Style Guide where colours are required and monochromatic designs also permitted.</li> <li>• Suggest increase size and remove requirement for red.</li> <li>• Significant cost and insufficient evidence that costs are justified.</li> </ul>	<p>Industry</p>	<p>FSANZ has decided to prescribe the red/black/white colour combination to achieve a consistent, high contrast label which is important for legibility and noticeability, as further discussed in section 3.3.7, but has decided to prescribe the colour red rather than the specific red colour Pantone 485 previously proposed.</p> <p>As shown by the evidence (SD1), monochromatic designs only would not have the same effect on attracting attention and warning identification as incorporating the colour red.</p> <p>In terms of environmental and cost issues, FSANZ acknowledges that depending on how a label is printed (e.g. conventional using plates and the CMYK colour process system with or without spot colours, conventional using plates and spot colours, digital, directly on alcoholic beverage container) and what colours are already being used in the label design, an additional plate/colour may be needed for the colour red, incurring additional set up and running costs. However the change to prescribe the colour red rather than a specific red is expected to reduce environmental impacts and costs. FSANZ notes the colours black and white are commonly used on labels of alcoholic beverages.</p>



Issue	Stakeholder group	FSANZ response
<ul style="list-style-type: none"> <li>• Limitations on how many colours can be used on a label.</li> <li>• Impacts on existing label designs.</li> <li>• Weak evidence to support mandating colour, no basis for mandating a single red.</li> <li>• Environmental impacts (need for more than one plate and may need to use heavy metals).</li> </ul>		<p>It is likely that any increased use of heavy metals from the requirement for the colour red would be minimal given the small amount of red ink that would be needed in the warning label in relation to the total ink used for printing the whole label.</p>
<p>Does not support prescription of Pantone 485. Comments included:</p> <ul style="list-style-type: none"> <li>• If colour is to be prescribed, prefers prescription of a range of red tones to allow flexibility and reduce costs.</li> <li>• May not work well on all package types and may not stand out on labels with red background.</li> <li>• Not consumer tested but rather based on DRIS.</li> </ul>	Industry	<p>As noted above, FSANZ has reconsidered the prescription of Pantone 485 for the circle and strikethrough of the pictogram and the signal words, and has decided to instead prescribe the colour red to provide some flexibility for industry (refer to section 3.3.7).</p> <p>FSANZ did consider prescribing a range of specific red colours. However, FSANZ considers it is reasonable to permit red used by industry in current or future label designs in the pregnancy warning label. This approach provides flexibility for industry while still maintaining a high level of prescription. FSANZ expects to include best practice examples of suitable red colours in guidance for industry.</p> <p>The label must be provided on a white background which will help the red to stand out on labels with an overall red background.</p> <p>FSANZ did not include the colour combination in consumer testing because the use of red in warning labels to increase attention and improve comprehension has been established by existing scientific evidence (SD1).</p>
<p>Second preferred option is for red strikethrough for retail packaging, with flexibility for the shade of red, and black for cartons (wholesale/trade units).</p>	Industry	<p>The requirement for the warning label applies only to packaged alcoholic beverages for retail sale, or sold as suitable for retail sale without any further processing, packaging or labelling (refer to draft variation at Attachment A). Outer cartons and other packages that are removed before retail sale are not required to display the warning label.</p>
<p>Recommend prescription of 3mm space around the border to be white.</p>	Public health	<p>The purpose of the 3 mm clear space around the border is to provide separation from this label to other elements on the product label. FSANZ has decided not to require this 3mm space to be white, noting the background colour of the warning label itself is prescribed to be white to ensure contrast (refer to section 3.3.7).</p>
<p>Suggest a square border around pictogram with a white background to ensure colour and contrast.</p>	Government	<p>The pictogram is required to be on a white background with the silhouette of the pregnant women in black and the circle and diagonal strikethrough in red to ensure colour and contrast. For products ≤200 ml that require the pictogram only, FSANZ has decided not to</p>

Issue	Stakeholder group	FSANZ response
		require a box around the pictogram as this could significantly increase the size of the label which would be unsuitable for these smaller product volumes.
<b>Other comments</b>		
<p>Supports less prescription for some elements. Comments included:</p> <ul style="list-style-type: none"> <li>• Drinking vessel, specific red colour, background colour and font type may be unnecessary given general legibility requirements in the Code.</li> <li>• Less prescription would provide some flexibility for industry.</li> <li>• No evidence increased prescription will have a measurable benefit.</li> </ul>	Government Industry	The warning label has been designed based on the best available evidence regarding elements that serve to attract attention and enhance understanding. The rationale for FSANZ's decision to prescribe certain design labelling elements is discussed in section 3.3. As noted above, FSANZ has decided to prescribe the general colour red rather than the specific colour Pantone 485 to provide some flexibility for industry.
<b>Beverages to display the warning label</b> <ul style="list-style-type: none"> <li>• <b>Option 1: requirement for all beverages &gt; 1.15% ABV to display warning label (proposed option)</b></li> <li>• <b>Option 2: requirement for all beverage ≥ 0.5% ABV to display warning label</b></li> </ul>		
<p>Supports Option 1, but noted inconsistency with <i>any amount</i> statement when not requiring all beverages containing alcohol to display the statement. Industry submitters recommended removing <i>any amount</i> to align with Option 1.</p>	Industry Public health Academic	<p>FSANZ has decided to require the pregnancy warning label on beverages with more than 1.15% ABV (option 1) for the reasons discussed in section 3.3.9.</p> <p>As previously noted, FSANZ has revised the text of the warning statement to <i>Alcohol can cause lifelong harm to your baby</i> (refer to section 3.3.3). The words <i>any amount</i> have therefore been removed which addresses issues raised from both public health and industry submitters about inconsistency.</p>
<p>Supports Option 2. Comments included:</p> <ul style="list-style-type: none"> <li>• Due to inconsistency of Option 1 with <i>any amount</i> statement.</li> <li>• Consistent with standard drinks labelling requirements.</li> <li>• More consistent with government advice that there is no known safe level of alcohol while pregnant.</li> <li>• Consistent with USA pregnancy warning label requirements (0.5%).</li> </ul>	Public health Industry Consumer Government	As discussed in section 3.3.9, FSANZ has decided to maintain option 1.



Issue	Stakeholder group	FSANZ response
<ul style="list-style-type: none"> <li>While supports Option 2, compromise could be to require products with 0.5% - 1.15% ABV to display the pictogram only.</li> </ul>		
<p>Brewed soft drinks containing alcohol should be required to display the warning label. Comments included:</p> <ul style="list-style-type: none"> <li>These products are often consumed by pregnant women.</li> <li>While not manufactured as alcoholic beverages the alcohol content of these products is important for consumers to know.</li> </ul>	<p>Public health Government Consumer</p>	<p>Refer to section 3.3.9 regarding FSANZ's decision to require the warning label on beverages with more than 1.15% ABV.</p> <p>A statement of alcohol content is required on beverages that contain no less than 0.5% ABV in accordance with section 2.7.1—3 of the Code (refer to section 2.6).</p>
<b>Application to different types of sales</b>		
<p>Appears all products sold to caterers will need to be labelled, e.g. kegs.</p>	<p>Industry</p>	<p>As discussed in section 3.3.10, FSANZ has decided to only require the warning label on products for retail sale (or sold as suitable for retail sale) and not to caterers, as the label is aimed at consumers rather than caterers.</p>
<p>Recommends capturing product packaged in the presence of the purchaser and situations (i.e. signage at point of sale).</p>	<p>Public health Government</p>	<p>Requiring signage is not consistent with the policy work carried out by FRSC and the Forum. The focus of this proposal is on the labelling of pre-packaged alcoholic beverages.</p>
<b>Application to different types of packages</b>		
<p>Application of requirements to certain packages:</p> <ul style="list-style-type: none"> <li>Requirements for intermediate layers (e.g. tissue between individual container and outer box) needs clarification.</li> <li>Warning label should be required on an individual product sold in a box.</li> <li>4/6 pack carrier packaging may need labelling although warning is visible on the individual can/bottle.</li> <li>Non-consumer facing shipping cartons may have to be labelled.</li> </ul>	<p>Government Industry</p>	<p>Refer to the discussion in section 3.3.11.</p> <p>FSANZ has revised the approach previously proposed of requiring the pregnancy warning label on each layer of packaging (when there is more than one layer of packaging), to only require the label on the innermost package containing the alcoholic beverage (i.e. defined as <i>individual unit</i> in the draft variation) and the outer package for retail sale. When there is more than one individual unit (e.g. six bottles of beer in a multipack), each individual unit must display the label. Any intermediate layers of packaging (e.g. tissue paper between the outer package and the innermost package) are not required to have the warning label).</p> <p>A pregnancy warning label is not required on an outer package (including the outer package of 4/6 packs of alcoholic beverages) if the warning label is clearly discernible on the innermost package and not obscured by the outer package (e.g. if it is clearly visible on an individual can in a six pack of beer, the outer package does not require the label).</p>

Issue	Stakeholder group	FSANZ response
<ul style="list-style-type: none"> <li>Does not support label on outer package or cartons of wine, paper bags used for transportation from point of purchase, or packaged as gift once decision to purchase made.</li> </ul>		<p>The requirement to have the pregnancy warning label applies to packaged alcoholic beverages for retail sale or sold as suitable for retail sale without any further processing, packaging or labelling. Outer and shipping cartons removed before retail sale do not require the warning label.</p> <p>An alcoholic beverage packaged in the presence of the purchaser is exempt from displaying the pregnancy warning label. This is intended to capture alcohol poured into and served in a glass, or additional packaging applied in the presence of the retail purchaser.</p>
<p>Requirements for outer, multipack and cartons are confusing and require clarification, including what type of outer will have the pictogram only.</p>	<p>Industry Public health Consumers</p>	<p>The draft variation has been amended to simplify and clarify the requirements (refer to Attachment A and explanatory statement at Attachment B).</p> <p>Tables 3a and 3b of this report provides an overall summary of the requirements, with further discussion provided in section 3.3.11.</p>
<p>The warning label should only be required on packaging that contains a barcode.</p>	<p>Industry</p>	<p>As noted above, FSANZ has decided to require the pregnancy warning label on alcoholic beverages for retail sale. When there is more than one layer of packaging, both the innermost package and the outer package require the label (unless the outer package is exempt as detailed above). This is consistent with the primary objective of pregnancy warning labels as identified in the DRIS, <i>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</i> (refer to section 1.2).</p>
<p><b>Consideration of costs and benefits</b></p>		
<p>FSANZ's assessment under-estimates the costs to industry.</p>	<p>Industry</p>	<p>FSANZ has a high degree of confidence in the range of cost estimates used across the scenarios. This confidence was confirmed by independent costing models, visits to label design and printing companies, and additional cost per SKU data estimates provided by industry in submissions to the CFS. Refer to section 3.5.1.1.2 for further discussion.</p>
<p>The consideration of costs and benefits indicates only a small number of cases of FASD need to be prevented to offset costs to industry. However, it does not establish a link between likely reduction in FASD and the proposed labelling change alone, beyond the reduction in alcohol consumption during pregnancy that is already being seen in Australia.</p>	<p>Industry</p>	<p>FSANZ approved the measure on the basis of its evidence-based assessment that, when used in conjunction with other public health measures, it can reasonably be expected to reduce the prevalence and/or severity of FASD more effectively than current voluntary labelling. FSANZ's consumer testing indicated the current statement, <i>It's safest not to drink while pregnant</i>, performed least well of the four statements tested in conveying the message not to drink alcohol while pregnant. Refer to section 3.3.2.</p>
<p>Behaviour change is incorrectly used as basis of consideration of costs and</p>	<p>Industry</p>	<p>Refer to the response above.</p>

Issue	Stakeholder group	FSANZ response
benefits.		
Cost to label both bottle and box is not proportionate to benefit.	Industry	Only a small reduction in the percentage of new annual FASD cases is required to justify the costs of the pregnancy warning label, i.e. 0.2% to 3.2%. Refer to section 3.5.1.1.4, part 6.
Prescribing the colour red will inflate costs and may require replacing numerous different print plates/cylinders, when the total number of colours available for packaged alcoholic beverage labels, in general, is limited.	Industry	FSANZ has researched print plate/cylinder costs and implications of including the colour red in the warning label. That included visits to and conversations with packaging print companies and label designers, and referring to the PricewaterhouseCoopers study on label change costs (PricewaterhouseCoopers (2014)), updated for inflation to 2019. This research was used to update average costs per SKU of the proposed mandatory warning label, referred to in section 3.5.1.1.2. Additionally, FSANZ has decided to prescribe the colour red instead of specifically Pantone 485 as previously proposed. This will allow the use of other red colours currently used on alcoholic beverage labels. This is expected to reduce costs of the warning label, particularly for companies currently using red colours other than Pantone 485.
Does not support assumption that producers will combine inclusion of pregnancy warning labels with other voluntary label changes or regulatory requirements. Producers unlikely to undertake a major label change that requires a change in colour, voluntarily. Key impetus for label change will be from regulatory requirements.	Industry	To ensure a fuller range of potential costs were considered, the highest cost scenario used the mean of costs provided by industry and did not assume any cost mitigation from combining compliance of the mandatory warning with voluntary label changes or compliance with other regulations.
The 2019/20 financial year of the DrinkWise FASD Awareness Program has been scheduled, using current messaging, with funding by Industry and assets already in place.	Industry	FSANZ acknowledges there may be costs of changed messaging for that FASD Awareness Program. These are taken into account in the cost calculations.
<b>Proposed Draft Code variation</b>		
Seeks clear drafting without need for <i>to avoid doubt</i> (i.e. 2.7.1—9(6)).	Industry	'To avoid doubt' is a standard drafting term and device designed to clarify the scope of provisions when and if required, and is used in numerous Australian and New Zealand statutes and regulations. However, the draft variation has been amended to simplify and clarify the requirements.
Legibility requirements are overly complex and will cause significant compliance costs (2.7.1—11).	Industry	As noted above, the draft variation has been amended to simplify and clarify requirements. Additionally, FSANZ expects to provide downloadable pregnancy warning label graphics available for use by industry.

Issue	Stakeholder group	FSANZ response
Requests commencement date be clearly articulated and not contained in another document (i.e. the gazette) to support business certainty.	Industry	This approach is required by the FSANZ Act. Section 93 of the FSANZ Act provides that a standard or a variation of standard takes effect on the day specified in a notice given under section 92 of that Act. This issue is therefore broader than the scope of this proposal.
Requirement for vessel in pictogram to be a wine glass should be made explicit.	Government	FSANZ has amended the draft variation to make this explicit in the definition of <i>pregnancy warning pictogram</i> (refer to Attachment A).
2.7.1—10 heading should read <i>requirements for the format of a pregnancy warning label</i> instead of <i>compliance</i> which is confusing.	Government	The amended draft variation no longer uses the term <i>compliance</i> .
Seeks clarity whether 2.7.1 – 10(3) permits a pregnancy warning label used in other countries to still be visible when the product is sold in Australia or New Zealand.	Government	The product will need to display clearly the pregnancy warning label required by the Code. FSANZ's understanding is that the Code will not prevent the product from also displaying a pregnancy warning label used in a country other than Australia or New Zealand.
Definition of outer pack is unclear. Need to work with industry on clearer definitions and dividing lines.	Industry	No definition for <i>outer package</i> is provided in the draft variation (noting existing provisions in the Code use this term without defining it). When there is more than one layer of packaging, the outer package is the most outer layer of packaging for retail sale.
<b>Transitional arrangements</b>		
Requests longer transition period than the proposed two years. Recommended options: <ul style="list-style-type: none"> <li>• 5 years for proposed approach or lesser timeframe with adoption of the voluntary DrinkWise initiative.</li> <li>• 4 years with options for phasing in elements over this period.</li> <li>• 3 year transition period.</li> </ul>	Industry	As discussed in section 4, FSANZ has decided on a two year transition period. FSANZ considers this will allow industry sufficient time to adopt the new requirement. A transition period greater than two years may unnecessarily prolong the implementation of the label.
Seeks shorter transition period. Comments included: <ul style="list-style-type: none"> <li>• 12 month transition period has been successful in other countries.</li> <li>• Companies typically only hold 4-6 months stock.</li> </ul>	Public health Consumer Academic	FSANZ considered a one year transition period, however, has determined this approach would likely impose a greater cost and re-labelling burden on industry (refer to section 4).  A two year transition period is a pragmatic decision that will not unduly delay implementation of the pregnancy warning label while increasing the opportunity for industry to combine voluntary label changes and/or other legislative changes with the adoption of the pregnancy warning label, thereby decreasing costs.

Issue	Stakeholder group	FSANZ response
<ul style="list-style-type: none"> <li>• Current messaging used in the voluntary scheme is ineffective.</li> <li>• Urgency and significance of the health message far outweigh industry costs and exposure to consumers sooner is important.</li> </ul>		
<p>Does not support proposed stock in trade exemption. Comments included:</p> <ul style="list-style-type: none"> <li>• It may falsely indicate that exempt products are safe.</li> <li>• Suggests over-stickering for products that are already labelled.</li> </ul>	Public health	<p>FSANZ has decided alcoholic beverages which are packaged and labelled before the end of the transition period may be sold after the transition period without having to display a pregnancy warning label (refer to section 4). This approach recognises alcoholic beverages with a slow market turnover or those intended for ageing/cellaring before sale but have been labelled. Given the relatively fast market turnover of beer, RTDs (Ready to Drink), cider and most wine and spirits (i.e. most of these beverage types produced after gazettal of the new requirement would be sold within two years), FSANZ expects only a relatively small proportion of beverages would not display the pregnancy warning label after the end of the two year transition period.</p>
<p>Requests the new requirements do not capture museum stock, or wines released with significant bottle age</p>	Industry	<p>Refer to the response above.</p>
<p>Proposed transition period and stock in trade disadvantages small producers. Packaging purchased prior to gazettal should be able to be used.</p>	Industry	<p>As noted above, FSANZ's assessment is that a two year period, with the exemption for beverages packaged and labelled before the end of the transition period, is sufficient for industry to adopt the new requirements.</p>
<ul style="list-style-type: none"> <li>• Requests alignment with other labelling changes being considered by FSANZ.</li> <li>• Requests FSANZ work with New Zealand Ministry for Environment who is considering container deposit/return schemes which will likely require label change.</li> </ul>	Industry	<p>FSANZ will consider options for alignment of any relevant future proposed labelling changes in the Code, if and when approved.</p>
<p>Proposed stock in trade exemption will be difficult from an enforcement perspective without a <i>packed-on</i> date.</p>	Government	<p>Due to high market turnover of many alcoholic beverage types, it is expected that after the end of the two year transition period the majority of alcoholic beverages will display the warning label. The lot identification and name and address of the supplier is required to be provided on the package which allows for traceability.</p>
<p>Concerned industry may expedite production of products through the</p>	Government	<p>FSANZ does not consider this a significant risk. As noted above, FSANZ expects only a relatively small proportion of beverages would not display the pregnancy warning label after</p>

Issue	Stakeholder group	FSANZ response
transition period.		the transition period.
<b>Implementation</b>		
Concerned no compliance scheme or government agency recognised for ensuring compliance.	Government	The state and territory departments, agencies and local councils in Australia, and Ministry for Primary Industries in New Zealand are responsible for compliance and enforcement of the Code. The Australian Department of Agriculture is responsible for inspection and sampling of imported food at the Australian border.
<b>Education</b>		
Mandated label should be accompanied by educational materials on how to read and interpret labelling about alcohol in pregnancy, and by broader public awareness campaigns.	Industry Public health Consumer	FSANZ will implement various education activities to alert industry (particularly small to medium enterprises), consumers and health professionals to the new labelling requirement and expects public health agencies will incorporate reference to the pregnancy warning label in their public health education campaigns (refer to section 5.1).
Concerned about inadequate financial investment in education and supports government funding be contributed.	Public health Government	This is outside the scope of FSANZ's responsibilities.
<b>Monitoring and evaluation</b>		
<p>Comments included:</p> <ul style="list-style-type: none"> <li>Strongly supports monitoring and evaluation to assess implementation and effectiveness.</li> <li>Support evaluation of the pictogram following adoption, particularly with minority groups.</li> <li>Needs robust framework.</li> <li>FSANZ should provide a clear and detailed plan for in-depth evaluation and monitoring to commence once labelling implemented.</li> <li>Section on monitoring is worryingly brief.</li> </ul>	Public health Government Consumer	FSANZ will pursue the development of a monitoring and evaluation plan during the transition period with the Food Regulation Standing Committee (FRSC).
<b>Trade</b>		
Proposed approach is in breach of the WWTG Agreement, particularly due to colour requirement. Agreement was premised on the idea that producers could have a single colourful market	Industry	<p>FSANZ's assessment is that the approved measure is consistent with the WWTG Agreement. See Section 2.8.</p> <p>The WWTG Agreement does not contain any restrictions on the colours that can be used on labels containing national mandatory information.</p>

Issue	Stakeholder group	FSANZ response
label for all jurisdictions and a single mandatory label that would change according to the market. The mandatory label would be less expensive to print and change, and could be in 2 colours. Introducing colour requirements will significantly undermine the value of the Agreement.		
Requests wine exports be exempt from the requirement to bear a pregnancy warning label otherwise such products will require two labels.	Industry	The pregnancy warning label is only required on alcoholic beverages with more than 1.15% ABV sold in Australia and New Zealand. The domestic label is not required on exported wine (refer to section 2.9).
Standard for pregnancy labelling needs to be expressly limited in application to only wine intended for New Zealand and Australia.	Industry	Australian and New Zealand laws determine the application of requirements set out in the Code. The Code itself states that it applies to food that is sold, processed or handled for sale in Australia or New Zealand or imported into Australia or New Zealand (refer to section 1.1.1—3 of the Code). The approved draft variation states that the requirements listed in it apply only to retail sale products.
Impact on trade and creation of a trade barrier by requiring prescribed text rather than generic logo.	Industry	FSANZ's assessment is that the approved measure is consistent with Australia's and New Zealand's obligations under international trade law. Refer to Table 2 and Attachment E.
Likely to be open to successful challenge through the WTO. The proposed label is the highest cost option and is therefore not proportionate, and is ineffective in changing behaviour of the at risk group.	Industry	FSANZ's assessment is that the approved measure is consistent with Australia's and New Zealand's WTO obligations. Refer to Table 2 and Attachment E.
Favours domestic markets whereas importers will need to over sticker.	Industry	FSANZ's assessment is that the approved measure is consistent with Australia's and New Zealand's obligations under international trade law. Over-stickering is an option for both producers in Australia/New Zealand and other countries.
Claims that <i>any amount</i> of alcohol can cause harm is not supported by best available scientific evidence. Mandating its use would be in breach of New Zealand's obligations under Article 5(1) of the WWTG Agreement.	Industry	FSANZ's assessment is that the approved measure is consistent with Australia's and New Zealand's obligations under international trade law.  <i>Any amount</i> is no longer used in the warning label. Refer to section 3.3.3.



