



4 October 2019

[97–19]

Call for submissions – Proposal P1050

Pregnancy warning labels on alcoholic beverages

FSANZ has assessed a proposal to consider a mandatory pregnancy warning label on packaged alcoholic beverages and has prepared a draft food regulatory measure. Pursuant to section 61 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [information for submitters](#). **Submitters are asked to use the submission template at Attachment H to this report.**

All submissions on applications and proposals will be published on our website. We will not publish material that we accept as confidential, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

Submissions should be made in writing, be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient to receive submissions electronically through the FSANZ website via the link on [documents for public comment](#). You can also email your submission directly to submissions@foodstandards.gov.au.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 27 October 2019

Submissions received after this date will not be considered. As Ministers have asked FSANZ to work expeditiously, due to the time frames for completion of this proposal, as indicated on our [work plan](#), we are not able to extend the consultation deadline.

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

Hard copy submissions may be sent to one of the following addresses:

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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.

Executive summary

The Australian and New Zealand governments advise women not to consume any 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.

At the October 2018 meeting of the Australia and New Zealand Ministerial Forum on Food Regulation (Forum), ministers considered a Decision Regulation Impact Statement (DRIS) about pregnancy warning labels on alcoholic beverages prepared by the Food Regulation Standing Committee. The DRIS included an impact analysis of mandatory versus voluntary approaches for a warning label on alcoholic beverages that would discourage drinking during pregnancy and concluded mandatory labelling provides the greatest net benefit to the community. On this basis, Ministers asked FSANZ to consider mandatory pregnancy warning labelling on packaged alcoholic beverages as a priority and that the work be completed expeditiously. In response, FSANZ prepared Proposal P1050 – Pregnancy warning labels on alcoholic beverages.

The focus of the proposal is the design and implementation of a mandatory pregnancy warning label on packaged alcoholic beverages. Based on the policy advice provided to FSANZ by ministers (the DRIS), the warning label is to include both a pictogram and a statement to convey a message that reflects government advice not to consume any alcohol during pregnancy.

FSANZ prepared a literature review on the evidence about the effectiveness of warning labels on packaged alcoholic beverages to inform warning label design. A number of design elements including colour, size, use of signal word(s) such as 'Warning', location of the warning on the beverage label, pictorials and statement length can be manipulated to enhance the noticeability of warning labels such that consumers are more likely to notice the warning. These design factors were therefore considered in the development of the proposed warning label.

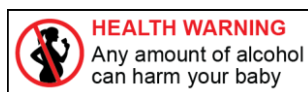
Given limited studies in the Australia and New Zealand context about wording of pregnancy warning statements, FSANZ commissioned Roy Morgan Research to implement an online survey across both countries to test four statements. The aim of the study was to identify which of the statements conveyed the government advice not to consume any alcohol during pregnancy in a manner that was believable, credible, convincing, and of relevance to women of childbearing age and the broader community.

FSANZ facilitated targeted consultation with industry and public health stakeholders, and jurisdictions in both Australia and New Zealand in January - February 2019 and June - July 2019 to help inform the design and implementation of the pregnancy warning label. FSANZ has considered the views and information provided by stakeholders in its assessment.

FSANZ has given consideration to the costs and benefits that may arise from the proposed pregnancy warning label for the purposes of meeting requirements under the *Food Standards Australia New Zealand Act 1991*. This updated and extended consideration of costs and benefits supports the conclusions of the 2018 DRIS that only a small proportion of FASD cases need to be prevented to offset the costs of label changes to industry. Therefore, mandatory labelling represents the option that is most likely to result in the largest net benefit to the community.

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Based on the policy advice provided to FSANZ, consideration of the best available evidence including the commissioned research, costs and benefits, stakeholder views and other relevant information, FSANZ proposes the following mandatory pregnancy warning label for packaged alcoholic beverages:



The pregnancy warning label is proposed to be required on all packaged alcoholic beverages with more than 1.15% alcohol by volume and on all layers of packaging. For alcoholic beverage volumes 200 ml and under, only the pictogram will be required. Minimum warning label size requirements for ranges of alcoholic beverage volumes are proposed. The location of the pregnancy warning label on alcoholic beverage containers is not prescribed, giving industry flexibility with the positioning of the warning label.

FSANZ proposes a two-year transition period for the mandatory pregnancy warning label from the date of gazettal of variations to the Code, and an exemption for alcoholic beverages packaged and labelled before the end of the transition period.

It is well recognised that labelling is one part of a broader suite of measures aimed to raise awareness of the risks of drinking alcohol during pregnancy. 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 FASD.

After assessing the proposal, FSANZ has prepared a draft variation to the Australia New Zealand Food Standards Code (the Code) to require a pregnancy warning label on packaged alcoholic beverages.

FSANZ welcomes views on the proposed warning label, its design and any of the various design elements. These views will be taken into consideration before final advice is provided to the FSANZ Board. A summary of views will be provided to the Board to assist its decision making process.

The FSANZ Board is expected to consider an approval report in early December 2019. If a draft variation to the Code is approved by the FSANZ Board, that decision will be notified to the Forum. If the Forum does not request a review, gazettal of the variation to the Code would be expected in March 2020.

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1 Introduction

1.1 The Proposal

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

1.2 Reasons for preparing the Proposal

Drinking alcohol during pregnancy can be associated with various types of harm to the unborn child. 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 response to recommendation 25¹ from *Labelling Logic: Review of Food Labelling Law and Policy* (Labelling Review) (Blewett et. al., 2011), the Legislative and Governance Forum on Food Regulation (now the Australia and New Zealand Ministerial Forum on Food Regulation (the Forum)) 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.

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. In 2017, ministers considered a second evaluation (Siggins Miller, 2017; Ministry for Primary Industries, 2017a, 2017b) and asked for a policy options paper to consider mandatory versus voluntary/non-regulatory approaches, the most appropriate pictogram and most appropriate 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 Decision Regulation Impact Statement (DRIS) was prepared (Food Regulation Standing Committee, 2018). The DRIS concluded mandatory labelling provides the greatest net benefit to the community.

At the Forum meeting in October 2018, ministers considered the DRIS and agreed to ask 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 response, FSANZ commenced this proposal in November 2018.

1.3 Policy advice

The DRIS provides policy advice to FSANZ including 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

¹ 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.*

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related to effective label design and a discussion of implementation issues (Food Regulation Standing Committee, 2018).

As stated in the DRIS (page 50), *the primary objective of pregnancy warning labels on packaged alcoholic beverages is to provide a clear and easy to understand trigger to remind pregnant women, at both the point of sale and the potential point of consumption, to not drink alcohol. A secondary objective of pregnancy warning labels on packaged alcoholic beverages is to provide information to the community about the need for pregnant women to not drink alcohol.*

The DRIS also states the pregnancy warning label should reflect Australia and New Zealand government advice not to drink any alcohol during pregnancy (pages 1, 83 in the DRIS).

A summary of evidence relating to the design of a warning label and stakeholder views from the 2018 targeted consultation is provided at Appendix 2 of the DRIS. It was concluded a warning label should include a pictogram and warning statement, be evidence based and consumer tested. The DRIS also stated the evidence suggests effective pregnancy warning labels should:

- include text that is readable and possibly the same size as all information on the product label
- use short warning messages, and words such as 'WARNING' or 'HEALTH WARNING' to indicate it is a warning label
- be separated from other information on the label (for example, placed in boxes with borders and away from messages such as *enjoy in moderation*)
- use contrasting colours, noting that the colour green should not be used as it can cause confusion and that the colour red receives the most attention and is readily associated with being a warning.

The DRIS also recommended FSANZ give consideration to including a two to three-year transition period and a stock-in-trade exemption whereby beverages packaged and labelled before the end of the transition period would not have to carry the pregnancy warning label.

The DRIS emphasises pregnancy warning labels need to be complemented by broader activities and targeted interventions to achieve behaviour change and ultimately a reduction in the prevalence of FASD. Pregnancy warning labels may help raise awareness of the risks of drinking alcohol during pregnancy, prompt discussions and support the establishment of cultural norms. Both Australia (Australian Department of Health, 2019a) and New Zealand (New Zealand Ministry of Health, 2019) have FASD Action Plans which include a number of activities that complement labelling (see Appendix 1 of the DRIS).

1.4 Procedure for assessment

The Proposal is being assessed under the General Procedure of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act).

1.5 Scope of the proposal

The scope of P1050 reflects the scope of the policy process undertaken by FRSC and the resulting DRIS.

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P1050 considers a mandatory warning label about the risks of drinking any alcohol during pregnancy on packaged² alcoholic beverages required to bear a label for sale in Australia and New Zealand. Imported alcoholic beverages are therefore in scope.

The focus of P1050 is the design and implementation of a mandatory pregnancy warning label. Based on the policy advice in the DRIS, the warning label is to include both a pictogram and a warning statement.

P1050 excludes consideration of the evidence related to the impact of alcohol exposure on the fetus as this was covered in the DRIS which drew on the scientific evidence review prepared by the National Health and Medical Research Council (see section 2.2 below). Reference to breastfeeding in the warning label is out of scope. The proposal also excludes consideration of the display of a warning label sign, for example, in licensed premises.

2 Background

2.1 Previous consideration of pregnancy warning labels

FSANZ has received two applications seeking to have warning labels on alcoholic beverages about the risks of drinking during pregnancy.

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 (noting the Health Promotion Agency is now the applicant) (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 (completed May 2009), and a study comparing the cost-effectiveness of mandatory labelling with other strategies to reduce alcohol consumption amongst pregnant women and ultimately FASD (completed May 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.

2.2 Alcohol consumption guidelines in Australia and New Zealand

Government advice in both Australia (Australian Department of Health, 2019b, 2019c) and New Zealand (New Zealand Ministry of Health, 2018; New Zealand Health Promotion Agency, 2019) is that pregnant women not consume any alcohol.

² *Package* is defined in section 1.1.2—2 of the Code.

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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 (Australian 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. As noted above, the risk to the fetus from low level alcohol consumption is likely to be low.

A review of the 2009 Australian guidelines commenced in 2017 (NHMRC, 2019). The review includes an evaluation of the evidence on the health effects of alcohol consumption including the effects of consumption during pregnancy. Public consultation of the draft guidelines is expected late 2019 with the final revised guidelines due to be published in the second quarter of 2020.

The New Zealand government 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 (New Zealand Ministry of Health, 2018; New Zealand Health Promotion Agency, 2019; New Zealand Ministry of Health and New Zealand Health Promotion Agency, 2018).

2.3 Alcohol 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).

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The general legibility requirements in the Code apply to mandatory labelling information on alcoholic beverages. Any words must be in English and any word, statement, expression or design must be legible and be 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) and the exact wording of warning statements is prescribed. Warning statements are required to be written in a font size of at least 1.5 mm for a small package³ and of at least 3 mm for all other sized packages (section 1.2.1—25).

2.4 Pregnancy warning labels in other countries

2.4.1 Countries with mandatory or voluntary pregnancy warning labels

There is no international consistency with the use of health warning labels on alcoholic beverages nor with format and/or wording. Information about requirements for pregnancy warning labels in other countries is provided at Attachment C.

Based on information provided by the International Alliance for Responsible Drinking (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 (Attachment C). 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 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.

There is no restriction with the use of the French pictogram in other countries. Lithuania, Mexico, 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 carry the pregnancy warning label are summarised at Attachment C.

Four countries have voluntary labelling initiatives about the risks of drinking alcohol during pregnancy (Australia, New Zealand, Japan, United Kingdom). In addition, 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 are not available (see Attachment C for further information).

2.4.2 Codex discussions about labelling of alcoholic beverages

Codex Alimentarius has no specific guidelines for the labelling of alcoholic beverages. However, at the 44th 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 that CCFL do new work to cover a definition of

³ Small package means a package with a surface area of less than 100 cm² (section 1.1.2—2 of the Code)

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 future work in this area 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.

2.5 Free trade agreements

Australia and New Zealand are parties to several free trade agreements that include clauses relevant to the labelling of alcoholic beverages, particularly wine and distilled spirits. The general purpose of the agreements, relevant to alcohol labelling, is to align technical regulations so they do not create unnecessary barriers to trade.

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 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).

Australia and New Zealand are signatories to the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) which includes Annex 8-A: Wine and Distilled Spirits (Australian Department of Foreign Affairs and Trade, 2019). The CPTPP came into force in Australia and New Zealand on 30 December 2018. 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. This means that should a pregnancy warning label be required in Australia and New Zealand, the warning label could be provided via a supplementary label on imported wines and distilled spirits. The Code does not prevent the use of supplementary labels.

2.6 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.

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Section 14(3) of the Wine Australia Regulations 2018 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* 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 requirements for wine products exported from New Zealand where the export market requires a pregnancy warning label.

3 Summary of the assessment

3.1 Evidence summary

3.1.1 Literature review on the effectiveness of warning labels

FSANZ undertook a literature review to inform the development of risk management options for a pregnancy warning label on packaged alcoholic beverages (Supporting Document 1 (SD1)). The literature review covered the period from November 2008 to July 2019. This period starts from the end of the search date for the FSANZ commissioned literature review by Wilkinson et al. (2009). The review was not limited to peer-reviewed papers, but includes studies from the grey literature, primarily government and non-government organisation (NGO) commissioned reports, as these are highly relevant to Australia and New Zealand populations. A total of 46 studies were included in the review.

For this review, we adopted the framework of Argo and Main (2004) to summarise relevant information. They identify five dimensions of warning label effectiveness: attention; reading and comprehension, recall, judgement, and behavioural compliance. We have discussed attention and recall together in this review.

3.1.1.1 Attention and recall

To be effective, a warning label has to be noticed. It must draw the attention of a consumer. Prompted awareness of existing pregnancy warning labels across the general Australian and New Zealand public ranged from about 26% to 53% and 25% to 29%, respectively. Prompted awareness was generally higher (around 33% to 74%) for specific populations focussed on women (e.g. women with children, women who are pregnant or planning to have a child or have had a child in the previous 18 months). Experience in the countries with mandated warning labels indicates the level of awareness of warning labels and recall of their content will increase over time.

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The reviewed literature shows trends in awareness with some consumer characteristics. The proportion of populations who are aware of pregnancy warning labels decreases as age increases. Those who drink at higher levels or who drink directly from packaged alcoholic containers were more likely to be aware of pregnancy warning labels than those who drink at lower levels or didn't drink directly from the container. There was also some evidence of those with higher levels of formal education being more likely to be aware of pregnancy warning labels than those with lower levels of formal education.

Consumers attention to warning labels is influenced by a range of design factors. These design factors can be manipulated to enhance the noticeability of warning labels such that consumers are more likely to notice the warning.

3.1.1.1.1 *Signal words*

There were no studies identified in the review that experimentally tested the influence of signal words on attention. However, a broader research literature has demonstrated that signals words are important in drawing attention to a warning. Signal words can also connote different levels of hazard. In some circumstances the use of authoritative sources can increase the credibility of warnings, but they may also result in a level of reactance⁴ in response to the message. A search of the literature for use of 'pregnancy warning' or 'pregnancy caution' did not locate any studies.

3.1.1.1.2 *Size*

For a pregnancy warning label to be effective it first must be noticed and the consumer direct their attention to it. That the size of an element in a label is related to the attention it receives has been long established in consumer and marketing research. The experimental studies using warning labels on alcohol found that increasing the size of warnings led to an increase in the noticeability of the warning. This was also supported by the findings of qualitative studies. There is likely to be a ceiling effect above which increasing the warning size will have only marginal additional benefit. The size and type of font used impacts its readability with larger fonts being more easily read than smaller fonts. Sentences in all capitals can be harder to read than those in sentence case. A clear and large font is particularly important for the visually impaired.

3.1.1.1.3 *Location*

There were few studies identified in the review that tested the impact of warning location on attention for alcohol products experimentally. Despite this there was evidence from qualitative studies that supports the general contention that location of a pregnancy warning label on the front of alcoholic beverages would receive quicker and/or more attention than those placed elsewhere on the packaging. This is also supported by the tobacco warning research where many studies have highlighted the greater effectiveness of tobacco warnings when placed on the front of tobacco packages compared with the back and side of packages. Borders have been used to draw attention to a warning. Studies highlighted that the context in which the warning is placed can impact attention, hence a border can be used to distinguish and separate the warning from other information that competes for attention.

3.1.1.1.4 *Colour and contrast*

Colour has been used in warnings to enhance the attention they receive. Experimental studies identified in the review have primarily tested red and black options. Using red in a

⁴ Reactance is a negative state of arousal that can be triggered when individuals feel some perceived or actual loss of freedom.

warning can increase the speed at which the warning is identified and also increase the reported level of attention the warning receives. The use of the red pictogram was also considered more noticeable in contrast to the black pictogram. Colour operates as a cue that in combination with an appropriate signal word is perceived as implying a greater hazard than the equivalent signal word in black text. 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 to enhance legibility.

3.1.1.1.5 Pictorials

Pictorials have been used in warnings to both draw attention to the warning and to convey information. Types of pictorial content include representative drawings, such as the standard pictogram, actual photographs, or more abstract symbols (as often used in road signs). Studies generally find that the addition of a pictorial element to a textual warning enhances the level of attention that the warning receives in comparison with a text only warning. Additionally, pictorial elements can bridge literacy and other educational gaps. Some studies have explored graphic warnings (realistic photographs) with pictorial warnings to find that graphic warnings may be more effective in altering judgements, however others have found increased resistance to messages as a reaction to graphic warnings. No literature was found that explored graphic warnings in the context of FASD.

3.1.1.2 Comprehension

Most of the relevant information on the comprehension of pregnancy warning labels in Australia and New Zealand has been conducted on behalf of government and NGOs. The research on the standard pictogram suggests it is well understood by participants across target populations of women of childbearing age and young women, as well as the general population. When the pictogram is red and black it is seen more like a warning than when other colour combinations are used.

Comprehension of the voluntary warning statement *It's safest not to drink while pregnant* has been explored in cross sectional surveys showing varying degrees of comprehension across studies. While some studies found very high levels of comprehension, others have identified a significant, but small proportion of key target populations who interpret the text as meaning *you can drink when pregnant but it is safer not to*. A degree of ambiguity was also identified in focus groups where the word 'safest' gave rise to the varying interpretations.

Few other text messages have been tested in Australian and New Zealand populations. However, research findings suggest it is important to personalise the message to make it more relevant, and to avoid using definitive language (*will cause*) about causal connections.

