

**30 June 2020**  
**[128-20]**

Review – Proposal P1050

## Pregnancy warning labels on alcoholic beverages

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On 31 January 2020, FSANZ approved a draft variation to the Australia New Zealand Food Standards Code to require a pregnancy warning label on packaged alcoholic beverages sold in Australia and New Zealand.

On 7 April 2020, the Australia and New Zealand Ministerial Forum on Food Regulation (Forum) requested FSANZ review that decision.

FSANZ was requested to review the decision within three months.

FSANZ has reviewed its decision and re-affirmed its approval of the draft variation, subject to amendments, on 23 June 2020. There are two amendments: the signal words HEALTH WARNING are changed to PREGNANCY WARNING; and the transition period for implementation of the pregnancy warning label is extended from two to three years.

This report sets out the reasons for FSANZ's decision to reaffirm the variation subject to the amendments and is provided pursuant to section 87 of the *Food Standards Australia New Zealand Act 1991* (Cth).

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## Executive summary

On 7 April 2020, the Australia and New Zealand Ministerial Forum on Food Regulation (Forum) requested Food Standards Australia New Zealand (FSANZ) review its decision to approve a draft variation to the Australia New Zealand Food Standards Code (the Code) arising from Proposal P1050 – Pregnancy warning labels on alcoholic beverages. In requesting a review, the Forum maintained its ongoing commitment to mandatory pregnancy warning labels on alcohol to ensure women and the broader community are aware of the need for pregnant women to not drink alcohol. The warning label is part of a suite of measures in Australia and New Zealand aimed to reduce the prevalence and severity of Fetal Alcohol Spectrum Disorder (FASD).

The Forum requested FSANZ consider the colour requirements of the label and signal wording. The request noted that the label as proposed *places an unreasonable cost burden on industry*. This review primarily considers the labelling cost to industry of the mandatory pregnancy warning label arising from Proposal P1050, and in particular the label's colour requirements and signal wording.

The Australian and New Zealand governments' health advice to women is not to consume alcohol during pregnancy. Exposure of the fetus to alcohol can cause a range of physical, cognitive, behavioural and neurodevelopmental disabilities with lifelong implications, collectively known as FASD. FASD significantly impacts individuals, families and the wider community. People with FASD have greater education, health and mental health needs, are more likely to have problems gaining employment and working independently, and are more likely to have early contact with the justice system.<sup>1</sup>

FSANZ has conservatively estimated the 'health related' cost of FASD across Australia and New Zealand to be A\$27.6 billion over 20 years. This estimate assumes only mild FASD cases and excludes wider social costs such as costs to the justice system, broader health and social care costs, costs of lost productivity from individuals with FASD, and emotional costs to individuals, families and wider communities.

FASD is entirely preventable by avoiding alcohol consumption during pregnancy. However, available data show that approximately 1 in 4 women in Australia and 1 in 5 women in New Zealand continue to consume alcohol after they become aware they are pregnant.

In the P1050 Approval Report<sup>2</sup>, the draft variation to the Code was to require a pregnancy warning label (incorporating pictogram and wording) on packaged alcoholic beverages with more than 1.15% alcohol by volume for retail sale, with a two year transition period for implementation.

FSANZ has re-examined cost estimates drawing on information used at assessment of P1050 as presented in the Approval Report and additional information gathered at review. To inform the review and validate cost information, FSANZ:

- sought clarification of cost estimates from four key Australian alcoholic beverage associations
- contacted jurisdictions across Australia and New Zealand to confirm if they were provided with any additional cost information from industry members or industry representative bodies
- sought clarification of the costs of mandating the colours of the pregnancy warning label from four label printing companies
- had its economic analysis of costs and benefits independently peer-reviewed by

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<sup>1</sup> [Australian National Alcohol Strategy 2019-2028](#)

<sup>2</sup> [P1050 Approval Report](#)

Marsden Jacob Associates, a leading private sector specialist economic consultancy with specific labelling cost expertise.

FSANZ has considered the costs of colour requirements and signal wording along with the evidence base for these label elements given the need to balance costs with efficacy of the pregnancy warning label.

The *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) requires FSANZ to have regard to specific matters when assessing a proposal and when deciding to approve a draft variation developed as a result of a proposal. These include the objectives and matters stated in section 18 of that Act. Subsection 18(1) of the FSANZ Act lists in order of priority three objectives for FSANZ when undertaking a review. The protection of public health and safety has the highest priority.

The matters listed in section 59 of the FSANZ Act also remain relevant considerations for FSANZ when conducting a review requested by the Forum. The FSANZ Act also makes clear that the Forum cannot direct what FSANZ must decide in a review.

## Matters addressed in the review

Forum issue	Summary of FSANZ'S response
<b>Unreasonable cost burden on industry</b>	
Break-even cost analysis	<p>FSANZ's assessment is that the cost burden to industry of the pregnancy warning label is not unreasonable because:</p> <ul style="list-style-type: none"> <li>• At Approval, the break-even analysis found: <ul style="list-style-type: none"> <li>– only a small proportion of cases of FASD (i.e. 1.3% or 225 cases per year over 20 years) need to be prevented to offset the total cost of label changes</li> <li>– there are large human, social and financial benefits to the community from avoiding or mitigating new FASD cases.</li> </ul> </li> <li>• Additional cost information identified during the review aligns with the cost estimates included in the break-even analysis of the costs and benefits of the pregnancy warning label as at Approval.</li> <li>• Information provided from printing companies shows some product labels may be replaced more regularly than assumed at Approval, for example once a year or more often. The average cost estimates of label changes per product may therefore be overestimated.</li> <li>• A peer review of the break-even analysis and outcomes from additional sensitivity analyses provide confidence in the conclusion that only a small number of FASD cases are required to offset the labelling costs to industry. The peer review also commented the estimated benefits were very conservative.</li> <li>• FSANZ reaffirms the conclusions from the break-even analysis which demonstrate a large potential positive net benefit from the reduction of FASD.</li> <li>• The best available evidence underpins the pregnancy warning label design resulting in an effective label, which when combined with other public health initiatives will meet the public health imperative of reducing the prevalence and severity of FASD.</li> </ul> <p>However, in recognition of the current challenging business environment from Australian bush fires and COVID-19 across Australia and New Zealand, FSANZ has extended the transition period from two to three</p>

Forum issue	Summary of FSANZ'S response
	<p>years. This will provide increased flexibility for industry to co-ordinate the implementation of the pregnancy warning label with voluntary label changes and to spread the costs over a longer period if they choose to do so. This longer transition period is estimated to further reduce average costs per product by between 15% and 20% (by between about A\$1,000 and A\$1,600), compared to the A\$7,575 per product (average cost of label changes before mitigation by a transition period).</p> <p>While recognising the extended transition period may delay avoidance of FASD cases, the three year transition period should not significantly reduce the benefits as producers of faster moving higher volume products are likely to be able to co-ordinate the change with voluntary label changes that will arise earlier in the transition period.</p>
Colour requirements	<p>In relation to colour requirements, FSANZ recognises the cost impact upon industry but assesses that this is not unreasonable because:</p> <ul style="list-style-type: none"> <li>• The wide range of costs for incorporating the prescribed colours in the pregnancy warning label, in particular the colour red, provided by industry and printing companies at review, accords with the range of total label cost estimates per product set out in the Approval Report (A\$0 to \$29,000). Therefore, as noted above FSANZ reaffirms the cost estimates and conclusions from the break-even analysis.</li> <li>• While there is a wide range in the cost of implementing colour requirements across the sector, the incremental cost of applying the colour red to a black and white warning label is in general likely to be small, at around 10% of total label change costs overall. The requirements allow for an existing red in a beverage label to be used for the warning label.</li> <li>• The best available scientific evidence: <ul style="list-style-type: none"> <li>– supports prescribing colours to achieve a consistent high contrast label which is important for legibility and noticeability and therefore label efficacy</li> <li>– shows that mandating red colour is the only way to maintain consistency in consumer understanding of the label as red is consistently rated as the colour with the greatest hazard connotation</li> <li>– shows that, if red was removed from the design, a significantly larger warning label than currently proposed would be required to maintain noticeability.</li> </ul> </li> <li>• Changing colour requirements, including removing the colour red, will undermine the label's effectiveness in reducing the prevalence and severity of FASD and will not significantly reduce costs to industry.</li> </ul>
Signal wording	<p>In relation to signal wording, FSANZ's assessment is that the cost burden to industry is not unreasonable. However, at the Forum's specific request, FSANZ has reviewed the signal words and has decided to amend the required signal words to PREGNANCY WARNING for reasons other than cost. FSANZ made this amendment for the following reasons:</p> <ul style="list-style-type: none"> <li>• The best available evidence shows the use of signal words can enhance credibility and increase likelihood to comply with the warning.</li> <li>• Using WARNING increases attention and credibility over no signal words.</li> </ul>