Issue	Stakeholder group	FSANZ response
<p>Does not support that trade agreements are a barrier to front of pack/horizontal placement on a label. Comments included:</p> <ul style="list-style-type: none"> <li>On the basis that pregnancy warning labels be considered a measure for the protection of public health and safety, as per WWTG Labelling Agreement, nations may mandate conditions for pregnancy warning labels, in accordance with WTO agreements.</li> <li>Precedence whereby WTO member states have mandated front of pack requirements for nutrition labelling, using public health justifications.</li> <li>The Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) does not specify or prohibit a particular location or orientation of labelling requirements, including the placement of supplementary labels.</li> </ul>	<p>Public health Consumer Government</p>	<p>No countries with mandatory pregnancy warning labels on alcoholic beverages require the label to be placed on the front of the container (IARD, 2019). The USA requires its warning label to be on <i>the brand label or separate front label, or on a back or side label, separate and apart from all other information.</i></p> <p>Also refer to the previous response above regarding FSANZ's decision not to prescribe the location noting:</p> <ul style="list-style-type: none"> <li>The prescribed design labelling elements will enable the warning label to be noticed irrespective of where it appears on the label.</li> <li>Not prescribing the location provides flexibility for industry.</li> </ul>
<p>Agreement between Australian/ New Zealand Governments<sup>11</sup> concerning a joint food standards system states food standards developed shall be consistent with the obligations of both Members under the Agreement establishing the World Trade Organisation. Mandatory labelling would fall within these international trade obligations.</p>	<p>Government</p>	<p>FSANZ's assessment is that the approved measure is consistent with Australia's and New Zealand's WTO obligations.</p> <p>Refer to Attachment E.</p>

<sup>11</sup> Agreement is available at <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/key-system-documents>.



Issue	Stakeholder group	FSANZ response
Requirement for colour undercuts simplicity of approach in the WWTG Agreement on the Requirements for Wine Labelling. Foreign producers may decide cost is prohibitive. Under WTO rules technical regulations of this nature must be scientifically justified.	Industry	<p>FSANZ's assessment is that the approved measure is consistent with Australia's and New Zealand's obligations under the WWTG Agreement and under the WTO. See section 2.8 above and Attachment E.</p> <p>The WWTG Agreement does not contain any restrictions on the colours that can be used on labels containing national mandatory information.</p>
No major export destination or import source presently mandates a three-colour pregnancy warning. All imported products entering New Zealand/ Australia will therefore require a new label unique to those markets. Many exported products will need to remove the Australia/New Zealand warning label as it will be non-compliant for markets which mandate their own pregnancy warning statement.	Industry	<p>The colours black and white are commonly already used for alcoholic beverage labels, therefore the pregnancy warning label is unlikely to require the addition of three new colours (refer to section 3.3.7). It is common practice for different label information to be required for different markets.</p>
A complex matrix for wine labels across many countries and for small producers in New Zealand is a barrier to export costs when have to relabel for each market. Aligning with EU requirements would ease this burden.	Industry	<p>FSANZ understands the New Zealand wine industry is encouraged to use the French style pictogram on wine exported to the EU. As discussed at Attachment E, FSANZ does not consider the pictogram equivalent to the Australian/New Zealand pregnancy warning label.</p>

### **3.1.2 WTO notification**

In October 2019 FSANZ made a notification to the WTO for this proposal in accordance with the WTO TBT Agreement.

Table 2 provides FSANZ's response to comments received from three Member countries and four industry associations. Comments were generally similar to those received in response to the CFS and included the use of stickers, whether the proposed mandatory pregnancy warning label is the least trade restrictive approach for achieving the objective of protecting human health and whether pregnancy warning labels used in other countries could be considered equivalent to the proposed warning label for Australia and New Zealand.

**Table 2: FSANZ response to comments received via the WTO notification**

Note: Column 2 of Table 2 indicates the stakeholder groups from which issues were raised. Issues raised are not necessarily representative views of all submitters in these stakeholder groups.

Issue	Raised by	FSANZ response
<b>Consistency with WTO TBT Agreement in particular Article 2.2</b>		
<p>While fully supportive of interventions that are proportionate, well evidenced and shown to be effective at changing harmful consumption behaviours, concerned about the lack of rigour of the proposal in this regard.</p> <p>New measures should not introduce unnecessary trade costs, create unnecessary obstacles to international trade and should be no more trade-restrictive than necessary to fulfil its objective.</p>	Industry	<p>The warning label has been designed based on the best available evidence, with consideration given to labelling elements that serve to attract attention and enhance understanding (e.g. size, location of the warning label on the beverage container or packaging, colour and contrast, and signal word(s)).</p> <p>Following consideration of the evidence and the FSANZ Act assessment requirements (refer to section 3.5), including issues raised in response to the CFS and the WTO notification (refer to section 3.1.2), FSANZ's decision is to require a pregnancy warning label on alcoholic beverages for retail sale.</p> <p>FSANZ is satisfied the measure: will not introduce unnecessary trade costs; will not create unnecessary obstacles to international trade; and is not more trade-restrictive than necessary to fulfil its objective to protect human health. Refer to FSANZ's response at Attachment E.</p>
<p>Supports mandating the voluntary scheme and considers this would be the <i>least trade restrictive approach</i>.</p> <p>Many industry members use, on a voluntary basis, the <i>pregnant lady</i> pictogram in all markets.</p>	Industry	<p>For the reasons stated in this report, FSANZ does not support mandating the voluntary scheme. Refer to FSANZ's response at Attachment E.</p>
<b>Effectiveness of label intervention</b>		
<p>Considers labels are not suitable to convey complex and targeted health information. Can be more effective to have link on label to a website. Labels cannot be more than a small part of the solution.</p>	Industry	<p>The pregnancy warning label reinforces public health advice and messaging not to drink alcohol when pregnant and supports and complements other initiatives aimed at influencing behaviour. Evidence from alcohol warnings (Pettigrew et al., 2016) and tobacco warning labels (Wilkinson et al., 2009) confirms that labels as part of a suite of measures can contribute to behaviour change (refer to section 3.2.3).</p>
<p>Considers all efforts to reduce the harmful use of alcohol should be directed to prevention through education in partnership with multitude of interested stakeholders. Does not believe it</p>	Industry	<p>There are a number of actions and activities underway in both Australia and New Zealand to educate consumers about the risk of drinking alcohol during pregnancy and FASD. The pregnancy warning label complements and reinforces these efforts. Refer to section 2.5.</p>

Issue	Raised by	FSANZ response
would be legitimate to justify such label intervention without the simultaneous implementation of a wider programme of state-supported activities.		
<b>Over-stickering labels</b>		
Seeks confirmation the warning label can be fixed via sticker either in the country-of-origin or in a bonded warehouse before products are released onto the Australian/New Zealand market.	Government Industry	The Code does not prohibit the use of stickers for providing labelling information. The warning label would be required on the product when it is available for retail sale. Therefore, stickers can be applied to imports into Australia or New Zealand in the country of origin or before release for retail sale in Australia and New Zealand.
<b>Equivalence of labels in other countries</b>		
Asks whether pregnancy warning labels used in other countries would be recognised as being compliant with the proposed label. e.g. existing pregnancy warning labels used in the EU.	Government Industry	FSANZ understands that France and Lithuania are the only EU countries to require mandatory pregnancy warning labels (refer to Attachment D). FSANZ also understands various voluntary pregnancy warning labels are used by the EU industry.  FSANZ did consider whether pregnancy warning labels used in other countries, including EU countries, could be recognised as equivalent to the Australia/New Zealand warning label. Refer to FSANZ's comments in relation to Article 2.7 of the TBT Agreement at Attachment E.
<b>Label design elements</b>		
Suggests the use of the colour red is re-examined as the cost of two or more colour printing could be relatively high compared with one colour printing. This could be disadvantageous to exporters who have small lots. Requests a monochromatic label.	Government	Refer to section 3.3.7 and Table 1.
Suggests the use of the colour red is eliminated and there be flexibility permitted with colours. There is not credible evidence to support the requirement for red.	Industry	Refer to section 3.3.7 and Table 1.
Suggests the signal words be changed to 'pregnancy advice'.	Government	Refer to section 3.3.4 and Table 1.
Credible evidence is not supplied to support 'Health Warning'.	Industry	Refer to section 3.3.4 and Table 1.
Suggests the statement is changed as medical knowledge is not settled about whether drinking small amounts has bad influence, e.g. could use	Government	The statement has been changed to: <i>Alcohol can cause lifelong harm to your baby</i> . Refer to section 3.3.3 of this report. The statement <i>It's safest not to drink while pregnant</i> is not supported by evidence (SD1 and SD2).

Issue	Raised by	FSANZ response
<i>It's safest not to drink while pregnant.</i>		
Asks for the evidence relied on to support <i>any amount</i> in the warning statement.	Industry	Refer to response above.

## 3.2 Evidence summary

FSANZ's decision is based on the best available evidence. The design and content of the pregnancy warning label was informed by a literature review of warning effectiveness. FSANZ used consumer testing with a representative survey of women of child-bearing age in Australia and New Zealand to guide the choice of statement. Both the literature review and the consumer testing were peer-reviewed by external independent academics with expertise in the behavioural sciences.

### 3.2.1 Literature review on the effectiveness of warning labels

FSANZ undertook a systematic search to identify relevant evidence to inform the design and content of a pregnancy warning label on packaged alcoholic beverages (SD1). The literature review covered the English language published peer-reviewed literature, as well as reports from the grey literature. The grey literature includes publications from both government and non-government organisations, and focussed on Australian and/or New Zealand populations. The literature review did not repeat the review that was commissioned by FSANZ and undertaken by Wilkinson et al. (2009), rather this review searched for new studies published since Wilkinson et al. (2009). A total of 47 studies were included in the review.

FSANZ adopted the framework of Argo and Main (2004) to extract, summarise and review relevant information from identified studies. They identify five dimensions of warning label effectiveness: attention; reading and comprehension, recall, judgement, and behavioural compliance. FSANZ has discussed attention and recall together in this review.

The literature review was peer-reviewed by an external independent academic with experience in the behavioural sciences. The peer-reviewer's comments have been considered and incorporated into the revised literature review (SD1).

The review confirmed that multiple design elements (size, location, colour, pictorials, and signal words) can be used in varying combinations to enhance the noticeability of warning labels. Thus larger, front of pack, warnings using colour, signal words and pictorial elements attract more attention than warning labels lacking those elements. While some studies have explored the interactions between several design elements, none have done so comprehensively. It is likely that some enhancement in attention level can be achieved by using different combinations of the design elements. For example a smaller front of pack warning may be as noticeable as a larger back of pack warning, or a larger black and white warning may be as noticeable as a smaller red warning. This provides some degree of flexibility in design options to optimise the level of attention a warning receives.

The literature review identified research on comprehension of existing warning statements and the standard pictogram<sup>12</sup> on alcohol in Australian and New Zealand populations. There was limited research on new warning statements and pictograms. However, while the research findings are not definitive in terms of what statements would work best in Australia and New Zealand, they do provide some guidance for statements that can be tested. The literature on judgements and behaviour was similarly limited with respect to FASD. While a number of different types of behavioural responses have been reported (e.g. changed alcohol consumption patterns, seeking further information, visiting websites, prompting discussions and conversations), these are largely self-reported.

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<sup>12</sup> The standard pictogram refers to the pictogram with a silhouette of a pregnant woman holding a drinking glass enclosed within a circle with a diagonal strikethrough as used in the DrinkWise Australia and Cheers voluntary labelling initiatives.

It is generally accepted that where alcohol warnings labels have been introduced they have had limited impact on consumption behaviour. It was also noted that current mandatory warnings in place in other countries have not been designed with a view to optimise the attention they receive.

### **3.2.2 Consumer testing of warning statements**

FSANZ tested four statements to guide which statement to include in the warning label. The statements were tested in the context of the design features identified from the literature review. This included: the signal words 'HEALTH WARNING', the pictogram used in the voluntary initiative, and an enclosing border. The statements tested were selected following a review of existing and recommended statements for use in Australia and New Zealand and internationally (Refer to CFS for further details). The four statements tested included the statement used in the voluntary labelling initiative: *It's safest not to drink while pregnant*. The other three statements tested were:

- *Any amount of alcohol can harm your baby.*
- *Any amount of alcohol can cause lifelong harm to your baby.*
- *Alcohol can harm your baby.*

The aim of the consumer testing was to identify which of the four statements were able to convey the desired public health message of not drinking alcohol while pregnant in a manner that was believable, credible, convincing, and of relevance to women of childbearing age and the broader community.

A between-subjects design was used; participants in the research were randomly allocated to respond to a series of questions regarding just one of the four statements. In this manner any average differences between the groups would arise due to their exposure to different warning statements. The between subjects design also eliminated any learning effects that could occur from viewing all four warning statements.

The survey report is at SD2. The survey report was peer-reviewed by an external independent academic with experience in the behavioural sciences. The peer-reviewer's comments have been considered and additional information has been included at SD3.

### **3.2.3 Labelling as part of a suite of measures**

Alcohol consumption does not exist in isolation from other individual behaviours and broader social, cultural and environmental influences, as evidenced in systems approaches to the prevention of alcohol harm (e.g. see Loxley et al., 2004 cited in Wilkinson et al., 2009). Just as individual awareness and understanding of warning labels can influence alcohol consumption, social influence from significant others and broader social norms can make alcohol consumption more or less socially acceptable (e.g. Tam & Greenfield, 2010).

Strategies to minimise harm from alcohol will utilise a range of interventions, for example social marketing conveying information, age and licencing restrictions to limit access, and taxes to reduce demand. The experience from tobacco regulation in Australia highlights that a suite of measures including prominent front of pack graphical warning labels has resulted in reductions in tobacco consumption (Wilkinson et al., 2009). Similarly for alcohol, evidence from experiments in Australia which simulated receiving information from a suite of measures (via interaction with a doctor; posters displayed at bus stops; messages from a child's health lesson at school; and warnings on packaged alcohol) resulted in reduced intentions to purchase alcoholic products (Pettigrew et al., 2016).

A multifaceted approach to the reduction of FASD has been developed in Australia and New Zealand (refer to section 2.5) and as such, broader measures will work to reinforce the effectiveness of warning labels on packaged alcoholic beverages, just as warning labels will help to reinforce the broader actions to reduce FASD.

### **3.3 Risk management**

#### **3.3.1 Pregnancy warning label overall approach**

##### **3.3.1.1 Decision**

FSANZ's decision is that a pregnancy warning label will be required on the labels of packaged alcoholic beverages for retail sale or sold as suitable for retail sale.

The pregnancy warning label will include a pictogram, signal words and a warning statement; or for volumes of 200 ml or less, a pictogram only.

Beverages with an alcohol by volume of more than 1.15% will be required to have the label and the label design elements will be prescribed in the Code (refer to sections 3.3.2 - 3.3.11 for details).

##### **3.3.1.2 Rationale for decision**

Following consideration of the evidence and FSANZ Act assessment requirements (refer to section 3.5), including issues raised in response to the CFS and the WTO notification (refer to sections 3.1.1 and 3.1.2), FSANZ's decision is to require a pregnancy warning label on packaged alcoholic beverages for retail sale or sold as suitable for retail sale. The specific reasons for this decision are discussed below.

The best available scientific evidence shows that consuming alcohol when pregnant poses a health risk to the unborn baby (NHMRC, 2009, NHMRC 2019b). Additionally, available data indicate 20% of women in New Zealand and 25% of women in Australia continue to consume alcohol during pregnancy (refer to section 2.4 above).

Evidence also demonstrates that pregnancy warning labels on alcoholic beverages can raise awareness of the risks of drinking alcohol during pregnancy and prompt discussion of these risks (SD1, Wilkinson et al., 2009). Further, evidence from alcohol warnings and tobacco warning labels confirms that the label as part of a suite of measures can contribute to behaviour change (refer to section 3.2.3). Therefore, when combined with other public health initiatives, pregnancy warning labels can contribute to increased awareness of the risks of drinking alcohol while pregnant and encourage behaviour change. It can also contribute to the development of social norms to support this behaviour change. These will ultimately reduce the prevalence and/or severity of FASD.

FSANZ has therefore decided to require a pregnancy warning label on packaged alcoholic beverages. The pregnancy warning label reinforces public health advice and messaging not to drink alcohol when pregnant and supports and complements other initiatives aimed at influencing behaviour change to reduce the prevalence and/or severity of FASD (refer to section 2.5).

In an evaluation of the voluntary pregnancy warning labels on packaged alcoholic beverages undertaken in 2016/17 in Australia and New Zealand, the adoption of the pregnancy health warning labels was low in some product categories. It was noted that some producers of alcohol indicated they would be unwilling to include a warning statement unless it was made mandatory (Siggins Miller, 2017). Mandatory labelling is the only approach that can provide



certainty of high coverage and label consistency across packaged alcoholic beverages, providing women of childbearing age with consistent information both at the point of purchase and consumption.

The combination of a pictogram, signal words and warning statement is based on the findings of the literature review (SD1) which confirmed multiple design elements can be used in varying combinations to enhance the noticeability of warning labels. The use of the statement with the pictogram reinforces the meaning of the pictogram (to not drink alcohol during pregnancy) and explains the consequences of alcohol consumption during pregnancy which may increase the effectiveness of the label. Signal words are also included as they can enhance credibility, attention and comprehension of a warning label. Pictorial elements combined with statements can bridge literacy and other educational gaps and enhance risk perceptions of alcoholic beverages compared with statement only warnings. Evidence also suggests the pictogram alone may not challenge some beliefs about the risks of drinking alcohol during pregnancy. This evidence based approach is also consistent with the policy advice from the Forum which recommended a warning label include both a pictogram and warning message.

Further, the warning label has been designed with consideration given to labelling elements that serve to attract attention and enhance understanding (e.g. size, location of the warning label on the beverage container or packaging, colour and contrast, and signal word(s)). FSANZ's literature review, together with outcomes from the consumer testing (SD2), suggest the pregnancy warning label, with specific design elements, is likely to better convey public health advice not to drink alcohol during pregnancy and also attract consumer attention to a greater extent than the warning labels commonly used in the voluntary initiative.

If the warning label is not noticed by consumers then it will not achieve its purpose of informing consumers not to drink alcohol during pregnancy. Consumers do not look for warning labels therefore they must be presented in a way that is likely to attract attention in order to achieve their purpose. Given evidence that the size, location, colour, contrast and signal words can all help enhance the noticeability of a warning label (section 3.2.1 and SD1), FSANZ has decided certain design elements of the pregnancy warning label should be prescribed in the Code. Such an approach will help achieve consistency and certainty in presentation of the warning label across the alcoholic beverage sector, help ensure the warning label is legible and attract attention. The specific decisions in relation to these elements are provided in sections 3.3.4 – 3.3.8.

In developing the specific label design elements, FSANZ has considered existing labelling guidance and requirements, such as the DrinkWise guidance for voluntary pregnancy warning labels, standard drink labelling guidance and existing Code requirements for legibility. Examples of approaches taken for the presentation of various labelling elements relevant to alcoholic beverages, including the DrinkWise guidance for the voluntary labelling initiative (Independent Brewers Association, 2019) are summarised at Attachment F.

The warning label will be required on foods for retail sale, to enable it to be readily visible by consumers at the point of purchase and consumption. Further detail about the requirement for and exemptions from, the warning label for specific types of sales is provided in section 3.3.10.

The overall approach for mandatory pregnancy warning labels outlined above is consistent with the approach proposed in the CFS. Following public consultation and WTO notification, amendments have been made to the design, namely the colour requirement (section 3.3.7) and the wording of the warning statement (section 3.3.3) in response to submitter comments. Specific issues raised by submitters are addressed in section 3.1 above.

FSANZ has also considered adoption of the mandatory or voluntary pregnancy warning labels of other countries (refer to section 2.7 and Attachment D). However, based on the available evidence, FSANZ considers none of the labels used in other countries are equivalent to the warning label required in Australia/New Zealand in terms of effectiveness in achieving the primary objective in the DRIS (to provide a clear and easy to understand trigger to remind pregnant women to not drink alcohol) in the local context (refer to section 3.5.3 and Attachment E for further discussion). Pregnancy warning labels from other countries can therefore not be used instead of the prescribed pregnancy warning label outlined in this report.

### 3.3.2 Pictogram

#### 3.3.2.1 Decision

FSANZ's decision is that the following pictogram design, with the silhouette of a pregnant woman holding a wine glass within a circle with a diagonal strikethrough, is used.



#### 3.3.2.2 Rationale for decision

Following assessment and consideration of submitter comments, FSANZ has decided to require the pictogram shown above, either on its own or with the signal words and warning statement, depending on the volume of the alcoholic beverage (as outlined in section 3.3.5), because:

- the pictogram design (excluding specific colours) is commonly used in the voluntary labelling initiative across Australia and New Zealand
- research indicates the inclusion of a graphic with text enhances the level of attention the warning receives in comparison with a text only warning (SD1)
- pictorial elements can bridge literacy and other educational gaps (SD1)
- there are moderate and increasing levels of prompted awareness and understanding of the prescribed pictogram among Australian and New Zealand women of childbearing age as well as men in the same age range (SD1).

The pictogram was generally well supported by submitters, who noted it is broadly used and well-recognised. Many submitters supported a pictogram being included as part of the warning label, however some raised issues about the prescribed design. Responses to these issues are provided in Table 1.

### 3.3.3 Warning statement

#### 3.3.3.1 Decision

FSANZ's decision is to prescribe a warning statement as part of the pregnancy warning label (comprising the pictogram and wording).

FSANZ's decision is for the wording of the warning statement to read:

*Alcohol can cause lifelong harm to your baby.*

### 3.3.3.2 Rationale for decision

Following assessment and consideration of submitter comments, FSANZ has decided to require a warning statement as part of the warning label comprising a pictogram and wording for the reasons discussed below. Note that the pictogram only is required on certain beverages subject to volume as outlined in section 3.3.5.

Australia and New Zealand governments' public health advice is for pregnant women not to consume alcohol. FSANZ considers it important a warning statement be required and that it is consistent with public health messages. As discussed in SD1, the use of a warning statement with a pictogram reinforces the meaning of the pictogram and explains the consequences of alcohol consumption during pregnancy, which may increase the effectiveness of the label.

FSANZ selected the statement to be included in the pregnancy warning label on the basis of the available evidence including World Health Organization (WHO) principles for warning statements (WHO, 2017), existing evidence relevant to warning statements (SD1), results from the consumer testing (SD2), stakeholder views and the public health advice.

Drawing on the WHO principles and available evidence for developing a pregnancy warning statement, FSANZ applied six principles that state a warning statement can be more effective if it:

- identifies the problem
- explains the consequences if exposed to the problem
- directly refers to low levels of alcohol consumption
- avoids definitive language that harm will always occur
- uses personalised language to increase relevance
- is as short as possible.

The pregnancy warning statement required by the approved draft variation is consistent with these principles.

The results of the FSANZ consumer testing indicate that overall for women both in Australia and New Zealand, the statement *It's safest not to drink while pregnant* performed least well of the four statements tested in conveying the message not to drink alcohol while pregnant. It also performed least well in terms of its believability, credibility and convincingness.