3.1.1.3 Judgement

Wilkinson et al. (2009) concluded that the impact of warning messages on judgements was equivocal highlighting results that both increased risk perceptions in some populations, and decreased risk perceptions in others. The studies we identified showed that warnings can influence judgements participants hold about alcohol, and about its risks. In particular, combinations of graphic warnings with text enhance the risk perceptions of products over the risk perceptions from text only warnings and those without warnings at all. Multiple exposure to the same warning across different situations can lead to stronger beliefs in alcohol as a risk factor in some chronic illnesses. The size of warnings also appeared to impact product evaluations such that larger warnings are more likely to reduce positive product evaluations.

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When considering warning message believability, convincingness and relevance, some types of warnings perform better than others. Positively framed warnings were rated more believable than those using fear appeals and those using numerical evidence. Language such as *increases risk* was also considered more believable than language like *can cause*.

3.1.1.4 Behaviour

The literature on the impact of warning labels on behaviour was limited. The experimental studies reviewed indicated that warning labels can have an impact on self-reported intentions to reduce alcohol consumption. Studies also identified other behaviours such as seeking further information, visiting a website, and talking to others about the risks of harm from alcohol. There was no strong evidence to suggest that where warning labels have been mandated there has been an impact on levels of consumption. Researchers typically note that the current mandated warnings do not incorporate relevant design factors to enhance their effectiveness.

3.1.1.5 Conclusion of literature review

FSANZ undertook a literature review to inform the design and development of the pregnancy warning label. The review confirmed that multiple design elements (size, location, colour, pictorials, 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 are likely to 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 through the application of different design factors, or to those design factors to varying degrees. 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 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 response have been reported (e.g. changed alcohol consumption patterns, seeking further information, visiting websites, prompting discussions and conversations), these reports are generally self-reported and correlational. 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.

Due to time constraints, FSANZ has arranged for the literature review to be peer reviewed during the public consultation period. The outcome of the peer review will be considered after public consultation and inform FSANZ's decision on whether to accept, amend or reject the draft variation.

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3.1.2 Consumer testing of warning statements

3.1.2.1 Approach

The policy advice to FSANZ stated the pregnancy warning label should include both a pictogram and warning statement (FRSC, 2018). In addition, signal word(s) such as 'Health Warning' or 'Warning' were recommended. Based on the policy advice and the FSANZ literature review (SD1), it is proposed the pregnancy warning label include a pictogram, signal word(s) and statement. Given the existing evidence base related to the pictogram and signal word(s), FSANZ decided not to consumer test these components of the label (see section 3.2.2 and SD1). The focus of the consumer testing was therefore on the statement to be used in the warning label. The following section outlines the approach taken in selecting the statements that were consumer tested.

3.1.2.2 Selection of statements tested

Based on available research capacity and considerations of study design, the number of statements to be consumer tested was restricted to four. Given the statement *It's safest not to drink while pregnant* has been commonly used in the voluntary labelling initiative it was important to test this statement alongside alternative options. The following discussion outlines the approach used to select the other three statements to be tested.

A discussion document on alcohol labelling prepared by the World Health Organization (WHO, 2017) suggests four aspects of a warning message could be considered when developing an effective health warning:

- signal word to attract attention
- identification of the problem
- explanation of the consequences if exposed to the problem
- instructions for avoiding the problem.

Previous research has indicated the following principles may also help to enhance consumer understanding of a pregnancy warning label:

- directly refer to low levels of alcohol consumption
- avoid definitive language that harm will always occur
- use personalised language to increase relevance
- statement to be as short as possible.

The inclusion of the principle - directly referring to low levels of alcohol consumption - is also supported by the policy advice in the DRIS which states the pregnancy warning label should reflect Australia and New Zealand government advice not to drink any alcohol during pregnancy (refer to sections 1.3 and 2.2 of this report).

FSANZ considers the proposed pictogram covers the principle relating to including instructions for avoiding the problem and so did not seek to include this aspect in the statement. As stated above, signal word(s) have been considered separately and are proposed to be included in the warning label.

FSANZ applied the remaining six principles above to a list of possible warning statements (Attachment D). Of the 35 statements in the list, the following statements best met the six principles:

- Drinking any alcohol can harm your unborn baby
- Any amount of alcohol may harm your unborn baby
- When pregnant, any alcohol can seriously damage your baby

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

The following statements were slightly adapted from those in the list to better meet the principles and were therefore also considered:

- Small amounts of alcohol can harm your unborn baby
- Drinking any alcohol may cause lifelong harm to your baby
- Any alcohol can harm your unborn baby

On the basis the word 'can' better reflects the evidence that alcohol consumption can cause FASD rather than 'may' cause, 'can' was preferred. Some of the above statements use the term 'unborn' baby and others do not. Given New Zealand and Australia consumer education materials tend not to use the term 'unborn' and to help reduce the number of words, it was decided to omit 'unborn' in the statements to be tested. We also considered 'drinking' to be redundant in the context of the warning label being placed on alcoholic beverages and the use of the pictogram alongside the statement.

Together with the statement used in the voluntary labelling initiative, the statements consumer tested were:

- It's safest not to drink while pregnant
- 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 shorter statement with no explicit reference to 'any amount' of alcohol was included to enable testing of the contribution 'any amount' has to consumer understanding of government advice not to drink any alcohol during pregnancy.

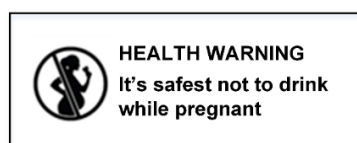
3.1.2.3 Study design and methodology

3.1.2.3.1 Study design

The aim of the consumer testing was to identify which of four statements were able to convey the desired public health message of not drinking any 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 effect from viewing all warning statements.

Four warning labels were developed that consisted of the pictogram, the signal words, and the warning statement contained within a box. The four warning labels were identical except for the statement wording. An example of the warning label format presented to participants is shown below.



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A range of measures were used to assess participants' evaluations of the warning label (refer to Appendix A of Supporting Document 2 (SD2) for the questionnaire). These were:

- comprehension – open ended and closed questions, evaluation on 5-point scale
- believability – evaluation on 5-point scale
- credibility – evaluation on 5-point scale
- convincingness – evaluation 5-point scale
- personal relevance – evaluation on a 5-point scale
- final comparison – first time participants saw all four statements and selected the one that best conveys the message not to drink any alcohol during pregnancy.

An online survey was used to implement the test. Roy Morgan Research (RMR) was commissioned to refine the questionnaire, obtain representative samples in both Australia and New Zealand, implement the survey and carry out the analysis (SD2). Ethics approval was sought and attained from Bellberry Limited, a non-profit provider of Human Research Ethics Committees certified and registered with the National Health and Medical Research Council (NHMRC).

3.1.2.3.2 Methodology

There were several stages in undertaking the consumer research each briefly described below.

Questionnaire development: After determining an appropriate design for the testing, FSANZ developed a draft questionnaire to measure the attributes of interest. The initial draft was workshopped with RMR, and ethical review was attained.

Cognitive interviews: A series of 29 cognitive interviews were undertaken in Australia and New Zealand to refine the questionnaire and ensure that it worked with the target sample. During the cognitive interviews, participants completed the questionnaire on-line as if they were undertaking the survey. Following that a trained interviewer talked through each question with the participants to ensure the questionnaire worked as intended. Cognitive interviews were held with 14 respondents in Australia and 15 in New Zealand. Some minor question and wording changes were introduced to resolve the issues identified.

Sampling: The samples for consumer testing were drawn from Roy Morgan's proprietary on-line panels in both Australia and New Zealand. Some younger demographics were supplemented from an additional commercial sample provider. Quotas were set for age by sex by region to ensure representativeness of both countries. A total sample of 1002 in each country was achieved. Given the primary target of women of childbearing age, females were oversampled, and only those aged 18-45 years were included. The final sample consisted of 802 females and 200 males in each country.

Fieldwork: An initial soft launch of the survey was implemented to ensure the survey and programming worked as expected. After this the full sample was invited. Data collection took place from 29 July to 9 August 2019.

Analysis and Reporting: RMR have analysed the data and prepared a report (SD2). The data were weighted to reflect national population estimates and significant differences between means and population proportions are reported. Open-ended questions were inductively coded to produce sets of exclusive categories. Means were calculated for scale questions ranging from a possible minimum of -2 to a maximum of +2. A score closer to +2 is more positive, while a score closer to -2 is more negative with respect to the measured attribute. FSANZ provided comments on a draft of the final report.

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Due to time constraints, FSANZ has arranged for the RMR report to be peer reviewed during the public consultation period. The outcome of the peer review will be considered after public consultation and inform FSANZ's decision on whether to accept, amend or reject the draft variation.

3.1.2.4 Summary of results

In the summary below we have reported the survey results for the key target audience of women of child bearing age being those aged between 18 and 45 years. A second set are termed proximate pregnant who are the women who are currently pregnant, have had a child in the previous 18 months, intended to have a child in the next 18 months and the partners and spouses of these women. A final section highlights the findings for Māori and Pacific people in New Zealand. We were unable to attain a reliable sample of Aboriginal and Torres Strait Islander people to report as a separate group. Results for males, and for Australia and New Zealand can be found in SD2.

3.1.2.4.1 Comprehension

After completing an open-ended question seeking their interpretation of the warning statement they saw, participants were asked to select one of five possible interpretations which closely matched their response. The five possible responses were:

1. If you are pregnant you should not drink any amount of alcohol as it can cause permanent harm to your baby.
2. If you are pregnant you should not drink any amount of alcohol as it can harm your baby.
3. If you are pregnant you should not drink alcohol as it can harm your baby.
4. If you are pregnant you can drink alcohol if you want, but it's better not to.
5. If you are pregnant it's best not to drink alcohol, but drinking a small amount is OK.

Statements 1, 2, and 3 reflect Australian and New Zealand public health advice not to drink any alcohol if you are pregnant. Statements 4 and 5 do not reflect Australian and New Zealand public health advice.

More than 75% of both New Zealand and Australian females selected one of the three statements reflecting current public health advice (Australia (AU):75.1%, New Zealand (NZ): 78.9%). However, of those allocated to the *It's safest not to drink while pregnant* statement, more than 20% of females in both countries selected one of the two statements that do not reflect current public health advice (AU 24.9%, NZ: 21.1%, Chart 19 in SD2). For the remaining three warning statements, 95% or more of females in both Australia and New Zealand selected interpretations that reflect current public health advice (Charts 20-22 in SD2).

For those in the proximate pregnancy category results were similar to those for women in each country. In Australia and New Zealand 28.7% and 19.2% of those who were allocated to the *It's safest not to drink while pregnant* statement selected one of the two statements that do not reflect current public health advice. More than 95% of New Zealanders in the proximate pregnancy category allocated to each of the other three statements gave responses that reflected current public health advice. In Australia this was different; 10.3% of respondents in the proximate pregnancy category that interpreted the *Alcohol can harm your baby* statement selected responses that did not reflect current public health advice. Proportions selecting statements that did not reflect current public health advice for *Any amount of alcohol can cause lifelong harm to your baby* and *Any amount of alcohol can harm your baby* were 2.9% and 5.5% respectively.

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Participants were asked to indicate the extent to which their allocated warning statement conveyed the public health message: *not to drink any alcohol while pregnant*. The results indicate that all statements conveyed the desired message positively. However, there were significant differences in the extent to which each statement conveyed the message. For females in Australia and New Zealand, the mean comprehension score for *It's safest not to drink while pregnant* (AU: 0.62, NZ: 0.67) and *Alcohol can harm your baby* (AU: 0.88, NZ: 1.29) were significantly lower than for *Any amount of alcohol can cause lifelong harm to your baby* (AU: 1.45, NZ: 1.55) and for *Any amount of alcohol can harm your baby* (AU: 1.43, NZ: 1.38) (Table 1).

The means for conveying the message for the *It's safest not to drink while pregnant* statement (AU: 0.52, NZ 0.81) were significantly lower than the means for the remaining three warning statements for both Australians and New Zealanders categorised as proximate pregnant (Table 1).

Table 1: Extent label conveys message not to drink any alcohol during pregnancy - Mean Score for label shown by sex and proximity to pregnancy by country

Extent label conveys message "Not to drink any alcohol during pregnancy" - Mean score	Females		Males		Proximate Pregnant		Not Proximate Pregnant	
	Australia	New Zealand	Australia	New Zealand	Australia	New Zealand	Australia	New Zealand
Shown "It's safest not to drink while pregnant" label	0.62	0.67	0.29	0.55	0.52	0.81	0.45	0.56
Shown "Any amount of alcohol can cause lifelong harm to your baby" label	1.45	1.55	1.47	1.41	1.55	1.42	1.44	1.50
Shown "Any amount of alcohol can harm your baby" label	1.43	1.38	1.22	1.52	1.40	1.42	1.31	1.47
Shown "Alcohol can harm your baby" label	0.88	1.29	1.08	1.23	1.30	1.31	0.88	1.23

Source: Alcohol Warning Label Survey 2019 – Table A.

Base: Australia females n=802; New Zealand females n=802, Australia males n=200, New Zealand females n=200, Australia proximate pregnant n=200, New Zealand proximate pregnant n=238, Australia not proximate pregnant n=802, New Zealand not proximate pregnant n=764.

Green text: Significantly higher for means in that column at the 95% confidence level; Red text: Significantly lower for means in that column at the 95% confidence level

While all four messages were at some level successful in conveying current public health advice to Australian and New Zealand women and those in the proximate pregnant category, more than 20% of women from both countries interpreted the message from the *It's safest not to drink while pregnant* statement in a manner that did not align with public health advice. Additionally, those shown the *Alcohol can harm your baby* statement considered it conveyed the message not to drink any alcohol during pregnancy, to a significantly lesser extent than both of the '*Any amount ...*' statements. The research suggests the statements *Any amount of alcohol can cause lifelong harm to your baby* and *Any amount of alcohol can harm your baby* are the best performing statements at conveying the desired message to both women of childbearing age and those in the proximate pregnant category in both countries.

3.1.2.4.2 Believable and Credible

The pattern for the extent to which the warning statements are believable and credible are similar for women in both countries, and also for those in the proximate pregnant category. For Australian women, the *It's safest not to drink while pregnant* statement was rated significantly lower than the other three statements for both believability and credibility (Tables 2 and 3).

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In contrast, New Zealand women rated the statement *Alcohol can harm your baby* significantly higher than the other three statements for both believability and credibility (Tables 2 and 3). While the means for both *Any amount ...* statements were significantly lower than the *Alcohol can harm your baby* statement for New Zealand women, the mean scores were high, being above 1.4 for believability and above 1.2 for credibility.

For those in the Australian proximate pregnancy category, the mean scores for believability for *Any amount of alcohol can cause lifelong harm to your baby* (1.60) and *Alcohol can harm your baby* (1.50) were significantly higher than the mean score for the *It's safest not to drink while pregnant* statement (1.13). The mean credibility scores for *It's safest not to drink while pregnant* was significantly lower than the other three statements for the Australian proximate pregnancy category (Tables 2 and 3).

In the New Zealand proximate pregnancy category there were no significant differences in mean scores across all four statements for both believability and credibility.

Across both believability and credibility, the worst performing statement was *It's safest not to drink while pregnant* except for among the New Zealand proximity to pregnancy group, where it performed as well as the other three statements. Overall the results suggest that except for *It's safest not to drink while pregnant* the statements perform well in terms of the extent of their credibility and believability among women of childbearing age and those in the proximate pregnant category.

Table 2: Extent label is believable to me – Mean Score for label shown by sex and proximity to pregnancy by country

Extent label is believable to me - Mean score	Females		Males		Proximate Pregnant		Not Proximate Pregnant	
	Australia	New Zealand	Australia	New Zealand	Australia	New Zealand	Australia	New Zealand
Shown "It's safest not to drink while pregnant" label	1.15	1.18	1.15	1.11	1.13	1.52	1.15	1.04
Shown "Any amount of alcohol can cause lifelong harm to your baby" label	1.44	1.46	1.59	1.37	1.60	1.52	1.50	1.39
Shown "Any amount of alcohol can harm your baby" label	1.43	1.49	1.17	1.33	1.38	1.58	1.28	1.33
Shown "Alcohol can harm your baby" label	1.38	1.61	1.64	1.44	1.50	1.56	1.50	1.50

Source: Alcohol Warning Label Survey 2019 – Table B

Base: Australia females n=802; New Zealand females n=802, Australia males n=200, New Zealand females n=200, Australia proximate pregnant n=200, New Zealand proximate pregnant n=238, Australia not proximate pregnant n=802, New Zealand not proximate pregnant n=764.

Green text: Significantly higher for means in that column at the 95% confidence level; Red text: Significantly lower for means in that column at the 95% confidence level

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Table 3: Extent label is credible to me – Mean Score for label shown by sex and proximity to pregnancy by country

Extent label is credible to me - Mean score	Females		Males		Proximate Pregnant		Not Proximate Pregnant	
	Australia	New Zealand	Australia	New Zealand	Australia	New Zealand	Australia	New Zealand
Shown "It's safest not to drink while pregnant" label	0.98	0.84	0.75	0.79	1.00	1.28	0.84	0.68
Shown "Any amount of alcohol can cause lifelong harm to your baby" label	1.22	1.28	1.18	1.26	1.39	1.34	1.15	1.25
Shown "Any amount of alcohol can harm your baby" label	1.24	1.22	1.10	1.21	1.34	1.38	1.14	1.14
Shown "Alcohol can harm your baby" label	1.15	1.47	1.36	1.25	1.33	1.37	1.23	1.35

Source: Alcohol Warning Label Survey 2019 – Table C

Base: Australia females n=802; New Zealand females n=802, Australia males n=200, New Zealand females n=200, Australia proximate pregnant n=200, New Zealand proximate pregnant n=238, Australia not proximate pregnant n=802, New Zealand not proximate pregnant n=764.

Green text: Significantly higher for means in that column at 95% confidence level; Red text: Significantly lower for means in that column at 95% confidence level

3.1.2.4.3 Relevance

In contrast to the other evaluations of the warning statements, the mean relevance scores for all warning statements were negative for Australian and New Zealand women (Table 4). That is, women in both countries considered that the warning statements did not directly apply to them. The only positive mean relevance scores were for those in the proximate pregnancy category in both countries. This difference between the general female population and those in the proximate pregnancy category is not surprising. The warning message is about pregnancy and many of the women in the general population would already have had children and are not considering further pregnancies. The higher scores for the proximate pregnancy category highlight that relative to other women, those in the proximate pregnancy category find the statements apply to them to a greater degree.