Forum issue	Summary of FSANZ'S response
	<ul style="list-style-type: none"> <li>• The addition of prefixes to the signal words may further enhance attention and credibility than using WARNING alone.</li> <li>• FSANZ is not aware of any specific evidence comparing the effect of PREGNANCY WARNING with HEALTH WARNING on credibility or ability to attract attention.</li> <li>• While there is no published evidence on the use of PREGNANCY WARNING, those signal words target a specific group at whom the warning label message is ultimately directed.</li> <li>• While PREGNANCY WARNING may not provide information to the broader community to the same extent as HEALTH WARNING, the label as a whole will still contribute to raising awareness of the risks of drinking alcohol during pregnancy and prompt discussion of these risks within the community.</li> </ul>

After reviewing the best available scientific evidence and carrying out the Forum's review request consistent with our legislative remit under the FSANZ Act, FSANZ's assessment is that the pregnancy warning label does not impose an unreasonable cost burden on industry. FSANZ reaffirms the conclusions from the break-even analysis and its approval of the prescribed colour requirements. However, for reasons outlined above, FSANZ has changed the signal words of the pregnancy warning label to PREGNANCY WARNING as shown below.



The Forum in October 2018, after considering the then available evidence, requested FSANZ to consider developing a mandatory pregnancy warning label for packaged alcoholic beverages that included a pictogram and relevant warning statement. For the reasons stated in this report, FSANZ is satisfied the approved draft variation, as amended to change the signal words HEALTH WARNING to PREGNANCY WARNING and to extend the transition period for implementation of the pregnancy warning label from two to three years (Attachment A), is the appropriate response to the 2018 ministerial request.

The evidence based pregnancy warning label as currently designed, balances the cost to industry against the public health imperative of reducing the prevalence and severity of FASD, and ensures that as part of a suite of measures, it can contribute to that outcome.

# 1 Introduction

## 1.1 Review request

On 7 April 2020, the Australia and New Zealand Ministerial Forum on Food Regulation (Forum) requested Food Standards Australia New Zealand (FSANZ) review its decision to approve a draft variation to the Australia New Zealand Food Standards Code (the Code) arising from Proposal P1050 – Pregnancy warning labels on alcoholic beverages.

In requesting a review of P1050, the Forum maintained its ongoing commitment to mandatory pregnancy warning labels on alcohol to ensure women and the broader community are aware of the need for pregnant women to not drink alcohol.

The criterion under which the Forum requested the review as set out in the Food Regulation Agreement<sup>3</sup> is:

*(vii) it places an unreasonable cost burden on industry or consumers.*

The Forum requested the review consider the colour requirements and signal wording of the proposed pregnancy warning label<sup>4</sup>.

FSANZ was requested to review the decision within three months.

## 1.2 Decision at Approval

The Australian and New Zealand governments advise women not to consume alcohol during pregnancy. Exposure of the fetus to alcohol can cause a range of physical, cognitive, behavioural and neurodevelopmental disabilities with lifelong implications, collectively known as Fetal Alcohol Spectrum Disorder (FASD). FASD significantly impacts individuals, families and the wider community. People with FASD have greater education, health and mental health needs, are more likely to have problems gaining employment and working independently, and are more likely to have early contact with the justice system.<sup>5</sup>

FSANZ has conservatively estimated the 'health related' cost of FASD across Australia and New Zealand to be A\$27.6 billion over 20 years. This estimate assumes only mild FASD cases and excludes wider social costs such as costs to the justice system, broader health and social care costs, costs of lost productivity from individuals with FASD, and emotional costs to individuals, families and wider communities.

FASD is entirely preventable by avoiding alcohol consumption during pregnancy. However, available data show that approximately 1 in 4 women in Australia and 1 in 5 women in New Zealand continue to consume alcohol after they become aware they are pregnant (see P1050 Approval Report<sup>6</sup>).

Following two evaluations of a voluntary labelling scheme, the Forum agreed in October 2018 that *based on the evidence, a mandatory labelling standard for pregnancy warning labels on packaged alcoholic beverages should be developed and should include a pictogram and relevant warning statement*. The Forum therefore asked FSANZ to consider mandatory pregnancy 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 prepared Proposal P1050.

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<sup>3</sup> [Food Regulation Agreement](#)

<sup>4</sup> See the [Forum communique](#) and [notice of publication of the request](#) on the Food Regulation website.

<sup>5</sup> [Australian National Alcohol Strategy 2019-2028](#)

<sup>6</sup> [P1050 Approval Report](#)

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



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

From the date of gazettal of the variation to the Code, there was a two year transition period for implementation of the mandatory pregnancy warning label.

The Approval Report contains FSANZ's reasons for the decision and summarises the evidence on which it is based. That report is available on the FSANZ website<sup>7</sup>.

## 2 Decision

FSANZ has reviewed its decision and has decided to re-affirm its approval of the draft variation, subject to two amendments: changing the signal words HEALTH WARNING to PREGNANCY WARNING (see label below); and extending the transition period from two years to three years. The amended draft variation is intended to take effect on gazettal.



FSANZ has also made a technical correction to the requirement for the size of type of the statement (Alcohol can cause lifelong harm to your baby) in the pregnancy warning label. This is only a technical correction that reflects what was intended at Approval. *Size of type* in the Code means the measurement from the base to the top of a letter or numeral. This means the size of the smallest lowercase letters (e.g. *can* in the statement) has to be at least the minimum stated size. Applying the size of type measurements for the three different sized labels as per the approved draft variation to the smallest lowercase letters would mean the overall statement would be larger than intended. We have therefore adjusted the size of type requirements to reflect the intent at Approval.

The approved draft variation as amended is at Attachment A. The explanatory statement is at Attachment B. FSANZ has amended the explanatory statement to clarify the operation of section 2.7.1—8 in regard to the label requirements for packaging. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

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<sup>7</sup> [P1050 Approval Report](#)

## **3 FSANZ's approach to the review**

### **3.1 Scope**

The stated grounds for the Forum's review request was that the pregnancy warning label *places an unreasonable cost burden on industry*. The Forum requested the review consider the colour requirements and signal wording of the pregnancy warning label. This review therefore considers the labelling cost to industry of the mandatory pregnancy warning label arising from Proposal P1050, and in particular the label's colour requirements and signal wording.