The other three warning statements included in consumer testing performed better in conveying the message not to drink alcohol while pregnant in both Australia and New Zealand. These statements are:

- *Alcohol can harm your baby*
- *Any amount of alcohol can harm your baby*
- *Any amount of alcohol can cause lifelong harm to your baby*

In the CFS, FSANZ proposed to require *Any amount of alcohol can harm your baby* in the pregnancy warning label. The proposed wording received mixed response from submitters. While many submitters strongly supported the proposed wording, there were issues raised across stakeholder groups. FSANZ acknowledges issues raised regarding the accuracy of the wording *any amount* in relation to the known evidence base, comments about consumer testing and consistency of the message with the requirement of beverages with more than 1.15% ABV to display the pregnancy warning label. These specific issues are addressed in Table 1.

In light of submitter views, FSANZ has reconsidered the approach taken in the CFS. Drawing on the available evidence, including the three statements that performed best in consumer testing, and government advice not to consume alcohol while pregnant, FSANZ has decided to remove the words *any amount* from the statement and to include the word *lifelong*. The statement required to be included in the pregnancy warning label is therefore *Alcohol can cause lifelong harm to your baby*.

The reasons for this decision are that the statement:

- is supported by the evidence base and the principles relevant to warning statements
- is more consistent with the known evidence base that *while the risk of harm to the fetus from low levels of alcohol (e.g. less than one standard drink per day) is likely to be low, there is not enough evidence to accurately estimate the level of risk from small amounts of alcohol* (NHMRC, 2019b, p 51)
- combines elements from the three best performing statements in consumer testing in both Australian and New Zealand populations and is consistent with government advice not to consume alcohol while pregnant
- better reflects the fact that FASD can cause permanent harm to the baby (NHMRC 2019b)
- is more consistent with the requirement that alcoholic beverages with more than 1.15% ABV display the pregnancy warning label (as opposed to beverages with 0.5% ABV or more) (refer to section 3.3.9), reducing the risk of confused messaging for consumers.

### **3.3.4 Signal words**

#### **3.3.4.1 Decision**

FSANZ's decision is to prescribe the signal words 'HEALTH WARNING' as part of the pregnancy warning label (comprising the pictogram and wording).
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#### **3.3.4.2 Rationale for decision**

Following assessment and consideration of submitter comments, FSANZ has decided to require the signal words 'HEALTH WARNING' as part of the pregnancy warning label (comprising the pictogram and wording). The reasons for this decision are discussed below. Note the signal words will not be required on beverages displaying the pictogram only, as outlined in section 3.3.5.

The best available evidence shows the use of signal words can help to enhance credibility and increase likelihood to comply with the warning (SD1). Signal words can also operate as a heuristic cue and enhance the attention and comprehension of a warning label. In experiments, 'WARNING' was found to increase the credibility of the message over a warning with no signal word. 'HEALTH WARNING' had benefit over 'GOVERNMENT WARNING' or 'WARNING' because the former increased the credibility of the message. The studies reviewed typically tested the signal words in all capitals.

Public health and government submitters who commented on the proposed signal words supported the use of 'HEALTH WARNING' (and the use of capitals).

Although alternative signal words such as 'PREGNANCY WARNING' or 'PREGNANCY ADVICE' were strongly supported by industry submitters (refer to Table 1), no evidence was provided to support their use. Nor did FSANZ's literature review identify any published studies comparing the effect of 'PREGNANCY WARNING/ADVICE' with other signal words on credibility or ability to attract attention. Noting FASD can cause permanent harm to the baby (refer to section 1.2), FSANZ considers the warning label is concerned with the health

of the baby not the pregnancy per se. FSANZ therefore considers 'HEALTH WARNING' is more relevant and appropriate than 'PREGNANCY WARNING/ADVICE'. FSANZ also considers that 'HEALTH WARNING' has a broader meaning than 'PREGNANCY WARNING/ADVICE' which helps support the secondary objective of the warning label identified in the DRIS of providing information to the broader community.

Further issues raised about signal words in submissions to the CFS are addressed in Table 1.

Refer to sections 3.3.5 and 3.3.7 for discussion about the requirements for the signal words to be in capitals and bold, and in the colour red, respectively.

### **3.3.5 Warning label size and font type**

#### **3.3.5.1 Decision**

FSANZ's decision is to prescribe the following:

- Size of font of the signal words and warning statement, and size of the pictogram, based on alcoholic beverage volumes as outlined in Tables 3a and 3b below.
- Require the pictogram only for alcoholic beverages with a beverage volume of  $\leq 200$  ml.
- Require the pregnancy warning label (pictogram and wording) for alcoholic beverages with a beverage volume  $> 200$  ml.
- Where there is more than one layer of packaging:

#### *Outer package*

Require the pictogram only on the outer package of alcoholic beverages with a beverage volume of  $\leq 200$  ml that contains only one individual unit (i.e. innermost package).

Require the pregnancy warning mark on the outer package of all other alcoholic beverages.

#### *Individual unit*

Require the pictogram only on an individual unit with a volume of  $\leq 200$  ml.

Require the pregnancy warning mark on an individual unit with a volume of  $> 200$  ml.

(Refer to section 3.3.11 for further information regarding application of the label to different packages, including individual unit(s), outer packages and exemptions.)

FSANZ's decision is to prescribe the following with respect to font:

- the signal words HEALTH WARNING in capitals and bold (refer to section 3.3.7 for requirement to also be in red)
- the warning statement to be in black and in sentence case
- sans-serif typeface for both the signal words and the warning statement.

The size of the box (border) and specific sans-serif typeface used are not prescribed.

### 3.3.5.2 Rationale for decision

Following assessment and consideration of submitter comments, FSANZ has decided on the size of font<sup>13</sup> and other font requirements described above, for the reasons outlined below. A summary of the size requirements is provided in Tables 3a (package containing the alcoholic beverage) and 3b (outer package). Note these tables also refer to the requirements for different layers of packaging which are further discussed in section 3.3.11.

In determining the size requirements FSANZ has taken into account that alcoholic beverages are sold in a large range of volumes and package sizes with varying label space.

The requirement for the pictogram only for alcoholic beverages with volumes of 200 ml or less (including requirements for outer packages and individual units described above) recognises the generally smaller available label space on these beverage volumes and package sizes. There are also comparatively few alcoholic beverages sold in this volume range.

The warning label (pictogram and wording) is required for all alcoholic beverages with volumes greater than 200 ml, with different minimum sizes for those greater than 200 ml and equal to or less than 800 ml and those greater than 800 ml. This approach takes into account the number of beverages, particularly beer and RTDs, sold in multipacks (e.g. six pack of beer) and the variability in label space for the greater than 200 ml and up to 800 ml volume range. There is typically a larger label space available when volumes are greater than 800 ml.

Evidence relevant to warning labels on alcoholic beverages indicates a larger warning label relative to other label elements can attract greater attention than smaller warning labels. The size of the font used also impacts its readability with larger font size being more easily read than smaller font sizes (SD1). A minimum font and pictogram size is therefore prescribed. In determining the size of font requirements, FSANZ has taken into account current size of font requirements in the Code for warning statements together with the space needed for the entire pregnancy warning label including the pictogram. The border size is not prescribed but will be somewhat dictated by the prescribed sizes of the font and pictogram.

Outer packages (when there is more than one layer of packaging) will generally need to display a larger sized pregnancy warning label (other than an outer package containing one individual unit with a volume less than or equal to 200 ml, which requires the pictogram only) (refer to Table 3b below). This approach recognises the greater available label space on the outer package. The size of font for the larger label is similar to the requirements in the Code for warning statements and the height of the whole label will likely be similar to recommended heights for standard drink labels in Australia and New Zealand.

Refer to section 3.3.11 for further detail on the application of the label when there is more than one layer of packaging, including outer packages and individual units which directly contain the alcoholic beverage (noting each individual unit must bear the warning label). This includes the exemption for an outer package to display the pregnancy warning label when it is clearly discernible on an individual unit and is not obscured by the outer package.

FSANZ notes the divergent views of stakeholders with respect to size, including the proposed requirements for font and pictogram sizes and specific requirements for various package sizes and beverage volumes. In particular, industry stakeholders and enforcement authorities preferred a relatively straightforward approach rather than several minimum size requirements for different beverage volumes. However public health stakeholders preferred a

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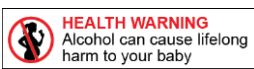
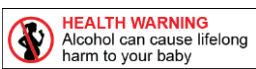
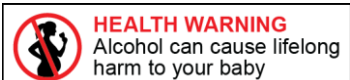
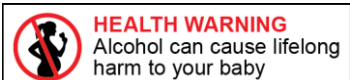
<sup>13</sup> In the draft variation (refer to Attachment A) the size of the font is referred to as *size of type*.

warning label as large as possible and a minimum 3 mm font size as currently required for warning statements in the Code (also supported by enforcement authorities). FSANZ has considered and provided responses to these views in Table 1.


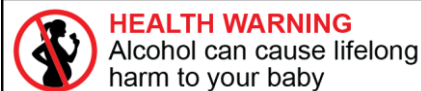
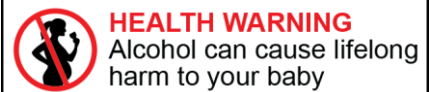
Regarding font, the signal words 'HEALTH WARNING' are to be in capitals and in bold (red) type to help attract attention. A sans-serif typeface is required for both the signal words and the warning statement to restrict the use of some fonts that can reduce readability. The warning statement is to be in black in sentence case to provide a distinction with the red capitalised signal words. Sentences in all capitals can be harder to read than those in sentence case (SD1).

In summary, FSANZ considers the approach responds on balance to the evidence supporting larger labels, the complex nature of the market and divergent stakeholder views, while aiming to require a minimum size and appropriate font type that will help to make the warning label noticeable and improve readability.

**Table 3a: Requirements for size of pictogram and font for pregnancy warning labels – package containing the alcoholic beverage**

Volume of alcoholic beverage	One layer of packaging only e.g. bottle of wine		Individual unit(s) (innermost package containing the alcoholic beverage) if more than one layer of packaging, e.g. bottle of wine in a box or each bottle of beer in a 6 pack <sup>14</sup>	
	Label required	Minimum size	Label required	Minimum size
≤ 200 ml		8 mm diameter		8 mm diameter
> 200 ml ≤ 800 ml		Pictogram 6 mm diameter  Size of type 2.1 mm		Pictogram 6 mm diameter  Size of type 2.1 mm
> 800 ml		Pictogram 9 mm diameter  Size of type 2.8 mm		Pictogram 9 mm diameter  Size of type 2.8 mm

**Table 3b: Requirements for size of pictogram and font for pregnancy warning labels – outer package**

Volume of alcoholic beverage	One individual unit e.g. outer box containing a bottle of wine		More than one individual unit e.g. outer package containing 6 bottles of beer or 12 bottles of wine	
	Label required	Minimum Size	Label required	Minimum Size
≤ 200 ml		8 mm diameter		Pictogram 11 mm diameter
> 200 ml		Pictogram 11 mm diameter  Size of type 3.5 mm		Size of type 3.5 mm

<sup>14</sup> Refer to section 3.3.11. The individual unit, or each individual unit if the packaging includes more than one individual unit, is required to display the pregnancy warning label.



### 3.3.6 Location and label orientation

#### 3.3.6.1 Decision

FSANZ's decision is:

- neither the location nor orientation of the pregnancy warning label will be prescribed
- a border must be around the three pregnancy warning label elements (the pictogram, signal words and warning statement) with at least 3 mm clear space outside the border.

#### 3.3.6.2 Rationale for decision

Following assessment and consideration of submitter comments, FSANZ has decided not to prescribe location and orientation of the pregnancy warning label because:

- this approach provides flexibility for industry with the orientation of the warning label taking into account overall label design
- this approach recognises the current practice of some companies presenting mandatory label information vertically on the container
- prescribing most design labelling elements will enable the warning label to be noticed irrespective of where it appears on the label
- none of the countries with mandatory pregnancy warning labels prescribe one location for the warning on a beverage container (refer to Attachment D).

There were mixed views from submitters regarding this issue, with some from the public health and government sectors wanting the orientation (horizontal) and location (prominent or front-of-pack) of the warning label prescribed. Some industry submitters noted the flexibility provided by not prescribing these elements. FSANZ has not prescribed orientation and location of the warning label for the reasons listed above.

FSANZ has considered issues raised by submitters about co-location of the warning label with other label information such as the *drink responsibly* type messages and conversely, industry concern about the requirement for at least 3 mm of clear space outside the border (refer to Table 1). No studies investigating whether the practice of co-location with other label information influences consumer understanding of a pregnancy warning label were identified. However, more broadly there is evidence that the context in which a warning is placed can impact attention (SD1). FSANZ has therefore decided to require a border around the pregnancy warning label (the pictogram and wording) along with at least 3 mm of clear space outside the border to help achieve separation of the warning label from other label information and to help attract attention.

### **3.3.7 Colour and contrast**

#### **3.3.7.1 Decision**

FSANZ's decision is to prescribe the following with respect to the colours of the pregnancy warning label:

- the warning statement text in black
- the silhouette of the pregnant women in the pictogram in black
- the pictogram on a white background
- the signal words in red
- the circle and diagonal strikethrough of the pictogram in red
- the border of the pregnancy warning label (around the combined pictogram and wording) in black
- the background within the border in white.

#### **3.3.7.2 Rationale for decision**

Following assessment and consideration of submitter comments, FSANZ has decided on the colour combinations described above (red and black on a white background) to achieve a consistent, high contrast label which is important for legibility and noticeability. The evidence indicates that some colour combinations produce contrast that is difficult to read (e.g. yellow on white), and legibility is reduced when the contrast between characters and the background is low. Dark lettering on a white background, or vice versa, rather than similar shades of a similar colour has been recommended in the literature to enhance legibility (SD1).

It is anticipated the use of black and white will not add unnecessarily to the costs to industry of adding the pregnancy warning label to existing labels, in particular if a label with a white background (white stock) is used and as black is a commonly used colour on alcoholic beverage labels. The prescribed colour scheme provides consistency in the colour of the warning labels across alcoholic beverages.

FSANZ has decided to prescribe the colour red for the signal words and for the circle and diagonal strikethrough of the pictogram with the silhouette of the pregnant women in black for the reasons outlined below.

Evidence indicates red can increase the speed of identification and level of attention the warning receives and red is more noticeable than black. Red has advantages over black as it is more effective in connoting the pictogram as a warning (e.g. 97% of New Zealand respondents associated the red and black pictogram with a warning compared to 1% of associating a black and grey pictogram with a warning (SD1)). Red is a common indicator of a hazard and assists understanding that the label is a warning (SD1). Research on the standard pictogram has found that when the pictogram is red and black it is interpreted more like a warning than when other colour combinations are used (SD1). Public health and government submitters supported the colour red because it enhances the cautionary message and is likely to stand out and attract attention.

In the CFS FSANZ proposed prescribing Pantone 485 as the specific red colour to be used. Some submitters, mainly government and public health stakeholders, supported the proposed approach because it increased contrast and prominence, and would ensure consistency across labels. However, industry submitters raised issues about the costs and impact on label design and prescribing red, in particular, the specific red Pantone 485.

FSANZ has decided not to require Pantone 485 as the specific red to be used. This will permit the use of red colours that are currently in use on alcoholic beverage labels for the warning label, hence saving costs for those companies currently using alternative reds to Pantone 485 compared to prescribing that particular colour. Red can be readily made using the CMYK colour process system (yellow and magenta). If yellow and magenta are already used in the label design, then it is likely no additional plates will be required to print the red in the warning label. FSANZ expects to include best practice examples of suitable red colours in guidance for industry.

FSANZ notes however, it is likely Pantone 485 is already being used on the labels of some alcoholic beverages. According to a Wellington based printer, Pantone 485 is commonly used over other reds on labels in general, including for warnings. Additionally, New Zealand standard drink guidelines require Pantone 485 for standard drink labelling (noting there is also a single-colour option).

FSANZ understands the various costs of using the colour red would likely be outweighed by the benefits of the label gaining greater attention and consequent benefits for mitigating or reducing prevalence/severity of future FASD cases. Further detail about the costs and benefits is provided in section 3.5.1.1 and responses to specific issues from submitters are provided in Table 1 in section 3.1.

There is no consistency in the use of colours in pregnancy warning labels internationally. It is noted Turkey prescribes the use of the colour red in a mandatory pregnancy warning pictogram and France is considering such an approach (refer to Attachment D).

Some submitters suggested prescribing a range of reds or not requiring a red colour at all. FSANZ has considered these options and has provided reasons for not taking either approach in Table 1 in section 3.1.

### 3.3.8 Summary of decision for pregnancy warning label design

In summary, FSANZ has decided on the following format for the pregnancy warning label (comprising the pictogram and wording).

The following label elements will be prescribed:

- Pictogram:



- Signal words: **HEALTH WARNING**
- Statement: Alcohol can cause lifelong harm to your baby.
- Border: to be around the above three label elements
- Clear space outside border.

For alcoholic beverage volumes  $\leq 200$  ml (and outer packages containing a single individual unit), the pictogram only is required.

**Table 4: FSANZ decision for colour and font requirements for the pregnancy warning label**

Pregnancy warning label element	Colour and font type
Pictogram	Black silhouette of pregnant woman with red circle and red diagonal strikethrough
Signal words	Red, in bold, capitalised, sans-serif typeface
Warning statement	Black, in sentence case, sans-serif typeface
Border around above elements	Black
Background within border and within pictogram	White
Clear space outside border	Colour not specified

Size requirements:

- Different text and pictogram sizes depending on volume of alcoholic beverage – refer to Tables 3a and 3b above.
- 3 mm clear space outside border of pregnancy warning label.

### 3.3.9 Beverages to display the pregnancy warning label

#### 3.3.9.1 Decision

FSANZ's decision is that a pregnancy warning label will be required on packaged beverages with more than 1.15% alcohol by volume (ABV) (referred to as a *prescribed alcoholic beverage* in the draft variation to the Code – refer to Attachment A).

#### 3.3.9.2 Rationale for decision

Following assessment and consideration of submitter comments, FSANZ has decided to require the pregnancy warning label on packaged beverages with more than 1.15% ABV for the reasons outlined below.

The approach is broadly consistent with alcoholic beverage definitions in relevant Australian and New Zealand legislation. These definitions generally refer to 1.15% ABV or more (noting three of the eight Australian jurisdictions require beverages with more than 0.5% ABV to be sold in licensed premises (refer to Attachment G)). In addition, the policy intent as applied during the voluntary initiative was that the warning label be on beverages commonly understood to be alcoholic, that is beverages with more than 1.15% ABV.

Under this approach, a pregnancy warning label will be required on the label of alcoholic beverages such as beer, grape and fruit and vegetable wine, wine products, cider, spirits, RTDs and any other beverages containing more than 1.15% ABV such as alcoholic ginger beer and alcoholic lemonade.

Although, requirements in other countries vary, FSANZ understands five of nine countries with mandated pregnancy warning labels apply a similar approach.

The approach is the same as that proposed in the CFS. There were mixed views from submitters across all sectors on this issue with some supporting the warning label to be required on beverages containing more than 1.15% ABV and others supporting the alternative option provided in the CFS of beverages containing 0.5% ABV or more. Issues raised in submissions to the CFS are considered and addressed in Table 1.

**3.3.10 Application to different types of sales**

**3.3.10.1 Decision**

FSANZ’s decision is that pregnancy warning labels are required for alcoholic beverages for retail sale and sold as suitable for retail sale without further processing, packaging or labelling.

Retail sale includes:

- where the alcoholic beverage is currently generally required to bear a label
- made and packaged on the premises from which they are sold, e.g. in winery, brewery
- delivered packaged and ready for consumption at the express order of the purchaser
- sold at a fundraising event
- displayed in an assisted service display cabinet.

Pregnancy warning labels are not required for the following types of sales of alcoholic beverages:

- sales to caterers
- wholesale (non-retail, not sold to caterers)
- intra-company transfers
- packaged in the presence of the purchaser, e.g. ‘fill your own’ and drinks poured into a drinking vessel ready for immediate consumption such as a glass of wine in a bar.

**3.3.10.2 Rationale for decision**

As noted in the DRIS, 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.* Hence the requirement is aimed at ensuring the label will be on alcoholic beverages for retail sale, i.e. sold to consumers, in as many situations as is practical. Under the Code, foods made and packaged on the premises from which they are sold,

delivered packaged and ready for consumption at the express order of the purchaser, sold at a fundraising event and displayed in an assisted service display cabinet are normally exempt from the generic requirement to bear a label. However FSANZ considers alcoholic beverages sold in these situations should be labelled with the pregnancy warning label. This will broaden the opportunities for consumers to be exposed to the warning label. It is likely alcoholic beverages sold in these situations would be fully labelled for retail sale even if not required to be by the Code. For example, a bottle of wine sold from the vineyard at which it is made, or sold at a fund raising event, is exempt from existing generic labelling requirements but is likely to be fully labelled to allow it to also be sold for retail sale elsewhere. Hence, requiring the warning label in these situations is expected to have limited additional impact on industry.

With regard to alcoholic beverages packaged in the presence of the purchaser, it is likely to be impractical to label containers or drinking vessels used in these situations. Alcoholic beverages packaged in the presence of the purchaser are therefore exempt from the requirement to display the warning label.

The pregnancy warning label will not be required in non-retail situations or intra-company transfers as the beverage is not sold directly to consumers.

The decision is consistent with the approach proposed in the CFS, except that the CFS also proposed the warning label would be required on alcoholic beverages sold to caterers. FSANZ has reconsidered this requirement noting a submitter comment that the label would be required on packages such as kegs supplied to caterers. FSANZ has decided to only require the warning label when the alcoholic beverage is for retail sale to the consumer (or is sold as suitable for retail sale) rather than to caterers as well, as the warning is aimed at consumers rather than caterers. If a beverage sold to a caterer is then sold for retail sale it would be required to be labelled with the warning label at that point (unless an exemption applied such as packaged in the presence of the purchaser). FSANZ considers it is likely that beverages sold to caterers that would require the warning label at the point of sale to the consumer, would already be labelled with the warning label, e.g. pre-labelled bottle of wine or beer.

The majority of submitters were supportive of the proposed approach. Issues were raised about alcoholic beverages sold to caterers as noted above, and about requiring signage for alcoholic beverages packaged in the presence of the purchaser (refer to Table 1).

### 3.3.11 Application to different types of packages

#### 3.3.11.1 Decision

FSANZ has decided on the following pregnancy warning label requirements for different types of packages of alcoholic beverages for retail sale or sold as suitable for retail sale without further processing, packaging or labelling:

- where there is only one layer of packaging, the pregnancy warning label must be on the package of the alcoholic beverage
- where there is more than one layer of packaging, the pregnancy warning label must be on:
  - the individual unit (i.e. innermost package) or each individual unit where packaging includes more than one individual unit, and
  - the outer package, except where the warning label on an individual unit is clearly discernible and not obscured by the outer package.