In Australia, *It's safest not to drink while pregnant* and *Any amount of alcohol can cause lifelong harm to your baby* statements both had mean relevance scores above 0.60 for the proximate pregnancy category, and were both significantly higher than the mean relevance score for *Alcohol can harm your baby* (-0.02) statement. In the New Zealand proximate pregnant category, *It's safest not to drink while pregnant*, *Any amount of alcohol can cause lifelong harm to your baby* and *Alcohol can harm you baby* all had mean scores around 0.45 and were all significantly greater than the mean for *Any amount of alcohol can harm your baby* (Table 4).

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Table 4: Extent label directly applies to me – Mean Score for label shown by sex and proximity to pregnancy by country

Extent label applies to me - Mean score	Females		Males		Proximate Pregnant		Not Proximate Pregnant	
	Australia	New Zealand	Australia	New Zealand	Australia	New Zealand	Australia	New Zealand
Shown "It's safest not to drink while pregnant" label	-0.53	-0.67	-1.23	-0.55	0.62	0.48	-1.14	-0.94
Shown "Any amount of alcohol can cause lifelong harm to your baby" label	-0.23	-0.64	-0.86	-0.98	0.61	0.46	-0.89	-1.13
Shown "Any amount of alcohol can harm your baby" label	-0.41	-0.73	-1.26	-0.54	0.25	-0.01	-1.04	-0.89
Shown "Alcohol can harm your baby" label	-0.71	-0.43	-1.20	-0.22	-0.02	0.45	-1.21	-0.69

Source: Alcohol Warning Label Survey 2019.

Base: Australia females n=802; New Zealand females n=802, Australia males n=200, New Zealand females n=200, Australia proximate pregnant n=200, New Zealand proximate pregnant n=238, Australia not proximate pregnant n=802, New Zealand not proximate pregnant n=764.

Green text: Significantly higher for means in that column at the 95% confidence level; Red text: Significantly lower for means in that column at the 95% confidence level

3.1.2.4.4 Convincing

For Australian women both *Any amount ...* warning statements were rated as significantly more convincing than both *It's safest not to drink while pregnant* and *Alcohol can harm your baby* statements (Table 5). For Australians in the proximate pregnancy category, *Any amount of alcohol can cause lifelong harm to your baby* (1.51) was considered significantly more convincing than the remaining three statements. However for this group all statements received a mean convincing score greater than 1.0.

New Zealand women rated the *Alcohol can harm your baby* (1.41) statement significantly more convincing than both *It's safest not to drink while pregnant* (0.83) and *Any amount of alcohol can harm your baby* (1.23) warning statements. There were no significant differences in the mean convincing score for those in the New Zealand proximate pregnant category, with all statements scoring above 1.30.

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Table 5: Extent is convincing to me – Mean Score for label shown by sex and proximity to pregnancy by country

Extent is convincing to me - Mean score	Females		Males		Proximate Pregnant		Not Proximate Pregnant	
	Australia	New Zealand	Australia	New Zealand	Australia	New Zealand	Australia	New Zealand
Shown "It's safest not to drink while pregnant" label	0.80	0.83	0.65	0.81	1.07	1.37	0.66	0.67
Shown "Any amount of alcohol can cause lifelong harm to your baby" label	1.28	1.31	1.16	1.15	1.51	1.54	1.13	1.16
Shown "Any amount of alcohol can harm your baby" label	1.21	1.23	0.88	1.13	1.13	1.36	1.02	1.10
Shown "Alcohol can harm your baby" label	0.97	1.41	1.06	1.23	1.14	1.40	0.98	1.27

Source: Alcohol Warning Label Survey 2019 Table E.

Base: Australia females n=802; New Zealand females n=802, Australia males n=200, New Zealand females n=200, Australia proximate pregnant n=200, New Zealand proximate pregnant n=238, Australia not proximate pregnant n=802, New Zealand not proximate pregnant n=764.

Green text: Significantly higher for means in that column at the 95% confidence level; Red text: Significantly lower for means in that column at the 95% confidence level

3.1.2.4.5 Statement that best conveys the message

After participants had rated their allocated warning label across the attributes described above they were presented with all four warning labels. This is the first time participants read the other three warning statements. Participants were asked to select the one warning label that best conveys the message not to drink any alcohol while pregnant.

Across both countries more than 50% of both women and those in the proximate pregnant category selected *Any amount of alcohol can cause lifelong harm to your baby* as the statement that best conveys the public health message (range from 52.4% to 54.1%) (Table 6). The next most common response for all groups was *Any amount of alcohol can harm your baby* (range from 24.1% to 28.7%). Generally, the third most common statement selected was *Alcohol can harm your baby* (range from 9.0 to 15.9%) and finally *It's safest not to drink while pregnant* (range from 5.0% to 12.7%). Those in the Australian proximate pregnant category chose *It's safest not to drink while pregnant* (12.7%) more frequently than *Alcohol can harm your baby* (9.0%).

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Table 6: Statement that best conveys message not to drink any alcohol while pregnant (% participants)

Statement	Females		Proximate pregnant	
	Australia	New Zealand	Australia	New Zealand
Any amount of alcohol can cause lifelong harm to your baby	52.4	53.3	54.1	53.3
Any amount of alcohol can harm your baby	28.7	28.5	24.1	24.4
Alcohol can harm your baby	11.2	13.2	9.0	15.9
It's safest not to drink while pregnant	7.6	5.0	12.7	6.4

3.1.2.4.6 Summary of data for Māori and Pacific people

The New Zealand survey achieved a sample of n=141 Māori and Pacific people and the mean scores for the various measures are shown in Table 7. The results generally follow the same patterns as for New Zealand females. However the differences tend not to be significant which could be due to the small sample limiting the power to detect significant differences or in fact no significant differences exist.

Table 7: Summary of evaluations of warning statement and choice of label best conveying message 'to not drink any alcohol while pregnant' for Māori/Pacific people

Warning statement	Conveys message	Believable	Credible	Applies to me	Convincing	Best conveys message
	(mean)	(mean)	(mean)	(mean)	(mean)	(% who selected)
Its safest not to drink while pregnant	0.25	1.03	0.47	-0.76	0.74	11.0%
Any amount of alcohol can cause lifelong harm to your baby	1.46	1.25	1.02	-0.63	1.29	47.1%
Any amount of alcohol can harm your baby	1.32	1.60	1.33	-0.57	1.45	23.8%
Alcohol can harm your baby	1.19	1.33	1.37	-0.19	1.40	18.1%

Source: Alcohol Warning Label Survey 2019 – Maori/Pacific sample – New Zealand.

Base: Shown 'It's safest no to drink alcohol while pregnant' label n=27, shown 'Any amount of alcohol can cause lifelong harm to your baby' label n=34, shown 'Any amount of alcohol can harm your baby' n=39, shown 'Alcohol can harm your baby' label n=41, Total Maori/Pacific people n=141.

Caution: small sample size for comprehension of warning statement questions (columns 1 to 5).

Green text: Significantly higher for means in that column at the 95% confidence level; Red text: Significantly lower for means in that column at the 95% confidence level

3.1.2.5 Conclusion

FSANZ tested four possible warning statements with a representative sample of Australians and New Zealanders aged 18-45 years. For the Australian sample the statement *Any amount of alcohol can cause lifelong harm to your baby* had the highest mean scores across the five rating questions. For the New Zealand sample no single statement consistently had the

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highest mean scores, though the statement *Alcohol can harm your baby* performed consistently well, if not the best across all rating questions.

Women and those in the proximate pregnant category are a key target group for the warning label. The sample was biased in favour of women to provide robust results for the key target group. Among these groups all four statements performed adequately across all measures except relevance. However the statement *It's safest not to drink while pregnant* was generally a poor performer when compared with the other statements. Moreover, this was the only statement that gave rise to interpretations that contradict public health advice for around 20% of women. Of the remaining three statements, *Any amount of alcohol can cause lifelong harm to your baby* and *Any amount of alcohol can harm your baby* were generally the best performing statements with highest mean scores for Australian women and those in the proximate pregnant category. However, while these statements also performed well for New Zealand women and those in the proximate pregnant category, the statement *Alcohol can harm your baby* was generally an equal or better performer. When shown all four statements, the most frequently chosen warning that best reflects the advice not to drink any alcohol while pregnant was *Any amount of alcohol can cause lifelong harm to your baby*.

3.2 Risk management

3.2.1 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 Sydney and Wellington and via teleconference with jurisdictions. Representatives of the Maori community attended the January 2019 consultations. We 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. Stakeholders were invited to provide written information about the costs of a labelling change based on a proposed warning label (similar to that proposed in this report) 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 (see section 3.4.1.1).

A summary of views and comments from the June/July 2019 consultation meetings, together with a list of organisations and groups represented are presented at Attachment E. These views are discussed in the following sections on the design and implementation of the warning label.

3.2.2 Proposed pregnancy warning label design

3.2.2.1 Approach

As noted previously, it is proposed the pregnancy warning label will include a pictogram and a warning statement. In addition, the approach for labelling elements that serve to attract attention and enhance understanding also need to be considered (e.g. size, location of the warning label on the beverage container or packaging, colour and contrast, and signal word(s)). This group of labelling elements are termed 'design' labelling elements in this report.

3.2.2.2 Pictogram

The pictogram design commonly used in the voluntary labelling initiative across Australia and New Zealand is shown below.



Research indicates the inclusion of a graphic with text helps make the warning more noticeable than text alone (SD1). A number of pictograms conveying the message not to drink alcohol during pregnancy have been examined in research conducted in Australia, while research in New Zealand and overseas has tended to focus on the voluntary pictogram. Australian research concluded the above pictogram was understood to mean not to drink alcohol and overall was the ‘strongest option’ among those tested (Hall & Partners, 2018). Given there are moderate and increasing levels of awareness and understanding of the pictogram shown above among women of childbearing age as well as men in the same age range, it is proposed this pictogram be part of the mandated pregnancy warning label..

3.2.2.3 Warning statement

FSANZ has considered the policy advice, WHO principles for warning statements, existing evidence relevant to warning statements, results from the consumer testing (section 3.1.2.4 and SD2) and stakeholder views in the selection of the statement to be included in the pregnancy warning label.

As noted earlier, the policy advice (FRSC, 2018) and the Forum’s October 2018 Communique (Australia and New Zealand Ministerial Forum on Food Regulation, 2018) both state that Australia and New Zealand government advice is for pregnant women not to consume any alcohol. It is therefore important the warning statement reflects this message to consumers so it is consistent with government advice.

It is also useful to return to the six principles for developing a pregnancy warning message discussed earlier (section 3.1.2.2). These principles suggest 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 DRIS (FRSC, 2018) and the FSANZ literature review refer to previous research indicating some study participants considered *It’s safest not to drink while pregnant* statement conveys the message *You can drink when pregnant but it is safer not to* (Rout & Hannan, 2016) and that the statement is ambiguous and weak, rather than a clear directive warning (Hall & Partners, 2018) (SD1). The results of the FSANZ consumer testing study, indicate that overall for women both in Australia and New Zealand, *It’s safest not to drink while pregnant* statement performed least well of the four statements tested (section 3.1.2.4 and SD2). For example:

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- More than 20% of women from both countries interpreted this statement to mean either *If you are pregnant you can drink alcohol if you want, but it's better not to* or *If you are pregnant it's best not to drink alcohol, but drinking a small amount is OK*. These interpretations are inconsistent with government advice.
- When survey participants were asked to what extent the *It's safest not to drink while pregnant* label conveyed the message not to drink any alcohol while pregnant, the mean comprehension score was significantly lower than those for *Any amount of alcohol can cause lifelong harm to your baby* and *Any amount of alcohol can harm your baby*.
- When survey participants were shown all four warning labels, a much lower proportion of participants selected *It's safest not to drink while pregnant* as the statement best conveying government advice not to drink any alcohol during pregnancy compared with *Any amount of alcohol can cause lifelong harm to your baby* and *Any amount of alcohol can harm your baby*.

In conclusion, it is clear from the available evidence *It's safest not to drink while pregnant* statement does not convey government advice as well as the other statements tested. For this reason, the following discussion focusses on the results related to the other three statements.

The other three warning statements tested performed better in conveying the message not to drink any alcohol while pregnant. However, identifying which of the remaining three statements consistently performs best across all measures in the survey is more difficult.

In relation to the question asking the extent to which the statement conveys the message not to drink any alcohol while pregnant, the statements *Any amount of alcohol can cause lifelong harm to your baby* and *Any amount of alcohol can harm your baby* were the best performing statements at conveying the desired message to both women of childbearing age and those in the proximate pregnant category, in both countries, compared with the remaining statement *Alcohol can harm your baby*.

On the extent to which the warning statements are believable and credible, all three statements tended to perform well among women of childbearing age and those in the proximate pregnancy category. New Zealand females considered *Alcohol can harm your baby* to be significantly more believable and credible than the other two statements, however, this was not the case amongst Australian females or those in the Australian and New Zealand proximate pregnant categories.

Mean scores for the extent to which the warning statements are relevant to women and those in the proximate pregnant category were much lower than scores for the other measures. The scores for the proximate pregnant category are clearly of most interest. The statement *Any amount of alcohol can cause lifelong harm to your baby* performed better than the other two statements in Australia while in New Zealand, *Alcohol can harm your baby* performed well.

Those in the Australian proximate pregnant category considered the statement *Any amount of alcohol can cause lifelong harm to your baby* to be more convincing than the other two statements. In contrast, for the equivalent group in New Zealand there were no significant differences across the three statements, though the statement *Any amount of alcohol can cause lifelong harm to your baby* received the highest mean score. *Alcohol can harm your baby* performed best for New Zealand women, though it was not significantly different from *Any amount of alcohol can cause lifelong harm to your baby*. This latter statement also had

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the highest mean score for Australian women in its ability to convince, though it was not significantly different from *Any amount of alcohol can harm your baby*. In the final measure, where participants were asked to choose the statement best at conveying the public health message, in both countries, the highest proportion of women and those in the proximate pregnant categories (ranging from 52% to 54%) selected *Any amount of alcohol can cause lifelong harm to your baby*. The next most common choice (ranging from 24% to 29%) was for *Any amount of alcohol can harm your baby*.

In conclusion, overall the statements *Any amount of alcohol can cause lifelong harm to your baby* and *Any amount of alcohol can harm your baby* tended to perform best in both Australia and New Zealand in conveying the desired message not to drink any alcohol while pregnant and are also believable, credible and seen as convincing to the key audience. While *Alcohol can harm your baby* performed well in some measures amongst New Zealand women and those in the New Zealand proximate pregnant category, it did not perform as well in Australia.

Therefore, FSANZ proposes to include *Any amount of alcohol can harm your baby* in the pregnancy warning label as overall it performed well and has the advantage of being a shorter statement than *Any amount of alcohol can cause lifelong harm to your baby*, a desirable feature noted by both industry and public health stakeholders. A shorter statement will improve readability and take up less space on the label. In addition, the concept of alcohol consumption during pregnancy causing lifelong harm is included in the broader suite of measures aimed at reducing alcohol consumption during pregnancy. FSANZ considers *Any amount of alcohol can harm your baby* meets all six principles listed above.

3.2.2.4 Design labelling elements

3.2.2.4.1 Principles

If the warning label is not noticed by consumers then it will not achieve its purpose of informing consumers not to drink any alcohol during pregnancy. Drawing on requirements under subsection 18(2) of the *Food Standards Australia New Zealand Act 1991* (refer to section 3.4.3 of this report), FSANZ developed three principles on which to base consideration of the regulatory approach for the design labelling elements. These principles are discussed below.

Principle 1: Have regard to policy advice in the DRIS provided to FSANZ, with particular reference to the recommendations related to warning label design.

Recommendations in the DRIS relevant to the design labelling elements are (page 10 of the DRIS):

- Text be readable and possibly the same size as other label information
- Use short warning messages and words such as 'Warning' or 'Health Warning' to indicate it is a warning label
- Warning label be separated from other information such as *enjoy in moderation*, e.g. placed in a box, clear space used around the warning label
- Contrasting colours are used. The colour green should not be used as it can cause confusion while the colour red receives the most attention and is readily associated with being a warning

It is also recommended in the DRIS consumer testing be undertaken to determine design, size and colour features of the pictogram, to examine wording and presentation of the statement and to explore the location of the warning label particularly in relation to proximity to other label information (see Appendix 2 of the DRIS). FSANZ decided not to consumer

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test design labelling elements because of the considerable existing evidence in the context of health warnings (see Principle 2).

Principle 2: Consider the best available evidence relating to design labelling elements in the context of health warnings and warning labels.

Key findings from the literature review (SD1) relevant to the design labelling elements are presented in section 3.1.1 of this report.

The size and legibility of pregnancy warning labels during the voluntary labelling initiative is of interest given the importance of these design elements in attracting attention to the warning. Of the total number of products assessed in Australia (n=1717), 82% had warning labels (predominantly the pictogram) of about 5 mm diameter with approximately 12% having a size smaller and the remaining 6% larger (Siggins Miller, 2017). Premium and craft beers had the highest proportion of beverages with pictogram sizes greater than 5 mm (25%).

In the 2017 Australian label evaluation, researchers assessed the legibility (described as *size, distinction against other stimuli, message complexity, exclusion area/bordering, spacing, font type and text casing (if applicable)*) and prominence (described as *size, location and position on packaging or label or labels, the noticeable nature of the text or picture, colour and image contrast, bordering, font differences, spacing and segmenting from other label stimuli*) of pregnancy warning labels using the legibility requirements in the Code as a reference (Siggins Miller, 2017 (Appendix 2.2)). Approximately 93% of beverages surveyed (n= 1717) were considered to have 'standard' or 'above standard' legibility and 90% 'standard' or 'above standard' prominence, however no information or examples of what was deemed 'standard' were provided. Colours and contrast used for the pictogram were not reported.

The 2017 New Zealand evaluation included a field survey of 297 products (MPI, 2017a). It was stated there was *a lot of variation in the type, colour and size of the pictogram used*, but details were not reported. The use of the colour green for the pictogram was noted.

Principle 3: Consider other information relevant to design labelling elements including existing guidance and requirements for alcohol labelling such as the DrinkWise guidance for voluntary pregnancy warning labels, standard drink labelling, existing Code requirements for legibility and requirements for warning labels in other countries.