### **3.2 Statutory context**

Section 87 of the FSANZ Act requires FSANZ to review an approved draft variation when requested by the Forum.

The FSANZ Act requires FSANZ to have regard to certain matters when undertaking that review. These are in addition to the Forum's stated reasons for requesting the review.

Subsection 18(1) of the FSANZ Act lists in order of priority three objectives for FSANZ when undertaking a review. The protection of public health and safety has the highest priority. Subsection 18(2) lists other secondary matters which FSANZ must have regard to in reviewing food regulatory measures.

Section 59 of the FSANZ Act requires FSANZ to have regard to specific matters when assessing a proposal and when deciding to approve a draft variation developed as a result of a proposal. These matters remain relevant considerations for FSANZ when conducting a review requested by the Forum.

Each of the above sections and matters are considered in section 6 of this report.

Paragraph 18(2)(e) of the FSANZ Act requires FSANZ to have regard to any written policy guidelines formulated by the Forum. The section makes clear that the requirement is only to have regard to the policy guidelines; they are not binding on FSANZ. The FSANZ Act also makes clear that the Forum cannot direct what FSANZ must decide in a review.

## **4 Review of labelling costs to industry**

### **4.1 Approach**

In response to the review request, FSANZ has re-examined cost estimates, in particular costs associated with the prescribed colour requirements and signal wording for the pregnancy warning label. We have drawn on information used at assessment of P1050 presented in the Approval Report and additional information gathered during this review.

FSANZ sought clarification of cost estimates given in public statements made by four key Australian alcoholic beverage associations leading up to the Forum's meeting on 20 March 2020 (Alcohol Beverages Australia, Brewers Association of Australia, Australian Grape & Wine, Independent Brewers Association). We have considered the additional information provided by these associations in our re-examination of cost estimates used in the break-even analysis included in the Approval Report.

FSANZ contacted jurisdictions across Australia and New Zealand to confirm if they were provided with any new cost information from industry members or industry representative bodies ahead of the Forum meeting on 20 March 2020. In response, jurisdictions provided FSANZ with industry cost information, some of which had already been directly provided to FSANZ via submissions.

Additionally, seven companies that print labels for alcoholic beverages across Australia and New Zealand were approached to seek clarification of the costs of a black, white and red label versus a black and white label. FSANZ had discussions with four companies which covered printing labels that are fixed to bottles or cans and label information printed directly on cans and retail cartons. FSANZ also became aware of, and approached the Foundation for Alcohol Research and Education (FARE) for information they had gathered about printing costs. FARE had asked seven printing companies in Australia for cost estimates of printing a black, white and red versus a black and white pregnancy warning label.

FSANZ has considered the costs of colour requirements and signal wording along with the evidence base for these label elements given the need to balance costs with efficacy of the pregnancy warning label.

## **4.2 Total cost estimates**

### **4.2.1 Break-even analysis at Approval**

The following provides a summary of the break-even analysis of costs and benefits that was included in the Approval Report.

The annual percentage of new FASD cases across Australia and New Zealand (combined) needing to be avoided to offset label costs of the warning label is estimated to range from 0.2 - 3.2% (35 to 555 cases per year). The most likely estimate, the Base Scenario, is 1.3%, i.e. around 225 cases of an estimated 17,338 annual cases of FASD would need to be avoided per year across both countries over 20 years after the end of the transition period to justify label costs of the warning label.

In undertaking the break-even analysis, the following key assumptions were made:

- The annual 'health related' cost of each new case of FASD was estimated to be A\$13,847. This cost is likely to have been underestimated as only mild FASD cases avoided were included and A\$13,847 is a conservative estimate compared with international data. In addition, the estimated cost excludes costs to the justice system due to the higher rate of offending amongst people with FASD, broader health and social care costs, costs of lost productivity from individuals with FASD, and emotional costs to individuals, families and wider communities.
- The average cost estimate per Stock Keeping Unit (SKU)<sup>8</sup> of the proposed pregnancy warning label was A\$4,924, taking into account:
  - the average (A\$7,575) of a wide range of per SKU costs (A\$0 to A\$29,000 per SKU) provided by industry, noting that costs can vary depending on a number of factors including printing process and existing colours used in the alcoholic beverage label
  - around 50% of SKUs being able to combine the warning label with voluntary label changes, where such a situation would reduce costs by around 70% (with the then proposed two-year transition period).

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<sup>8</sup> A stock keeping unit is a distinct type of item for sale, such as a product or service, and all attributes associated with the item type that distinguish it from other item types. For a product, these attributes could include manufacturer, description, material, size, colour and packaging.

- An upper estimate of the number of SKUs affected was used (71,223 SKUs).
- Costs to most companies are normally one-off with little ongoing costs of using the colour red or including the warning label per se, although there are exceptions that may have influenced the range of cost estimates provided by alcohol beverage producers and associations.

#### **4.2.2 Cost information**

In response to FSANZ's request, industry associations provided clarification of cost estimates given in public statements and also reiterated information previously provided to FSANZ. FSANZ had already accounted for this information in its analysis of the range of label cost estimates provided by the alcohol industry (refer to Attachment H of the Approval Report) and therefore in determining the average cost per SKU for implementing the pregnancy warning label. While some additional cost estimates from individual alcohol producers provided to FSANZ via jurisdictions had not previously been considered, all estimates were in the range of label cost estimates reported in the Approval Report (A\$0 to A\$29,000 per SKU).

Printing companies suggested that printing costs per additional colour would range from A\$110 to A\$600 per printing plate. This suggests that certain alcoholic beverage industry estimates (at A\$1,000 or more per plate) are outliers.

Alcohol industry associations and individual companies frequently commented about the negative impact of the challenging environment on their sector in public statements leading up to the Forum meeting on 20 March 2020. They cited COVID-19 and bush fires and smoke in Australia. The impact of COVID-19 on the alcohol sector across both Australia and New Zealand was clearly not considered in the Approval Report, given its more recent development. In a report released on 24 May 2020<sup>9</sup>, Alcohol Beverages Australia emphasised that the alcoholic beverages industry has been affected by COVID-19 particularly via reduced business activity in the hospitality sector.

New information from printing companies shows many beer and cider products have their labels replaced regularly in an increasingly competitive market, e.g. once a year or more often. Timing the inclusion of the pregnancy warning label with these voluntary label replacements would reduce the expense of complying with any new warning label requirement. The existing Base Scenario estimate already takes some of these reduced marginal costs into account, but this new evidence suggests that voluntary label changes are occurring more regularly than previously thought. Therefore our Base average label cost estimate may overestimate the average cost per SKU.

Besides the above comment, the new evidence broadly supports the previous estimated Base Scenario average of A\$4,924 per SKU of total label change costs for the proposed pregnancy warning label (refer to section 4.2.1 above). The new evidence also supports the range of costs per SKU given in the Approval Report (A\$0 to A\$29,000 per SKU).

##### **4.2.2.1 Peer review of the break-even analysis**

At Approval, FSANZ undertook its own independent analysis of costs and benefits and was confident in the quality of the analysis undertaken in the Decision Regulation Impact Statement (DRIS) prepared by FRSC (Food Regulation Standing Committee, 2018). We note the Office of Best Practice Regulation (OBPR) was satisfied that the DRIS met the requirements of the Council of Australian Governments Best Practice Regulation Guide (refer

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<sup>9</sup> See the [report on the impact of coronavirus on the alcoholic beverage sector](#) (Alcohol Beverages Australia)

to the Approval Report).

To provide further robustness to the review, FSANZ had its economic analysis independently peer reviewed by Marsden Jacob Associates, a leading private sector specialist economic consultancy with specific labelling cost expertise. They concluded FSANZ has conducted the analysis in a satisfactory manner, using sound economics methodology and undertaken calculations correctly.