A pregnancy warning label is not required on:

- a bladder within a box of an alcoholic beverage
- transportation outers (removed before retail sale)
- hampers (the hamper itself which is not included in the definition of a *package*).

Note the pregnancy warning label is required on the package of an alcoholic beverage sold within a hamper.

#### 3.3.11.2 Reason for decision

Following assessment and consideration of submitter comments, FSANZ has decided on the above approach to enable the pregnancy warning label to be visible to consumers at both the point of purchase and potential point of consumption. This is consistent with the primary objective of pregnancy warning labels on packaged alcoholic beverages as noted in the DRIS, i.e. *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* (Food Regulation Standing Committee, 2018).

In the CFS, FSANZ proposed a similar approach to that described above, however it was also proposed that the warning label be required on all layers of packaging of a particular product (unless discernible through the outer package). Broadly, the approach taken was supported by public health and government submitters. There were mixed views from industry submitters with some supporting the proposed approach and some raising issues or seeking clarification, as noted in the summary of submissions in Table 1 of section 3.1.

FSANZ has reconsidered the requirement for the warning label to be on each layer of packaging and decided that when there is more than one layer of packaging, only the individual unit(s) (i.e. the innermost package containing the alcoholic beverage) and the outer package for retail sale will require the pregnancy warning label. Any intermediate layers will not be required to display the label. This approach still ensures the warning label is visible to consumers at the point of purchase and potential point of consumption, without imposing additional, unnecessary labelling requirements for any intermediate layers of packaging (e.g. tissue paper between the outer package and innermost package). For retail cartons containing several multipacks, the warning label is not required on the intermediate packages containing the individual units, however FSANZ notes it is likely that these would be labelled

with the pregnancy warning label anyway, as they could also be sold as a separate retail unit.

There are two exemptions from this requirement, i.e. a pregnancy warning label will not be required on:

- the outer package if the warning label on an individual unit is clearly discernible and not obscured by the outer package, avoiding unnecessary costs of additional labelling as the warning label will still be visible at the point of sale.
- a bladder of an alcoholic beverage contained within a box (e.g. bladder in a cask of wine); based on the assumption that a label on the bladder would not be seen as typically the beverage is dispensed from the bladder whilst still contained within the box.

Under existing Code requirements, the pregnancy warning label is not required on the outside of hampers as these are excluded from the definition of *package* (section 1.1.2 —2). However the package of an alcoholic beverage within a hamper for retail sale is required to display the warning label.

Note the details of the pregnancy warning label to be included on various packages (i.e. pictogram only or pregnancy warning label with pictogram and wording) and size requirements are discussed in section 3.3.5 and summarised in Tables 3a and 3b.

### **3.3.12 Summary of amendments to draft variation provided in CFS**

The main amendments to the draft variation following consideration of submissions are as follows:

- The Pantone 485 colour requirement for the circle and strikethrough of the pictogram and the signal words has been amended to the colour red.
- The wording of the warning statement has been changed to *Alcohol can cause lifelong harm to your baby* instead of *Any amount of alcohol can harm your baby*.
- The application of the pregnancy warning label to each layer of packaging (when there is more than one layer of packaging) has been amended to only require the label on the outer package and the individual unit(s) (see point below).
- New definition of *individual unit* (i.e. innermost package that contains the alcoholic beverage) to apply when there is more than one layer of packaging (i.e. the individual unit must display the label, or each individual unit if there is more than one in the packaging). This replaces the reference to individual portion packs.
- The requirement for the pregnancy warning label on foods sold to caterers has been removed.
- The definition of *pregnancy warning pictogram* has been expanded to refer to the silhouette of a pregnant woman holding a wine glass.
- Size requirements now refer to *size of type* rather than point size (*size of type* is defined in the Code).
- Editorial amendments for the purposes of simplification and clarification, e.g. size, legibility and application to different packages requirements.



## **3.4 Risk communication**

### **3.4.1 Public consultation**

Consultation is a key part of FSANZ's standards development process.

FSANZ developed a communication strategy for this proposal. Subscribers and interested parties were notified about the public consultation period via the FSANZ Notification Circular, media release and through FSANZ's website, social media tools and Food Standards News.

FSANZ sought submissions to the proposed draft variation in the CFS from 4 – 27 October 2019. 130 submissions were received and seven submissions were received following the end of the submission period.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this proposal. All comments are valued and contribute to the rigour of our assessment. In accordance with the requirements of the FSANZ Act, FSANZ has had regard to all submissions.

### **3.4.2 Targeted stakeholder consultations**

In January/February and June/July 2019, FSANZ completed two rounds of targeted stakeholder consultation, meeting face-to-face with industry and public health groups in both Australia and New Zealand, and via teleconference with jurisdictions. Representatives of the Māori community attended the January 2019 consultations. FSANZ also held a teleconference with two Australian Indigenous stakeholder representatives in July 2019. FSANZ sought views from stakeholders on key aspects including warning label design (excluding statement wording as consumer testing had not been completed) and implementation. These views were considered when developing the design and implementation of the label. Stakeholders were also invited to provide written information about the costs of a labelling change based on a proposed warning label (similar to the warning label design at Approval) following the June/July 2019 consultation. Information received from six industry stakeholders (with some representing a number of businesses) is included in the assessment of the proposal (refer to section 3.5.1.1.2).

### **3.4.3 World Trade Organization (WTO) consultation**

For this proposal, FSANZ made a notification to the WTO in accordance with the WTO TBT Agreement. Comments were received from three WTO Member countries and four industry organisations. FSANZ has had regard to all comments received and responses are provided in Table 2.

Attachment E outlines FSANZ's consideration of the relevant requirements of the WTO TBT Agreement (Articles 2, 4 and Annex 3).

## **3.5 FSANZ Act assessment requirements**

### **3.5.1 Section 59**

When assessing this proposal and in the subsequent development and approval of a food regulatory measure, FSANZ has had regard to the following matters in section 59 of the FSANZ Act.

### **3.5.1.1 Consideration of costs and benefits**

#### *3.5.1.1.1 Introduction*

FSANZ has given consideration to the costs and benefits that may arise from the regulatory measure for the purposes of meeting FSANZ Act requirements. The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the regulatory measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 59(2)(a) of the FSANZ Act).

The Office of Best Practice Regulation (OBPR) exempted FSANZ from the need to undertake a formal Regulation Impact Statement (RIS) in relation to the regulatory change proposed. The OBPR was satisfied that the necessary range of potential regulatory changes had already been considered through the DRIS (Food Regulation Standing Committee, 2018) that informed the Ministerial Forum's request, in October 2018.

FSANZ is confident in the quality of the analysis undertaken in the DRIS. This is especially the case given the OBPR's assessment that it meets the requirements of the Council of Australian Governments Best Practice Regulation Guide (Council of Australian Governments, 2014). However, FSANZ has undertaken its own independent analysis. Whilst FSANZ had regard to the DRIS:

- significant effort was made to ensure we could be confident in label change cost estimates and significant new evidence was gathered
- primary sources and all calculations in the DRIS were checked and not accepted on face value
- all new risk assessment and risk management work undertaken by FSANZ was taken into account
- the value of a number of key variables (such as additional colours and different printing methods) were reconsidered in light of more defined interventions and additional evidence (from industry submissions and information from label printing and design companies)
- updated calculations were made using some updated variable costs across three scenarios to extend the analysis to provide a plausible range of potential results.

Paragraph 59(2)(a) of the FSANZ Act requires FSANZ to consider the costs and benefits of a food regulatory measure developed as a result of a proposal. It does not require FSANZ to undertake cost benefit analysis. Other forms of analysis such as cost effectiveness analysis or break-even analysis are often more appropriate and technically feasible.

Break-even analysis was chosen because it allows the consideration and comparison of costs and the potential benefits without a precise understanding of the size and attribution of the benefits. The purpose of the analysis is to highlight the approximate range beyond which positive net benefit can be expected. Difficulties of establishing precise attribution and the magnitude of the benefit is not unusual for complex policy matters where outcomes are dependent on multiple events, with a number of different factors supporting or opposing a desired outcome.

FSANZ expects a benefit from the mandated pregnancy warning label beyond the status quo because:

- The mandated pregnancy warning label integrates design elements that evidence shows will increase the attention a warning will receive.
- The mandated warning label includes a statement that combines elements from the three best performing statements in the consumer testing, which were shown to score significantly better than the voluntary statement *It's safest not to drink while pregnant* in comprehension and credibility.
- A mandated approach with prescribed design elements will ensure a high level of consistency and coverage in the warning label across packaged alcohol, providing women of childbearing age with consistent information both at the point of purchase and consumption.
- The pregnancy warning label is part of a broader suite of measures aimed to raise awareness of the risks of drinking alcohol during pregnancy (refer to section 2.5). Evidence from alcohol warnings (Pettigrew et al., 2016) and tobacco warning labels (Wilkinson et al., 2009) confirms that the label as part of a suite of measures can contribute to behaviour change (refer to section 3.2.3).

#### 3.5.1.1.2 *Basis of the updated consideration of costs and benefits*

The alcohol industry considered the analysis in the DRIS, which was partly based on a cost survey in 2017, underestimated costs per Stock Keeping Unit (SKU) of labelling changes associated with moving away from the voluntary to a mandatory system. At the time of the DRIS, the specific approach for the warning label had not been developed.

Therefore, significant effort was put into collecting and verifying our labelling change cost estimates to ensure the estimates were as reliable as possible. The range of costs per SKU considered by FSANZ and average costs in the Base Case (assumed most likely), Best Case (lowest industry costs) and Worst Case (highest industry costs) scenarios were triangulated and supported by the following:

- cost estimates provided by industry to the Australian Department of Health for the 2018 DRIS and subsequently to FSANZ in mid-2019
- data from an independent Cost Schedule (PricewaterhouseCoopers, 2014) on total label costs, where the cost of a 'Major change' (similar in magnitude to the unmitigated Worst Case scenario in the CFS) covers changes to six colours, image redesign, and changes to print layout and package size
- visits to, and conversations with, label printing companies
- visits to label design companies
- online searches of label design costs.

FSANZ has a high degree of confidence in the range of cost estimates used across the scenarios. This confidence was confirmed by additional cost per SKU data estimates provided by industry in the submissions to the CFS.

Nine industry submitters gave costs per SKU data as lower than the \$4,924 average in the CFS Base Scenario. Twelve submitters gave costs per SKU data higher than the Base Scenario average, but still well within the range of costs per SKU previously considered by FSANZ. Other industry submitters claimed the labelling costs were underestimated but provided no evidence to support that claim.

The FSANZ analysis does not distinguish cost impacts among different sized businesses. Relatively few small businesses have provided cost data to FSANZ. Some industry submitters suggested that proposed labels may disproportionately impact the profit margins of smaller producers, particularly those producing a larger number of SKUs with smaller product batches. However, evidence gathered by FSANZ through visits to label companies, submissions to the CFS and online searches is inconclusive as to a large cost differential based on business size.

A few submitters to the CFS that appeared to be small businesses provided cost per SKU data significantly below the \$4,924 average in the CFS Base Scenario. At least some small businesses:

- may use digital printing for smaller sized label batches. Digital printing has lower costs for making label changes compared to conventional printing
- appear to be more agile than many of their larger competitors, and are more regularly changing their marketing and product offering to meet market demand, further reducing the marginal impact of the change.

Some industry submitters raised issues about costs of incorporating the colour red in the proposed warning label. The 2014 PwC Cost Schedule on total label costs used by FSANZ to assist with the estimation of label change costs envisaged major design costs with the use of up to six colours that could include red. Therefore, these costs are likely to be already incorporated in current estimates, when different printing methods are also considered.

Additionally, FSANZ has decided to prescribe the colour red instead of specifically Pantone 485 as previously proposed. This will allow the use of other red colours currently used on alcoholic beverage labels. This is expected to reduce costs of the warning label, particularly for companies currently using alternative reds to Pantone 485.

It is also expected that a two year transition period with an exemption for some products would provide sufficient notice to mitigate against loss from unused label stocks (that were not able to incorporate warning labels). From FSANZ's visits and telephone conversations with label, cardboard and can printing companies in July and August 2019, most packaging companies store label stock for a maximum of four months. There may be occasional exceptions of labels being stored for more than four months for beverages that are slower to sell. It is also recognised that some alcoholic beverage companies themselves can store labels.

#### *3.5.1.1.3 Developing alternative assumptions*

FSANZ developed a series of alternative assumptions to extend the analysis that was already undertaken in the DRIS. Alternative estimates have been created as a result of judgements being made as to whether assumptions that have been used are likely to be 'base' estimates or 'best case' or 'worst case' estimates.

This approach has continued to be conservative in assuming:

- Annual costs of new FASD cases (i.e. annual benefits of avoiding those new cases) to be at the lower end of the range quoted in the DRIS, apart from for the 'Best Case' scenario that took the DRIS's 'plausible central case'.
- The number of SKUs needing to incorporate the warning label, and hence overall costs of doing that for industry, being at the higher end of the range quoted in the DRIS.

FSANZ's literature review, together with outcomes from the consumer testing (refer to section 3.2), suggest the proposed pregnancy warning label is likely to better convey government advice not to drink alcohol during pregnancy and attract consumer attention to a greater extent than the warning labels commonly used in the voluntary initiative.

#### *3.5.1.1.4 Break-even consideration of costs and benefits*

### **Option 1 – Maintain the status quo (abandon the proposal)**

The status quo, i.e. the current arrangements for a voluntary pregnancy warning label, is the option that option 2 is compared against.

### **Option 2 – Mandatory labelling (as approved in this Approval Report)**

This analysis considers the new mandatory pregnancy warning label.

### **Comparison of the proposed approach with the status quo**

The cost and benefit figures in this comparison are for Australia and New Zealand combined, treating Australia - New Zealand as one combined region.

Given the uncertainties around a number of variables, this updated consideration of costs and benefits has tested a range of scenarios for Australia - New Zealand, and has estimated costs and benefits under three main scenarios. These scenarios are compared in Table 5 later in this section.

The annual percentage of new FASD cases across Australia - New Zealand combined, needing to be avoided (or reduced in severity), to justify costs of the mandatory pregnancy warning label to industry, is estimated in this updated consideration of costs and benefits as ranging between 0.2% and 3.2% (around 35 to 555 cases a year). The Base (assumed most likely) estimate is 1.3% (around 225 cases a year). That 'break-even consideration' is over 20 years after the end of the transition period of the new pregnancy warning label, and accounts for the typical nine month duration of pregnancy.

The original DRIS estimate of 1.18% of new FASD cases (in a year for Australia) clearly sits within the range of these updated estimates.

The key assumptions and variables that underpin the three scenarios are:

#### **1. Number of SKUs likely to be affected, taken from DRIS's upper estimates:**

An upper estimate for the Australian market in the DRIS was 40,296 SKUs. There were no reliable data for the total number of SKUs in the market in New Zealand. The total number of SKUs in New Zealand was roughly estimated in the DRIS as being somewhere between the number of SKUs reported by the Siggins Miller Second Evaluation (Siggins Miller, 2017) for Australia (21,557) and the estimate that included additional industry data for Australia (40,296). Therefore, the number of SKUs in the scenarios is assumed to range between a lower combined estimate of 40,296 + 21,557 (Australian upper estimate plus New Zealand lower estimate) = 61,853 SKUs, and an upper combined estimate for both countries of 40,296 + 40,296 = 80,592 SKUs.

The DRIS noted that some products in the market in Australia will be imported from New Zealand and vice-versa, and thus included in the number of SKUs available in both markets. Accordingly, the number of SKUs may be overestimated with some double-counting, compared to if unique SKUs that are present in both countries could be identified and

counted once, especially in the Worst Case Scenario (with highest total industry costs).

## **2. Average cost of incorporating a warning label per SKU:**

It is likely that costs will vary greatly depending on the nature of the SKU and the number of layers of packaging requiring pregnancy warning labels, e.g. cans wrapped in retail cardboard packages. Given available data from industry and other sources, it is difficult to estimate a single point estimate for the cost. However, a mean of the cost data received by FSANZ from industry in 2018/19 was taken at A\$7,575 per SKU. That A\$7,575 cost per SKU is high compared to the per SKU costs in the DRIS and risks of strategic bias do exist. However, this average is close to the A\$7,872 cost of a 'Major' label change as derived by a separate PricewaterhouseCoopers study on label change costs (PricewaterhouseCoopers, 2014), adjusted for inflation and higher print cylinder costs for aluminium cans. Therefore, for the purpose of extending the analysis, this higher estimate of cost per SKU will be used.

For most SKUs, the total size of the pregnancy warning label is assumed to be able to be incorporated onto existing packaging space, especially given the different requirements and sizes for the warning label for alcoholic beverage volumes of 200 ml and under, > 200 ml and ≤ 800 ml and over 800 ml.

## **3. Assumed cost savings per SKU from incorporating the warning label during label changes that are voluntary or made due to other legislation, and the proportion of SKUs where such cost savings would be available:**

Undertaking multiple labelling changes at the same time is assumed to reduce the marginal cost of incorporating the pregnancy warning label. Transition periods are provided to allow industry to take advantage of this so they can co-ordinate regulatory changes with other changes they would have made in their ordinary course of business. Examples include combining changes to incorporate the mandatory warning label with general label changes that would have been made voluntarily anyway (in the absence of the warning label), or changes to comply with other legislative requirements.

Undertaking the pregnancy warning label change with other labelling changes is, on average, assumed to cost around 30% of the costs of otherwise incorporating the warning label. This is based on the warning label requiring an assumed average of three extra printing plates for beverage labels and for outer packages (beyond an existing change that occurs at the same time), with design and approval costs assumed to increase by approximately one third. This implies that combining the pregnancy warning label change with other labelling changes would, on average reduce costs per SKU by 70%. Given the general costs of using different colours and adjusting label designs to incorporate the warning label, it is assumed that the marginal costs of the warning label will not be zero (i.e. reduced by 100%), even when incorporating it as part of multiple changes.

Reducing costs of the mandatory pregnancy warning label by 70%, on average, when undertaking multiple labelling changes, would make the estimated average cost A\$ 2,272 per SKU (rounded from the exact calculation). From a literature review (Muth et al., 2012), the PricewaterhouseCoopers study on label change costs (PricewaterhouseCoopers, 2014), information provided by industry (as noted in section 3.5.1.1.2) and discussions with label printing companies undertaken by FSANZ, it is estimated that around 50% of SKUs would be able to include the pregnancy warning label combined with other label changes within the proposed two year transition period.

The Base (assumed most likely) Scenario, therefore takes the average of the unmitigated cost of the pregnancy warning label (A\$7,575) and the mitigated cost above (A\$2,272), i.e. estimated average of A\$4,924 per SKU.

The Worst Case Scenario assumes that all SKUs would experience the unmitigated cost of A\$7,575 per SKU.

The Best Case Scenario assumes a more optimistic mitigated cost at 10% of otherwise incorporating the pregnancy warning label, i.e. reducing average costs per SKU by 90% to A\$757 per SKU for 50% of the SKUs. Therefore, its estimated average cost per SKU is the average of A\$757 and A\$7,575 at A\$4,166 per SKU.

#### **4. *The estimated value of avoided disability, expressed as \$ benefits, taken from DRIS estimates:***

The benefits of avoiding new FASD cases used estimates of the annual costs of new FASD cases at the lower end of the range quoted in the DRIS. Page 30 of the DRIS quoted a Canadian study and estimated annual 'health related' costs of new mild cases of FASD at an average of A\$13,785 (A\$13,847 per year, updated for inflation between late 2018 and mid-2019). Those costs exclude any costs to the prison or juvenile detention system and exclude a number of costs associated with FASD that are outlined later in this section. Both the Base Case (assumed most likely) and Worst Case Scenario assume that only mild new cases of FASD are avoided at an average benefit of A\$13,847 per case per year.

The Best Case Scenario assumes that an equal mix of mild, moderate and severe cases of FASD are avoided or reduced in severity per year, with an average benefit of A\$76,002 per new case per year in Australia and A\$92,395 in New Zealand.

Several public health submissions to the CFS and a third-party economics consultant engaged by an industry submitter highlighted that the break-even analysis appears to make a conservative estimate of the benefits of avoiding / downgrading new FASD cases compared to other sources.

For instance, in a recent November 2018 review of 32 different studies, mainly from the United States and Canada (Walters Kluwer Health, 2018) costs of FASD were estimated at around A\$34,900 per year for children and A\$36,500 for adults with FASD (when converted into 2019 Australian dollars). That is, those estimated FASD costs are 2.5 to 2.6 times the A\$13,847 estimate used in the break-even's Base Case and Worst Case scenarios.

Benefits were conservatively estimated and are likely to be an underestimation. However, FSANZ is of the view that this is more appropriate than providing estimates that cannot be confidently quantified as the latter approach could negatively impact on the credibility of the analysis.

#### **5. *Comparison of Costs and benefits over 20 years and discount rates:***

The above costs (industry costs per SKU multiplied by numbers of SKUs for incorporating the pregnancy warning label) are compared with the benefits of avoiding new FASD cases over 20 years after the end of the transition period for all packaged alcoholic beverages.

Benefits in future years are discounted by a range of rates. The Base Scenario uses a 4% discount rate, in line with real interest rates and consumption per capita growth rates over the past 15 years. The Best Case Scenario uses a low discount rate of 3%, and the Worst Case Scenario uses a high discount rate of 7%. Discount rates between 3% and 7% are in-line with those used within the Australian Government.

A 20 year timeframe is used because:

- new cohorts of pregnant women could be influenced by the warning labels every nine months and it is likely to be a salient message to them
- social norms around not drinking whilst pregnant developed as a result of the label and other intervention could build over time and increase (not reduce) the impact of the label
- there is a clear causal link between alcohol consumption and FASD that will not change over time
- FASD is a lifelong condition with costs to individuals with FASD and their families that do not reduce over time.

#### **6. Range of new annual FASD cases avoided to justify the costs to industry:**

The 0.2% to 3.2% range (Table 5) is conservative and may over-estimate the number of new annual FASD cases needing to be avoided to justify the costs of label changes, because it does not account for the following factors:

- reduced FASD cases would continue indefinitely, beyond the 20 year time horizon, and most costs of label changes to industry would occur only once
- greater numbers of FASD cases could be avoided each year due to more people being born in Australia - New Zealand each year, if a similar percentage of those being born would otherwise have had FASD (in the absence of the new pregnancy warning label being part of a suite of measures). That would reduce the percentage of cases needing to be avoided. The number of annual births in both Australia and New Zealand has generally increased over the last 40 years
- increasing real health care costs, including of treating conditions associated with FASD
- saving the costs of lost economic productivity directly from individuals with FASD
- emotional costs to individuals, their families, and communities that are avoided through reduced FASD cases
- neither the Base (assumed most likely) Scenario or Worst Case Scenario assume any benefits to the prison or youth detention systems from avoiding costs of behavioural challenges of FASD, although avoiding those costs is assumed in the Best Case Scenario.

There may also be some overestimates of the number of SKUs of alcoholic beverages in Australia and New Zealand (the upper estimate is taken from the DRIS), as described under point 1 above.