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 Code requires the font size of warning statements to be at least 3 mm and 1.5 mm for small packages. The general legibility requirements also apply to warning statements. Guidance for standard drink labelling and the recycle logo recommends a larger label height (12-14 mm) than that for the voluntary pregnancy warning label (8 mm box height with a pictogram of about 5 mm diameter) (Attachment F).

3.2.2.4.2 Stakeholder views

At the targeted consultations, industry stakeholders indicated a preference for a smaller warning label and a less prescriptive approach to label design, particularly in regards to colour and contrast. Industry stakeholders advised that given the large range of products in the market, the limited label space for an increasing number of mandatory label elements and challenges associated with complying with labelling requirements of international markets, flexibility would be preferred. Industry stakeholders indicated costs to industry under

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a more prescriptive approach, would be considerable. There was a suggestion the pictogram, only, or a smaller complete warning label be required on container volumes < 440 ml instead of the proposed < 100 ml and on beverage containers sold in retail multipacks or cartons. Such an approach was suggested by stakeholders representing the beer sector as about 95% of beer is sold in multipacks or cartons. In terms of the signal words, some industry stakeholders called for 'Pregnancy Warning' instead of 'Health Warning' and queried the relative importance of a pregnancy warning label in relation to other mandatory information on alcoholic beverages.

In contrast, public health stakeholders supported a higher level of prescription as they considered such an approach would draw greater attention and help to reinforce the health message. Public health stakeholders were concerned about the possible close proximity of a pregnancy warning label with *drink responsibly* type messages and the potential for this to cause confusion. There was a preference for a larger warning label but they recognised a pragmatic approach may be needed. Public health stakeholders supported a font size of at least 3 mm in line with current requirements in the Code for warning statements, a larger pictogram particularly if some beverages only need to carry the pictogram, and prescription for label orientation.

Jurisdictions indicated a general preference for a more prescriptive approach but acknowledged the challenge this may pose for industry and the need to consider whether flexibility is appropriate. There were mixed views regarding the proposed size of the warning label. Some considered the minimum font size should be consistent with existing Code requirements (at least 3 mm) while others acknowledged a pragmatic approach may be necessary and that the whole warning label would likely be larger than other mandatory labelling elements on alcoholic beverages.

Australian indigenous stakeholder representatives raised a concern about the wine glass held by the woman in the pictogram, and whether this would be meaningful for an indigenous audience in remote communities who may not use this type of vessel. Indigenous stakeholders generally supported the approach for beverage containers <100 ml to have the pictogram only.

3.2.2.4.3 Proposed approach

Based on recommendations in the DRIS and the relevant evidence base it is proposed that most of the design elements of the pregnancy warning label are prescribed in the Code. Such an approach will help achieve consistency in presentation of the warning label across the alcoholic beverage sector, help ensure it is legible and attract attention. 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 suggests size, location of the warning label on the beverage container or packaging, colour and contrast, and signal words can all help enhance the noticeability of a warning label (section 3.1.1 and SD1), the application of these design elements to a pregnancy warning label is discussed below.

Signal word(s)

Evidence on the use of signal word(s) suggests they can help to attract attention (SD1). 'Health Warning' has some benefit over 'Government Warning' or 'Warning' because the former increases credibility of the message. There is also some evidence 'Health Warning' attracts attention more than 'Warning' due to the fact it is two words. No published studies have compared the effect of 'Pregnancy Warning' with other signal words on credibility or ability to attract attention. 'Health Warning' has a broader meaning than 'Pregnancy Warning'

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which could help support the secondary objective of the warning label as stated in the DRIS (to provide information to the broader community). Therefore, FSANZ’s preferred approach is to include ‘Health Warning’ in the proposed pregnancy warning label. However, FSANZ would welcome any further evidence or views being provided in submissions on the use of other signal words such as ‘Pregnancy Warning’ or ‘Warning’.

Warning label size

Evidence relevant to warning labels on alcoholic beverages indicates a larger warning label size relative to other label elements would attract greater attention than smaller warning labels (SD1). Alcoholic beverages are sold in a large range of container volumes and packages which is different to most other foods and beverages (see Table 8 below).

Table 8: Examples of alcoholic beverage volumes and packages in the alcoholic beverage sector in Australia and New Zealand

Alcoholic beverage volume or package	Examples of beverage types
< 100 ml	spirits
100 ml and ≤ 200 ml	liqueur
250 ml	wine in can, ready to drink (RTDs)
300 ml	liqueur, RTDs
320 ml	RTDs
330 ml	beer, cider, RTDs
375 ml	cider, beer
440 ml	beer
500 ml	liqueur, cider, beer
650 ml	beer
700 ml	liqueur, spirits, RTDs
720 ml	liqueur
750 ml	wine, spirits, liqueur, beer
900 ml	beer
1 litre	whisky, gin, vodka, brandy, liqueur
1.25 litre	cider, RTD, alcoholic ginger beer
1.75 litre	liqueur, whisky
2 litre	RTD, wine
3 litre	wine, spirits
4 litre	wine
4.5 litre	spirits
5 litre retail keg	beer
5 litre	wine
Retail multipacks (4, 6, 9,10, 12, 15, 18, 24, 30 units)	beer (e.g. 330 ml, 345 ml, 355 ml, 375 ml, 750 ml), RTDs (e.g. 200 ml, 250 ml, 275 ml, 300 ml, 330 ml, 355 ml, 375 ml, 420 ml, 440 ml), shots (30 ml) wine (e.g. 187 ml, 200 ml) cider (e.g. 330 ml)
Single bottle in retail box	wine, champagne, spirits

Adding to the complexity of determining a minimum label size appropriate for such a large range of beverage volumes, is the variability in the amount of space dedicated to a label on containers. For example, the amount of space taken up by a label on a 750 ml bottle of wine may not be much larger than on a 500 ml bottle of beer, depending on the overall design of the label and container shape.

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Our consideration of typography and minimum size for the pregnancy warning label was guided by:

- the policy advice in the DRIS (text be possibly the same size as other label elements)
- findings from the literature review (SD1) relating to label size and font type and size affecting readability
- the large range of beverage volumes in the market
- more limited label space generally on smaller beverage volumes (under 200 ml) compared with greater volumes
- views of industry stakeholders and enforcement authorities to develop a relatively straightforward approach and not have several minimum size requirements for different beverage volumes
- public health stakeholder views to have a warning label as large as possible and at least the 3 mm font size as currently required for warning statements (also supported by enforcement authorities).

FSANZ considers the proposed approach (see summary Table 10 below) reasonably responds to the evidence supporting larger labels, the complex nature of the market and stakeholder views, while aiming to require a minimum size that will help to make the warning label noticeable. There is a minimum font and pictogram size but the border size is not prescribed given there will be some variation in the amount of space taken up by the words depending on the font used. FSANZ expects to provide a downloadable pregnancy warning label graphic for easy use by industry.

FSANZ proposes the signal words be in capitals and in bold (red) type to help attract attention. Sans serif fonts are proposed so as to restrict the use of some font types that may reduce readability. The warning statement is proposed to be non-bolded black in sentence case to provide a distinction with the red bolded, capitalised signal words. Table 10 also includes requirements for the warning label on multipacks and outer packaging for completeness and clarity, however, requirements for packaging layers are discussed later in section 3.2.5 of this report.

The requirement for the pictogram only for alcoholic beverage volumes ≤ 200 ml, recognises the generally smaller available label space on these beverage containers. There are also comparatively fewer alcoholic beverages sold in these volumes. The full warning label is required for all alcoholic beverage volumes greater than 200 ml, with different minimum sizes for those > 200 ml and ≤ 800 ml and > 800 ml. As discussed above, this approach takes into account the number of beverages, particularly beer and RTDs, sold in multipacks and the variability in label space for the > 200 ml and ≤ 800 ml volume range. There is typically a larger label space available when volumes are > 800 ml.

In relation to multipacks (e.g. six pack of beer), the package containing individual portion packs will need to carry a larger sized warning label (minimum pictogram diameter 11 mm and font size 3.5 mm), recognising the greater available label space on outer packaging layers. Retail cartons containing several multipacks would also need to have this same sized pregnancy warning label. This font size is similar to the requirements in the Code for warning statements and the height of the whole label would be similar to recommended heights for standard drink labels in Australia and New Zealand.

Single alcoholic beverage containers sold with outer retail packaging (e.g. bottle of sparkling wine in a box) will also have to carry the larger pregnancy warning label (other than for alcoholic beverage volumes ≤ 200 ml, where a pictogram only is required).

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FSANZ notes several countries with mandatory pregnancy warning labels also prescribe different sized warning labels for specific ranges of beverage volumes (Attachment C).

Location and label orientation

One of the findings from the literature review is consumers would be more likely to notice the warning label if it was located front-of-pack. However, we propose not to regulate location of the warning label because such an approach could contravene wine free-trade agreements. In addition, there are currently no requirements for the location of mandatory labelling elements in the Code. FSANZ considers prescribing most design labelling elements will enable the warning label to be noticed in the field of vision in which it is placed. Although some evidence suggests warnings presented vertically on an alcoholic beverage label (with respect to the bottom) may not be noticed as quickly as warnings presented horizontally (SD1), it is proposed that orientation of pregnancy warning labels will not be prescribed. This provides flexibility with the orientation of the warning label in overall label design and recognises the current practice of some companies presenting mandatory label information vertically on the container. None of the countries with mandatory pregnancy warning labels prescribe one location for the warning on a beverage container (Attachment C).

FSANZ has considered stakeholder concerns with possible co-location of the warning label with other label information such as the *drink responsibly* type messages. This issue was identified both in the DRIS (FRSC, 2018 - pg 44) and by public health stakeholders at the June 2019 targeted consultations as the practice has been observed during the voluntary labelling initiative. To date, no studies have investigated whether this specific practice influences consumer understanding of a pregnancy warning label, although more broadly there is some evidence that the context in which a warning is placed can impact attention. FSANZ is therefore proposing the use of a border around the pictogram, statement and signal words along with clear space outside the border to help achieve some separation of the warning label from other label information and help attract attention. In addition, based on the outcomes of the FSANZ consumer testing, the inclusion of the words 'any amount' in the warning statement is likely to help consumers to understand government advice not to drink any alcohol during pregnancy (SD2).

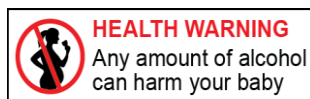
Colour and contrast

It is proposed the colour red be required for the circle and diagonal strikethrough in the pictogram and the signal words. The colour red will help to attract attention and enhance recognition of the label being a warning (SD1). A specific red colour to be used (Pantone 485⁵) is proposed to be prescribed to provide a level of consistency across alcoholic beverages. Pantone 485 is also required when the trademarked New Zealand standard drink icon is used voluntarily (Attachment F). Some countries with mandatory pregnancy warning labels also prescribe the use of the colour red in a pictogram and France is considering such an approach (Attachment C). The warning statement is to be in black on a white background to achieve a consistent high contrast which is important for legibility.

⁵ The corresponding CYMK process colour and RGB on-screen colours can be used.

3.2.2.5 Summary of proposed pregnancy warning label design

In summary, FSANZ proposes the following format for the pregnancy warning label.



The following label elements would be prescribed:

- Pictogram: as shown above
- Signal words: HEALTH WARNING
- Statement: Any amount of alcohol can harm your baby
- Border: to be around the above three label elements
- Background colour within border
- Clear space outside border

Note for alcoholic beverage volumes ≤ 200 ml, only the pictogram is required (see Table 10).



Table 9: Proposed colour and font requirements for the pregnancy warning labels






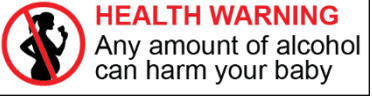
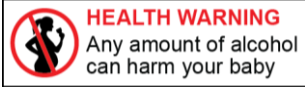
Pregnancy warning label element	Colour and font type
Pictogram	Black silhouette of pregnant woman with red circle and red diagonal strikethrough Red colour must be Pantone 485
Signal words	Red (Pantone 485), in bold, capitalised, sans serif font type
Warning statement	Black, not bolded, in sentence case, sans serif font type
Border around above elements	Black
Background within border	White
Clear space outside border	Colour not specified

Proposed size requirements:

- See Table 10 on following page
- 3 mm clear space outside border of pregnancy warning label

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Table 10: Proposed requirements for size of pregnancy warning labels on packaged alcoholic beverages for retail sale¹

Alcoholic beverage volume	Single container and each layer of packaging other than the outer package, and individual portion packs (i.e. in a multipack)		Outer package		Package containing individual portion packs (i.e. multipacks) including a carton containing several multipacks	
	Label required	Minimum Size	Label required	Minimum Size	Label required	Minimum Size
≤ 200 ml		8 mm diameter		8 mm diameter	 HEALTH WARNING Any amount of alcohol can harm your baby	Pictogram 11 mm diameter
> 200 ml ≤ 800 ml		Pictogram 6 mm diameter Font size 2.1 mm (6 point)		Pictogram 11 mm diameter Font size 3.5 mm (10 point)		Font size 3.5 mm (10 point)
> 800 ml		Pictogram 9 mm diameter Font size 2.8 mm (8 point)				

¹When Table 10 is printed, the pregnancy warning labels are approximately the minimum required sizes.

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3.2.3 Beverages to carry the pregnancy warning label

3.2.3.1 Policy considerations

The scope of the DRIS is for pregnancy warning labels to be on packaged 'alcoholic beverages'. In the DRIS, 'alcoholic beverages' are discussed in a general sense however, the specific beverages which would require the pregnancy warning label, by reference to percentage alcohol content by volume (%ABV), is not defined. As this proposal is for a mandatory requirement, FSANZ has considered what beverages will be required to have a pregnancy warning label, to provide clarity in the Code.

3.2.3.2 Relevant legislation and guidance

There are requirements in the Code and in relevant New Zealand and Australian legislation and guidelines, that provides some context for what beverages could be considered in scope of this proposal, with reference to %ABV.

In summary, the Code:

- includes standards for beer, fruit wine, vegetable wine and mead (includes cider and pear cider), wine and wine products, and spirits (Part 2.7)
- states a brewed soft drink (e.g. ginger beer) must not contain more than 1.15% ABV (Standard 2.6.2 - Non-alcoholic beverages and brewed soft drinks)
- states a non-alcoholic beverage or a brewed soft drink must not be represented as an alcoholic beverage (Section 2.6.2—8)
- includes requirements for alcohol content, standard drinks and low alcohol representations (Standard 2.7.1 - Labelling of alcoholic beverages and food containing alcohol)
- requires a statement of the number of standard drinks for food that is consumed as a beverage and contains more than 0.5% ABV (Section 2.7.1—4).

Relevant New Zealand and Australian legislation and guidance on 'alcoholic beverage' provide definitions that refer to the process of manufacture e.g. fermentation, brewing, distilling (see Attachment G). Relevant legislation also includes a reference to alcohol content which are generally 1.15% ABV or more. Three Australian jurisdictions require beverages with more than 0.5% ABV to be sold in licensed premises.

3.2.3.3 Options

Based on the above legislation and policy guidance, FSANZ considered two options for determining what 'alcoholic beverages' would be required to carry the warning label, with reference to %ABV:

- Option 1: beverages containing more than 1.15% ABV, and
- Option 2: beverages containing 0.5% ABV or more.

Under option 1, a pregnancy warning label would be required on the label of any beverage with more than 1.15% ABV. This would generally include 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.

Beverages listed above with less than 1.15% ABV such as brewed soft drinks would not be required to include a pregnancy warning label under option 1.

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Under option 2, all beverages captured under option 1 would be included plus beverages with an alcohol content of 0.5% to 1.15% ABV.

Beverages with 0.5% ABV or more could include brewed soft drinks. In accordance with the Code, brewed soft drinks are not permitted to be represented as alcoholic beverages (section 2.6.2—8).

3.2.3.4 Stakeholder views

At the targeted consultations, industry stakeholders and jurisdictions generally supported Option 1, noting this approach would be broadly consistent with what the industry accepts as alcohol. However, both groups noted a possible inconsistency with the message not to drink any alcohol during pregnancy. On the other hand industry stakeholders also claimed it could be confusing for consumers if beverages with 0.5% ABV or more had to have a pregnancy warning label given such beverages are not able to be represented as 'alcoholic'.

In contrast, public health stakeholders generally indicated support for Option 2 with the view that this approach would:

- more closely align with the evidence that there is no known safe level of drinking alcohol during pregnancy
- be consistent with the requirement for certain beverages to display alcohol content and standard drinks
- acknowledge the risk that products such as brewed soft-drinks with an alcohol content, may be consumed frequently or in higher concentrations during pregnancy.

Public health stakeholders were also concerned about regulation of the brewed soft-drink industry in terms of alcohol content, and called for tighter regulation in this regard. This issue is however out-of-scope of P1050.

While there was some support from public health stakeholders for Option 1 as a pragmatic approach, this view did not share the strength of support given for Option 2.

3.2.3.5 Proposed approach

On consideration of the relevant legislative and policy context, and the views of stakeholders, FSANZ proposes Option 1 as a reasonable and pragmatic approach that will result in broad application of the pregnancy warning label across the alcoholic beverage sector.

The proposed approach is broadly consistent with relevant requirements in the Code relating to alcohol and non-alcoholic beverages, and with relevant Australian and New Zealand legislation and guidance on alcoholic beverage definitions. Option 1 is also consistent with the scope and key objectives of the proposal, as set out in the DRIS. For example, beverages such as brewed soft drinks were not included in the cost-benefit analysis in the DRIS nor in the voluntary labelling initiative. Requirements in other countries vary, however, five of the nine countries with mandated pregnancy warning labels for which we have information have a similar approach to option 1 (Attachment C).

FSANZ acknowledges the support from some stakeholders for Option 2, and notes the concerns regarding the potential frequent or high consumption of brewed soft-drinks by women who are pregnant. It is also acknowledged that Option 2 would align with the requirements for standard drinks labelling (i.e. that all foods containing more than 0.5% ABV display standard drinks). However, Option 2 does present a numbers of challenges. Option 2 would mean beverages such as brewed soft-drinks, which may have an alcohol content above 0.5% ABV, but which cannot be represented as an alcoholic beverage (in accordance with the requirements of the Code), would require the pregnancy warning label. This may result in inconsistency across the brewed soft-drink market and therefore cause confusion for

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consumers. Industry stakeholders also advised brewed soft-drink beverages are not typically considered part of the alcohol industry, which also may cause confusion for both industry and consumers. Requiring beverages with 0.5% ABV or more to have the pregnancy warning label would also be inconsistent with the scope of the voluntary labelling initiative and the intent of the decision made by the Forum for FSANZ to consider warning labels on 'alcoholic beverages'.