The peer review suggested additional sensitivity analysis would add confidence that the overall results from the break-even analysis do not significantly change with higher or lower costs. Based on this suggestion, FSANZ undertook the additional sensitivity analyses, specifically:

- varying the labelling change cost per SKU for the Base Scenario by minus and plus 20%
- increasing the possible benefit per FASD case avoided of between plus 20% and plus 50%
- increasing the discount rate to 10%.

Extending the analysis in these ways does not markedly affect the overall conclusion of the break-even analysis.

Varying the cost of labelling change per SKU by minus and plus 20% would only slightly adjust the Base Scenario's percentage of annual FASD cases needing to be avoided, from 1.3% to 1.1% (costs minus 20%) and 1.6% (costs plus 20%).

In Marsden Jacob Associates' view, the analysis has taken a very conservative approach to the estimation of expected benefits by excluding some known benefits such as the avoided costs of FASD on future economic productivity. Inflating the benefits as they recommended by 20% to 50% would bring down the percentage of annual FASD cases needing to be avoided to justify labelling costs to 1.1% and 0.9% respectively under the Base Scenario, down from the previously estimated 1.3%.

The peer review suggested an additional sensitivity test using a 10% discount rate for future benefits. Even with this higher discount rate the proportion of annual FASD cases needing to be avoided would still be under 5%:

- 2.6% in the Base Scenario and 4.5% in the Worst Case Scenario without inflating the conservative benefits, or
- 1.7% in the Base Scenario and 3.0% in the Worst Case Scenario with the less conservative benefit estimations suggested by the peer review.

These estimates compare to the current Base Scenario and Worst Case scenario estimates of 1.3% and 3.2%.

However, FSANZ does not recommend using a 10% discount rate for benefits that are already conservative. Real interest rates and real economic growth (average returns to investment above inflation) have been markedly lower over the last 15 years compared to the time when 10% was first recommended. The 4% discount rate FSANZ used was also more in-line with more recent UK guidelines from the UK Treasury.

In summary, the Marsden Jacob Associates' peer review and outcomes from the additional sensitivity testing provide confidence in the conclusion from the break-even analysis that only a small proportion of FASD cases need to be prevented to offset labelling costs.

### 4.2.3 Review response

FSANZ's assessment is that the cost burden to industry of the pregnancy warning label is not unreasonable because:

- At Approval, the break-even analysis found:
  - only a small proportion of cases of FASD (i.e. 1.3% or 225 cases per year) need to be prevented to offset the total cost of label changes
  - there are large human, social and financial benefits to the community from avoiding or mitigating new FASD cases.
- Additional cost information identified during the review aligns with the cost estimates included in the break-even analysis of the costs and benefits of the pregnancy warning label as at Approval. The outcomes from the independent peer review also support the analysis undertaken at Approval.
- Information provided from printing companies shows some product labels may be replaced more regularly than assumed at Approval, for example once a year or more often. The average cost estimates of label changes per product may therefore be overestimated.
- FSANZ reaffirms the conclusions from the break-even analysis which demonstrate a large potential positive net benefit from the reduction of FASD.
- The best available evidence underpins the pregnancy warning label design resulting in an effective label, which when combined with other public health initiatives will meet the public health imperative of reducing the prevalence and severity of FASD.

However, in recognition of the current challenging business environment from Australian bush fires and COVID-19 across Australia and New Zealand, FSANZ has extended the transition period for label implementation from two to three years. This will provide increased flexibility for industry to manage implementation of the pregnancy warning label.

With an extra year of transition, we estimate that between 20 - 30%<sup>10</sup> more alcoholic beverage SKUs will be able to combine the pregnancy warning label changes with other voluntary changes, reducing the overall industry average label change costs by a further 15 - 20% (by between about A\$1,000 and A\$1,600), compared to the A\$7,575 per SKU (average cost of label changes before mitigation by a transition period)<sup>11</sup>.

It is also a reasonable hypothesis that extending the transition period will most likely benefit smaller and larger producers of slower moving SKUs who may not voluntarily change labelling for marketing reasons as quickly as other parts of the industry.

While recognising the extended transition period may delay avoidance of FASD cases, the three year transition period should not significantly reduce the benefits as producers of faster moving higher volume products are likely to be able to co-ordinate the change with voluntary label changes that will arise earlier in the transition period.

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<sup>10</sup> This estimate of 20-30% of alcoholic beverages combining the pregnancy warning label with other changes in one year is based on previous FSANZ surveys of label change frequencies, conversations with print companies and an international label change model.

<sup>11</sup> We have assumed combining the pregnancy warning label change with other changes during a transition period would reduce the marginal cost of pregnancy warning label by 70% (refer to P1050 Approval Report).

## **4.3 Colour of pregnancy warning label**

### **4.3.1 Decision at Approval**

FSANZ's decision as discussed in the Approval Report was to prescribe the colours of the pregnancy warning label as follows:

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

The reasons for this decision were as follows:

- The best available evidence showed that a high contrast label is important for legibility and noticeability. 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 enhances legibility (Supporting Document (SD1) to the Approval Report).
- Using red increases the speed of identification and level of attention the warning receives. Red is more noticeable than black. Red has been consistently found to connote the highest levels of hazard when compared to black and other colour warnings. A red and black pictogram is interpreted more like a warning than a black and white pictogram (SD1 to the Approval Report).
- Public health and government submitters supported the colour red because it enhances the cautionary message and is likely to stand out and attract attention.
- The colour red is required rather than a specific red such as Pantone 485 to reduce costs for companies already using a red colour in alcoholic beverage labels.
- Based on the cost of labelling changes in the 2014 PricewaterhouseCoopers report (PricewaterhouseCoopers, 2014), cost estimates provided by industry and information from label printing companies, FSANZ considered that the cost of using red was already included in the updated average total costs per SKU used in the break-even analysis.
- The prescribed colour scheme provides consistency in the colour of warning labels across alcoholic beverages.

### **4.3.2 Cost information about requiring colour**

In general, printing companies, individual alcohol producers and industry associations have pointed out that the cost impacts of prescribing colours on the label for any individual SKU will depend on numerous factors. Those factors include but are not limited to:

- whether printing is done digitally or conventionally
- the material that labels will go onto (e.g. cans, carton, glass, or plastic)
- type of label material (e.g. plastic, card, paper, or spray-on)

- existing colours used in the label (e.g. if black and/or white and/or red are already included)
- limits on number of colours in a print run (that may necessitate more extensive redesign of labels or more than one pass through the printing machine)
- space on the existing label
- if ceramic labels without red need replacing with other label materials
- number of layers of packaging that require the warning label.

Some of these factors were accounted for in the average cost of a 'major' label change (A\$7872) derived from the 2014 PricewaterhouseCoopers study which was very close to the FSANZ average cost determined from industry data (A\$7575). The range of label cost estimates provided by the alcohol industry reflect these different factors (refer to Attachment H of the Approval Report).

Printing companies have noted that unlike for most large print jobs that use conventional printing processes, most small-scale label runs are printed digitally so would normally incur lower set-up costs of changing and adding colours as plates are not used, e.g. A\$80 set-up cost per SKU. Smaller businesses generally tend to print small-scale label runs. Even though some smaller businesses may have a proportionally larger number of SKUs per total stock of alcoholic beverages produced, we expect that in most cases, the following factors would help mitigate any disproportionate effects on smaller businesses from the pregnancy warning label requirements:

- greater cost-efficiency from using digital (compared to conventional) printing
- faster and less complex internal processes for having new label designs approved compared to larger businesses.