The three break-even scenarios are presented in Table 5 below to show situations where the benefits to communities of FASD cases avoided or reduced in severity would justify the costs to industry of incorporating the pregnancy warning label on packaged alcoholic beverages. Refer to Attachment H for supporting information.

The costs to industry are one-off and do not reflect any ongoing costs from the proposed use of the colour red. However, most information received suggests ongoing costs from incorporating the pregnancy warning label would be very small in relation to the one-off initial costs, particularly since FSANZ has decided to require the colour red instead of specifically Pantone 485.

DrinkWise undertakes awareness-raising activities around the message *It's safest not to drink while pregnant*. DrinkWise is funded by industry and believes that new messaging may cost its FASD awareness program around A\$650,000, excluding staff costs to facilitate the changes. That is, mandated changes to the design or wording of the alcohol and pregnancy



message (appearing on packaged alcoholic beverages), could render its existing FASD awareness assets inconsistent. The A\$650,000 DrinkWise estimate is included in the figures for total costs to industry.

**Table 5: Break-even scenarios: costs to industry vs community benefits of FASD cases avoided or reduced in severity compared to the Status Quo of voluntary arrangements for the pregnancy warning label (PWL)**

Scenario	Annual new FASD Cases needing to be avoided for 20 years after transition period of new PWL	Assumed no of SKUs (AU and NZ)	Average Cost per SKU over all involuntary and voluntary changes	Annual benefits per new FASD Case avoided
Base (assumed most likely)	<u>1.3%</u> of all cases, or around <b>225</b> cases per year across Australia and New Zealand combined	<b>71,223 SKUs</b>	A\$ <b>4,924</b> per SKU - average of:  (a) <b>unmitigated costs</b> , i.e. needing to incorporate the new PWL outside making label changes voluntarily or due to other legislation; and  (b) <b>mitigated costs</b> , i.e. being able to incorporate the new PWL when making voluntary changes or complying with other legislation.  Total costs to industry SKUs = <b>\$351,319,009</b> (including DrinkWise costs for their FASD Awareness Program)	= A\$ <b>13,847</b> per case in AU and NZ  Assumes <b>only new mild</b> cases avoided, as defined in the DRIS.  Discount rate of benefits in future years = 4%, based on real interest and per capita consumption growth rates over the last decade. Using this discount rate is also supported by UK Treasury guidelines that are taken as a reliable benchmark by independent international economists.
Best Case	<u>0.2%</u> of all cases, or around <b>35</b> cases per year across Australia and New Zealand combined	<b>61,853 SKUs</b>	A\$ <b>4,166</b> per SKU –average of: (a) Unmitigated costs (b) Lower estimated mitigated costs  Total costs to industry SKUs = <b>A\$258,333,865</b> (including DrinkWise costs for their FASD Awareness Program)	<b>A\$ 76,002</b> per case in AU and A\$ <b>92,395</b> <sup>15</sup> in NZ.  “Plausible central case” taken from DRIS. Discount rate of benefits in future years = 3%
Worst Case	<u>3.2%</u> of all cases, or around <b>555</b> cases per year across Australia and New Zealand combined	<b>80,592 SKUs</b>	A\$ <b>7,575</b> per SKU  Mean of cost submissions received. Assumes no costs over any SKUs are mitigated.  Total costs to industry SKUs = <b>A\$611,107,875</b> (including DrinkWise costs for their FASD Awareness Program)	= A\$ <b>13,847</b> per case in AU and NZ  Assumes only <b>new mild cases</b> avoided  Upper discount rate of benefits in future years = 7%

<sup>15</sup> All annual benefits figures are taken from the October 2018 DRIS and updated for inflation. The A\$13,847 per case for the Base and Worst Case scenarios is conservative and assumes that only mild cases of FASD would be avoided, with no avoided costs to the prison or youth detention systems (corrections systems). For the Best Case scenario, the A\$76,002 per case in Australia and A\$92,395 in New Zealand assume some of the FASD cases avoided would be more severe and that costs to the corrections systems would also be avoided. Those latter figures were based on different modelled FASD incidence rates, and different costs of putting one person in prison in each country.

#### 3.5.1.1.5 *Costs of implementation to government agencies*

There will be some costs to government regulatory agencies that are not included in the above break-even analysis, including adjusting to the changed requirements and promoting and enforcing those new requirements.

A few industry stakeholders (not regulatory authorities) stated that FSANZ did not consider costs for regulatory authorities to administer and implement the regulation. However, no regulatory authorities have commented that their administration or implementation costs would be notably affected. The proposals do not require new implementation of enforcement systems to be adopted.

#### 3.5.1.1.6 *Conclusion*

This updated consideration of costs and benefits does not change the conclusion of the 2018 DRIS (as shown below), even though costs per SKU for incorporating the pregnancy warning label have been revised upwards to account for industry's revised estimates.

*Conclusion: A small proportion of cases of FASD need to be prevented to offset the costs of label changes on industry. A mandatory approach offers certainty that high coverage of pregnancy warning labels will be achieved and the warning labels are designed to support consumer understanding and consistency with Government advice. Therefore the mandatory option represents the greatest net benefit to the community (Food Regulation Standing Committee, 2018).*

There are large human and financial benefits to the community from avoiding or mitigating new FASD cases. Relatively few annual cases need to be avoided or reduced in severity to justify industry costs of incorporating the warning label.

The benefits of the new mandatory pregnancy warning label, compared with the current voluntary situation, are assumed to be further enhanced by ongoing information, education, and other actions to prevent, mitigate and manage FASD, as described in section 2.5 of this report.

#### **3.5.1.2 *Other measures***

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the proposal.

FSANZ notes that other mandatory but less prescriptive measures, for example through co-regulation (industry working with government to regulate businesses) or quasi-regulation, would not be more cost-effective than a food regulatory measure. While such measures may have resulted in reduced costs to industry, it is highly likely that this would have been at the expense of the effectiveness of the labelling given the strong preference expressed by industry to maintain the status quo or something close to it. It is unlikely that such measures would result in any benefit above the status quo.

Additionally, FSANZ notes that the use of co-regulation and quasi-regulation can be problematic for major public health concerns as there are mixed incentives for industry to comply, and it is unlikely that an agreed and widely accepted solution could be developed by industry given the diversity of participants in the industry. This is evidenced from attempts at self-regulating to address this issue to date, and noting that some producers have previously indicated that they would not include a warning label unless mandated (Siggins Miller 2017).

As noted in section 3.5.1.1.6 above, the mandatory approach offers certainty that high coverage of pregnancy warning labels will be achieved. The warning label has been designed based on the best available evidence to attract attention and enhance

understanding of government public health advice for pregnant women to not drink alcohol; and has been applied in such a way to achieve an effective and pragmatic labelling approach.

Mandatory and voluntary pregnancy warning labels used in other countries are not permitted as an alternative to the prescribed label. FSANZ considers the Australia and New Zealand warning label will be more effective in achieving the primary objective stated in the DRIS (to provide a clear and easy to understand trigger to remind pregnant women to not drink alcohol) in the local context than labels used in other countries (refer to further detail in section 3.5.3 and at Attachment E).

### **3.5.1.3 Any relevant New Zealand standards**

There are no relevant New Zealand Standards.

### **3.5.1.4 Any other relevant matters**

Other relevant matters are considered below.

## **3.5.2 Subsection 18(1)**

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

### **3.5.2.1 Protection of public health and safety**

The mandatory pregnancy warning label supports Australia and New Zealand governments' public health advice and messages for women not to drink alcohol during pregnancy to reduce the risk to the health and safety of the unborn child. Evidence demonstrates that pregnancy warning labels on alcoholic beverages can raise awareness of the risks of drinking alcohol during pregnancy and prompt discussion of these risks (Wilkinson et al., 2009; SD1). Further to this, evidence from alcohol warnings and tobacco warning labels confirms that the label as part of a suite of measures can contribute to behaviour change (refer to section 3.2.3). Therefore, when combined with other public health initiatives, pregnancy warning labels can contribute to increased awareness of the risks of drinking alcohol while pregnant and encourage behaviour change. It can also contribute to the development of social norms to support this behaviour change. These will ultimately reduce the prevalence and/or severity of FASD.

### **3.5.2.2 The provision of adequate information relating to food to enable consumers to make informed choices**

The evidence available to FSANZ is that the pregnancy warning label required by the approved draft variation will ensure consistent, understandable and noticeable information on packaged alcoholic beverages to alert consumers about the risks of drinking alcohol during pregnancy and enable them to make an informed choice.

### **3.5.2.3 The prevention of misleading or deceptive conduct**

FSANZ has not identified any issues relevant to this matter.

### 3.5.3 Subsection 18(2) considerations

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

FSANZ has used the best available evidence to develop the mandatory pregnancy warning label including a literature review (SD1) and consumer testing (SD2).

- **the promotion of consistency between domestic and international food standards**

FSANZ has considered overseas regulations for pregnancy warning labels. A pictogram is also used in some overseas regulations. However, there is no consistency across food standards in other countries in the format or wording of a pregnancy warning label.

Current mandatory or voluntary pregnancy warnings in place in other countries have not been designed with a view to optimise the attention they receive (SD1). None of the 13 countries with pregnancy warning labels (refer to Attachment D) prescribe the particular combination of design elements included in the warning label for Australia and New Zealand. Based on the available evidence it is expected the Australia and New Zealand warning label will be more effective in achieving the primary objective stated in the DRIS (to provide a clear and easy to understand trigger to remind pregnant women to not drink alcohol) in the local context than labels used in other countries. Refer to further details regarding Article 2.7 of the TBT agreement at Attachment E.

FSANZ notes the Code does not prohibit the use of more than one pregnancy warning label on an alcoholic beverage container, provided the required warning label is displayed.

- **the desirability of an efficient and internationally competitive food industry**

FSANZ does not anticipate any significant impact on efficiency and international competition. FSANZ notified WTO members about the proposed warning label and considers it is consistent with obligations under the WTO GATT and TBT Agreement (refer to Attachment E).

- **the promotion of fair trading in food**

FSANZ has not identified any issues relevant to this matter.

- **any written policy guidelines formulated by the Forum on Food Regulation**

There are no specific policy guidelines formulated and notified by the Forum under paragraph 18(2)(e) of the FSANZ Act which apply to this proposal. However, FSANZ has had regard to policy advice provided by the Forum (refer to section 3.5.4 below).

### 3.5.4 Decision Regulation Impact Statement

The Forum provided FSANZ with a DRIS (Food Regulation Standing Committee, 2018) as policy advice that was assessed by OBPR as compliant in accordance with the Council of Australian Governments' RIS requirements. FSANZ has had regard to that policy advice as a relevant matter (as per subsection 18(2) of the FSANZ Act). OBPR exempted FSANZ from the need to undertake a formal RIS in relation to the tasks of this P1050 project.

### 3.5.5 Joint Food Standards Treaty Between Australia and New Zealand

FSANZ has also had regard to *The Agreement between the Government of Australia and the Government of New Zealand establishing a System for the Development of Joint Food Standards*.<sup>16</sup>

## 4 Transitional arrangements

### 4.1 Decision

FSANZ has decided on a two year transition period for the mandatory pregnancy warning label.

Additionally, prescribed alcoholic beverages<sup>17</sup> packaged and labelled before the end of the two year transition period may be sold after the transition period without having to display a pregnancy warning label.

### 4.2 Rationale for decision

Following assessment and consideration of submitter comments, FSANZ has decided on these transitional arrangements for the reasons outlined below.

The approach provides certainty and balances minimising costs for businesses with not unduly delaying exposure of the pregnancy warning label to consumers.

FSANZ considered a one year transition period favoured by public health submitters, however while this may mean consumers are exposed to the warning label sooner, a one year transition period would likely impose a greater cost burden on industry and may not be a realistic timeframe for companies to relabel multiple SKUs. A two year rather than a one year transition period increases the opportunity for industry to combine voluntary label changes and/or other legislative changes with the adoption of the pregnancy warning label, thereby decreasing costs. Alignment of transitional arrangements for any other mandatory changes to alcoholic beverage labels will be considered in the future.

The exemption for all alcoholic beverages packaged and labelled before the end of the transition period aims to reduce the need for re-labelling. This approach allows for alcoholic beverages with a slow market turnover or those which have been labelled but are intended for ageing/cellaring before sale. Such alcoholic beverages may include but are not limited to, top-shelf spirits and premium wines. FSANZ acknowledges concerns raised by government submitters about the challenges of enforcing the exemption. However, given the relatively fast market turnover of beer, RTDs, cider and most wine and spirits, most of these beverage types produced after gazettal of the new requirement are expected to be sold within two years. On that basis FSANZ expects only a relatively small proportion of beverages would not be required to display the pregnancy warning label after the end of the two year transition period. In relation to the wine market, the majority of wines have the vintage on the label. FSANZ considers it reasonable to not expect the small proportion of top-shelf spirits and premium wines which may remain in the market for some years to be relabelled (or over-stickered with a pregnancy warning label).

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<sup>16</sup> Agreement is available at <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/key-system-documents>.

<sup>17</sup> *Prescribed alcoholic beverage* is defined in the draft variation to the Code (refer to Attachment A).

FSANZ considered a range of possible alternate options for transitional arrangements including: a delayed variation commencement date to assist the wine industry with managing its seasonal harvest, shorter and longer transition periods, extended transition periods for businesses that have adopted the voluntary labelling scheme, and restricted and expanded stock in trade exemptions. Though considered, these options are not recommended on the basis such arrangements:

- may unnecessarily delay exposure of the warning label to consumers (e.g. a transition period of more than two years)
- are more complex than the approach taken, and may result in heightened confusion for industry and consumers (e.g. if businesses who adopted the voluntary labelling had a longer transition period; if only specified products were subject to the exemption)
- could be more difficult to enforce (e.g. if businesses who adopted the voluntary labelling had a longer transition period)
- as compared to the approach taken, do not provide significant additional benefit to industry (e.g. a delayed variation commencement date).

While the recommended approach was supported by some submitters to the CFS, FSANZ notes the divergent views between industry stakeholders, and public health and government stakeholders. FSANZ has considered these views, and has decided based on the reasons outlined above that the proposed approach in the CFS be maintained. Specific responses to submitter comments about the transition period are provided in Table 1.

## **5 Implementation**

Industry stakeholders have asked that any guidance on the implementation of the requirements for the pregnancy warning label be available at the time of gazettal of changes to the Code. FSANZ will discuss the development of guidance with the enforcement agencies. Should guidance be developed, FSANZ agrees it would be desirable for it to be available soon after gazettal to assist industry making label changes during the transition period.

FSANZ expects to make downloadable pregnancy warning label graphics available for use by industry.

### **5.1 Education**

It is recognised pregnancy warning labelling is intended to be part of a broader suite of measures aimed to raise awareness of the risks of drinking alcohol during pregnancy (refer to the DRIS (Food Regulation Standing Committee, 2018), section 3.2, Wilkinson et al., 2009). Both Australian and New Zealand public health agencies have a number of activities and action plans aimed at educating consumers about the risks of drinking alcohol during pregnancy and FASD (refer to section 2.5). It is expected public health agencies will incorporate reference to the pregnancy warning label in their education materials thereby drawing attention to the labelling requirement and linking the warning label message to broader education messages about not drinking during pregnancy and FASD prevention. FSANZ will focus on informing consumers, health professionals, FASD community support groups and the alcohol beverage sector, particularly smaller businesses, of the new labelling requirements. This will include webpages aimed at consumers and industry along with articles for health professional and industry communications including social media. FSANZ will work with peak industry organisations and community groups in providing information about the new labelling requirements to their members.

## 6 Monitoring and evaluation

It is good practice to monitor and evaluate the implementation of a change in labelling requirements in the Code. As labelling is part of a broader suite of activities, responsibility for certain aspects of monitoring and evaluation may extend beyond FSANZ's remit. Therefore, FSANZ will pursue options with the Food Regulation Standing Committee and other stakeholders during the transition period with a view to establishing a plan for monitoring and evaluation of the implementation of the pregnancy warning label.

Monitoring and evaluation could include assessing: the coverage of the label across the alcoholic beverage sector; compliance with the presentation of the warning label on beverage containers and packaging; the extent to which consumers notice the label and understand the warning; and changes in risk perceptions of alcohol and changes in alcohol consumption behaviour.

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## Attachments

- A. Approved draft variations to the *Australia New Zealand Food Standards Code*
- B. Explanatory Statement
- C. Draft variations to the Australia New Zealand Food Standards Code (Call for Submissions)
- D. Pregnancy warning labels in other countries
- E. The TBT Agreement
- F. Guidance for design labelling elements and Code requirements relevant to alcoholic beverages
- G. New Zealand and Australian legislation and guidance including alcoholic beverage definitions
- H. Supporting information for the consideration of costs and benefits

## Attachment A – Approved draft variations to the Australia New Zealand Food Standards Code



### Food Standards (Proposal P1050 – Pregnancy warning labels on alcoholic beverages) Variation

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The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by Delegate]

[Insert name and position of Delegate]  
Delegate of the Board of Food Standards Australia New Zealand

**Note:**

This variation will be published in the Commonwealth of Australia Gazette No. FSC **XX on XX Month 20XX**. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

## 1 Name

This instrument is the *Food Standards (Proposal P1050 – Pregnancy warning labels on alcoholic beverages) Variation*.

## 2 Variation to standards in the *Australia New Zealand Food Standards Code*

The Schedule varies Standards in the *Australia New Zealand Food Standards Code*.

## 3 Commencement

The variation commences on the date of gazettal.

## 4 Effect of the variations made by this instrument

- (1) Section 1.1.1—9 of Standard 1.1.1 does not apply to the variations made by this instrument.
- (2) During the transition period, a food product may be sold if the product complies with one of the following:
  - (a) the Code as in force without the variations made by this instrument; or
  - (b) the Code as amended by the variations made by this instrument.
- (3) A food product that was packaged and labelled before the end of the transition period may be sold after the transition period if the product complies with one of the following:
  - (a) the Code as in force without the variations made by this instrument; or
  - (b) the Code as amended by the variations made by this instrument.
- (4) For the purposes of this clause, the **transition period** means the period commencing on the variation's date of commencement and ending 24 months after the date of commencement.

### Schedule

#### Standard 1.1.2

- [1] **Standard 1.1.2** is varied by inserting in subsection 1.1.2—2(3) in alphabetical order

**individual unit** means a container that:

- (a) is an innermost package; and
- (b) contains a beverage with more than 1.15% alcohol by volume.

**pregnancy warning label** means either the pregnancy warning pictogram or the pregnancy warning mark.

**pregnancy warning mark** means the following image comprising

- (a) the pregnancy warning pictogram,
  - (b) the signal words "Health Warning" and
  - (c) the statement "Alcohol can cause lifelong harm to your baby",
- all within a border.



**pregnancy warning pictogram** means the following pictogram with the silhouette of a pregnant woman holding a wine glass within a circle with a strikethrough:



**prescribed alcoholic beverage** means a beverage that

- (a) has more than 1.15% alcohol by volume; and
- (b) either:

- (i) is for retail sale; or
- (ii) is sold as suitable for retail sale without any further processing, packaging or labelling; and
- (c) does not include a beverage that:
  - (i) is sold for retail sale; and
  - (ii) is packaged in the presence of the purchaser.

### Standard 1.2.1

[2] **Standard 1.2.1** is varied by

[2.1] omitting the Note to subsection 1.2.1—6(1), substituting

**Note 1** See section 1.2.1—9 for information requirements for food for sale that does not need to bear a label.

**Note 2** See Division 4 of Standard 2.7.1 for the requirements relating to a \*pregnancy warning label.

[2.2] omitting the Note to subsection 1.2.1—6(2), substituting

**Note 1** See also section 1.2.1—24

**Note 2** See Division 4 of Standard 2.7.1 for the requirements relating to a \*pregnancy warning label.

### Standard 2.7.1

[3] **Standard 2.7.1** is varied by

[3.1] inserting after Note 2 to Standard 2.7.1

## Division 1 Preliminary

[3.2] omitting the Note to section 2.7.1—2, substituting

**Note** In this Code (see section 1.1.2—2):

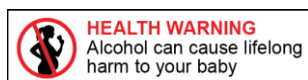
**individual unit** means a container that:

- (a) is an innermost package; and
- (b) contains a beverage with more than 1.15% alcohol by volume.

**pregnancy warning label** means either the pregnancy warning pictogram or the pregnancy warning mark.

**pregnancy warning mark** means the following image comprising

- (a) the pregnancy warning pictogram,
  - (b) the signal words “Health Warning” and
  - (c) the statement “Alcohol can cause lifelong harm to your baby”,
- all within a border.



**pregnancy warning pictogram** means the following pictogram with the silhouette of a pregnant woman holding a wine glass within a circle with a strikethrough:



**prescribed alcoholic beverage** means a beverage that:

- (a) has more than 1.15% alcohol by volume; and
- (b) either:
  - (i) is for retail sale; or



- (ii) is sold as suitable for retail sale without any further processing, packaging or labelling; and
- (c) does not include a beverage that:
  - (i) is sold for retail sale; and
  - (ii) is packaged in the presence of the purchaser

**standard drink**, for a beverage containing alcohol, means the amount that contains 10 grams of ethanol when measured at 20°C.

**size of type** means the measurement from the base to the top of a letter or numeral.

[3.3] inserting after section 2.7.1—2

## **Division 2 Requisite statements**

[3.4] inserting after section 2.7.1—4

## **Division 3 Restricted representations**

[3.5] inserting after section 2.7.1—7

## **Division 4 Pregnancy warning labels**

### **2.7.1—8 Requirement to display a pregnancy warning label**

- (1) A \*prescribed alcoholic beverage that has one layer of packaging must display a \*pregnancy warning label on its package.
- (2) A \*prescribed alcoholic beverage that has more than one layer of packaging must display a \*pregnancy warning label on:
  - (a) the outer package; and
  - (b) either:
    - (i) the \*individual unit; or
    - (ii) each \*individual unit—if the packaging includes more than one individual unit.
- (3) Subsection (2) does not require a \*pregnancy warning label to be on the outer package if a pregnancy warning label on an \*individual unit is clearly discernible and not obscured by the outer package.
- (4) Subsection (2) does not require a \*pregnancy warning label to be on the bladder within a box of a \*prescribed alcoholic beverage.