In summary, FSANZ proposes pregnancy warning labels be required on packaged beverages (referred to as *prescribed alcoholic beverage* in the draft variation to the Code) with more than 1.15% alcohol by volume (ABV).

3.2.4 Application to different types of sales

3.2.4.1 Policy context

The scope of the DRIS is for pregnancy warning labels to be on 'packaged' alcoholic beverages. FSANZ has therefore considered whether the pregnancy warning label should be required for specific types of sales of packaged alcoholic beverages.

3.2.4.2 Relevant Code requirements

3.2.4.2.1 Intra-company transfers, non-retail sales and non-catering sales

The Code (Standard 1.2.1, Division 4) does not currently require warning statements to be on the label of foods sold, where the sale is not a retail sale or sold to a caterer, for example, a keg of beer sold to a bar. The Code sets out that the purchaser must be provided with any information requested to enable them to comply with the Code requirements. If not a retail sale or sale to a caterer, 'transportation outers⁶' only require labelling with the name and address of the supplier (unless in documentation), name of the food and lot identification (section 1.2.1—20).

3.2.4.2.2 Retail sales

For most retail sales of packaged alcoholic beverages from retail premises such as bottle stores and supermarkets, it is proposed the pregnancy warning label applies, consistent with the request from ministers. FSANZ has considered whether or not the pregnancy warning label should be required for specific types of retail sales of packaged alcoholic beverages, for example, 'fill your own', fundraising events etc.

The Code requirements for labelling of 'retail sales' apply to:

- retail sales of a food, e.g. a sale of a bottle of wine from a supermarket
- food sold as suitable for retail sale without any further processing, packaging or labelling.

Section 1.2.1—6 requires food for sale in a package to bear a label, with some exemptions. Section 1.2.1—8 includes a requirement for foods required to bear a label (unless exempt) to be labelled with various warning statements.

⁶ A transportation outer is defined in section 1.1.2—2 as: *a container or wrapper which (a) encases packaged or unpackaged foods for the purpose of transportation and distribution; and (b) is removed before the food is used or offered for retail sale or which is not taken away by a purchaser of the food.*

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The exemptions from the general requirement for **packaged**⁷ foods to bear a label include food (beverages in this case) (section 1.2.1—6):

- made and packaged on the premises from which it is sold (e.g. wine made in and sold from a winery, beer made in and sold from a brewery)
- packaged in the presence of the purchaser (e.g. a drink poured in a bar or restaurant, fill your own bottle)
- delivered packaged, and ready for consumption, at the express order of the purchaser (excluding from vending machines) (e.g. orders delivered to consumers by a liquor retailer)
- sold at a fundraising event
- displayed in an assisted service display cabinet⁸ (e.g. a drink in an enclosed display cabinet such as glass fronted fridge).

Beverages sold from vending machines are not subject to the exemption for delivered packaged, ready for consumption at the express order of the purchaser, i.e. in most situations a bottle etc. obtained from a vending machine would be required to bear a label.

Hampers are not included in the definition of ‘package’ in the Code. Packaged food sold in a hamper, such as alcoholic beverages are required to bear a label (subsection 1.2.1—8(2)).

If an exemption from the general requirement to bear a label applies, the food may still be subject to some specific labelling requirements (in section 1.2.1—9), either accompanying the food, displayed in connection with the display of the food, declared or provided to the purchaser, or provided to the purchaser upon request.

3.2.4.2.3 Sales of food to caterers

Packaged foods sold to caterers are required to bear a label with certain information, including some warning statements (section 1.2.1—15). Other information such as standard drink labelling and % ABV can be provided either on the label or in documentation (1.2.1—16). There are certain circumstances for foods that have more than one layer of packaging, where the label does not have to be on the outer package (but must still be on a package) (section 1.2.1—12), e.g. boxes of bottles/cans of beer.

3.2.4.3 Targeted consultations

The proposed approach for the application of the pregnancy warning label to different types of sales, was discussed with stakeholders in June 2019 as summarised in Table 11 below.

⁷ ‘Package’ is defined in section 1.1.2—2 and includes any container or wrapper in or by which food for sale is wholly or partly encased, covered, enclosed, contained or packaged.

⁸ ‘Assisted service display cabinet is defined in section 1.1.2—2: means an enclosed or semi-enclosed display cabinet which requires a person to serve the food as requested by the purchaser.

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Table 11: Summary of proposed application of pregnancy warning labels to different types of sales

Packaged alcoholic beverage – type of sale	Pregnancy warning label required?	Is the proposed approach a change to existing Code requirements?
Wholesale (non-retail, not sold to caterers), intra-company transfers	No	No
Transportation outers (if not retail sale or sale to caterers)	No	No
Alcoholic beverages required to bear a label	Yes	No
Alcoholic beverages sold to caterers	Yes Not required on outer package if more than one layer of packaging	No
Made and packaged on premises from which it is sold, e.g. in winery, brewery	Yes	Yes
Delivered packaged and ready for consumption, at the express order of the purchaser	Yes	Yes
Sold at fundraising event	Yes, unless subject to the exemption for packaged in presence of purchaser.	Yes
Displayed in an assisted service display cabinet	Yes	Yes
Packaged in presence of purchaser. e.g 'fill your own' and also drinks poured into drinking vessel ready for immediate consumption, e.g. glass of wine in a bar	No (out of scope)	No
Alcoholic beverages sold from a vending machine	Yes	No
Vending machine itself	No (not a package according to the definition of package in the Code)	No
Alcoholic beverages sold in a hamper	Yes	No
Hamper itself	No (not a package according to the definition of package in the Code)	No

3.2.4.4 Stakeholder views

Stakeholders generally supported the overall proposed approach for the application of the pregnancy warning label to different types of retail sales. That is, a pregnancy warning label would be required on packaged alcoholic beverages: made and packaged on the premises from which they are sold; delivered packaged ready for consumption at the express order of the purchaser; sold at a fundraising event; and displayed from an assisted service display cabinet. However, industry stakeholders had concerns with the lack of clarity in the wording

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of these retail situations and how they applied to alcoholic beverages. Industry called for clear, specific and unambiguous sales requirements and exemptions.

3.2.4.5 Proposed approach

The proposed approach is as shown in Table 11 above.

FSANZ considers it is likely alcoholic beverages sold in the situations proposed to require the warning label would usually be labelled as for retail sale. For example, a bottle of wine sold from the vineyard at which it is made is likely to be fully labelled to allow it to also be sold for retail sale elsewhere. Hence, requiring the warning label is expected to have limited additional impact on industry.

The exemption for alcoholic beverages packaged in the presence of the purchaser from providing the warning label is consistent with the DRIS which notes that beverages such as a glass of wine served in a restaurant are out of scope.

The application of the pregnancy warning label on packaged alcoholic beverages sold to caterers, from vending machines, in hampers and in non-retail and non-catering sales situations is proposed to be consistent with existing Code requirements for warning statements. That is, the pregnancy warning label would be required on packaged alcoholic beverages sold from vending machines, in hampers and to caterers, and not be required in non-retail and non-catering sales situations or in intra-company transfers as in the latter situations the beverage is not sold directly to consumers.

In drafting these requirements in the Code, FSANZ has sought to ensure there is clarity for the application of the pregnancy warning label to the different types of retail sales of alcoholic beverages.

3.2.5 Application to different types of packages

3.2.5.1 Policy context

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* (FRSC, 2018).

While the DRIS does not specifically consider layers of packaging, under cost considerations, the DRIS states *It is relevant to note that pregnancy warning labels may not be required on the outer packaging...* and that *This would be considered during implementation* (FRSC, 2018).

FSANZ has considered whether to apply existing Code requirements to pregnancy warning labels on alcoholic beverages with more than one layer of packaging, and packaging that includes individual packages or containers intended to be used separately (i.e. individual portion packs).

3.2.5.2 Relevant Code Requirements

Sections 1.2.1—6(2) and 1.2.1—6(3) set out labelling requirements for food that has more than one packaging layer.

If a food for sale has more than 1 layer of packaging, only 1 label is required (section 1.2.1—6(2)). This would usually mean a label would need to be on the outermost layer so that it is

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legible. e.g. a bottle of whisky inside an outer carton, a bladder of wine inside a carton ('cask' wine).

If the food for sale is sold in packaging that includes individual packages for servings that are intended to be used separately (individual portion packs) (e.g. a 12 pack of beer) but which:

- (a) are not designed for individual sale; and
- (b) have a surface area of 30 cm² or greater;

then the individual portion pack is also required to bear a label with information about warning statements and declarations (e.g. allergens) (section 1.2.1—6(3)).

3.2.5.3 Stakeholder views

Industry stakeholders at the June 2019 targeted consultations generally supported the proposal to apply existing Code requirements for labelling of multilayer packages to the pregnancy warning label. However as discussed previously (section 3.2.2.4), industry stakeholders considered it would be appropriate to only require the pictogram on a beverage container or a smaller warning label if outer retail packaging had the full warning label. It was noted retailers want flexibility for beverages sold in multipacks and therefore prefer individual containers to be labelled as for individual sale so they can break packs for sale if desired. Industry stakeholders noted relabelling of multilayers of packaging is costly.

Public health stakeholders preferred all packaging layers be required to carry the warning label so that it would be visible at both the point of sale and point of consumption (i.e. on the bottle/can, and on the outside retail packaging layer). This view was also shared by jurisdictions who advised such an approach would more closely align with the primary objective in the DRIS.

3.2.5.4 Proposed approach

FSANZ has considered the objectives of the pregnancy warning label as stated in the DRIS, and stakeholder views.

FSANZ is proposing that for a multipack (e.g. a six pack of beer), the pregnancy warning label would be required on each individual portion pack and the package containing the individual portion packs. Such an approach is similar to that set out in section 1.2.1—6(3). A pregnancy warning label would also be required on a retail carton containing several multipacks (i.e. several six packs of beer). This approach is consistent with the objectives in the DRIS.

In relation to the situation where a single beverage container is sold in a box with or without other packaging, it is proposed a pregnancy warning label be required on all packaging layers. FSANZ understands, industry typically includes all mandatory labelling information both on the container and outer packaging layer so there is flexibility with how the product is sold. Consequently, the proposed requirement is unlikely to result in significant additional cost for industry but will be consistent with the requirements for multipacks. Two exemptions are proposed for this requirement. A pregnancy warning label will not be required on:

- outer packaging if a warning label on an inner package is clearly discernible through the outer packaging (including the package containing individual portion packs);
- a bladder within a box of a *prescribed alcoholic beverage*⁹ (based on the assumption

⁹ The proposed draft variation to the Code defines *prescribed alcoholic beverage* as a beverage that has more than 1.15% alcohol by volume.

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that typically the beverage is dispensed from the bladder whilst still contained within the box).

For alcoholic beverages sold to a caterer with more than one layer of packaging, a pregnancy warning label is not required to be on the outer package.

Note the details of the pregnancy warning label to be included on various packages (i.e. pictogram or full warning label and size requirements) was discussed in section 3.2.2.4 and is summarised in section 3.2.2.5.

In summary, FSANZ proposes where there is more than one layer of packaging, e.g. a bottle of whisky in a box, the warning label would be required on all layers of packaging except where the warning label on an inner package is clearly discernible through the outer packaging. A pregnancy warning label would not be required on a bladder within a box of a *prescribed alcoholic beverage*.

For alcoholic beverages sold to a caterer with more than one layer of packaging, a pregnancy warning label is not required to be on the outer packaging.

Consistent with existing Code requirements, for individual portion packs, e.g. 6 pack of beer, the pregnancy warning label would be required on each individual portion pack e.g. bottle or can, and the package containing the individual portion packs, except where the warning label on an individual portion pack is clearly discernible through the outer packaging. A retail carton containing several multipacks would also need to carry the pregnancy warning label.

Refer to Table 10 in section 3.2.2.5 for pregnancy warning label size requirements on packaging.

3.3 Risk communication

3.3.1 Consultation

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

FSANZ has developed a communication strategy for this proposal. Subscribers and interested parties have been notified about this call for submissions via the FSANZ Notification Circular, media release and through FSANZ's social media tools and Food Standards News.

FSANZ undertook targeted consultation with industry and public health stakeholders, and jurisdictions in both Australia and New Zealand, in January - February 2019 and June - July 2019, to discuss proposed approaches for the design and implementation of the pregnancy warning label (refer to section 3.2.1). Representatives of the Maori community attended the January 2019 consultations. In addition, FSANZ held discussions with two Australian indigenous stakeholder representatives in July 2019. FSANZ has considered the views and information provided by stakeholders in its assessment.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this proposal. To assist FSANZ with considering submissions, submitters are asked to use the submission template at Attachment H. All comments are valued and contribute to the rigour of our assessment. Comments received will be taken into account when developing any draft variation(s) for approval by the FSANZ Board. A summary of views will be provided

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to the Board to assist its decision making process.

The FSANZ Board is expected to consider an approval report in early December 2019. If a draft variation to the Code is approved by the FSANZ Board, that decision will be notified to the Forum. If the Forum does not request a review, gazettal of the variation to the Code would be expected in March 2020. Stakeholders including the public, would be notified of the gazettal of the variation to the Code in the national press and on the FSANZ website.

3.3.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are relevant overseas standards for pregnancy warning labels on alcoholic beverages but there is no international standard. Amending the Code to require a pregnancy warning label on packaged alcoholic beverages is unlikely to have a significant effect on international trade as currently importers of alcoholic beverages into Australia and New Zealand have to comply with local labelling requirements and similarly, Australia and New Zealand exporters have to comply with labelling requirements of the country to which they export. However, as a mandatory warning label is proposed and due to a high level of interest in warning labels on alcoholic beverages around the world, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade Agreement has been made to enable other WTO members to comment on the proposed amendments.

3.4 FSANZ Act assessment requirements

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

3.4.1 Section 59

3.4.1.1 Consideration of costs and benefits

3.4.1.1.1 Introduction

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

The Office of Best Practice Regulation (OBPR) has 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 change had already been considered through the DRIS (FRSC, 2018) that informed the Ministerial Forum's request, in October 2018.

The alcohol industry raised concerns that the analysis in the DRIS, partly based on a cost survey in 2017, underestimated costs per Stock Keeping Unit (SKU) of labelling changes to manufacturers from moving away from the voluntary to a mandatory system. At the time of the DRIS, the specific approach for warning label size, wording, colours or the packaging layer on which the warning label would appear had not been developed.

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Since the DRIS was prepared there has been further scoping around the detailed design elements of the proposed mandatory pregnancy warning label, including the prescribed:

- red, white and black colours for all SKUs
- minimum size of the pictogram and text
- application to multiple packaging layers for certain types of SKUs.

FSANZ is confident in the quality of the analysis undertaken in the DRIS and that it serves as a solid foundation to enable the consideration of costs and benefits in relation to this proposal. 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 decided to extend the analysis of costs and benefits of the mandatory pregnancy warning label by considering how making a series of additional and/or alternative assumptions around key variables would affect the results of the analysis. In developing and using alternative assumptions, FSANZ is not suggesting the original DRIS was in any way deficient. What the extension of the analysis provides is additional information to decision makers by providing a wider range of potential results.

3.4.1.1.2 Basis of the updated consideration of costs and benefits

This updated consideration of costs and benefits draws upon 2018/19 cost information provided to FSANZ, including:

- from information included in the DRIS (FRSC, 2018), that drew on data provided by industry in response to a consultation regulation impact statement
- from targeted consultations on this Proposal (P1050)
- from letters received on this proposal following targeted consultations
- in responses to an earlier 2019 FSANZ survey of costs of removing low carb and low sugar claims on alcoholic beverages (Proposal P1049 – Carbohydrate and sugar claims on alcoholic beverages)
- in responses to a request from FSANZ to industry stakeholders in July 2019 to provide further information on this Proposal (P1050)
- from additional information gathered from packaging print companies and graphic designers, including site visits and telephone calls
- from past modelling and surveys by FSANZ and other independent organisations.

To help further frame the analysis, some key industry concerns about costs per SKU, expressed at the targeted consultations and FSANZ responses are set out in Table 12 below.

Table 12: FSANZ responses to industry concerns about the cost of changing labels

Key industry concerns about costs per SKU	FSANZ responses
The colour red may involve replacing numerous different print plates / cylinders when the total number of colours available for packaged alcoholic beverage labels, in general, is limited.	FSANZ has done additional research into print plate / cylinder costs and implications of including the colour red in the warning label. That includes 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 additional research has been used to update average costs per SKU of the proposed mandatory warning label, referred to later in this section.
There may be lost stocks of labels for businesses with slower-selling alcoholic beverages that do not have time to adopt the warning label before the end of the transition period.	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. A two-year transition period with the proposed stock-in-trade exemption are assumed to provide sufficient notice to mitigate against lost label stock.
The full size of the proposed warning label would be impractical for beverage volumes of under 400 ml.	This proposal now includes flexibility of different requirements and sizes of the warning label for beverage volumes 200 ml and under, > 200 ml and ≤ 800 ml and over 800 ml.
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.	FSANZ acknowledges that there may be costs of changed messaging for that FASD Awareness Program. These are taken into account below.

3.4.1.1.3 *Developing alternative assumptions*

FSANZ has developed a series of alternative assumptions to extend the analysis that has already been undertaken. 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” (assumed most likely) 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 3.1), suggest the proposed pregnancy warning label is likely to better convey government advice not to drink any alcohol during pregnancy, and attract consumer attention to greater extent than the warning labels commonly used in the voluntary initiative.

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3.4.1.1.4 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 the other option is compared against.

Option 2- Mandatory labelling (as proposed in this Call for Submissions report)

This analysis considers the new mandatory pregnancy warning label. FSANZ is of the view that no other realistic food regulatory measures exist at this stage, however, information received may result in FSANZ arriving at a different outcome.

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, i.e. a Base Scenario (assumed most likely), Best Case Scenario and Worst Case Scenario. Those scenarios are compared in Table 13 later in this section.

The annual percentage of new FASD cases across Australia - New Zealand combined, needing to be avoided (or down-graded), 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 maximum estimate for the Australian market in the DRIS was 40,296 SKUs, incorporating Australian industry estimates. 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 incorporating some Australian industry estimates (40,296). Therefore, the number of SKUs in the scenarios is assumed to range between a lower combined estimate of $40,296 + 21,557$ (Australia and New Zealand) = 61,853 SKUs, and an upper combined estimate of $40,296 + 40,296 = 80,592$ SKUs.