Specifically in relation to including the colour red, printing companies indicated that the incremental costs will generally be small relative to some estimates supplied by the alcohol beverages industry, but will greatly vary by product. That accords with the range of label cost estimates per SKU shown at Attachment H to the Approval Report.

Discussions with several printing companies suggest that for most SKUs, including the colour red incurs one-off costs and is unlikely to add ongoing costs to labels. However, in some cases, ongoing costs may occur, for example if paper or card packaging has a complex design and uses more colours than could be provided by the printing press in one run, thereby requiring a second run through the printing press.

It is likely that for the majority of SKUs presently in the market, including the colour red would not increase total label change costs by more than 10%<sup>12</sup> and in some cases under 10%. That is, the average cost per SKU of the proposed design using red is likely to be about 10% more costly than the proposed design in black and white.

For those SKUs with digitally printed labels the addition of the colour red in isolation will result in minimal extra costs, because all colour changes for digital printing can be done at once and new printing plates are not required. These make up an estimated 20%<sup>13</sup> of all SKUs.

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<sup>12</sup> Based on print plate cost data from printing companies and using the 2014 PricewaterhouseCoopers schedule of total labelling costs (PricewaterhouseCoopers, 2014).

<sup>13</sup> Based on advice from printing companies.

However, there are also a limited number of SKU's where the addition of red may result in more than a 10% increase in cost. For example, where the maximum number of colours for certain conventional printing methods are already being used. This could result in the need to substitute red for another colour and require extensive redesign of the label.

In conclusion, the new cost information obtained during this review from including the colour red and also from including the entire pregnancy warning label as proposed (refer to sections 4.2.2 and 4.3.2 above) aligns with the previous estimated Base Scenario average of A\$4,924 per SKU for total label change costs of the proposed pregnancy warning label in its entirety plus the range of costs around that average. Note that average costs would reduce further with extending the transition by another year.

### **4.3.3 Effectiveness of the colour red and size label design elements**

#### **4.3.3.1 Red**

In addition to reviewing the costs of colour requirements (i.e. three prescribed colours, black, white and red), FSANZ has further considered the relevant evidence base, given the need to balance costs with efficacy of the pregnancy warning label.

The policy advice given by Ministers with respect to the use of warning design and colour in the DRIS stated (Food Regulation Standing Committee, 2018):

*Use contrasting colours. Should not use the colour green as this can cause consumer confusion. Use of the colour red receives the most attention and is readily associated as being a warning.*

FSANZ's review of the literature on warnings confirms the colour red increases the level of attention a warning receives and increases the speed at which a warning is identified (SD1 to the Approval Report). Red signal words and graphics deliver an immediately understood cue to consumers that this is a warning. Put simply, the use of red signal words and graphics on a white background with black text will make the warning label stand out and be noticed against a sea of competing visual cues. The switch of consumers' attention to the warning label is the necessary condition for consumers to read and act on the warning's message. Without achieving this attention switch, the warning fails.

In addition to attracting attention, red conveys meaning. Red is consistently rated by consumers as the colour with the greatest hazard connotation. This finding is consistent across many studies. Some other colours (e.g. yellow) may also connote hazard but at levels lower than red, while other colours are found not to connote hazard at all well (e.g. green) (Wogalter et al., 2015).

The combination of the attention switching effects and hazard connotation of red in the warning design creates a cue that requires little further processing for consumers to realise it is a warning. It is a cue that is processed automatically and quickly with little effort required. Consequently, consumers notice the warning with little conscious control (see Kahneman 2011). The use of red ensures that the necessary condition of noticing the warning is achieved in an efficient manner. Subsequent reading and evaluating the warning's text message to effect behaviour requires additional cognitive effort.

#### **4.3.3.2 Size**

While there is no better colour for hazard connotation than red, attracting attention can be also be achieved through warning size. A larger warning will achieve higher levels of attention than a smaller warning (see SD1 of Approval Report). Red will significantly enhance the attraction of consumers' attention while maintaining the size of the warning. Research with consumers in Australia and New Zealand has consistently found that the voluntary

warnings are easy to miss and do not attract attention. If red is not used the warning would have to be larger in order to attract attention to the same extent.

While the minimum size required to offset the loss of red is unknown, a recent high quality Canadian study found positive real-world effects on behavioural change, as well as knowledge and awareness, with a red and yellow warning label approximately 16 cm<sup>2</sup>. This is more than four times larger than the proposed warning label<sup>14</sup>. Research by Al-Hamdani and Smith (2015; 2017) report a ceiling effect in consumer response when the warning size reaches around 50% of the area of the front of a package label. Similarly, research from tobacco suggests warning sizes of 30 - 50% of the area of the front of package optimises effectiveness. The alcohol industry consistently maintains that package label space is at a premium. The proposed warning label balances a modest size by using the colour red to attract attention. While we are unable to suggest an absolute size to offset the loss of the red from the proposed warning label, it is clear from available evidence that such a label would need to be many times larger than that currently proposed using red.

In summary, if red is removed from the current label design without significantly increasing the size of the warning, the warning's noticeability will be reduced. This runs the very real risk of imposing costs on the alcohol industry with limited chance of reducing FASD cases.

#### **4.3.3.3 Effectiveness of using contrast and legibility requirements**

During assessment of P1050, FSANZ also considered relying on existing contrast and legibility requirements in the Code only, instead of mandating black, white and red. The use of contrast and legibility guidelines (rather than regulation) would result in multiple versions of the warning with varying colours being displayed. As noted above the level of hazard connoted by the warning would be variable and not predictable. In some circumstances e.g. when signal words or pictogram are in blue or green, the mixed message may be confusing to consumers. Consumers are more likely to make errors in judgement when warnings are in colours not associated with high levels of hazard connotation (Wogalter et al., 2015). Mandating red colour is the only way in which to maintain consistency in consumer understanding of the label, that is, a consistent level of hazard connotation and meaning from the warning.

#### **4.3.3.4 New Canadian research on warning labels**

There is new evidence from a Yukon-based study that well-designed alcohol warning labels on packaged alcohol can increase levels of knowledge and understanding of alcohol harms (Hobin et al., 2020; Schoueri-Mychasiw et al., 2020) and decrease alcohol consumption (Zhao et al., 2020). The Yukon alcohol labelling study used the government-run alcohol store in Whitehorse (Yukon) as an intervention site with stores in rural Yukon and in the neighbouring North West Territories as control sites. Three intervention labels were designed with information on 1) breast and colon cancer<sup>15</sup>, 2) low risk drinking guidelines, and 3) standard drink information. The study is powerful as it used real-world control and intervention sites with labels affixed to 98% of the intervention site stock rather than a laboratory or web-based experiment.

Zhao et al. (2020) argue that the evidence-informed design of the warning labels (the labels incorporated colours (red and yellow), were of adequate size (approximately 16 cm<sup>2</sup>), and included text and images) contributed to impacts on knowledge, understanding and alcohol sales. The design of the intervention labels were 'strikingly different' to the smaller, monochrome text warning labels of the US which have had limited impact on consumption

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<sup>14</sup> This is for a 750 ml bottle of wine/spirits, a 375 ml can of beer/cider or a 330 ml Ready-to-drink (RTD).

<sup>15</sup> Due to alcohol industry opposition to the study, the cancer label was applied at the start of the intervention and was not re-applied at subsequent rounds. The analysis incorporated the different time-periods that the three labels were applied.

behaviour (Greenfield 1997). Schoueri-Mychasiw et al. (2020) analysed consumer unprompted and prompted recall of the low risk drinking guideline and knowledge of daily and weekly drink limits. As for the cancer label, there were significant increases in outcome measures at the intervention site compared to the control site over the study period. The results from the study highlight that well-designed warning labels, including using specified colours, can increase consumer awareness and knowledge of warning labels and reduce alcohol consumption.