### **2.7.1—9 Pregnancy warning label for one layer of packaging**

- (1) A \*prescribed alcoholic beverage that:
  - (a) is required by subsection 2.7.1—8(1) to display a \*pregnancy warning label on its package; and
  - (b) is listed in Column 1 of the table to subsection (3):

must display the pregnancy warning label listed in Column 2 of that table on its package.
- (2) The pregnancy warning label required by subsection (1) must comply with any corresponding size requirements listed in Columns 3 and 4 of the table to subsection (3).
- (3) The table to this subsection is:

**Pregnancy warning label required**

<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<i>Prescribed alcoholic beverage</i>	<i>Pregnancy warning label to be displayed</i>	<i>Size of the *pregnancy warning pictogram or the pictogram of a *pregnancy warning mark</i>	<i>*Size of type of the signal words and the statement of a pregnancy warning mark</i>
A *prescribed alcoholic beverage with a volume not more than 200 ml.	The *pregnancy warning pictogram.	At least 8 mm diameter	Not applicable
A *prescribed alcoholic beverage with a volume more than 200 ml but not more than 800 ml.	The *pregnancy warning mark.	At least 6 mm diameter	At least 2.1 mm
A *prescribed alcoholic beverage with a volume more than 800 ml.	The *pregnancy warning mark.	At least 9 mm diameter	At least 2.8 mm

**2.7.1—10 Pregnancy warning label for an outer package**

- (1) A \*prescribed alcoholic beverage that:
  - (a) is required by paragraph 2.7.1—8(2)(a) to display a \*pregnancy warning label on its outer package; and
  - (b) is listed in Column 1 of the table to subsection (3);
 must display the pregnancy warning label listed in Column 2 of that table on its outer package.
- (2) The pregnancy warning label required by subsection (1) must comply with any corresponding size requirements listed in Columns 3 and 4 of the table to subsection (3).
- (3) The table to this subsection is:

**Pregnancy warning label required**

<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<i>Prescribed alcoholic beverage</i>	<i>Pregnancy warning label to be displayed</i>	<i>Size of the *pregnancy warning pictogram or the pictogram of a *pregnancy warning mark</i>	<i>*Size of type of the signal words and the statement of a pregnancy warning mark</i>
A *prescribed alcoholic beverage with: a volume not more than 200 ml; and packaging that includes only one *individual unit.	The *pregnancy warning pictogram.	At least 8 mm diameter	Not applicable
All other *prescribed alcoholic beverages.	The *pregnancy warning mark.	At least 11 mm diameter	At least 3.5 mm

**2.7.1—11 Pregnancy warning label for an individual unit**

- (1) A \*prescribed alcoholic beverage that:
  - (a) is required by paragraph 2.7.1—8(2)(b) to display a \*pregnancy warning label on one or more individual units; and
  - (b) is an individual unit that is listed in Column 1 of the table to subsection (3);
 must display the pregnancy warning label listed in Column 2 of that table on each

such individual unit.

- (2) The pregnancy warning label required by subsection (1) must comply with any corresponding size requirements listed in Columns 3 and 4 of the table to subsection (3).
- (3) The table to this subsection is:

**Pregnancy warning label required**

<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<i>Individual unit</i>	<i>Pregnancy warning label to be displayed</i>	<i>Size of the *pregnancy warning pictogram or the pictogram of a *pregnancy warning mark</i>	<i>*Size of type of the signal words and the statement of a pregnancy warning mark</i>
An *individual unit with a volume not more than 200 ml.	The *pregnancy warning pictogram.	At least 8 mm diameter	Not applicable
An *individual unit with a volume more than 200 ml but not more than 800 ml.	The *pregnancy warning mark.	At least 6 mm diameter	At least 2.1 mm
An *individual unit with a volume more than 800 ml.	The *pregnancy warning mark.	At least 9 mm diameter	At least 2.8 mm

### **2.7.1—12 Required form for pregnancy warning labels**

- (1) A \*pregnancy warning label required by this Division to be displayed must comply with this section.
- (2) The background of the \*pregnancy warning label must be in the colour white.
- (3) The circle and strikethrough of the \*pregnancy warning pictogram must be in the colour red.
- (4) The silhouette of a pregnant woman on the \*pregnancy warning pictogram must be in the colour black.
- (5) The signal words of the \*pregnancy warning mark must be:
  - (a) in the colour red; and
  - (b) in bold font; and
  - (c) in a sans-serif typeface; and
  - (d) in capital letters; and
  - (e) in English.
- (6) The statement of the \*pregnancy warning mark must be:
  - (a) in the colour black; and
  - (b) in a sans-serif typeface; and
  - (c) in sentence case; and
  - (d) in English.
- (7) The border of the \*pregnancy warning mark must be in the colour black.
- (8) The \*pregnancy warning mark must be displayed on the package with a clear space that:
  - (a) surrounds the outside of the border of the pregnancy warning mark; and
  - (b) is at least 3mm in width.
- (9) The \*pregnancy warning label must be displayed as a whole and without modification.

## **Attachment B – Explanatory Statement**

### **1. Authority**

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 2 of Part 3 of the FSANZ Act specifies that the Authority may prepare a proposal for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering a proposal for the development or variation of food regulatory measures.

FSANZ prepared P1050 to consider mandatory pregnancy warning labelling on packaged alcoholic beverages. The Authority considered the proposal in accordance with Division 2 of Part 3 and has approved a draft variation to the Code.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunseting under the *Legislation Act 2003*.

### **2. Purpose**

The Authority has approved a draft variation to:

- amend Standards 1.1.2, 1.2.1 and 2.7.1 of the Code to require pregnancy warning labels in the form of a pictogram or a pictogram with associated wording, on packaged alcoholic beverages for retail sale or sold as suitable for retail sale with more than 1.15% alcohol by volume; and
- amend Standard 2.7.1 to prescribe the form, legibility and design of pregnancy warning labels for different packages of alcoholic beverages.

### **3. Documents incorporated by reference**

The variations to food regulatory measures do not incorporate any documents by reference.

### **4. Consultation**

In accordance with the procedure in Division 2 of Part 3 of the FSANZ Act, the Authority's consideration of P1050 included one round of public consultation following an assessment and the preparation of a draft variation and associated reports. Submissions were called for on 4 October 2019 for a three week submission period.

The Office of Best Practice Regulation (OBPR) exempted the Authority from a requirement to undertake a Regulation Impact Statement as the potential regulatory change had already been considered through the Decision Regulation Impact Statement prepared by the Food Regulation Standing Committee.

## 5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

## 6. Variation

**Item [1]** varies Standard 1.1.2.

Item [1] varies subsection 1.1.2—2(3) by inserting in alphabetical order new definitions for *individual unit*, *pregnancy warning label*, *pregnancy warning mark*, *pregnancy warning pictogram* and *prescribed alcoholic beverage*:

- An *individual unit* means a container that: is an innermost package; and contains a beverage with more than 1.15% alcohol by volume.
- A *pregnancy warning label* is defined as being either the specified *pregnancy warning pictogram*, or the specified *pregnancy warning mark*.
- *Prescribed alcoholic beverage* means a beverage that has more than 1.15% alcohol by volume, and is either for retail sale or sold as suitable for retail sale (without any further processing, packaging or labelling); but does not include a beverage sold for retail sale that is packaged in the presence of the purchaser (this means, for example, wine or beer served in a glass in a restaurant or bar is not required to display a pregnancy warning label). Retail sale includes, for instance, prescribed alcoholic beverages that are: made and packaged on the premises from which they offered for retail sale; delivered packaged and ready for consumption at the express order of the retail purchaser; sold at a fund raising event; displayed in an assisted service display cabinet; sold from a vending machine; or sold at retail in a hamper.

These new definitions apply to the new pregnancy warning label requirements in Division 4 of Standard 2.7.1 (see item [3.5] below).

**Item [2]** varies Standard 1.2.1.

As explained below, Item [2] inserts Notes into Standard 1.2.1. No variations are made to Division 4 of Standard 1.2.1 as the other sales to which that Division applies are not required to display a pregnancy warning label. Division 5 of Standard 1.2.1 applies to pregnancy warning labels because a pregnancy warning label is a 'label' on a package of food (see the definition of 'label' in subsection 1.1.2—2(3) of the Code). The general legibility requirements in Division 6 of Standard 1.2.1 also apply to pregnancy warning labels, however, additional specific legibility requirements relating to pregnancy warning labels are set out in Division 4 of Standard 2.7.1 (see item [3.5] below).

**Item [2.1]** omits the Note to subsection 1.2.1—6(1) and substitutes it with two Notes: 'Note 1' (consisting of the existing Note) and a new 'Note 2' referring to the new pregnancy warning label requirements in Division 4 of Standard 2.7.1. Note 2 advises that requirements relating to pregnancy warning labels are set out separately in that Division (see item [3.5] below).

**Item [2.2]** omits the Note to subsection 1.2.1—6(2) and substitutes it with two Notes: 'Note 1' (consisting of the existing Note) and a new 'Note 2' referring to the new pregnancy warning label requirements in Division 4 of Standard 2.7.1. Note 2 advises that requirements relating to pregnancy warning labels, where there is more than one layer of packaging of a prescribed alcoholic beverage, are set out separately in that Division (see item [3.5] below).

**Item [3]** varies Standard 2.7.1.

**Item [3.1]** inserts a new heading 'Division 1 - Preliminary' after Note 2 of Standard 2.7.1.

Division 1 contains section 2.7.1—2 – Definitions.

**Item [3.2]** omits the Note to subsection 2.7.1—2 and substitutes it with a new Note. The new Note restates the reference to the *standard drink* definition and adds references to the definitions of the following terms in subsection 1.1.2—2(3):

- individual unit;
- pregnancy warning label;
- pregnancy warning mark;
- pregnancy warning pictogram;
- prescribed alcoholic beverage; and
- size of type.

**Item [3.3]** inserts a new heading 'Division 2 – Requisite statements' after section 2.7.1—2. Division 2 contains existing sections 2.7.1—3 and 2.7.1—4, which set out the labelling provisions for the statement of alcohol content and the statement of the number of standard drinks respectively.

**Item [3.4]** inserts a new heading 'Division 3 – Restricted representations' after section 2.7.1—4. Division 3 contains existing sections 2.7.1—5, 2.7.1—6 and 2.7.1—7, which restrict representations relating to 'low alcohol', 'non-intoxicating' and 'non-alcoholic' respectively.

**Item [3.5]** inserts a new Division after subsection 2.7.1— 7.

The new Division is 'Division 4 – Pregnancy warning labels' and contains new sections 2.7.1—8 to 2.7.1—12. The new Division and sections set out the new requirements for pregnancy warning labels. The effect of the new sections is as follows:

**Section 2.7.1—8** imposes a requirement for a package of a prescribed alcoholic beverage to display a pregnancy warning label in specified circumstances.

Subsection 2.7.1—8(1) requires a prescribed alcoholic beverage that has one layer of packaging to display a pregnancy warning label on its package. For example, for a bottle containing wine or spirits (the wine or spirits being the beverage, and the bottle being the single layer of packaging), the bottle is required to display a pregnancy warning label.

Subsection 2.7.1—8(2) requires a prescribed alcoholic beverage that has more than one layer of packaging to display a pregnancy warning label on the outer package (paragraph 2.7.1—8(2)(a)); and either on the individual unit, or each individual unit if the packaging includes more than one individual unit (paragraph 2.7.1—8(2)(b)). The outer package is the most outer layer of packaging for retail sale. For example, a pregnancy warning label must be displayed:

- for a box containing a bottle of wine, on the box and the bottle of wine.
- for a carton containing multiple bottles of wine, on the carton and on each bottle of wine.
- for a pack containing six bottles of beer, on the pack and on each bottle of beer.

Any package between the outer package and the individual unit(s) is not required to display a pregnancy warning label. For example, tissue paper between the outer box and individual unit(s) is not required to display a pregnancy warning label.

Subsection 2.7.1—8(3) exempts the outer package from the requirement to display a pregnancy warning label if this label can be clearly seen on an individual unit and is not

obscured by the outer package (for example, where there is clear wrapping around a bottle of wine, or where the pregnancy warning label on a bottle of beer in a 6-pack can be seen).

Subsection 2.7.1—8(4) exempts the bladder within a box of a prescribed alcoholic beverage from the requirement to display a pregnancy warning label (for example, the bladder within a cask of wine will not be required to display a pregnancy warning label).

**Section 2.7.1—9** sets out how the requirement imposed by subsection 2.7.1—8(1) will apply to the package of a prescribed alcoholic beverage with one layer of packaging.

Subsection 2.7.1—9(1) provides that a prescribed alcoholic beverage required by subsection 2.7.1—8(1) to display a pregnancy warning label on its package, and which is listed in Column 1 of the table to subsection 2.7.1—9(3), must display the pregnancy warning label listed in Column 2 of that table. This requires:

- a pregnancy warning pictogram to be displayed on the package of a prescribed alcoholic beverage with a volume not more than 200 ml.
- a pregnancy warning mark to be displayed on the package of a prescribed alcoholic beverage with a volume more than 200 ml.

Subsection 2.7.1—9(2) provides that the pregnancy warning label required by subsection 2.7.1—9(1) must comply with any corresponding size requirements listed in columns 3 and 4 of the table to subsection 2.7.1—9(3). The size requirements that apply (as set out in the table to the subsection) depend on the volume of the prescribed alcoholic beverage.

The table to subsection 2.7.1—9(3) prescribes the minimum of: the diameter size (in millimetres) of the pictogram to be used (for both a pregnancy warning pictogram and for the pictogram in a pregnancy warning mark); and where applicable—the size of type of the signal words and statement of a pregnancy warning mark (in millimetres).

**Section 2.7.1—10** sets out how the requirement imposed by paragraph 2.7.1—8(2)(a) will apply to the outer package of a prescribed alcoholic beverage.

Subsection 2.7.1—10(1) provides that, a prescribed alcoholic beverage required by paragraph 2.7.1—8(2)(a) to display a pregnancy warning label on its outer package, and which is listed in Column 1 of the table to subsection 2.7.1—10(3), must display the pregnancy warning label listed in Column 2 of that table. This requires:

- A pregnancy warning pictogram to be displayed on the outer package of a prescribed alcoholic beverage with a volume not more than 200 ml and packaging that only contains one individual unit. This means, for example, an outer box which contains a singular bottle of spirits which has a volume not more than 200 ml.
- A pregnancy warning mark to be displayed on the outer package for all other prescribed alcoholic beverages. This means the pregnancy warning mark is required on the outer package of all other prescribed alcoholic beverages with volumes greater than 200 ml (regardless of the number of individual units in the outer package); and for prescribed alcoholic beverages with: volumes not more than 200 ml; and packaging that contains more than one individual unit.

Subsection 2.7.1—10(2) provides that, the pregnancy warning label required by subsection 2.7.1—10(1) must comply with any corresponding size requirements listed in columns 3 and 4 of the table to subsection 2.7.1—10(3). Different size requirements apply for the pregnancy warning pictogram and pregnancy warning mark.

The table to subsection 2.7.1—10(3) prescribes the minimum of: the diameter size (in millimetres) of the pictogram to be used (for both a pregnancy warning pictogram and for the pictogram in a pregnancy warning mark); and where applicable—the size of type of the signal words and statement of a pregnancy warning mark (in millimetres).

**Subsection 2.7.1—11** sets out how the requirement imposed by paragraph 2.7.1—8(2)(b) will apply to an individual unit.

Subsection 2.7.1—11(1) provides that a prescribed alcoholic beverage required by paragraph 2.7.1—8(2)(b) to display a pregnancy warning label on an individual unit, and has an individual unit that is listed in Column 1 of the table to subsection 2.7.1—11(3), must display the pregnancy warning label listed in Column 2 of that table on each of those individual units. The liquid volume of the individual unit will determine which pregnancy warning label must be displayed on that unit. That is:

- A pregnancy warning pictogram must be displayed on an individual unit if the individual unit has a liquid volume not more than 200 ml.
- A pregnancy warning mark must be displayed on an individual unit if the individual unit has a liquid volume more than 200 ml.

For example:

- for two 100 ml bottles of liqueur contained in a box, a pregnancy warning pictogram must be displayed on each 100 ml bottle of liqueur
- for a 1L bottle of spirits and a 100 ml bottle of liqueur contained in a box, a pregnancy warning mark must be displayed on the 1L bottle and a pregnancy warning pictogram must be displayed on the 100 ml bottle;
- a pregnancy warning mark must be displayed:
  - for six 750ml bottles of wine contained in a carton, on each bottle of wine.
  - for six 375ml cans of beer contained in a pack, on each can of beer.

Subsection 2.7.1—11(2) provides that, the pregnancy warning label required by subsection 2.7.1—11(1) must comply with any corresponding size requirements listed in columns 3 and 4 of the table to subsection 2.7.1—11(3). The size requirements that apply depend on the liquid volume of the individual unit.

**Section 2.7.1—12** sets out the required form for pregnancy warning labels.

For a pregnancy warning label (pregnancy warning pictogram or pregnancy warning mark), the section prescribes the background colour of the label.

For the pregnancy warning pictogram, the section prescribes the colour of the circle and strikethrough and the silhouette of a pregnant women. This applies to the pictogram when used alone, or when used in the pregnancy warning mark.

For the pregnancy warning mark, the section prescribes the format of the signal words and the statement (for example, colour, typography, English language), as well as the colour of the border of the mark. The section also prescribes the size of clear space (in millimetres) surrounding the outside border of the pregnancy warning mark.

The section also prescribes that a pregnancy warning label must be displayed as a whole and without any modification.



### ***Transitional arrangements***

The above variations will commence or take effect on the date of gazettal. See clause 3 of the instrument of variation.

The stock-in-trade exemption provided by section 1.1.1—9 of Standard 1.1.1 will not apply to any of the above variations. See clause 4 of the instrument of variation.

Clause 4 provides two transitional arrangements. First, there is a general transitional arrangement where during a two year transition period commencing on the date of gazettal, a prescribed alcoholic beverage may be sold if the beverage complies with either the Code as in force without the amendments made by the draft variation; or the Code as amended by the draft variation. Second, there is a specific transitional arrangement where prescribed alcoholic beverages packaged and labelled *before* the end of the transition period may be sold after the transition period without having to display a pregnancy warning label. The intent of these transitional arrangements is to assist in minimising the costs of complying with the draft variation for industry while not unduly delaying exposure of the pregnancy warning label to consumers.

## Attachment C – Draft variations to the Australia New Zealand Food Standards Code (call for submissions)



### Food Standards (Proposal P1050 – Pregnancy warning labels on alcoholic beverages) Variation

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The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by Delegate]

[Insert name and position of Delegate]  
Delegate of the Board of Food Standards Australia New Zealand

**Note:**

This variation will be published in the Commonwealth of Australia Gazette No. FSC **XX on XX Month 20XX**. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

## 1 Name

This instrument is the *Food Standards (Proposal P1050 – Pregnancy warning labels on alcoholic beverages) Variation*.

## 2 Variation to standards in the *Australia New Zealand Food Standards Code*

The Schedule varies Standards in the *Australia New Zealand Food Standards Code*.

## 3 Commencement

The variation commences on the date of gazettal.

## 4 Effect of the variations made by this instrument

- (1) Section 1.1.1—9 of Standard 1.1.1 does not apply to the variations made by this instrument.
- (2) During the transition period, a food product may be sold if the product complies with one of the following:
  - (a) the Code as in force without the variations made by this instrument; or
  - (b) the Code as amended by the variations made by this instrument.
- (3) A food product that was packaged and labelled before the end of the transition period may be sold after the transition period if the product complies with one of the following:
  - (a) the Code as in force without the variations made by this instrument; or
  - (b) the Code as amended by the variations made by this instrument.
- (4) For the purposes of this clause, the **transition period** means the period commencing on the variation's date of commencement and ending 24 months after the date of commencement.

### Schedule

#### Standard 1.1.2

[1] **Standard 1.1.2** is varied by

[1.1] omitting the definition of individual portion pack from subsection 1.1.2—2(3), substituting

***individual portion pack***—see subsection 1.2.1—6(3) and subsection 2.7.1—9(5).

[1.2] inserting in subsection 1.1.2—2(3) in alphabetical order

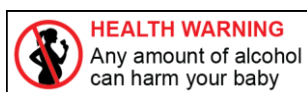
***pregnancy warning label*** means either the pregnancy warning pictogram or the pregnancy warning mark.

***pregnancy warning pictogram*** means the following pictogram:



***pregnancy warning mark*** means the following image comprising

- (d) the pictogram,
  - (e) the signal words “Health Warning” and
  - (f) the statement “Any amount of alcohol can harm your baby”,
- all within a border.



***prescribed alcoholic beverage*** means a beverage that has more than 1.15%

alcohol by volume.

### Standard 1.2.1

[2] **Standard 1.2.1** is varied by

[2.1] by omitting the Note to subsection 1.2.1—6(1), substituting

**Note 1** See section 1.2.1—9 for information requirements for food for sale that does not need to bear a label.

**Note 2** See Division 4 of Standard 2.7.1 for the requirements relating to a \*pregnancy warning label.

[2.2] by omitting the Note to subsection 1.2.1—6(2), substituting

**Note 1** See also section 1.2.1—24

**Note 2** See Division 4 of Standard 2.7.1 for the requirements relating to a \*pregnancy warning label.

[2.3] by inserting after subsection 1.2.1—6(3)

**Note** See Division 4 of Standard 2.7.1 for the requirements relating to a \*pregnancy warning label.

[2.4] by inserting after subsection 1.2.1—12(1)

**Note** See Division 4 of Standard 2.7.1 for the requirements relating to a \*pregnancy warning label.

### Standard 2.7.1

[3] **Standard 2.7.1** is varied by

[3.1] inserting after Note 2 to Standard 2.7.1

## Division 1 Preliminary

[3.2] omitting the Note to section 2.7.1—2, substituting

**Note** In this Code (see section 1.1.2—2):

**caterer** means a person, establishment or institution (for example, a catering establishment, a restaurant, a canteen, a school, or a hospital) which handles or offers food for immediate consumption.

**pregnancy warning label** means either the pregnancy warning pictogram or the pregnancy warning mark.

**pregnancy warning pictogram** means the following pictogram:

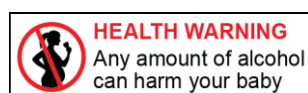


**pregnancy warning mark** means the following image comprising

(d) the pictogram,

(e) the signal words “Health Warning” and

(f) the statement “Any amount of alcohol can harm your baby”,  
all within a border.



**prescribed alcoholic beverage** means a beverage that has more than 1.15% alcohol by volume.

**standard drink**, for a beverage containing alcohol, means the amount that contains 10 grams of ethanol when measured at 20°C.

[3.3] inserting after section 2.7.1—2

## Division 2 Requisite statements

[3.4] inserting after section 2.7.1—4

## Division 3 Restricted representations

[3.5] inserting after section 2.7.1—7

## Division 4 Pregnancy warning labels

### 2.7.1—8 Requirement for a pregnancy warning label

- (1) The package of a \*prescribed alcoholic beverage must display a \*pregnancy warning label if the beverage:
  - (a) is for retail sale; or
  - (b) is sold to a \*caterer; or
  - (c) is sold as suitable for retail sale without any further processing, packaging or labelling.
- (2) Subsection (1) does not apply to a \*prescribed alcoholic beverage that:
  - (a) is sold for retail sale; and
  - (b) is packaged in the presence of the purchaser.