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, in retail cardboard packages. Given available data from industry and other sources, it is difficult to estimate a single point estimate for the cost.

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However, a straight mean of the cost data received by FSANZ from industry in 2018/19 was taken at AU \$7,575 per SKU. That \$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 cost of a “Major” label change as derived by a separate PricewaterhouseCoopers study on label change costs (PricewaterhouseCoopers, 2014). 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 **proposed flexibility with 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.**

It is also recognised smaller producers may experience higher overall cost burdens of incorporating the warning label as batches that make up a SKU are likely to be smaller. That would mean fewer sales to spread the costs per SKU over. However, FSANZ understands that for glass bottles smaller producers often use digital printing. This form of printing is suited to printing smaller numbers of labels as label changes can be made more easily and cheaply than for higher volume printing processes.

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 the mandatory warning label with general label changes that would have been made voluntarily anyway (in the absence of the warning label), or 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, reducing average 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 \$AU 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 3.4.1.1.2) and discussions with label printing companies undertaken by FSANZ, it is estimated that around 50% of SKUs would be able to have the pregnancy warning label combined with other 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 (\$7,575) and the mitigated cost above (\$2,272), i.e. estimated average of \$AU 4,924 per SKU.

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

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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 \$AU 757 per SKU for 50% of the SKUs. Therefore, its estimated average cost per SKU is the average of \$757 and \$7,575 at \$AU 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 average annual “health related” costs of new mild cases of FASD at an average of \$AU 13,785 (\$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 \$AU 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 downgraded per year, with an average benefit of \$ AU 76,002 per new case per year in Australia and \$ AU 92,395 in New Zealand.

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

The above costs (industry costs per SKU and 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.

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

The 0.2% to 3.2% range (in the table below) 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 contracted 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.

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- Neither the Base (assumed most likely) Scenario or Worst Case Scenario (below) 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 (the upper maximum estimate is taken from the DRIS) and New Zealand
- average costs per SKU for redesign and approval of art work.

The three “break even” scenarios are presented in Table 13 below to show situations where the benefits to communities of reduced or down-graded FASD cases would justify the costs to industry of incorporating the pregnancy warning label on packaged alcoholic beverages. Refer to Attachment I for supporting information.

The costs to industry are one-off and do not reflect any ongoing costs from the proposed use of the colour. 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.

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 \$AU 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 \$AU 650,000 DrinkWise estimate is included in the above figures for total costs to industry.

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Table 13: Break-even scenarios: costs to industry vs community benefits of reduced or down-graded FASD cases 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 225 cases per year across Australia and New Zealand combined	71,223 SKUs	\$AU 4,924 per SKU - average of: (a) unmitigated costs , i.e. needing to incorporate the new PWL outside making label changes voluntarily or due to other legislation; and (b) mitigated costs , i.e. being able to incorporate the new PWL when making voluntary changes or complying with other legislation. Total costs to industry SKUs = AU \$351,319,009 (including DrinkWise costs for their FASD Awareness Program)	= \$ AU 13,847 per case in AU and NZ Assumes only new mild 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 35 cases per year across Australia and New Zealand combined	61,853 SKUs	\$AU 4,166 per SKU –average of: (a) Unmitigated costs (b) Lower estimated mitigated costs Total costs to industry SKUs = AU \$258,333,865 (including DrinkWise costs for their FASD Awareness Program)	\$ AU 76,002 per case in AU and \$ AU 92,395¹⁰ 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 555 cases per year across Australia and New Zealand combined	80,592 SKUs	\$AU 7,575 per SKU Mean of cost submissions received. Assumes no costs over any SKUs are mitigated. Total costs to industry SKUs = AU \$611,107,875 (including DrinkWise costs for their FASD Awareness Program)	= \$ AU 13,847 per case in AU and NZ Assumes only new mild cases avoided Upper discount rate of benefits in future years = 7%

¹⁰ All annual benefits figures are taken from the October 2018 DRIS and updated for inflation. The \$ AU 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 \$ AU 76,002 per case in Australia and \$ AU 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.

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3.4.1.1.5 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. It is anticipated that those activities can be performed as part of existing functions.

There may also be other costs to government agencies and the health sector of providing education, advice, and broader interventions around women who are pregnant or thinking of becoming pregnant not consuming any alcohol.

3.4.1.1.6 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.

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. (FRSC, 2018)

The marginal 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 and manage FASD, as described in Appendix 1 of the DRIS.

3.4.1.2 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.

3.4.1.3 Any relevant New Zealand standards

There are no relevant New Zealand Standards.

3.4.1.4 Any other relevant matters

Other relevant matters are considered below.

3.4.2 Subsection 18(1)

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

3.4.2.1 Protection of public health and safety

The proposed mandatory pregnancy warning label would support Australia and New Zealand government advice and messages for women not to drink any alcohol during pregnancy to reduce the risk to the health and safety of the unborn child. As discussed in the DRIS, pregnancy warning labels on packaged alcoholic beverages can raise awareness of the risks of drinking alcohol during pregnancy and prompt discussion of these risks. The effects of pregnancy warning labels combined with other initiatives, can contribute to changes in cultural norms and drinking behaviour amongst pregnant women and ultimately the prevalence and/or severity of FASD (FRSC, 2018).

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

The proposed mandatory pregnancy warning label would 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.

3.4.2.3 *The prevention of misleading or deceptive conduct*

FSANZ has not identified any issues relevant to this matter.

3.4.3 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 proposed 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. The proposed use of the pictogram is consistent with some overseas regulations. However, there is no consistency across international food standards in the format or wording of a pregnancy warning label.

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

FSANZ does not anticipate any significant impact on efficiency and international competition. However, a notification has been made to enable other WTO members to comment on the proposed draft variation to the Code (see section 3.3.2).

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

Mandating the pregnancy warning label and prescribing the design would apply across the alcoholic beverage sector and thereby promote fair trading.

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

There are no specific policy guidelines formulated by the Forum which apply to this proposal, however, the DRIS provides ministerial policy advice to FSANZ.

FSANZ considers the proposed mandatory pregnancy warning label is consistent with the objectives and advice in the DRIS.

4 Draft variation

The draft variation to the Code is at Attachment A and is intended to take effect on gazettal.

A draft 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.

4.1 Transitional arrangements

4.1.1 Policy considerations

The DRIS recommends FSANZ give consideration to including a two to three year transition period to minimise impacts on industry with the introduction of mandatory warning labels. Further, the DRIS also recommends *FSANZ give consideration to stock-in-trade exemptions so that products that have already been packaged and labelled prior to the end of the transition period would not have to change their label.*

The policy advice notes efforts should be made to minimise the costs of label changes to industry through transition periods and stock-in-trade exemptions. A transition period allows time for industry to adopt new regulations and reduce costs associated with labelling changes. The DRIS acknowledges these costs are likely to be disproportionately higher for smaller businesses than larger businesses. Reducing costs to industry may also reduce the potential for costs to be passed on to consumers. At the October 2018 Forum meeting, ministers also called for *appropriate transition timelines and stock-in-trade exemptions on new arrangements* in recognition of many industry members voluntarily adopting pregnancy warning labels.

4.1.2 Stakeholder views

At the targeted consultations in June 2019, FSANZ discussed transitional arrangements whereby there would be a two year transition period with an exemption for beverages packaged and labelled before the end of the transition period from having to carry the pregnancy warning label.

Industry stakeholders tended to support the proposed combination of a transition period with an exemption for beverages packaged and labelled before the end of transition period. However, they considered a transition period of three to four years and a delayed date of commencement of the variation to the Code following gazettal would be more feasible and help to reduce costs compared with the proposed two years. In addition, they noted such an approach would be particularly helpful for smaller producers who might have label stocks and for larger producers as it would take some time to relabel large numbers of SKUs. Industry stakeholders stated label redesign would not start until gazettal of new requirements and if gazettal occurred in March 2020, there would likely not be sufficient time for a significant volume from the 2020 wine vintage to be labelled with the pregnancy warning label. Stakeholders also indicated their support for alignment of this proposal with other proposals that may result in labelling changes for alcoholic beverages.

Public health stakeholders were strongly of the view that a one year transition period should be sufficient as most alcoholic beverages are sold within one year. They were concerned a longer transition period may delay or compromise intended public health outcomes. Public health stakeholders acknowledged the proposed exemption was a pragmatic approach, however, it was suggested there could be a tiered approach by which some products could have a longer transition period and that only specified beverages should be granted an exemption e.g. high value spirits, high value vintage wines. Public health stakeholders stated the best approach for health outcomes should be considered.

Jurisdictions tended to not support an exemption for some beverages from having to carry a warning label as they considered this would be difficult to enforce. That is, after the end of the transition period it would be difficult to determine whether the beverage had been packaged and labelled before or after the end of the transition period unless they contacted the business. It was suggested a longer transition period of three years with no exemptions could be implemented instead. Both public health stakeholders and jurisdictions were

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concerned industry may delay compliance until the end of the transition period and that under the proposed exemption, industry might produce greater volumes of alcohol and label them before the end of the transition period to avoid the pregnancy warning label.

4.1.3 Proposed approach

FSANZ has considered the policy advice in the DRIS, the views of industry, public health stakeholders and jurisdictions, costs and practicalities of transition for industry, and the range of products in the market which would need to carry the pregnancy warning label.

As discussed at the targeted consultations, FSANZ is proposing a two-year transition period with an exemption for alcoholic beverages packaged and labelled before the end of the transition period from having to carry the pregnancy warning label. This approach balances minimising costs for businesses with not unduly delaying the exposure of the pregnancy warning label to consumers. While a transition period of one year would potentially mean consumers may be 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. A transition period greater than two years may unnecessarily prolong the implementation of the label and create possible consumer confusion.

Application of an exemption to all alcoholic beverages packaged and labelled before the end of the transition period aims to reduce the need for re-labelling. This approach recognises alcoholic beverages with a slow market turnover or those intended for ageing/cellaring before sale but have been labelled. Such alcoholic beverages may include but are not limited to, top-shelf spirits and premium wines. FSANZ acknowledges the jurisdictions' concern with the challenges of enforcing the proposed exemption. Given the relatively fast market turnover of beer, RTDs, cider and most 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 carry 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 beverage container. FSANZ considers it reasonable to not expect the small proportion of premium wines which remain in the market for some years to be relabelled (or over-stickered with a pregnancy warning label). After the end of the two year transition period the majority of alcoholic beverages would be expected to carry the warning label.

The Forum's request to FSANZ in October 2018 was to consider mandatory pregnancy warning labels expeditiously. In the most recent communique from the Forum (Australia and New Zealand Ministerial Forum on Food Regulation, 2019) the *Forum agreed to refer the work on energy labelling on alcoholic beverages to FSANZ and request FSANZ consider energy labelling as part of the work relating to alcohol labelling which is already underway, but not to delay the work on developing pregnancy warning labels for alcoholic beverages.* Therefore while alignment of any further changes to alcoholic beverage labels will be considered in the future, FSANZ is proceeding with P1050 consistent with the Ministers request.

FSANZ has considered a range of possible alternate options for transitional arrangements including: a delayed variation commencement date to assist the wine industry, 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 proposed on the basis such arrangements:

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- are inconsistent with policy advice in the DRIS
- may unnecessarily delay the exposure of the warning label to consumers (e.g. a transition period of more than two years).
- are more complex than the proposed approach, 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 proposed approach, do not provide significant additional benefit to industry (e.g. a delayed variation commencement date).

4.2 Implementation

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

FSANZ will be making downloadable pregnancy warning label graphics available for easy use by industry.

In summary, FSANZ proposes a two year transition period for the mandatory pregnancy warning label, and an exemption for alcoholic beverages packaged and labelled before the end of the transition period.

A transition period of two years would begin on the date of gazettal of the variation. During the two years, an alcoholic beverage can comply with either the Code as in force as if the variation had not taken effect, or with the Code as amended by the variation. After the transition period, all alcoholic beverages would need to comply with the variation (i.e. have the pregnancy warning label), except for those subject to the exemption below.

An alcoholic beverage packaged and labelled before the end of the two year transition period (i.e. compliant with either the Code as in force as if the variation had not taken effect i.e. not carry the mandatory pregnancy warning label, or with the Code as amended by the variation i.e. carry the mandatory pregnancy warning label) would be deemed compliant with the Code as amended, if sold after the end of the transition period. Such an exemption would also apply to imported alcoholic beverages.

4.3 Education

It is recognised pregnancy warning labelling is part of a broader suite of measures aimed to raise awareness of the risks of drinking alcohol during pregnancy (refer to the DRIS (FRSC, 2018)). 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 (see Appendix 1 of the DRIS (FRSC, 2018)). 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.

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FSANZ expects to focus on informing consumers, health professionals, FASD community support groups and the alcoholic beverage sector, particularly smaller businesses, of the new labelling requirements. This activity 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.

4.4 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 monitoring and evaluation may extend beyond FSANZ's remit. Therefore, FSANZ will discuss options with the Food Regulation Standing Committee and other stakeholders in regards to undertaking monitoring and evaluation after the end of the transition period.

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, and the extent to which consumers notice the label and understand the warning.

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Attachments

- A. Draft variation to the *Australia New Zealand Food Standards Code*
- B. Draft Explanatory Statement
- C. Pregnancy warning labels in other countries
- D. Examples of pregnancy warning statements
- E. Summary of stakeholder views from June 2019 targeted consultations
- F. Guidance and Code requirements for design labelling elements
- G. Legislation and guidance for alcoholic beverage definitions
- H. Template for submitters
- I. Supporting information for consideration of costs and benefits

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Attachment A – Draft variation to the *Australia New Zealand Food Standards Code*



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

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.

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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

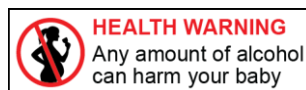
pregnancy warning label means either the pregnancy warning pictogram or the pregnancy warning mark.

pregnancy warning pictogram means the following pictogram:



pregnancy warning mark means the following image comprising

- (a) the pictogram,
 - (b) the signal words “Health Warning” and
 - (c) 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.

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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.

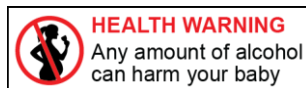
pregnancy warning label means either the pregnancy warning pictogram or the pregnancy warning mark.

pregnancy warning pictogram means the following pictogram:



pregnancy warning mark means the following image comprising

- (a) the pictogram,
 - (b) the signal words “Health Warning” and
 - (c) 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

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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.

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The pregnancy warning label to be displayed

Column 1	Column 2
<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

Column 1	Column 2
<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.

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Legibility requirements for pregnancy warning labels

Column 1	Column 2	Column 3	Column 4
<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.

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Legibility requirements for pregnancy warning labels

Column 1	Column 2	Column 3	Column 4
<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 \leq 200 ml.	At least 8 mm diameter	Not applicable	Not applicable
An individual portion pack with a volume of $>$ 200 ml and \leq 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 B – Draft 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 prepared a draft variation to the Code.

2. Purpose

The Authority has prepared 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 the package of most alcoholic beverages 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 will include one round of public consultation following an assessment and the preparation of a draft Standard and associated assessment summary.

The Office of Best Practice Regulation (OBPR) has exempted the Authority from a requirement to undertake a Regulation Impact Statement as the potential regulatory change has already been considered through the Decision Regulation Impact Statement prepared by the Food Regulation Standing Committee (FRSC, 2018).

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 [1.1] varies subsection 1.1.2—2(3) by omitting the existing definition of *individual portion pack* and substituting a new definition. The new definition restates the reference to

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subsection 1.2.1—6(3) and adds a new reference to individual portion packs defined in subsection 2.7.1—9(5) for the purpose of the new pregnancy warning label requirements in Standard 2.7.1 (see item [3.5] below).

Item [1.2] varies subsection 1.1.2—2(3) by inserting in alphabetical order new definitions for *pregnancy warning label*, *pregnancy warning pictogram*, *pregnancy warning mark* and *prescribed alcoholic beverage*. 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. 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 a series of 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 are layers of packaging of a prescribed alcoholic beverage, are set out separately in that Division (see item [3.5] below).

Item [2.3] inserts a Note after subsection 1.2.1—6(3) to refer to the new pregnancy warning label requirements in Division 4 of Standard 2.7.1. The new Note advises that requirements relating to pregnancy warning labels for individual portion packs are set out separately in that Division (see item [3.5] below).

Item [2.4] inserts a Note after subsection 1.2.1—12(1) to refer to the new pregnancy warning label requirements in Division 4 of Standard 2.7.1. The new Note advises that requirements for pregnancy warning labels for prescribed alcoholic beverages sold to caterers 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.

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Item [3.2] varies subsection 2.7.1—2 by omitting the existing Note and substituting 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):

- caterer;
- pregnancy warning label;
- pregnancy warning pictogram;
- pregnancy warning mark; and
- prescribed alcoholic beverage (see item [1.2] above).

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 the package of a prescribed alcoholic beverage to display a pregnancy warning label if the beverage is: for retail sale; sold to a caterer; or sold as suitable for retail sale without any further processing, packaging or labelling. 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.

Subsection 2.7.1—8(2) provides that the requirement imposed by subsection 2.7.1—8(1) does not apply to prescribed alcoholic beverages that are sold for retail sale and packaged in the presence of the purchaser. This will mean, for example, that wine or beer served in a glass in a restaurant or bar 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 a prescribed alcoholic beverage that: has more than one layer of packaging; or contains individual portion packs.

Subsection 2.7.1—9(1) provides that, if subsection 2.7.1—8(1) requires a pregnancy warning label to be on a package of a prescribed alcoholic beverage, the pregnancy warning label must be displayed on:

- the package of a prescribed alcoholic beverage; or
- each layer of packaging if there is more than one layer of packaging (for example for a box containing bottle(s) of wine, displayed on the bottle(s) and on the box).

Subsection 2.7.1—9(2) exempts outer packaging from the requirement to display a pregnancy warning label if this label can be clearly seen on the inner packaging through the

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outer packaging (for example, where there is clear wrapping around a bottle of wine).

Subsection 2.7.1—9(3) 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).

Subsection 2.7.1—9(4) provides a partial exemption from the requirement in paragraph 2.7.1—9(1)(b) for prescribed alcoholic beverages with more than one layer of packaging and which are sold to a caterer. The subsection will provide that these beverages do not have to display a pregnancy warning label on the outer package.