#### **4.3.3.5 New World Health Organization report on warning labels**

In June 2020, the World Health Organization (WHO) European Region released a report outlining alcohol labelling practice in that region and the barriers and facilitators to the development and implementation of alcohol labelling policy (Jané-Llopis et al., 2020). Following review of alcohol health warning labels, including pregnancy warning labels, in place in Europe, the authors concluded that most do not fully align with the recommendations in the WHO's 2017 discussion paper (WHO, 2017) particularly with regard to the size and visibility of the label and message rotation. The new report recommends regulations include specific directions on how all information should be presented on labels and noted that in countries where such an approach has not been taken, for example, France, the alcohol industry has found a way of implementing the label to cause as little visual disturbance as possible.

The finding of this report supports FSANZ's decision to specify the design of the pregnancy warning label.

#### **4.3.4 Review Response**

In relation to colour requirements, FSANZ recognises the cost impact upon industry but assesses that this is not unreasonable because:

- The wide range of costs for incorporating the prescribed colours in the pregnancy warning label, in particular the colour red, provided by industry and printing companies at review, accords with the range of total label cost estimates per product set out in the Approval Report (A\$0 to \$29,000). Therefore, as noted previously FSANZ reaffirms the cost estimates and conclusions from the break-even analysis.
- While there is a wide range in the cost of implementing colour requirements across the sector, the incremental cost of applying the colour red to a black and white warning label is in general likely to be small, at around 10% of total label change costs overall. The requirements allow for an existing red in a beverage label to be used for the warning label.

- The best available scientific evidence:
  - supports prescribing colours to achieve a consistent high contrast label which is important for legibility and noticeability and therefore label efficacy
  - shows mandating red colour is the only way to maintain consistency in consumer understanding of the label as red is consistently rated as the colour with the greatest hazard connotation
  - shows a significantly larger warning label than currently proposed would be required to maintain noticeability if red was removed from the design.
- Changing colour requirements, including removing the colour red, will undermine the label's effectiveness in reducing the prevalence and severity of FASD and will not significantly reduce costs to industry.

FSANZ reaffirms its approval of the prescribed colour requirements for the pregnancy warning label.

## 4.4 Signal words

### 4.4.1 Decision at Approval

FSANZ's decision as discussed in the Approval Report was to prescribe the signal words HEALTH WARNING as part of the pregnancy warning label. The reasons for this decision were as follows:

- The best available evidence showed the use of signal words can help to enhance credibility and increase likelihood to comply with the warning. In experiments, WARNING was found to increase the credibility of the message over a warning with no signal word. HEALTH WARNING had benefit over GOVERNMENT WARNING or WARNING because it increased the credibility of the message.
- Public health and government submitters who commented on the proposed signal words supported the use of HEALTH WARNING.
- Although alternative signal words such as PREGNANCY WARNING or PREGNANCY ADVICE were strongly supported by industry submitters, no evidence was provided to support their use. FSANZ's literature review also did not identify any published studies comparing the effect of PREGNANCY WARNING/ADVICE with other signal words on credibility or ability to attract attention.
- The warning label is concerned with the health of the baby not the pregnancy per se, therefore HEALTH WARNING is more relevant and appropriate than PREGNANCY WARNING/ADVICE.
- HEALTH WARNING has a broader meaning than PREGNANCY WARNING/ADVICE and supports the secondary objective in the DRIS<sup>16</sup> of providing information to the broader community.

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<sup>16</sup> The Forum provided FSANZ with a DRIS as policy advice. The DRIS states that *the **primary objective** of pregnancy warning labels on packaged alcoholic beverages is to provide a clear and easy to understand trigger to remind pregnant women, at both the point of sale and the potential point of consumption, to not drink alcohol. A **secondary objective** of pregnancy warning labels on packaged alcoholic beverages is to provide information to the community about the need for pregnant women to not drink alcohol.*

#### **4.4.2 Review response**

In response to the review request, FSANZ has reviewed the costs to industry of the signal wording. Based on information from label printing companies and the alcoholic beverage industry, changing signal words would not affect industry costs, given there would be little difference in the cost of printing HEALTH WARNING or alternative words such as WARNING or PREGNANCY WARNING. One industry association provided clarification to FSANZ that in their public statement about the decision by the Forum to request a review, they did not mean to imply that removing HEALTH WARNING would reduce the cost of the label.

FSANZ considers the requirement for the signal words HEALTH WARNING does not impose an unreasonable cost burden to industry. However, given the Forum specifically requested FSANZ review the signal words, we have taken into account other relevant matters in this review, including the available evidence base.

The best available evidence shows the use of signal words can help to enhance credibility and increase likelihood to comply with the warning (SD1 of the Approval Report). Signal words can also operate as a heuristic cue and enhance the attention and comprehension of a warning label. The presence of a signal word has also been found to raise hazard perceptions compared to when no signal words are present. We reaffirm the reasons for including signal wording in the pregnancy warning label.

FSANZ has however, decided to amend the required signal words to PREGNANCY WARNING for the following reasons:

- The best available evidence shows the use of signal words can help enhance credibility and increase likelihood to comply with the warning.
- Using WARNING increases attention and credibility over no signal words.
- The addition of prefixes to the signal words may further enhance attention and credibility than using WARNING alone.
- FSANZ is not aware of any evidence comparing the effect of PREGNANCY WARNING with HEALTH WARNING on credibility or ability to attract attention.
- While there is no published evidence on the use of PREGNANCY WARNING, those signal words target a specific group at whom the warning label message is ultimately directed.
- While PREGNANCY WARNING may not support the secondary objective in the DRIS to the same extent as HEALTH WARNING, the pregnancy warning label on alcoholic beverages as a whole will provide information to the broader community, thereby raising awareness of the risks of drinking alcohol during pregnancy and prompt discussion of these risks within the community.

## **5 Reasons for the decision**

At Approval, FSANZ's decision to approve an amendment to the Code to require a pregnancy warning label on packaged alcoholic beverages was based on best available scientific evidence that demonstrated:

- (a) prescribing the colour of the label, including the colour red will increase the attention the warning receives and contribute to the understanding of the warning;
- (b) prescribing the signal words HEALTH WARNING rather than WARNING or GOVERNMENT WARNING would enhance the credibility of the message;

(c) both these label elements will contribute to the efficacy of the label.

In addition, the conclusion of the consideration of costs and benefits of the pregnancy warning label (with the prescribed colour and signal word requirements) was that only a small proportion of cases of FASD need to be prevented to offset the total cost of label changes.

In undertaking this review, FSANZ has considered the costs of colour requirements and signal wording along with the evidence base for these label elements given the need to balance costs with efficacy of the pregnancy warning label.

Following review, our assessment of the costs has not changed. We also maintain the best available evidence underpins the pregnancy warning label design resulting in an effective label. However, for the reasons stated above, FSANZ has decided to amend the required signal words to PREGNANCY WARNING.

In recognition of the current challenging business environment from Australian bush fires and COVID-19 across Australia and New Zealand, FSANZ has extended the transition period for label implementation from two to three years. This will provide increased flexibility for industry to co-ordinate the implementation of the pregnancy warning label with voluntary label changes and will allow for the costs to be spread over a longer period.

While recognising the extended transition period may delay avoidance of FASD cases, the three year transition period should not significantly reduce the benefits as producers of faster moving higher volume products are likely to be able to co-ordinate the change with voluntary label changes that will arise earlier in the transition period.