### 2.7.1—9 Requirements for pregnancy warning labels on layers of packaging

- (1) If subsection 2.7.1—8(1) requires a \*pregnancy warning label to be displayed on a package, the pregnancy warning label must be:
  - (a) on the package; or
  - (b) if there is more than 1 layer of packaging—on each layer of packaging.
- (2) Subsection (1) does not require a \*pregnancy warning label to be located on outer packaging if a pregnancy warning label on the inner packaging is clearly discernible through the outer packaging.
- (3) Subsection (1) does not require a \*pregnancy warning label to be located on the bladder within a box of a \*prescribed alcoholic beverage.
- (4) Subsection (1) does not require a \*pregnancy warning label to be located on outer package of a prescribed alcoholic beverage that is sold to a \*caterer if the beverage has more than 1 layer of packaging.
- (5) If a package of a \*prescribed alcoholic beverage required by subsection 2.7.1—8(1) to display a \*pregnancy warning label contains individual packages for servings that are:
  - (a) intended to be used separately (*individual portion packs*); and
  - (b) not designed for individual salethen a pregnancy warning label must also be displayed on each individual portion pack.
- (6) To avoid doubt, subsection (1) does not require a \*pregnancy warning label to be located on the package of a \*prescribed alcoholic beverage that contains individual portion packs if a pregnancy warning label on an individual portion pack is clearly discernible through that package.

### 2.7.1—10 Compliance with a requirement for a pregnancy warning label

- (1) If a provision of this Division requires a \*pregnancy warning label to be displayed on a package or layer of packaging listed in Column 1 of the following table, the pregnancy warning label that must be displayed on that package or packaging is the pregnancy warning label listed in Column 2 of that table.

**The pregnancy warning label to be displayed**

<b>Column 1</b>	<b>Column 2</b>
<i>Package or packaging</i>	<i>Pregnancy warning label</i>
A package (including each layer of packaging) of a *prescribed alcoholic beverage with a volume of ≤ 200 ml.	The *pregnancy warning pictogram.
A package (including each layer of packaging) of a prescribed alcoholic beverage with a volume of >200 ml.	The *pregnancy warning mark.
1. A package (including each layer of packaging) of a prescribed alcoholic beverage that contains individual portion packs. 2. To avoid doubt, a reference to a package or packaging in item 1 does not include an individual portion pack.	The pregnancy warning mark.

- (2) If subsection 2.7.1—9(5) requires a \*pregnancy warning label to be displayed on an \*individual portion pack listed in Column 1 of the following table, the pregnancy warning label that must be displayed on that individual portion pack is the pregnancy warning label listed in Column 2 of that table.

**The pregnancy warning label to be displayed**

<b>Column 1</b>	<b>Column 2</b>
<i>Individual Portion Pack</i>	<i>Pregnancy warning label</i>
An *individual portion pack with a volume of ≤ 200 ml.	The *pregnancy warning pictogram.
An individual portion pack with a volume of > 200 ml.	The *pregnancy warning mark.

- (3) If a provision of this Division requires a \*pregnancy warning label to be displayed, the pregnancy warning label must be displayed as a whole and without modification.

**2.7.1—11 Legibility requirements for pregnancy warning labels**

- (1) If a provision of this Division requires a \*pregnancy warning label to be displayed on a package or layer of packaging listed in Column 1 of the following table, the pregnancy warning label must comply with any corresponding legibility requirements listed in Columns 2, 3 and 4 of that table.

**Legibility requirements for pregnancy warning labels**

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

- (2) If subsection 2.7.1—9(5) requires a \*pregnancy warning label to be displayed on an \*individual portion pack listed in Column 1 of the following table, the pregnancy warning label must comply with any corresponding legibility requirements listed in Columns 2, 3 and 4 of that table.

### Legibility requirements for pregnancy warning labels

<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<i>Individual Portion Pack</i>	<i>Size of the *pregnancy warning pictogram or the pictogram of a *pregnancy warning mark</i>	<i>Size of signal words and statement of a pregnancy warning mark</i>	<i>Size of clear space outside a pregnancy warning mark</i>
An *individual portion pack with a volume of ≤ 200 ml.	At least 8 mm diameter	Not applicable	Not applicable
An individual portion pack with a volume of > 200 ml and ≤ 800 ml.	At least 6 mm diameter	At least 6 point (2.1 mm)	At least 3 mm
An individual portion pack with a volume of > 800 ml.	At least 9 mm diameter	At least 8 point (2.8 mm)	At least 3 mm

#### 2.7.1—12 Required form for pregnancy warning labels

- (1) The circle and strikethrough of:
  - (a) the \*pregnancy warning pictogram; and
  - (b) the pictogram of a \*pregnancy warning mark;
 must be printed in the colour known as Pantone 485.
- (2) The silhouette of a pregnant woman on:
  - (a) the \*pregnancy warning pictogram; and
  - (b) the pictogram of a \*pregnancy warning mark;
 must be printed in the colour black.
- (3) The background of:
  - (a) the \*pregnancy warning pictogram; and
  - (b) the pictogram of a \*pregnancy warning mark;
 must be printed in the colour white.
- (4) The signal words of a \*pregnancy warning mark must be printed:
  - (a) in the colour known as Pantone 485; and
  - (b) in bold font; and
  - (c) in a sans-serif typeface; and
  - (d) in capital letters; and
  - (e) in English.
- (5) The statement of a \*pregnancy warning mark must be printed:
  - (a) in the colour black; and
  - (b) in a sans-serif typeface; and
  - (c) in sentence case; and
  - (d) in English.
- (6) A \*pregnancy warning mark must be printed with:
  - (a) the border in the colour black; and
  - (b) the background within the border in the colour white.



## Attachment D – Pregnancy warning labels in other countries

Table D1 presents information about the requirements for mandatory pregnancy warning labels in 11 countries (developed from information provided by the International Alliance for Responsible Drinking as at December 2019 (IARD, 2019a) and the regulations for these countries). Of the 11 countries that mandate pregnancy warning labels on alcoholic beverages:

- five require the label on beverages with between 1 and 1.5% ABV or more (France, Republic of Korea, Moldova, Turkmenistan, Indonesia)
- two require the warning label on beverages with 0.5% ABV or more (USA, Lithuania (with 1.2% for distilled beverages in Lithuania))
- one requires the label on alcoholic beverages higher than 6.0% ABV (Mexico)
- South Africa requires beverages to display at least one of seven warnings (including one about pregnancy) determined by product type rather than % ABV except for beer (other than traditional African beer), ale, cider and stout which have to display the label if they are more than 1% ABV
- requirements relating to % ABV for the remaining two countries are unknown (Russian Federation, Turkey).

Of the 11 countries with mandatory pregnancy warning labels, several have requirements for the size of the label. For example, the USA specifies minimum size for different volumes of beverage container (refer to Table D1). In South Africa, an amendment to the health warning regulations to require a warning statement to be one eighth of the total size of the container<sup>18</sup> is due to come into effect on 22 December 2020 (South African Wine Industry Information and Systems (SAWIS), 2018a). The requirements in Turkey set out different label sizes for a number of different packaging volumes. For example, within a specified box size, the pictogram has to be at least 17 mm in diameter for beverage volumes  $\geq 500\text{ml}$  and  $\leq 1$  litre and 14 mm diameter for volumes  $\geq 350$  ml and less than 500 ml. Box heights need to be at least 11 mm for beverage volumes  $\geq 350$  ml and less than 500 ml and 14 mm for volumes  $\geq 500$  ml and less than 700 ml. In Turkmenistan, the warning statement must take up 20% or more of the 'area', however, it is not clear whether this is the area of the label or the container. The requirements in Mexico specify a minimum pictogram size of 10 mm diameter for beverage volumes over 500 ml (or 7 mm if three pictograms are presented together), and for beverage volumes up to 500 ml, a minimum diameter of 5 mm (or 3.5 mm if three pictograms are presented together).

Currently in France, the pictogram must be presented in the same field of view as the information about alcohol concentration with no requirements for size and colour. However, new mandatory criteria aimed to improve readability and visibility of the pictogram are being considered (e.g. red pictogram of 14 mm in diameter) (Meiningers Wine Business International, 2019).

Most countries require the warning label to be presented in a contrasting colour to the background colour. South Africa requires the text to be in black on a white background. Turkey requires the colour red in the pictogram.

In Ireland, a public consultation seeking expert research on the effectiveness of certain health warnings (including a pregnancy warning) and other alcohol labelling information closed mid-October 2019 (Food Safety Authority of Ireland, 2019). As set out in the Irish

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<sup>18</sup> Requirement in South Africa: *A health warning must be one eighth of the total size of the container (not label). "Container" is now defined to include "any package, box, bottle, can or packet, in which an alcoholic beverage is sold or offered for sale". Thus, outer packaging will also be affected. All 7 warnings must be rotated with equal regularity, on each product line, within a 36 month cycle.*

*Public Health (Alcohol) Act 2018* (Government of Ireland, 2018), the Minister may prescribe the form of a warning statement including its size and colour, and the size, colour and font type of the printed material on the warning.

According to the IARD (2019a), there are two countries that have a voluntary scheme for pregnancy warning labelling in addition to Australia and New Zealand (Japan, United Kingdom). The voluntary statement used in Japan is *Drinking alcohol during pregnancy or nursing may adversely affect the development of your fetus or child* (to be displayed in an easy to read location using uniform Japanese font, at least 6 pts in size). In the United Kingdom, the Department of Health recommends the message: *It is safest not to drink alcohol when pregnant*, or a symbol to that effect.

In the 2018 Global Status Report on Alcohol and Health (World Health Organization, 2018a), the World Health Organization (WHO) reports that of 164 countries responding to a 2016 survey, 47 require warning labels on bottles or containers of alcoholic beverages. Of these, 27 countries are reported to have a legal requirement for a pregnancy health warning label, however, details of the requirements are not available (World Health Organization, 2018b). In addition to 8 of the 11 countries listed in Table D1, the WHO reports the following countries also have mandatory requirements for a pregnancy health warning label: Albania, Belarus, Columbia, Equatorial Guinea, Guinea, Israel, Kenya, Lebanon, Lesotho, Panama, Peru, Philippines, Poland, Portugal, Sweden, Tajikistan, the former Yugoslav republic of Macedonia (the Republic of North Macedonia), Uzbekistan and Zimbabwe. While the IARD reports Indonesia, Moldova and the Russian Federation have mandatory requirements for pregnancy warning labelling, the WHO reports the opposite.


In 2001, the Canadian Parliament voted in favour of a pregnancy warning label (*Drinking alcohol during pregnancy can cause birth defects*) to be on alcoholic beverage containers, however, this has not been implemented (Canadian House of Commons, 2001). Nonetheless, there are a number of initiatives involving both labelling and information being displayed in licensed establishments in various parts of Canada. There is an ongoing project involving warning statements on alcoholic beverages (via the use of self-adhesive labels) in the Yukon. The fluorescent orange self-adhesive labels measure 3.5 cm by 2.2 cm and display the statement **WARNING, DRINKING ALCOHOL DURING PREGNANCY CAN CAUSE BIRTH DEFECTS** and a French translation<sup>19</sup>. In Ontario, a health warning about the consumption of alcohol during pregnancy is required to be displayed in specified licensed establishments<sup>20</sup>. The required warning statement is *WARNING: Drinking alcohol during pregnancy can cause birth defects and brain damage to your baby*. Similarly, warning statements are also required to be displayed in specified licensed establishments in certain areas of British Columbia (British Columbia Ministry of Health and Centre of Excellence for Women's Health, 2014). Municipal governments are able to pass by-laws for warning statements about drinking during pregnancy. Examples of statements include: *Healthy Communities Support Women And Their Partners To Avoid Alcohol During Pregnancy*; **FETAL ALCOHOL SPECTRUM DISORDER WARNING – DRINKING ALCOHOLIC BEVERAGES DURING PREGNANCY CAN CAUSE BIRTH DEFECTS**. The Canadian Food Inspection Agency reports voluntary use of the warning statement mandated in the USA is acceptable in Canada (Canadian Food Inspection Agency, 2019).

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<sup>19</sup> Yukon Liquor Corporation December, personal communication, 2018

<sup>20</sup> Requirements are in the Ontario Liquor Licence Act 1990  
<https://www.ontario.ca/laws/regulation/900718>

**Table D1: Mandatory labelling requirements in other countries about the risk of drinking alcohol during pregnancy**  
(adapted from information provided by the IARD, 2019)

Country	Requirements for mandated pregnancy warning label	Authority
France	<p>Labels of beverages of above 1.2% ABV must include either the text <i>Consumption of alcohol beverages during pregnancy, even in small amounts, can have serious consequences for the child's health</i> OR a pictogram to that effect.</p>  <p>The health warning must appear in the same visual field as the mandatory alcohol strength by volume, showing a contrast in colour with the label background to be visible, readable, understandable and indelible.</p>	<p>Order of 2 October 2006 on implementation of Law 2005-102 Public Health Code Article L. 3322-2</p> <p>(European centre for monitoring alcohol marketing, 2018)</p>
Indonesia	<p>Labels of alcohol beverages with 1% ABV or more must state <i>Alcohol beverage and bear the warning ages under 21 and pregnant women are prohibited to drink</i> in Indonesian</p>	<p>Ministry of Trade Regulation 15/M-DAG/Per/3/2006</p> <p>(Government of Indonesia, 2006)</p>
Republic of Korea	<p>Labels of beverages of 1% ABV or higher must include one of three warnings: <i>Drinking during pregnancy increases the risk for congenital anomaly. Alcohol is [a] carcinogen, so excessive drinking causes liver cancer, gastric adenocarcinoma and so on. Drinking during pregnancy, underage drinking, and excessive drinking cause congenital anomaly, brain development disruptions and cancer, respectively. Drinking during pregnancy increase[s] the risk for congenital anomaly, Excessive drinking cause[s] stroke, memory loss and dementia.</i></p>	<p>National Health Promotion Act: Enforcement Decree of the National Health Promotion Act</p> <p>Ministry of Health and Welfare Notice No. 2016-488</p> <p>Administrative Notice of Proposed Partial Amendment to Notification on Phrase of Warning against Smoking and Excessive Drinking, etc.</p>
Lithuania	<p>Labels of distilled beverages of 1.2% ABV or higher and fermented beverages of 0.5% or higher are required to include a pictogram warning of the potential effects of drinking alcohol during pregnancy.</p>	<p>Alcohol Control Law Article 9</p> <p>(Republic of Lithuania, 1995)</p>
Mexico	<p>Labels of alcohol beverages of higher than 6.0% ABV: Of three pictogram warnings (against consumption by minors aged under 18 and by pregnant women and against driving under the influence of alcohol), either all three must be included simultaneously, or a single one may be included in which case the pictogram chosen must be changed on a rotating principle every four months.</p> <p>When all three symbols are included simultaneously, they must: have a</p>	<p>Mexican Official Standard NOM-142-SSA1 / SCFI-2014 Alcoholic beverages. Health specifications. Sanitary and commercial labeling (Appendix)</p>

Country	Requirements for mandated pregnancy warning label	Authority
	minimum diameter of 7 mm. If only one symbol is included, it must have a minimum diameter of 10 mm. For those alcoholic beverages whose volume is from 0 to 500 ml if only one symbol is included, it must have a minimum diameter of 5 mm. When all three symbols are included simultaneously, they must have a minimum diameter of 3.5 mm.	
Moldova	Alcoholic beverages above 1.5% ABV must display a symbol that warns against alcohol consumption during pregnancy.	Ministry of Agriculture, Regional Development and Environment (MADRM) - amendments to Law 1100/2000 require underage and pregnancy warning labels.
Russian Federation	Labels of wine and spirits, including vodka, must contain the message: <i>Alcohol is not for children and teenagers up to age 18, pregnant and nursing women, or for persons with diseases of the central nervous system, kidneys, liver, and other digestive organs.</i>	Ministry of Health Decree No. 49 of 19 January 2007
South Africa	Container labels for alcohol beverages must contain at least one of the [seven] health messages, which must be in black on a white background, visible, legible, and indelible and must be at least one eighth of the total size of the container label. The health message about pregnancy is: <i>Drinking during pregnancy can be harmful to your unborn baby</i>	Regulations Relating to Health Messages on Container Labels of Alcoholic Beverages, 24 August 2007 for the Foodstuffs, Cosmetics and Disinfectants Act 1972  (South African Wine Industry Information and Systems (SAWIS), 2018b)
Turkey	Labels of all alcohol beverages must include the text <i>Alcohol is not your friend</i> and three pictograms: against drinking by minors aged below 18, against drinking by pregnant women, and against driving under the influence of alcohol, presented in a box in the colour red. Detailed size requirements for the box, font and pictogram sizes for various container sizes are specified.	Tobacco and Alcohol Regulatory Authority, <a href="#">Communique</a> on warning messages to be affixed on the packaging of alcoholic beverages per Law No. 6487 of 11/06/2013.

Country	Requirements for mandated pregnancy warning label	Authority
	<p>(1) </p> <p>(2) </p> <p>(3) </p> <p>(4) Alcohol is not your friend.</p>	
Turkmenistan	<p>Effective 1 July 2019</p> <p>Labels of beverages of 1.5% ABV or higher must include warnings that take up 20% or more of the area in Turkmen and Russian or English: <i>Alcohol beverages harm your health!, Alcohol beverages are contraindicated for those below age 21, pregnant and breastfeeding women, and those with diseases of the central nervous system diseases, kidneys, liver, and other digestive organs.</i></p> <p>Labels of alcoholic beverages up to 7% ABV must include a statement on the recommended dose of not more than a single package per day. A single consumer package may not exceed 330 mL.</p>	Law on Prevention of the Harmful Impact of Alcohol 2018 Art 14, 15
United States	<p>The health warning statement must appear on the brand label or separate front label, or on a back or side label, separate and apart from all other information. It must be readily legible under ordinary conditions, and must appear on a contrasting background. Labels bearing the warning must be firmly affixed to the container. Minimum type size is specified for containers of various sizes.</p> <p>'Government Warning' must be in capital letters and in bold type. The warning statements must not be in bold type. The maximum number of characters per inch is specified depending on the container size. For containers of 237 ml or less, the mandatory statement must not be smaller than 1mm; for containers more than 237 ml and up to 3 litres the mandatory statement must not be smaller than 2 mm, and for containers of more than 3 litres, the mandatory</p>	<p>Title 27: Alcohol, Tobacco and Firearms. Part 16 – Alcoholic Beverage Health Warning Statement, § 16.21 Mandatory Label Information</p> <p>(USA Government, 2019)</p>

Country	Requirements for mandated pregnancy warning label	Authority
	<p>statement must not be smaller than 3 mm.</p> <p>Alcoholic beverage is defined: <i>Includes any beverage in liquid form which contains not less than one-half of one percent (0.5%) of alcohol by volume and is intended for human consumption.</i></p> <p><i>GOVERNMENT WARNING: (1) According to the Surgeon General, women should not drink alcoholic beverages during pregnancy because of the risk of birth defects. (2) Consumption of alcoholic beverages impairs your ability to drive a car or operate machinery, and may cause health problems.</i></p>	

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## Attachment E – The TBT Agreement

The TBT Agreement expressly recognises that no country should be prevented from taking measures for the protection of human health at the level it considers appropriate provided that such measures are in accordance with that Agreement.

FSANZ has had regard to the relevant obligations imposed on the Australian and New Zealand Government by the TBT Agreement.

For the reasons summarised below, FSANZ is satisfied that the approved draft variation is consistent with those obligations.

**Table E1: Consideration of the consistency of the mandatory pregnancy warning label with the TBT Agreement**

Article/Annex	Article/Annex text	Key aspects	Response
Article 2.1	Members shall ensure that in respect of technical regulations, products imported from the territory of any Member shall be accorded treatment no less favourable than that accorded to like products of national origin and to like products originating in any other country.	Imported products must be treated no less favourably than domestically produced like products.	The mandatory pregnancy warning label is required on all packaged alcoholic beverages with more than 1.15% ABV for retail sale in Australia and New Zealand. Hence the domestic requirements and requirements for imported products are the same.
Article 2.2	Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create. Such legitimate objectives are, inter alia: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the	Assessment of objective of the measure	<p>The primary objective of the pregnancy warning label on packaged alcoholic beverages is to provide a clear and easy to understand trigger to remind pregnant women, at both the point of purchase and consumption, to not drink alcohol. A secondary objective is to provide information to the community about the need for pregnant women to not drink alcohol.</p> <p>The rationale is that drinking alcohol during pregnancy can cause various types of harm to the unborn child, collectively known as FASD. Evidence demonstrates that pregnancy warning labels on alcoholic beverages incorporating specific design aspects can raise awareness of the risks of drinking alcohol during pregnancy and prompt discussion of these risks. Further to this, evidence from alcohol warnings and tobacco warning labels confirms that the label as part of a suite of measures can contribute to behaviour change (refer to section 3.2.3). Therefore, when combined with other public</p>

Article/Annex	Article/Annex text	Key aspects	Response
	environment. In assessing such risks, relevant elements of consideration are, inter alia: available scientific and technical information, related processing technology or intended end-uses of products.		health initiatives, pregnancy warning labels can contribute to increased awareness of the risks of drinking alcohol while pregnant and encourage behaviour change. It can also contribute to the development of social norms to support this behaviour change. These will ultimately reduce the prevalence and/or severity of FASD, thus protecting human health, a legitimate objective as stated in Article 2.2.
		Legitimacy of the objective	The ultimate objective of the measure in conjunction with other public health initiatives is the protection of human health through reducing the prevalence and/or severity of FASD. The protection of human health is expressly stated to be a legitimate objective in Article 2.2.
		Whether the technical regulation fulfils the legitimate objective	<p>Based on the available evidence, FSANZ is satisfied that the mandated pregnancy warning label, used in conjunction with other public health measures, can and will contribute to the protection of human health.</p> <p>As explained elsewhere in this report and its supporting documents:</p> <ul style="list-style-type: none"> <li>• The mandated pregnancy warning label integrates design elements that evidence shows will increase the attention a warning will receive.</li> <li>• The mandated warning label includes a statement that combines elements from the three best performing statements in the consumer testing, which were shown to score significantly better than the voluntary statement <i>It's safest not to drink while pregnant</i> in comprehension and credibility.</li> <li>• A mandated approach with prescribed design elements will ensure a high level of consistency and coverage in the warning label across packaged alcohol providing women of childbearing age with consistent information both at the point of purchase and consumption.</li> <li>• The pregnancy warning label is part of a broader suite of measures aimed to raise awareness of the risks of drinking</li> </ul>

Article/Annex	Article/Annex text	Key aspects	Response
		<p>Whether the measure is necessary to fulfil the objective.</p>	<p>alcohol during pregnancy and reducing the prevalence and/or severity of FASD. Evidence from alcohol warnings and tobacco warning labels confirms that the label as part of a suite of measures can contribute to behaviour change (refer to section 3.2.3). The range of public health measures underway in Australia and New Zealand are outlined in section 2.5 of this report.</p> <p>Article 2.2 states that the technical regulations should not be any more trade restrictive than necessary to fulfil a legitimate objective.</p> <p>After having regard to the evidence, FSANZ remains satisfied that:</p> <ul style="list-style-type: none"> <li>• the measure is not more trade restrictive than necessary to fulfil the above-mentioned objective; and</li> <li>• there is no less trade restrictive alternative that is reasonably available and that would make an equivalent contribution to the objective of the protection of human health through the prevention/reduction of FASD.</li> </ul> <p>Industry submitters have suggested ongoing labelling costs may restrict trade. Alternative options suggested include public education, mandating the existing voluntary labelling scheme and including a website link on the label, removing the use of the colours red, black and white and instead requiring the text on a contrasting background, mandating text <b>or</b> pictogram, recognising a number of alternative labels used around the world.</p> <p>The nature of the risk of not fulfilling the objective of the mandatory pregnancy warning label would be that the prevalence/severity of FASD would not be reduced. Therefore, there are extremely grave consequences of not fulfilling the public health objective.</p> <p>The alternate suggestions listed above may be less trade restrictive than the pregnancy warning label in terms of costs to industry. However, they would likely not be equivalent in meeting the public health objectives of the warning label. Evidence shows the approved warning label would be more likely to be noticed and understood to mean not to drink alcohol during pregnancy than the other labelling</p>

Article/Annex	Article/Annex text	Key aspects	Response
			<p>approaches listed above. Consumer research indicates the statement <i>It's safest not to drink while pregnant</i>, does not perform as well in conveying the measure to not drink alcohol during pregnancy compared with other statements tested (SD2). Public education initiatives, while important in the suite of measures, cannot achieve the labelling objective of reminding consumers at the point of purchase and consumption, to not drink alcohol during pregnancy. While a warning sign in licensed establishments could help to educate consumers, consumers would clearly not be exposed to such signs when drinking outside of licensed establishments. Labelling provides the warning in such situations. Evidence shows that few people visit a website included on the voluntary warning label (SD1) raising questions about the effectiveness of such an approach.</p> <p>Given the design of the voluntary pregnancy warning label scheme that has been used in Australia and New Zealand is not supported by the evidence, it would not be appropriate to mandate the voluntary warning label. The evidence and information presented in SD1, SD2 and this report support the approach for the new technical regulations.</p> <p>Also refer to the responses below in relation to Articles 2.4 and 2.7 and the efficacy of adopting and relying on warning labels used in other countries.</p>
Article 2.3	Technical regulations shall not be maintained if the circumstances or objectives giving rise to their adoption no longer exist or if the changed circumstances or objectives can be addressed in a less trade-restrictive manner.		This Article is more relevant in the context of the review of an existing technical regulation rather than the adoption of a new one.
Article 2.4	Where technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations	Regulations must use existing or imminent relevant international standards as their basis except where they would be ineffective or an	There are no relevant international standards for pregnancy warning labels on alcoholic beverages, therefore this Article is not relevant.