Subsection 2.7.1—9(5) provides for prescribed alcoholic beverages that contain individual portion packs (for example, six packs of beer sold together in a package). The subsection will provide that, if subsection 2.7.1—8(1) requires a pregnancy warning label to be on a package of a prescribed alcoholic beverage that contains individual portion packs, then a pregnancy warning label must also be displayed on each individual portion pack (for example, each can of beer in the package must display a pregnancy warning label).

Subsection 2.7.1—9(6) provides that, despite subsection 2.7.1—9(1), the package of a prescribed alcoholic beverage that contains individual portion packs is not required to display the pregnancy warning label if the pregnancy warning label on an individual portion pack can be clearly seen through that package.

Section 2.7.1—10 sets out which of the two pregnancy warning labels must be displayed for the purposes of the requirements imposed by sections 2.7.1—8 and 2.7.1—9.

Subsection 2.7.1—10(1) sets out which type of pregnancy warning label must be displayed a package or a layer of packaging of a prescribed alcoholic beverage. The subsection requires:

- A pregnancy warning pictogram to be displayed on the package or packaging of a prescribed alcoholic beverage with a volume less than and equal to 200 ml.
- A pregnancy warning mark to be displayed on the package or packaging of a prescribed alcoholic beverage with a volume greater than 200 ml.
- A pregnancy warning mark to be displayed on the package or packaging of a prescribed alcoholic beverage which contains individual portion packs (regardless of the volume of the prescribed alcoholic beverage or of an individual portion pack).

Subsection 2.7.1—10(2) sets out which pregnancy warning label must be displayed on an individual portion pack for the purposes of subsection 2.7.1—9(5). The subsection requires:

- A pregnancy warning pictogram to be displayed on an individual portion pack with a volume of less than or equal to 200 ml.
- A pregnancy warning mark to be displayed on an individual portion pack with a volume greater than 200 ml (e.g. each can of beer in a 6 pack would display a pregnancy warning mark).

Subsection 2.7.1—10(3) requires a pregnancy warning label to be displayed as a whole and without any modification.

Section 2.7.1—11 sets out the legibility requirements for pregnancy warning labels.

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Subsection 2.7.1—11(1) sets out the legibility requirements for pregnancy warning labels displayed on a package or a layer of packaging of a prescribed alcoholic beverage. The legibility requirements that apply (as set out in the table to the subsection) depend on:

- the volume of the prescribed alcoholic beverage;
- whether the package of the prescribed alcoholic beverage is an outer package; and
- whether the package of the prescribed alcoholic beverage contains individual portion packs.

Subsection 2.7.1—11(2) sets out the legibility requirements for pregnancy warning labels displayed on an individual portion pack. The legibility requirements that apply (as set out in the table to the subsection) depend on the volume of the individual portion pack.

The tables to subsections 2.7.1—11(1) and 2.7.1—11(2) prescribe 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 font size of the signal words and statement of a pregnancy warning mark (in point and millimetres), and the size of clear space (in millimetres) outside the border of a pregnancy warning mark.

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

For the pregnancy warning pictogram and the pictogram in a pregnancy warning mark, the section prescribes the colour of the circle and strikethrough, the silhouette of a pregnant woman, and the background of the pictogram.

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 and the background within the border of the mark.

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 – Pregnancy warning labels in other countries

Table C1 presents information about the requirements for mandatory pregnancy warning labels in 11 countries (adapted from the International Alliance for Responsible Drinking (IARD, 2019)).

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 (1.2% for distilled beverages in Lithuania), and
- one requires the label on alcoholic beverages higher than 6.0% ABV (Mexico).

In South Africa, beverages required to carry at least one of seven warnings (including one about pregnancy) are determined via product type rather than %ABV except for beer (other than traditional African beer), ale, cider, stout which have to carry a 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 size. For example, the USA specifies minimum size for different volumes of beverage container (see Table C1). 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 container¹¹ 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 ≤ 1 litre and 14 mm diameter for volumes ≥ 350 ml and < 500 ml. Box heights need to be at least 11 mm for beverage volumes ≥ 350 ml and < 500 ml and 14 mm for volumes ≥ 500 ml and < 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 in France (e.g. red pictogram of 14 mm in diameter) (Meiningers Wine Business International, 2019)

Most countries state the warning label must be presented in a contrasting colour to the background colour. Very few countries specify the colour of the warning label (e.g. South Africa requires the text to be in black on a white background, Turkey requires the colour red in the pictogram).

¹¹ 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.*

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In Ireland, a public consultation seeking expert research on the effectiveness of certain health warnings (including a pregnancy warning) and other alcohol labelling information closes mid-October 2019 (Food Safety Authority of Ireland, 2019). As set out in the Irish 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, there are four countries that have a voluntary scheme for pregnancy warning labelling (Australia, New Zealand, Japan, United Kingdom) (IARD, 2019). 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 UK, 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 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 Organisation, 2018b). In addition to 8 of the 11 countries listed in Table C1, 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 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 carry the statement **WARNING, DRINKING ALCOHOL DURING PREGNANCY CAN CAUSE BIRTH DEFECTS** and a French translation¹². In Ontario, a health warning about the consumption of alcohol during pregnancy is required to be displayed in specified licensed establishments¹³. 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 US is acceptable in Canada (Canadian Food Inspection Agency, 2019).


¹² Personal communication: Yukon Liquor Corporation December 2018

¹³ Requirements are in the Ontario Liquor Licence Act 1990

<https://www.ontario.ca/laws/regulation/900718>

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Table C1: 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>




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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 500ml 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, Communique on warning messages to be affixed on the packaging of alcoholic beverages per Law No. 6487 of 11/06/2013.

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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!</i> , <i>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>	<p>Law on Prevention of the Harmful Impact of Alcohol 2018 Art 14, 15</p>
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 237ml and up to 3 litres the mandatory statement must not be smaller</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>

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Country	Requirements for mandated pregnancy warning label	Authority
	<p>than 2 mm, and for containers of more than 3 litres, the mandatory 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 D – Examples of pregnancy warning statements

Statements tested or suggested in previous Australian and New Zealand research
(Rout and Hannan, 2016; Hall and Partners, 2018)

- 1 During pregnancy no amount of alcohol is safe
- 2 Do not drink alcohol when pregnant
- 3 Alcohol causes birth defects, do not drink when pregnant
- 4 Do not use if pregnant: alcohol causes birth defects
- 5 Drinking any alcohol can harm your unborn baby
- 6 Even small amounts of alcohol can harm unborn babies
- 7 This product should not be used when pregnant or breastfeeding
- 8 Warning: Do not use if pregnant or breastfeeding
- 9 Don't drink pregnant
- 10 Any amount of alcohol may harm your unborn baby
- 11 It's safest not to drink while pregnant

Australian government guidelines

- 12 For women who are pregnant or planning a pregnancy, not drinking is the safest option
- 13 For women who are breastfeeding, not drinking is the safest option

New Zealand government guidelines

- 14 Stop drinking alcohol if you could be pregnant, are pregnant or are trying to get pregnant
- 15 There is no known safe level of alcohol consumption during pregnancy

Statements used around the world

- 16 Consumption of alcohol beverages during pregnancy, even in small amounts can have serious consequences for the child's health (**France**)
- 17 Ages under 21 and pregnant women should not drink (**Indonesia**)
- 18 Drinking during pregnancy increases the risk for congenital anomaly (**Republic of Korea**)
- 19 Drinking during pregnancy can be harmful to your unborn baby (**South Africa**)
- 20 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 (**USA**)
- 21 Drinking alcohol during pregnancy or nursing may adversely affect the development of your fetus or child (**Japan – voluntary**)
- 22 It is safest not to drink alcohol when pregnant (**UK voluntary**)
- 23 WARNING, DRINKING ALCOHOL DURING PREGNANCY CAN CAUSE BIRTH DEFECTS (**Yukon, Canada – local project**)
- 24 Drinking alcohol during pregnancy can cause birth defects (**proposed in Canada but not adopted**)

Suggestions from stakeholders

- 25 Alcohol harms your unborn baby
- 26 Don't drink alcohol when pregnant or trying to conceive
- 27 Drinking during pregnancy can cause life-long harm (or brain damage) to the baby
- 28 Drinking while pregnant can hurt your baby

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- 29 Warning: Drinking during pregnancy can harm your unborn baby
- 30 Drinking alcohol during pregnancy increases the risk of birth defects
- 31 When pregnant, any alcohol can seriously damage your baby or When pregnant, any alcohol at all, no matter how small, can seriously damage babies
- 32 Alcohol causes fetal alcohol spectrum disorder. Don't drink pregnant
- 33 Any amount of alcohol can cause lifelong harm to your baby
- 34 Any alcohol harms your unborn baby
- 35 No amount of alcohol is safe for your unborn baby

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Attachment E – Summary of stakeholder views from targeted consultations held in June/July 2019

List of Participants:

Australia	New Zealand
Alcohol Beverages Australia	Activity and Nutrition Aotearoa
Australian Chronic Disease Prevention Alliance	Alcohol Healthwatch
Australian College of Midwives	Brewers Association of New Zealand
Australian Distillers Association	Brewers Guild of New Zealand
Australian Department of Agriculture	Consumer New Zealand
Australian Department of Health	Countdown
Australian Grape and Wine	Distilled Spirits Aotearoa (NZ)
Brewers Association of Australia	DB Breweries
Carlton United Breweries	FASD-CAN Incorporated
Coles	Foodstuffs NZ
DrinkWise Australia	Independent Liquor
Endeavour Drinks Group	Lion Breweries
FASD Research Australia – Centre for Research Excellence	Ministry for Primary Industries
Foundation for Alcohol Research and Education	New Zealand Alcohol Beverages Council
Independent Brewers Association	New Zealand College of Midwives
Lion Beer Australia	New Zealand Food & Grocery Council
New South Wales Food Authority	New Zealand Health Promotion Agency
New South Wales Ministry of Health	New Zealand Nurses Organisation
Public Health Association of Australia	New Zealand Winegrowers
Public Health Advocacy Institute of Western Australia	Public Health Association of New Zealand
Queensland Health	Spirits New Zealand
Pernod Ricard Winemakers	
Retail Drinks Australia	
South Australia Health	
Spirits and Cocktails Australia	
Tasmania Department of Health	
Victorian Alcohol & Drug Association	
Victorian Department of Health and Human Services	
Western Australia Department of Health	
Western Australian Network of Alcohol & other Drug Agencies (WANADA)	

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Stakeholder views		
Industry	Public Health	Jurisdictions
<p>Support for flexibility in warning label design, particularly given the range of product types and packages available in the market.</p> <p>Support for mandating the voluntary scheme as is, to support flexibility and reduce labelling costs.</p> <p>Concern that a highly prescriptive approach would result in significant cost for industry and set a precedence for future proposals.</p> <p>Suggestion that costs to industry be considered in the context of other public health initiatives that may be more effective than labelling in terms of public health outcomes.</p> <p>Concern that costs in the DRIS don't reflect costs of the warning label as currently proposed.</p>	<p>General support for higher levels of prescription for label format, noting the importance of prescription for attracting attention.</p> <p>Strong support for prescribing all elements of the label noting that each individual element helps to reinforce the message (red, box, statement, signal words, pictogram etc.).</p> <p>Some concern that if imported products contain a pregnancy warning statement required for international markets, it may cause confusion with the Aust/NZ statement.</p> <p>Concern that close proximity of the pregnancy warning with 'drink responsibly' type messages, may result in confusion.</p>	<p>Support for prescriptive approach but also need to consider appropriate flexibility and choice for industry.</p> <p>Higher prescription will be challenging for products exported to international markets.</p> <p>Concern about inconsistency of label font size with existing current Code requirements, and recommendation the font size be a minimum of 3 mm.</p> <p>Recommendation that minimum box height be 14 mm, consistent with standard drinks labelling.</p> <p>Some acknowledgement that a pragmatic approach is necessary and that the whole warning label would be bigger than other mandatory labels.</p>

Topic: Warning label design

Proposed approach (containers over 100 ml):
Prescribed labelling elements:

- pictogram, 'HEALTH WARNING' signal words and statement in a box
- pictogram of pregnant woman within circle with strikethrough across circle
- signal words in capital letters, bolded
- warning statement in sentence case, bolded
- min. box height 11 mm
- min. font size 2.8 mm
- min. pictogram diameter 8 mm
- clear space of at least 3 mm outside box
- non serif font type



Proposed approach (containers 100 ml and under):

- only pictogram be required
- same size as for containers over 100ml (8 mm diameter)

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<p>Some concern regarding the size of the label and the importance of the pregnancy warning label, relative to other elements on alcoholic beverage labels (e.g. %ABV, standard drinks).</p> <p>Challenge of meeting requirements for those products sold to international markets.</p> <p>Concern with process used for development of 'attention' elements of warning label.</p> <p>Support for signal words to read "PREGNANCY WARNING" instead of 'HEALTH WARNING'.</p> <p>Referred to a study about the effect of warning signs on birth weight (https://www.ansirh.org/research/alcohol-and-pregnancy-policy-study)</p> <p>Requested consideration of broader evidence base than what was in the DRIS, for inclusion in consultation paper. Questioned use of term 'best available evidence' and consider evidence base has not been shared with stakeholders.</p> <p>Support for smaller label size overall, given the challenge to comply with multiple markets and the increasing number of elements required on the label.</p> <p>Support for the pictogram only for all products <330/440 ml instead of the proposed <100 ml.</p> <p>Suggestion that the pictogram only be displayed on the inner-most layer if products have multiple layers of packaging, or a three-tiered approach for small, medium and larger products. Size needs to be considered in context of packaging layers.</p>	<p>Preference for label to be bigger overall but acknowledgement of the need for a pragmatic approach.</p> <p>Some support for increased font size to 3/3.2 mm as per existing requirements in the Code.</p> <p>Support for larger pictogram (e.g 10 mm), particularly for products that will only require the pictogram and not the full warning label.</p> <p>Some concern about legibility if orientation of the label is not prescribed.</p> <p>Indigenous stakeholder representatives raised a concern about the wine glass held by the women in the pictogram, and whether this would capture an Indigenous audience in remote communities who may not use this type of vessel.</p> <p>Indigenous stakeholders generally support approach for products <100 ml to have pictogram only.</p>	
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<p>Removing the black border of the label would be preferable to reduce size.</p> <p>Concern that consideration of size of this warning label is challenging, without having certainty of future proposals and future labelling requirements.</p>		
<p>Topic: Colour and contrast</p>		
<p>Proposed approach (Option 1) Colour & contrast prescribed Black box White background inside box Statement in black text 'HEALTH WARNING' in colour red Pregnant woman in black Pictogram circle and strikethrough in red</p>	<p>Proposed approach (Option 2) Existing Code legibility requirements would apply Colour green prohibited (Code) Style guide would provide guidance on colour and contrast with examples of high and low contrast</p>	
<p>Stakeholder views/comments</p>		
<p>Industry</p>	<p>Public Health</p>	<p>Jurisdictions</p>
<p>Prescription of colour and contrast would be challenging for industry, particularly for labelling of cans which are limited to 6/7 colours per label.</p> <p>If style guide used it would need to be ready at the time of gazettal.</p>	<p>Support for prescriptive approach. Concerns that a style guide approach (Option 2) may result in colours or contrast that obscures the messages.</p> <p>Concern that red text can be hard to read which may be limiting in some settings. Generally however, red text, high-contrast and bolding was supported.</p> <p>Indigenous groups generally support a more prescriptive approach for colour and contrast, however there was some concern regarding the women being a black figure. Some people may be concerned the black figure is targeting Indigenous women only.</p> <p>Indigenous stakeholders also suggested a sticker over the existing label may draw more attention.</p>	<p>Some support for option 1 i.e. a prescriptive approach especially given colour has already been raised as an issue in the DRIS.</p> <p>Use of red may be useful for less literate consumers.</p>

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Topic: Consumer testing of the warning statement		
Stakeholder views/comments		
Industry	Public Health	Jurisdictions
<p>Four warning statements to be consumer tested:</p> <ol style="list-style-type: none"> 1. It's safest not to drink while pregnant 2. Alcohol can harm your baby 3. Any amount of alcohol can harm your baby 4. Any amount of alcohol can cause lifelong harm to your baby 	<p>Some concern about the potential adverse impact on participants of the consumer testing who have consumed alcohol in past or current pregnancies.</p> <p>Health warning statements that focus the blame on the alcohol rather than on the pregnant woman would be preferred to reduce adverse reactions to reading the label.</p> <p>Shorter warning statement may be more easily understood as a long statement may obscure the message. Another option could be <i>Alcohol can cause lifelong harm to your baby</i>.</p> <p>The words '<i>any amount of alcohol</i>' are important to reduce possible confusion between the pregnancy warning label and the 'drink in moderation' statements. Some stakeholders suggested '<i>lifelong harm</i>' may be more important than '<i>any amount</i>'.</p> <p>FARE focus group testing found the term 'unborn baby' was an important part of communicating the message. Also favour the use of 'pregnant/cy' in message.</p> <p>Some support for bilingual (English/Maori)</p>	<p>Query about whether the pictogram would be permitted to be placed above the statement.</p>

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	<p>labelling.</p> <p>Suggestion to ask respondents to compare the four statements being tested.</p> <p>Indigenous stakeholders indicated their preference for a stronger, more affirmative warning statement but acknowledged the warning statement needs to align with the public health guidelines.</p> <p>Of the four stakeholders, Indigenous stakeholders preferred the message '<i>any amount of alcohol can harm your baby</i>' but also queried whether the link to pregnancy (as the Drink Wise statement includes) would be important.</p>	
<p>Topic: Beverages to carry the warning label</p>		
<p>Proposed Option (Option 1) Beverages with more than 1.15% alcohol by volume (ABV) would be required to carry the pregnancy warning label.</p>	<p>Alternative Option (Option 2) Beverages with 0.5% ABV or more would be required to carry the pregnancy warning.</p>	
<p style="text-align: center;">Stakeholder comments/views</p>		
<p style="text-align: center;">Industry</p>	<p style="text-align: center;">Public Health</p>	<p style="text-align: center;">Jurisdictions</p>
<p>General support for the proposed approach that the pregnancy warning label be required on packaged beverages with more than 1.15% ABV (Option 1).</p> <p>Requirement for beverages with 0.5% ABV or more (Option 2) may cause confusion among consumers as it would capture non-alcoholic beverages such as brewed soft-drinks.</p> <p>Requiring beverages with more than 1.15% ABV to carry a warning label could contradict the message that no amount of alcohol is safe.</p>	<p>General support for all products with 0.5% ABV or more to carry the warning label (Option 2) for the reasons that:</p> <ul style="list-style-type: none"> - it is more consistent with message that no amount of alcohol is determined safe during pregnancy - it is consistent with the requirement for these products to display alcohol content and standard drinks - products such as brewed soft-drinks that have an alcohol content may be consumed frequently or in higher concentrations during pregnancy. 	<p>General agreement for the approach of requiring beverages with more than 1.15% ABV to carry a pregnancy warning label (Option 1).</p> <p>Noted a requirement for beverages between 0.5% and 1.15% ABV to carry a warning label would be consistent with the policy intent of the message that no alcohol should be consumed during pregnancy.</p>

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	<p>Some support for products with 1.15% ABV or more, as a pragmatic approach.</p> <p>Calls for tighter regulation of lower-alcohol and brewed soft-drinks industries.</p> <p>Indigenous group stakeholders support the approach of requiring beverages with more than 1.15% ABV to carry a pregnancy warning label.</p>	
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Topic: Application to different types of sales

Proposed approach
 A pregnancy warning label would be required on a packaged alcoholic beverage when the beverage is required to bear a label (as per Code requirements).