After reviewing the best available scientific evidence and carrying out the Forum's review request consistent with our legislative remit under the FSANZ Act, FSANZ's assessment is that the pregnancy warning label does not impose an unreasonable cost burden on industry. FSANZ reaffirms the conclusions from the break-even analysis and its approval of the prescribed colour requirements. FSANZ has changed the signal words of the pregnancy warning label to PREGNANCY WARNING as shown below.



The Forum in October 2018, after considering the then available evidence, requested FSANZ to consider developing a mandatory pregnancy warning label for packaged alcoholic beverages that included a pictogram and relevant warning statement. FSANZ is satisfied the approved draft variation, as amended to change the signal words HEALTH WARNING to PREGNANCY WARNING and to extend the transition period for implementation of the pregnancy warning label from two to three years (Attachment A), is the appropriate response to the 2018 ministerial request.

The evidence based pregnancy warning label as currently designed, balances the cost to industry against the public health imperative of reducing the prevalence and severity of FASD, and ensures that as part of a suite of measures, it can contribute to that outcome.

## **6 FSANZ Act – statutory assessment criteria**

### **6.1 Section 59**

#### **6.1.1 Consideration of costs and benefits**

FSANZ has given consideration to the costs and benefits that may arise from the regulatory measure for the purposes of meeting FSANZ Act requirements. The FSANZ Act requires

FSANZ to have regard to whether costs that would arise from the regulatory measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 59(2)(a) of the FSANZ Act).

The Forum provided FSANZ with a DRIS (Food Regulation Standing Committee, 2018) as policy advice that was assessed by the Office of Best Practice Regulation (OBPR) as compliant in accordance with the Council of Australian Governments' Regulation Impact Statement (RIS) requirements. OBPR exempted FSANZ from the need to undertake a formal RIS in relation to the tasks of this P1050 project. The OBPR was satisfied that the necessary range of potential regulatory changes had already been considered through the DRIS (Food Regulation Standing Committee, 2018) that informed the Ministerial Forum's request, in October 2018.

A summary of the consideration of costs and benefits, including the break-even analysis, as presented in the Approval Report is presented in section 4.2.1 above. FSANZ has considered the additional cost information gathered in this review (refer to sections 4.2.2 and 4.3.2 above) and reaffirms the conclusion from the break-even analysis set out in the Approval Report. The conclusion is that the cost burden for industry is not unreasonable as only a small proportion of cases of FASD need to be prevented to justify industry costs of incorporating the evidence based warning label. There are large human, social and financial benefits to the community from avoiding or mitigating new FASD cases.

#### **6.1.2 Are there other more cost effective measures?**

At Approval, FSANZ concluded there are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the Proposal. FSANZ is not aware of any new information from the review to change this conclusion. FSANZ remains satisfied that based on the best available scientific evidence the approved draft variation (with amendment) is the most cost effective measure available.

#### **6.1.3 Any relevant New Zealand standards**

There are no relevant New Zealand-only standards.

#### **6.1.4 Any other relevant matters**

Other relevant matters are considered below.

### **6.2 Subsection 18(1)**

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

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

As discussed in the Approval Report, the mandatory pregnancy warning label supports Australia and New Zealand governments' public health advice and messages for women not to drink alcohol during pregnancy to reduce the risk to the health and safety of the unborn child. Evidence demonstrates that pregnancy warning labels on alcoholic beverages can raise awareness of the risks of drinking alcohol during pregnancy and prompt discussion of these risks (Wilkinson et al., 2009; SD1 of the Approval Report). Further to this, evidence from alcohol warnings and tobacco warning labels confirms that the label as currently designed and as part of a suite of measures can contribute to behaviour change (section 3.2.3 of the Approval Report). Recent evidence from the Yukon real world alcohol labelling study highlights that well-designed warning labels can increase consumers' awareness and knowledge of warning label content and reduce alcohol consumption (Hobin et al., 2020;

Schoueri-Mychasiw et al., 2020; Zhao et al., 2020).

Therefore, evidence shows when combined with other public health initiatives, the pregnancy warning label required by the approved draft variation (as amended) can contribute to increased awareness of the risks of drinking alcohol while pregnant and encourage behaviour change. It can also contribute to the development of social norms to support this behaviour change. These outcomes will ultimately reduce the prevalence and severity of FASD.

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

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

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

FSANZ has not identified any issues relevant to this matter.

### **6.3 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 scientific evidence in assessing the Proposal. FSANZ undertook a detailed analysis of the best available scientific evidence available at the time of its assessment of P1050. In accordance with the scope of the review, FSANZ has sought clarification of cost estimates from key alcohol industry associations and printing companies. FSANZ remains satisfied that the clarifying information provided from industry and printing companies concurs with the evidence relied on at assessment.

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

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

Current mandatory or voluntary pregnancy warnings in place in other countries have not been designed with a view to optimise the attention they receive (SD1 to the Approval Report; Schoueri-Mychasiw et al., 2020). Based on the available evidence, it is expected the pregnancy warning label required by the approved draft variation (as amended) will be more effective in achieving the primary objective stated in the DRIS (to provide a clear and easy to understand trigger to remind pregnant women to not drink alcohol) in the local context than labels used in other countries.

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

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

FSANZ does not anticipate any significant impact on efficiency and international competition.

FSANZ notified World Trade Organization (WTO) members about the proposed warning label in October 2019. Food standards developed under the Australia New Zealand Food Standards System must be consistent with the obligations of both Australia and New Zealand under WTO and related trade agreements.<sup>17</sup> After consideration of the evidence (including the submissions received from WTO members), FSANZ remains satisfied that the pregnancy warning label, as currently designed, is consistent with Australia's and New Zealand's obligations under international trade law (see Attachment E of the Approval Report).

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

FSANZ has not identified any issues relevant to this matter.

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

There are no specific policy guidelines formulated and notified by the Forum under paragraph 18(2)(e) of the FSANZ Act which apply to this proposal. However, FSANZ has had regard to policy advice provided by the Forum (refer to section 6.1.1 above).

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<sup>17</sup> See, for example, Article 4(2) and clause (2)(c) of Annex A to the [Agreement between the Government of Australia and the Government of New Zealand concerning a joint food standards system](#).

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## **Attachments**

- A. Approved draft variation to the Australia New Zealand Food Standards Code (as amended)
- B. Explanatory Statement
- C. Approved draft variation to the Australia New Zealand Food Standards Code on which review was requested

## Attachment A – Approved draft variation to the Australia New Zealand Food Standards Code (as amended)



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

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

Dated [To be completed by Delegate]

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

**Note:**

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

## 1 Name

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

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

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

## 3 Commencement

The variation commences on the date of gazettal.

## 4 Effect of the variations made by this instrument

- (1) Section 1.1.1—9 of Standard 1.1.1 does not apply to the variations made by this instrument.
- (2) During the transition period, a food product may be sold if the product complies with one of the following:
  - (a) the Code as in force without the variations made by this instrument; or
  - (b) the Code as amended by the variations made by this instrument.
- (3) A food product that was packaged and labelled before the end of the transition period may be sold after the transition period if the product complies with one of the following:
  - (a) the Code as in force without the variations made by this instrument; or
  - (b) the Code as amended by the variations made by this instrument.
- (4) For the purposes of this clause, the **transition period** means the period commencing on the variation's date of commencement and ending 36 months after the date of commencement.