Article/Annex	Article/Annex text	Key aspects	Response
	except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems.	inappropriate means to fulfil the legitimate objective pursued.	
Article 2.5	A Member preparing, adopting or applying a technical regulation which may have a significant effect on trade of other Members shall, upon the request of another Member, explain the justification for that technical regulation in terms of the provisions of paragraphs 2 to 4. Whenever a technical regulation is prepared, adopted or applied for one of the legitimate objectives explicitly mentioned in paragraph 2, and is in accordance with relevant international standards, it shall be rebuttably presumed not to create an unnecessary obstacle to international trade.	Members must explain the justification for regulations that may have a significant effect on trade of other Members.	FSANZ has explained the justification for the warning label in the WTO TBT notification to Members. Further, the justification is provided in this Approval Report.
Article 2.6	With a view to harmonizing technical regulations on as wide a basis as possible, Members shall play a full part, within the limits of their resources, in the preparation by appropriate international standardizing bodies of international standards for products for which they either have adopted, or expect to adopt, technical regulations.	Requires Members to cooperate in the work of international standard setting bodies to develop harmonized technical regulations.	Not relevant to this measure.
Article 2.7	Members shall give positive	WTO Members must give	FSANZ did give positive consideration to acceptance and adoption

Article/Annex	Article/Annex text	Key aspects	Response
	<p>consideration to accepting as equivalent technical regulations of other Members, even if these regulations differ from their own, provided they are satisfied that these regulations adequately fulfil the objectives of their own regulations.</p>	<p>positive consideration to accepting equivalent technical regulations of other WTO Members, even if these regulations differ from their own.</p>	<p>of the mandatory or voluntary pregnancy warning labels of other WTO Members.</p> <p>In doing so, FSANZ considered whether mandatory or voluntary pregnancy warning labels used in other countries could be considered equivalent to the new technical regulations.</p> <p>As discussed in section 3.2.1, the literature review confirmed that multiple design elements (including pictorials and signal words) can be used in varying combinations to enhance the noticeability of warning labels. Warnings that use signal words and pictorial elements (and other elements such as colour) attract more attention than labels lacking those elements. The use of the statement with the pictogram reinforces the meaning of the pictogram (to not drink alcohol during pregnancy) and explains the consequences of alcohol consumption during pregnancy which may increase the effectiveness of the label (SD1). Evidence also suggests the pictogram alone may not challenge some beliefs about the risks of drinking alcohol during pregnancy (SD1). As noted in section 2.4, up to 20-25% of women in Australia and New Zealand drink alcohol while pregnant.</p> <p>Evidence states that pictorial elements combined with statements can bridge literacy and other educational gaps and enhance risk perceptions of alcoholic beverages compared with statement only warnings (SD1). Evidence also suggests the pictogram alone may not challenge some beliefs about the risks of drinking alcohol during pregnancy (SD1).</p> <p>None of the 13 mandatory or voluntary pregnancy warning labels used in other countries (refer to Attachment D) require a pictogram and a statement and only one includes signal words (with a statement only). With reference to the above evidence, FSANZ therefore considers none of the 13 warning labels are equivalent to the warning label required in Australia and New Zealand. In addition, the statement in the approved warning label is aligned with the recently released draft Australian alcohol guidelines and so is suited to the Australian and New Zealand populations, noting New Zealand</p>

Article/Annex	Article/Annex text	Key aspects	Response
			<p>draws on the Australian guidelines in its public health messaging about alcohol consumption.</p> <p>Current mandatory warnings in place in other countries have not been designed with a view to optimise the attention they receive (SD1). None of the 13 countries with pregnancy warning labels prescribe the particular combination of design elements included in the warning label for Australia and New Zealand. Based on the available evidence it is expected the Australia and New Zealand warning label will be more effective in achieving its stated objectives in the local context than labels used in other countries, in particular it is likely to have enhanced noticeability and be clearer and easier to understand.</p> <p>FSANZ notes the Australia New Zealand Food Standards Code does not prohibit the use of more than one pregnancy warning label on an alcoholic beverage container, provided the required warning label is included.</p>
Article 2.8	Wherever appropriate, Members shall specify technical regulations based on product requirements in terms of performance rather than design or descriptive characteristics		Article 2.8 is not relevant in the context of assessing the consistency of the pregnancy warning label with the TBT Agreement. It is clear that the objective of informing the community, and in particular women who are pregnant or may become pregnant, about the risks of alcohol consumption to unborn babies, cannot be achieved by imposing product requirements on alcoholic beverages.
Article 2.9	<p>Whenever a relevant international standard does not exist or the technical content of a proposed technical regulation is not in accordance with the technical content of relevant international standards, and if the technical regulation may have a significant effect on trade of other Members, Members shall:</p> <p>2.9.1 publish a notice in a publication at an early appropriate stage, in such a manner as to</p>	Prior notification and consultation must occur if a relevant standard does not exist or the technical content of a proposed technical regulation is not in accordance with the technical content of relevant international standards, and the technical regulation may have a significant effect on trade.	FSANZ notified WTO Members of the draft technical regulations on October 4 2019 via New Zealand and 8 October 2019 via Australia for a period of 60 days. Seven submissions (three from Member countries, four from industry organisations) were received. Refer to Table 2 in this report. No WTO Members have asked to discuss the measure with FSANZ.

Article/Annex	Article/Annex text	Key aspects	Response
	<p>enable interested parties in other Members to become acquainted with it, that they propose to introduce a particular technical regulation;</p> <p>2.9.2 notify other Members through the Secretariat of the products to be covered by the proposed technical regulation, together with a brief indication of its objective and rationale. Such notifications shall take place at an early appropriate stage, when amendments can still be introduced and comments taken into account;</p> <p>2.9.3 upon request, provide to other Members particulars or copies of the proposed technical regulation and, whenever possible, identify the parts which in substance deviate from relevant international standards;</p> <p>2.9.4 without discrimination, allow reasonable time for other Members to make comments in writing, discuss these comments upon request, and take these written comments and the results of these discussions into account.</p>		
Article 2.10	2.10 Subject to the provisions in the lead-in to paragraph 9, where urgent problems of safety, health, environmental protection or national security arise or threaten to arise for a Member, that Member may omit	Emergency regulations can be approved without prior TBT notification and consultation if the criteria in Article 2.10 are met.	Not relevant to these new technical regulations.





Article/Annex	Article/Annex text	Key aspects	Response
	<p>such of the steps enumerated in paragraph 9 as it finds necessary, provided that the Member, upon adoption of a technical regulation, shall:</p> <p>2.10.1 notify immediately other Members through the Secretariat of the particular technical regulation and the products covered, with a brief indication of the objective and the rationale of the technical regulation, including the nature of the urgent problems;</p> <p>2.10.2 upon request, provide other Members with copies of the technical regulation;</p> <p>2.10.3 without discrimination, allow other Members to present their comments in writing, discuss these comments upon request, and take these written comments and the results of these discussions into account.</p>		
Article 2.11	Members shall ensure that all technical regulations which have been adopted are published promptly or otherwise made available in such a manner as to enable interested parties in other Members to become acquainted with them		Section 92 of the <i>Food Standards Australia New Zealand Act 1991</i> (FSANZ Act) sets out the publication requirements for new or revised food regulatory measures. This includes publication in the Australian and New Zealand Gazette and publication on FSANZ's website. In addition, once the food regulatory standard comes into effect it is accessible through the Code, which can be found on the FSANZ website and the Federal Register of Legislation website. In light of this, the requirements of Art 2.11 will be met in the context of food regulatory standards.
Article 2.12	Except in those urgent circumstances referred to in paragraph 10, Members shall allow	There be a reasonable time for entry into force of the new technical regulations.	Paragraph 5.2 of the Doha Ministerial Decision provides: <i>Subject to the conditions specified in paragraph 12 of Article 2 of the Agreement on Technical Barriers to Trade, the phrase "reasonable</i>

Article/Annex	Article/Annex text	Key aspects	Response
	<p>a reasonable interval between the publication of technical regulations and their entry into force in order to allow time for producers in exporting Members, and particularly in developing country Members, to adapt their products or methods of production to the requirements of the importing Member.</p>		<p><i>interval" shall be understood to mean normally a period of not less than 6 months, except when this would be ineffective in fulfilling the legitimate objectives pursued.</i></p> <p>The transitional arrangements for the new technical regulations are set out in section 4 of this report. There will be a two year transition period and an allowance for products already labelled before the end of the transition period to not be required to display the pregnancy warning label. The requirements of Article 2.12 are satisfied.</p>
Article 4.1	<p>Members shall ensure that their central government standardizing bodies accept and comply with the Code of Good Practice for the Preparation, Adoption and Application of Standards in Annex 3 to this Agreement (referred to in this Agreement as the "Code of Good Practice"). They shall take such reasonable measures as may be available to them to ensure that local government and nongovernmental standardizing bodies within their territories, as well as regional standardizing bodies of which they or one or more bodies within their territories are members, accept and comply with this Code of Good Practice. In addition, Members shall not take measures which have the effect of, directly or indirectly, requiring or encouraging such standardizing bodies to act in a manner inconsistent with the Code of Good Practice. The obligations of Members with respect to compliance of standardizing bodies with the provisions of the Code of Good</p>	<p>Members are to ensure that their central government standardizing bodies accept and comply with the Code of Good Practice for the Preparation, Adoption and Application of Standards in Annex 3 to the Agreement.</p>	<p>FSANZ notes the Code of Good Practice (Annex 3) largely replicates, and provides additional detail to, the requirements of Article 2 of the TBT Agreement.</p> <p>The relevant clauses in Annex 3 are provided below.</p>

Article/Annex	Article/Annex text	Key aspects	Response
	Practice shall apply irrespective of whether or not a standardizing body has accepted the Code of Good Practice.		
Article 4.2	Standardizing bodies that have accepted and are complying with the Code of Good Practice shall be acknowledged by the Members as complying with the principles of this Agreement.		
Annex 3 cl D	In respect of standards, the standardizing body shall accord treatment to products originating in the territory of any other Member of the WTO no less favourable than that accorded to like products of national origin and to like products originating in any other country.		Covered in Article 2.1 above
Annex 3 cl E	The standardizing body shall ensure that standards are not prepared, adopted or applied with a view to, or with the effect of, creating unnecessary obstacles to international trade.		Covered in Article 2.2 above
Annex 3 cl F	Where international standards exist or their completion is imminent, the standardizing body shall use them, or the relevant parts of them, as a basis for the standards it develops, except where such international standards or relevant parts would be ineffective or inappropriate, for instance, because of an insufficient level of protection or fundamental climatic or geographical factors or fundamental technological problems.		Covered in Article 2.4 above
Annex 3 cl I	Wherever appropriate, the		Covered in Article 2.8 above

Article/Annex	Article/Annex text	Key aspects	Response
	standardizing body shall specify standards based on product requirements in terms of performance rather than design or descriptive characteristics.		
Annex 3 cl L	Before adopting a standard, the standardizing body shall allow a period of at least 60 days for the submission of comments on the draft standard by interested parties within the territory of a Member of the WTO. This period may, however, be shortened in cases where urgent problems of safety, health or environment arise or threaten to arise. No later than at the start of the comment period, the standardizing body shall publish a notice announcing the period for commenting in the publication referred to in paragraph J. Such notification shall include, as far as practicable, whether the draft standard deviates from relevant international standards.	A period of at least 60 days should be allowed for submission of comments on a draft standard by interested parties within a territory of a Member of the WTO.	Covered in Article 2.9 above
Annex 3 cl N	The standardizing body shall take into account, in the further processing of the standard, the comments received during the period for commenting. Comments received through standardizing bodies that have accepted this Code of Good Practice shall, if so requested, be replied to as promptly as possible. The reply shall include an explanation why a deviation from relevant international standards is necessary.	In addition to requiring comments received to be taken into account, requires a response to be provided as promptly as possible if it is requested.	FSANZ has taken into account the comments received via the WTO notification process (refer to Table 2). Responses will be sent to submitters.

## Attachment F – Guidance for design labelling elements and Code requirements relevant to alcoholic beverages

Labelling element/documents	Size	Other legibility requirements/guidance
Australia New Zealand Food Standards Code	Font size of warning statements (e.g. royal jelly, kava) is required to be at least 3 mm and at least 1.5 mm for small packages (section 1.2.1—25)	<i>any words must be in English and any word statement, expression of design must, wherever occurring be legible and be prominent so as to contrast distinctly with the background of the label.</i>
	Font size for warning statements about infant formula specified in terms of container weight – 3 mm for containers more than 500 g and 1.5 mm for containers of 500 g or less (section 2.9.1—20)	
DrinkWise guidance for voluntary pregnancy warning label	8 mm box height; pictogram approx. 5 mm	<ul style="list-style-type: none"> <li>• Exclusion area around label (capital D from DrinkWise)</li> <li>• DrinkWise charcoal or prominent colour from own colour palette</li> </ul>
Guide for standard drink information	Australian guidance (Independent Brewers Association): <ul style="list-style-type: none"> <li>• minimum height of 14 mm</li> <li>• clear zone of at least 3 mm from other elements on packaging</li> </ul>  <a href="http://iba.org.au/iba-beer-labeling-guidelines/">http://iba.org.au/iba-beer-labeling-guidelines/</a>	Clearly legible against background.
	New Zealand guidance: <ul style="list-style-type: none"> <li>• minimum height of 12 mm</li> </ul>  <a href="https://www.alcohol.org.nz/help-advice/about-standard-drinks/using-the-standard-drink-icon">https://www.alcohol.org.nz/help-advice/about-standard-drinks/using-the-standard-drink-icon</a>	
Guide for recycle logo	Australian guidance: <ul style="list-style-type: none"> <li>• minimum height of 14 mm</li> <li>• minimum clear zone of 3 mm</li> </ul>	Logo must be legible against background.
10 cent refund statement on specified types of containers (requirement for various states and territories in Australia)	<ul style="list-style-type: none"> <li>• Numeric '10' must have minimum height of 3 mm.</li> <li>• Smallest letter in the wording must have a minimum height of 1.5 mm.</li> <li>• A minimum of 3 mm clear space around the refunding marking is recommended.</li> </ul> For an example of this scheme refer to the container deposit	

Labelling element/documents	Size	Other legibility requirements/guidance
	guidelines in South Australia <a href="https://www.epa.sa.gov.au/environmental_info/container_deposit/industry">https://www.epa.sa.gov.au/environmental_info/container_deposit/industry</a>	

## Attachment G – New Zealand and Australian legislation and guidance including alcoholic beverage definitions

Legislation/Guidance	Administered by	Relevant requirement	Description
<b>New Zealand</b>			
Food Act 2014, Schedule 2, Part 3	Ministry for Primary Industries	Part 3 food Sectors subject to National Programme Level 3 – includes brewers, distillers, alcoholic beverages	Applies to food businesses that brew, distil or manufacture from fermentation vinegar, or beverages or malt extract. Applies to beverages containing 1.15% alcohol or more.
Sale and Supply of Alcohol Act 2012	Ministry of Justice	Section 5	Alcohol means a substance (a) that (i) is or contains a fermented, distilled, or spirituous liquor; and (ii) at 20C is found on analysis to contain 1.15% or more ethanol by volume.
Alcoholic beverages advertising code (ABAC) scheme	Advertising Standards Agency	Responsible alcohol marketing code	Alcohol beverage means a beverage containing at least 0.5% alcohol by volume.
<b>Australia</b>			
	Queensland	Liquor means a beverage which contains the % by volume of ethanol (alcohol) more than:	>0.5%
	Tasmania		>0.5%
	Victoria		>0.5%
	ACT		>1.15%
	New South Wales		>1.15%
	Northern Territory		>1.15%
	South Australia		>1.15%
	Western Australia		>1.15%
<b>Wine Equalisation Tax (WET)</b>  Further information: <a href="https://www.ato.gov.au/Business/Wine-equalisation-tax/Products-WET-applies-to/">https://www.ato.gov.au/Business/Wine-equalisation-tax/Products-WET-applies-to/</a>			WET applies to certain beverages where they contain more than 1.15% by volume of ethyl alcohol <ul style="list-style-type: none"> <li>- grape wine, including sparkling and some fortified wine</li> <li>- grape wine products (such as marsala)</li> <li>- fruit wines and vegetable wines</li> <li>- cider and perry (except for some flavoured ciders)</li> <li>- mead</li> <li>- sake</li> </ul>
<b>Schedule to Excise Tariff Act 1921</b>			Beer has an alcohol content of more than 1.15% by volume. Spirits and other excisable beverages – alcohol content not further specified. Wine etc. excluded from this Act and instead covered under WET.

## Attachment H – Supporting information for the consideration of costs and benefits

All \$ figures in Australian dollars. Exchange rate of AU \$1 = NZ \$ 1.05				Most figures rounded to nearest whole number			
					Base Scenario at 225 live births	Best Case Scenario at 35 live births	Worst Case Scenario at 555 live births
				Benefits and Costs Table			
	Base Scenario	Best Case Scenario	Worst Case Scenario	Year 1 = after end of transition then after 9 months pregnancy for 3 months of benefits			
					\$780,260	\$673,479	\$1,920,639
<b>Benefits per year</b>				Year 2, i.e. 2-0.75 years	\$3,901,298	\$3,367,396	\$9,603,194
Total No. of new live births that need to benefit in A-NZ combined, then in...	225	35	555	Year 3, i.e. 3-0.75 years	\$7,022,336	\$6,061,313	\$17,285,749
...in Australia	202	31	498	Year 4, i.e. 4-0.75 years	\$10,143,374	\$8,755,230	\$24,968,304
...in New Zealand	23	4	57	Year 5, i.e. 5-0.75 years	\$13,264,412	\$11,449,147	\$32,650,860
Benefit \$ per prevented FASD case per year AU	\$13,847	\$76,002	\$13,847	Year 6, i.e. 6-0.75 years	\$16,385,450	\$14,143,065	\$40,333,415
Benefit \$ per prevented FASD case per year NZ	\$13,847	\$92,395	\$13,847	Year 7, i.e. 7-0.75 years	\$19,506,488	\$16,836,982	\$48,015,970
Total \$ Benefits for all prevented FASD cases per year, AU-NZ combined	\$3,121,038	\$2,693,917	\$7,682,555	Year 8, i.e. 8-0.75 years	\$22,627,526	\$19,530,899	\$55,698,525
Percentage of all A-NZ annual FASD births this represents	1.3%	0.2%	3.2%	Year 9, i.e. 9-0.75 years	\$25,748,564	\$22,224,816	\$63,381,080
	Base	Best Case	Worst Case	Year 10, i.e. 10-0.75 years	\$28,869,602	\$24,918,733	\$71,063,635
<b>Costs AU and NZ combined</b>				Year 11, i.e. 11-0.75 years	\$31,990,640	\$27,612,650	\$78,746,191
Average \$ cost per SKU effected	\$4,924	\$4,166	\$7,575	Year 12, i.e. 12-0.75 years	\$35,111,678	\$30,306,567	\$86,428,746
Number of SKUs effected	71,223	61,853	80,592	Year 13, i.e. 13-0.75 years	\$38,232,716	\$33,000,484	\$94,111,301
Sub-Total \$ costs over all SKUs	\$350,669,009	\$257,683,865	\$610,457,875	Year 14, i.e. 14-0.75 years	\$41,353,754	\$35,694,401	\$101,793,856
Drinkwise \$ costs estimate	\$650,000	\$650,000	\$650,000	Year 15, i.e. 15-0.75 years	\$44,474,792	\$38,388,318	\$109,476,411
Total \$ cost including Drinkwise	\$351,319,009	\$258,333,865	\$611,107,875	Year 16, i.e. 16-0.75 years	\$47,595,830	\$41,082,235	\$117,158,967
				Year 17, i.e. 17-0.75 years	\$50,716,868	\$43,776,152	\$124,841,522
				Year 18, i.e. 18-0.75 years	\$53,837,906	\$46,470,069	\$132,524,077
				Year 19, i.e. 19-0.75 years	\$56,958,944	\$49,163,986	\$140,206,632
				Year 20, i.e. 20-0.75 years	\$60,079,982	\$51,857,903	\$147,889,187
					Base	Best Case	Worst Case
				Discount Rate for benefits	4%	3%	7%
				NPV of discounted benefits over 20 years	\$358,801,609	\$351,604,741	\$615,814,904
				Total Benefits minus Total Costs	\$7,482,600	\$93,270,877	\$4,707,029



**Figure 1: Total A\$ costs of changing labels per SKU from data received from industry by FSANZ in 2018/19 (Thick Black line represents the mean)**