In addition, for foods normally exempt from the general requirement to bear a label, we propose a pregnancy warning label would be required. This includes packaged alcoholic beverages:

- made and packaged on premises from which it is sold
- 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.

A pregnancy warning label would not be required on alcoholic beverages **packaged in the presence of the purchaser**, including when packaged in the presence of the purchaser in the situations listed above, for example, a glass of wine poured and sold at a fundraising event.

Packaged alcoholic beverages sold from a vending machine or inside a hamper would be required to carry a pregnancy warning label as per current Code requirements.

Stakeholder views/comments

Industry	Public Health	Jurisdictions
<p>Query regarding whether the exemption would apply to beer kegs sold for either wholesale or retail.</p> <p>Concern standard exemptions in the Code are not fit-for-purpose for alcohol.</p>	<p>General support for the proposed approach.</p>	<p>General support for the proposed approach.</p> <p>Some concern regarding the exemption and whether it would apply to BYO containers. Any potential 'gap' caused by an exemption may not be an issue as the message would be communicated by the labelling of all other products.</p>

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<p>Challenge for small-batch production in particular e.g. a dozen bottles.</p> <p>Suggestion that the same requirements that apply for %ABV and standard drinks apply.</p> <p>Requirements need to be pragmatic, clear and unambiguous.</p> <p>Some support for exemptions to be kept to a minimum so as not to undermine the purpose of the mandatory regulation.</p>		
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Topic: Application to different types of packages

Proposed approach
 Consistent with existing Code requirements, where there is more than one layer of packaging, e.g. a bottle of whisky in a box, the warning label would be required on one layer of packaging only (the outermost layer so that it is legible).

For individual portion packs, e.g. 12 pack of beer inside an outer carton, the warning label would be required on the outermost layer of packaging and on the individual portion packs e.g. bottle or can.

Stakeholder views/comments

Industry	Public Health	Jurisdictions
<p>Recommendation that products such as beer that have three layers of packaging (i.e. the bottle, the 6-pack and the box), only require the pictogram on the bottle, if the other two layers carry the warning label. This would benefit smaller individual units. Approx. 95% of all beer sales are in 6 packs or cartons.</p> <p>Discussion about distinction between a package and a 'transport outer' (defined by the Code).</p> <p>Retailers want flexibility for products to be sold in multi-packs or as individual units. Manufacturer</p>	<p>Preference for the label to be on all layers of packaging, that is, visible at point of sale and the potential point of consumption (e.g. on the whisky bottle and the exterior box).</p> <p>Suggestion that bladders of wine could be exempt as they are less often removed from the box before consumption.</p> <p>Some support for taking an approach that is consistent with other mandatory labelling requirements for alcohol. However, some considered a warning label to be different from</p>	<p>Some concerns regarding the proposed approach for only one layer of packaging to carry the warning label with strong support for all layers of packaging to carry the label.</p> <p>Suggestion the pictogram be included on the bladder for cask wine.</p> <p>Requiring all layers of packaging to carry the label would ensure an equitable approach across all sectors of the market.</p> <p>Requiring the warning label on all layers of</p>

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<p>cannot regulate what the retailer does. Mandatory labelling on all layers currently but a large pregnancy warning label may change this.</p> <p>Products without a barcode would not need to carry a warning label.</p> <p>In the case where a bottle is sold within an outer box, typically the bottle is labelled as well, to allow the bottle to be sold separately. Smaller producers however, may not label each packaging layer.</p> <p>Re-labelling on multiple layers of packaging is costly.</p> <p>Concern regarding the reducing space available on labels and the risk to commercial agreements of removing voluntary components.</p> <p>Consistency of requirements across the industry is important.</p>	<p>%ABV or standard drink information as there is a risk of industry non-compliance as a warning label may deter consumers from purchasing the product.</p> <p>Suggestion that signage at the point of sale should be aligned with the pregnancy warning label requirement.</p> <p>Preference of Indigenous stakeholders is for all layers of packaging to carry the pregnancy warning label.</p>	<p>packaging would be consistent with the primary objective to remind pregnant women '<i>at the point of sale and at the potential point of consumption</i>' not to drink alcohol.</p>
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Topic: Transitional arrangements

Proposed approach

FSANZ recommends a two year industry transition period for the pregnancy warning label requirement, and an exemption for products compliant with the Code before the end of the transition period.

A transition period of two years would begin on the date of gazettal of the variation. During this time, an alcoholic beverage could comply with either the Code as in force as if the variation had not taken effect, or with the Code as amended by the variation. After the transition period, all alcoholic beverages would need to comply with the variation (i.e, have the pregnancy warning label), except for those subject to exemption below.

A product that was compliant with the Code before the end of the two year transition period (i.e. compliant with either the Code as in force as if the variation had not taken effect i.e not carry the mandatory pregnancy warning label, or with the Code as amended by the variation i.e carry the mandatory pregnancy warning label) would be deemed compliant with the Code as amended, if sold after the end of the transition period. No additional exemption for imported products is proposed.



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Stakeholder views/comments		
Industry	Public Health	Jurisdictions
<p>Support the combination of transition period and stock-in-trade exemption but preference for longer transition period (3-4 years). A longer transition period could be helpful for smaller producers.</p> <p>Not feasible for large producers to review all labels at one time. Also redesign won't start until gazettal.</p> <p>Most products would be sold within 1-2 years and so would carry the warning label after the end of the transition period. Only a small number of products would not have the warning label after a 2 year transition period.</p> <p>Support for timing to align with other labelling projects to reduce cost to industry.</p> <p>Small businesses can purchase labels up to three years in advance.</p> <p>Concern regarding proposed date of gazettal for wine industry with respect to wine harvest season as a high volume of wine is packaged in May.</p> <p>Concern regarding 'stock-in-trade' terminology and suggestion to consider 'stock produced'.</p> <p>Costs are disproportionate across different sectors and business types/sizes.</p> <p>Request that sufficient information for industry is available at the time of gazettal (ie style guide).</p>	<p>Support a 12 month transition period given most product is sold within 12 months.</p> <p>A longer transition period could be applied for by industry on a case-by-case basis.</p> <p>Concern industry may delay compliance until the very end of the transition period.</p> <p>Suggestion for tiered approach that allows longer transition period for some products only (e.g. imported products).</p> <p>Stock-in-trade seems pragmatic and will only apply to a small section of the market. Some calls for stock-in-trade exemption to be further limited and that broad application of the label is important.</p> <p>Best approach for health outcomes need to be considered.</p> <p>Indigenous stakeholders generally support proposed transitional arrangements.</p>	<p>Query regarding how to manage and the challenges associated with enforcement post-transition; i.e determining whether beverages not carrying a warning label were compliant before end of transition period.</p> <p>Query regarding management of stock-in-trade for imported goods. Suggestion for stock-in-trade be removed for imported goods and instead have a longer transition period.</p> <p>Interested in data on what products would be sold during transition period.</p> <p>Concern that the proposed arrangements may encourage businesses to expedite production through the transition period in order to avoid the labelling requirement.</p>

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

Labelling element/documents	Size	Other legibility guidance/requirements
Australia New Zealand Food Standards Code	<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> <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>
	<ul style="list-style-type: none"> font size for warning statements about infant formula preparation specified in terms on 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	<ul style="list-style-type: none"> 8 mm box height; pictogram approx. 5 mm 	<ul style="list-style-type: none"> Exclusion area around label (capital D from DrinkWise) DrinkWise charcoal or prominent colour from own colour palette
Guide for standard drink information	<p>Australian guidance (Independent Brewers Association):</p> <ul style="list-style-type: none"> minimum height of 14 mm clear zone of at least 3 mm from other elements on packaging  <p>http://iba.org.au/iba-beer-labeling-guidelines/</p>	<ul style="list-style-type: none"> clearly legible against background
	<p>New Zealand guidance:</p> <ul style="list-style-type: none"> minimum height of 12 mm  <p>https://www.alcohol.org.nz/help-advice/about-standard-drinks/using-the-standard-drink-icon</p>	
Guide for recycle logo	<p>Australian guidance:</p> <ul style="list-style-type: none"> minimum height of 14 mm minimum clear zone of 3 mm 	<ul style="list-style-type: none"> logo must be legible against background
10 cent refund statement on specified types of containers (requirement for various states and	<ul style="list-style-type: none"> Numeric '10' must have minimum height of 3 mm and the smallest letter in the wording must have a minimum height of 1.5 mm. 	

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Labelling element/documents	Size	Other legibility guidance/requirements
territories in Australia)	<ul style="list-style-type: none">• A minimum of 3 mm clear space around the refunding marking is recommended. <p>For an example of this scheme refer to the container deposit guidelines in South Australia https://www.epa.sa.gov.au/environmental_info/container_deposit/industry</p>	

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

Legislation/Guidance	Administered by	Relevant requirement	Description
New Zealand			
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% by volume.
Australia			
	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%
Wine Equalisation Tax (WET) Further information: https://www.ato.gov.au/Business/Wine-equalisation-tax/Products-WET-applies-to/			WET applies to certain beverages where they contain more than 1.15% by volume of ethyl alcohol <ul style="list-style-type: none"> - grape wine, including sparkling and some fortified wine - grape wine products (such as marsala) - fruit wines and vegetable wines - cider and perry (except for some flavoured ciders) - mead - sake
Schedule to Excise Tariff Act 1921			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 – Submission Template

Please use the template below to provide your submission to Proposal P1050 – Pregnancy warning labels on alcoholic beverages. Please submit this to FSANZ as a word document (if required, a pdf of the submission may also be provided in addition to the word document).

For information about making a submission, including what your submission should include, visit the FSANZ website at [information for submitters](#).

Submission to Proposal P1050 – Pregnancy warning labels on alcoholic beverages

- A. Name and contact details (position, address, telephone number, and email address):**

Text here

- B. For organisations, the level at which the submission was authorised:**

Text here

- C. Summary (optional but recommended if the submission is lengthy):**

Text here

Comments to specified sections of P1050 Call for Submissions (CFS) report:

- D. Literature review on the effectiveness of warning labels (section 3.1.1 of CFS)**

Text here

- E. Consumer testing of warning statements (section 3.1.2)**

Text here

- F. Pictogram (section 3.2.2.2)**

Text here

- G. Warning statement (section 3.2.2.3)**

Text here

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H. Design labelling elements (section 3.2.2.4)

Text here

I. Summary of proposed pregnancy warning label design (section 3.2.2.5)

Text here

J. Beverages to carry the pregnancy warning label (section 3.2.3)

Text here

K. Application to different types of sales (section 3.2.4)

Text here

L. Application to different types of packages (section 3.2.5)

Text here

M. Consideration of costs and benefits (section 3.4.1.1 of CFS)

Text here

N. Transitional arrangements (section 4.1 of CFS)

Text here

O. Draft variation to the Australia New Zealand Food Standards Code (Attachment A of CFS)

Text here

P. Other comments (within the scope of P1050 – see section 1.5 of the CFS)

Text here

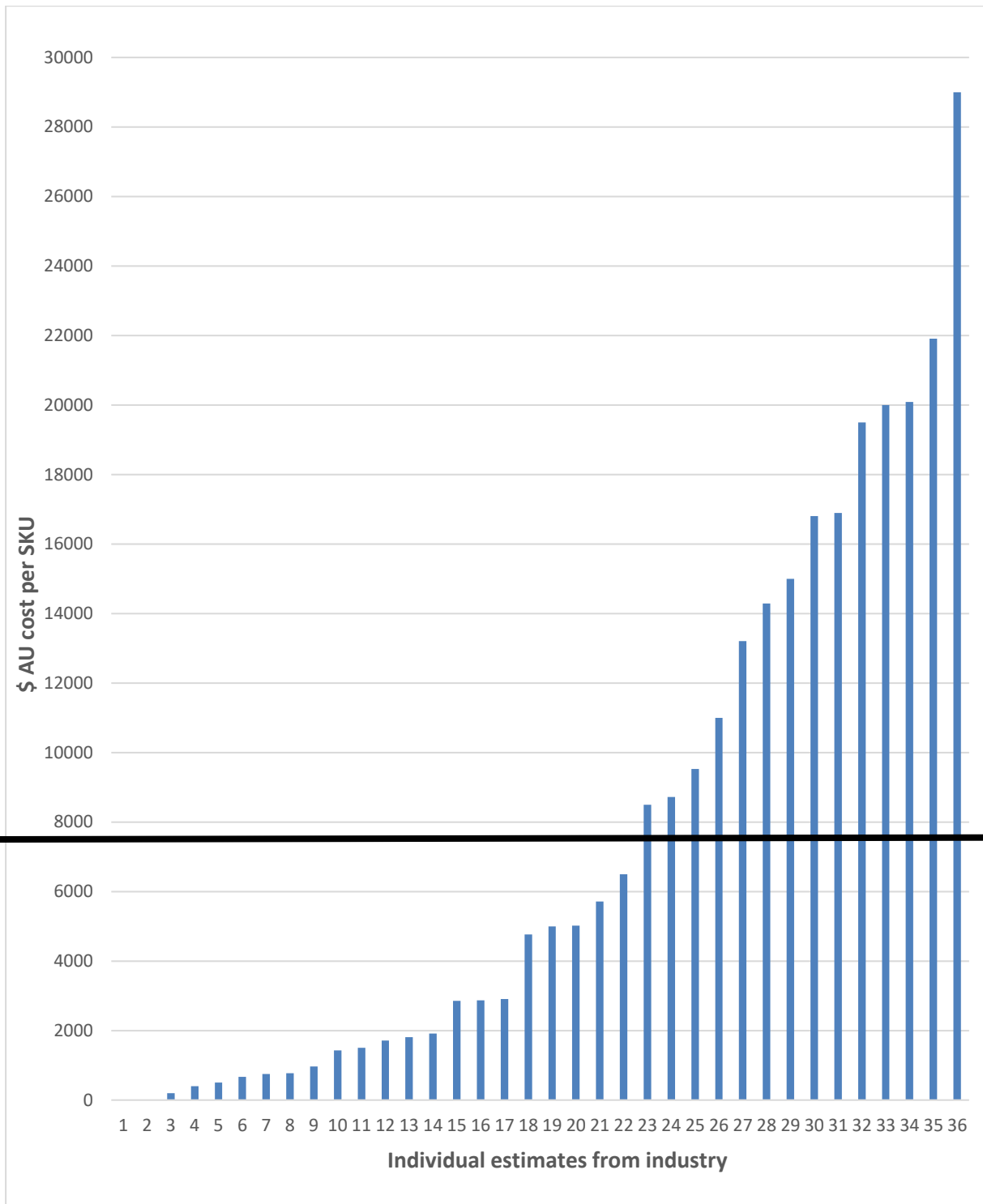
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Attachment I – Supporting information for the consideration of costs and benefits

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			
Benefits per year				Year 2, i.e. 2-0.75 years	\$780,260	\$673,479	\$1,920,639
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	\$3,901,298	\$3,367,396	\$9,603,194
...in Australia	202	31	498	Year 4, i.e. 4-0.75 years	\$7,022,336	\$6,061,313	\$17,285,749
...in New Zealand	23	4	57	Year 5, i.e. 5-0.75 years	\$10,143,374	\$8,755,230	\$24,968,304
Benefit \$ per prevented FASD case per year AU	\$13,847	\$76,002	\$13,847	Year 6, i.e. 6-0.75 years	\$13,264,412	\$11,449,147	\$32,650,860
Benefit \$ per prevented FASD case per year NZ	\$13,847	\$92,395	\$13,847	Year 7, i.e. 7-0.75 years	\$16,385,450	\$14,143,065	\$40,333,415
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	\$19,506,488	\$16,836,982	\$48,015,970
Percentage of all A- NZ annual FASD births this represents	1.3%	0.2%	3.2%	Year 9, i.e. 9-0.75 years	\$22,627,526	\$19,530,899	\$55,698,525
	Base	Best Case	Worst Case	Year 10, i.e. 10-0.75 years	\$25,748,564	\$22,224,816	\$63,381,080
				Year 11, i.e. 11-0.75 years	\$28,869,602	\$24,918,733	\$71,063,635
Costs AU and NZ combined				Year 12, i.e. 12-0.75 years	\$31,990,640	\$27,612,650	\$78,746,191
Average \$ cost per SKU effected	\$4,924	\$4,166	\$7,575	Year 13, i.e. 13-0.75 years	\$35,111,678	\$30,306,567	\$86,428,746
Number of SKUs effected	71,223	61,853	80,592	Year 14, i.e. 14-0.75 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 15, i.e. 15-0.75 years	\$41,353,754	\$35,694,401	\$101,793,856
Drinkwise \$ costs estimate	\$650,000	\$650,000	\$650,000	Year 16, i.e. 16-0.75 years	\$44,474,792	\$38,388,318	\$109,476,411
Total \$ cost including Drinkwise	\$351,319,009	\$258,333,865	\$611,107,875	Year 17, i.e. 17-0.75 years	\$47,595,830	\$41,082,235	\$117,158,967
				Year 18, i.e. 18-0.75 years	\$50,716,868	\$43,776,152	\$124,841,522
				Year 19, i.e. 19-0.75 years	\$53,837,906	\$46,470,069	\$132,524,077
				Year 20, i.e. 20-0.75 years	\$56,958,944	\$49,163,986	\$140,206,632
					\$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

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



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