### Schedule

#### Standard 1.1.2

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

**individual unit** means a container that:

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

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

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

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



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



**prescribed alcoholic beverage** means a beverage that

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

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

### Standard 1.2.1

[2] Standard 1.2.1 is varied by

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

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

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

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

**Note 1** See also section 1.2.1—24

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

### Standard 2.7.1

[3] Standard 2.7.1 is varied by

[3.1] inserting after Note 2 to Standard 2.7.1

## Division 1 Preliminary

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

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

**individual unit** means a container that:

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

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

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

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

all within a border.



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



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

- (a) has more than 1.15% alcohol by volume; and
- (b) either:
  - (i) is for retail sale; or
  - (ii) is sold as suitable for retail sale without any further processing, packaging or labelling; and
- (c) does not include a beverage that:

- (i) is sold for retail sale; and
- (ii) is packaged in the presence of the purchaser

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

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

[3.3] inserting after section 2.7.1—2

## **Division 2 Requisite statements**

[3.4] inserting after section 2.7.1—4

## **Division 3 Restricted representations**

[3.5] inserting after section 2.7.1—7

## **Division 4 Pregnancy warning labels**

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

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

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

- (1) A \*prescribed alcoholic beverage that:
  - (a) is required by subsection 2.7.1—8(1) to display a \*pregnancy warning label on its package; and
  - (b) is listed in Column 1 of the table to subsection (3):must display the pregnancy warning label listed in Column 2 of that table on its package.
- (2) The pregnancy warning label required by subsection (1) must comply with any corresponding size requirements listed in Columns 3, 4 and 5 of the table to subsection (3).
- (3) The table to this subsection is:

**Pregnancy warning label required**

<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>	<b>Column 5</b>
<i>Prescribed alcoholic beverage</i>	<i>Pregnancy warning label to be displayed</i>	<i>Size of the *pregnancy warning pictogram or the pictogram of a *pregnancy warning mark</i>	<i>*Size of type of the signal words</i>	<i>*Size of type of the statement of a pregnancy warning mark</i>
A *prescribed alcoholic beverage with a volume not more than 200 ml.	The *pregnancy warning pictogram.	At least 8 mm diameter	Not applicable	Not applicable
A *prescribed alcoholic beverage with a volume more than 200 ml but not more than 800 ml.	The *pregnancy warning mark.	At least 6 mm diameter	At least 2.1 mm	At least 1.6 mm
A *prescribed alcoholic beverage with a volume more than 800 ml.	The *pregnancy warning mark.	At least 9 mm diameter	At least 2.8 mm	At least 2.1 mm

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

- (1) A \*prescribed alcoholic beverage that:
  - (a) is required by paragraph 2.7.1—8(2)(a) to display a \*pregnancy warning label on its outer package; and
  - (b) is listed in Column 1 of the table to subsection (3);
 must display the pregnancy warning label listed in Column 2 of that table on its outer package.
- (2) The pregnancy warning label required by subsection (1) must comply with any corresponding size requirements listed in Columns 3, 4 and 5 of the table to subsection (3).
- (3) The table to this subsection is:

**Pregnancy warning label required**

<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>	<b>Column 5</b>
<i>Prescribed alcoholic beverage</i>	<i>Pregnancy warning label to be displayed</i>	<i>Size of the *pregnancy warning pictogram or the pictogram of a *pregnancy warning mark</i>	<i>*Size of type of the signal words</i>	<i>*Size of type of the statement of a pregnancy warning mark</i>
A *prescribed alcoholic beverage with: a volume not more than 200 ml; and packaging that includes only one *individual unit.	The *pregnancy warning pictogram.	At least 8 mm diameter	Not applicable	Not applicable
All other *prescribed alcoholic beverages.	The *pregnancy warning mark.	At least 11 mm diameter	At least 3.5 mm	At least 2.7 mm

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

- (1) A \*prescribed alcoholic beverage that:
  - (a) is required by paragraph 2.7.1—8(2)(b) to display a \*pregnancy warning

label on one or more individual units; and  
 (b) is an individual unit that is listed in Column 1 of the table to subsection (3);  
 must display the pregnancy warning label listed in Column 2 of that table on each such individual unit.

(2) The pregnancy warning label required by subsection (1) must comply with any corresponding size requirements listed in Columns 3, 4 and 5 of the table to subsection (3).

(3) The table to this subsection is:

**Pregnancy warning label required**

<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>	<b>Column 5</b>
<i>Individual unit</i>	<i>Pregnancy warning label to be displayed</i>	<i>Size of the *pregnancy warning pictogram or the pictogram of a *pregnancy warning mark</i>	<i>*Size of type of the signal words</i>	<i>*Size of type of the statement of a pregnancy warning mark</i>
An *individual unit with a volume not more than 200 ml.	The *pregnancy warning pictogram.	At least 8 mm diameter	Not applicable	Not applicable
An *individual unit with a volume more than 200 ml but not more than 800 ml.	The *pregnancy warning mark.	At least 6 mm diameter	At least 2.1 mm	At least 1.6 mm
An *individual unit with a volume more than 800 ml.	The *pregnancy warning mark.	At least 9 mm diameter	At least 2.8 mm	At least 2.1 mm

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

- (1) A \*pregnancy warning label required by this Division to be displayed must comply with this section.
- (2) The background of the \*pregnancy warning label must be in the colour white.
- (3) The circle and strikethrough of the \*pregnancy warning pictogram must be in the colour red.
- (4) The silhouette of a pregnant woman on the \*pregnancy warning pictogram must be in the colour black.
- (5) The signal words of the \*pregnancy warning mark must be:
  - (a) in the colour red; and
  - (b) in bold font; and
  - (c) in a sans-serif typeface; and
  - (d) in capital letters; and
  - (e) in English.
- (6) The statement of the \*pregnancy warning mark must be:
  - (a) in the colour black; and
  - (b) in a sans-serif typeface; and
  - (c) in sentence case; and
  - (d) in English.
- (7) The border of the \*pregnancy warning mark must be in the colour black.
- (8) The \*pregnancy warning mark must be displayed on the package with a clear space that:
  - (a) surrounds the outside of the border of the pregnancy warning mark; and

- (b) is at least 3mm in width.
- (9) The \*pregnancy warning label must be displayed as a whole and without modification.

## **Attachment B – Explanatory Statement**

### **1. Authority**

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

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

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

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

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

### **2. Purpose**

The Authority has approved a draft variation to:

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

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

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

### **4. Consultation**

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

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

## 5. Statement of compatibility with human rights

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

## 6. Variation

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The requirement imposed by section 2.7.1—8 is limited to the package of a prescribed alcoholic beverage. The requirement therefore does not apply to the package of a product sold other than by retail sale or sold other than as suitable for retail sale. This means, for example, that a transportation outer is not required by section 2.7.1—8 to display a pregnancy warning label.

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

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

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

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

Subsection 2.7.1—8(3) exempts the outer package from the requirement to display a pregnancy warning label if this label can be clearly seen on an individual unit and is not obscured by the outer package (for example, where there is clear wrapping around a bottle of wine, or where the pregnancy warning label on a bottle of beer in a 6-pack can be seen).

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

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

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

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

Subsection 2.7.1—9(2) provides that the pregnancy warning label required by subsection 2.7.1—9(1) must comply with any corresponding size requirements listed in columns 3, 4 and 5 of the table to subsection 2.7.1—9(3). The size requirements that apply (as set out in the table to the subsection) depend on the volume of the prescribed alcoholic beverage.

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

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

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

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

Subsection 2.7.1—10(2) provides that, the pregnancy warning label required by subsection 2.7.1—10(1) must comply with any corresponding size requirements listed in columns 3, 4

and 5 of the table to subsection 2.7.1—10(3). Different size requirements apply for the pregnancy warning pictogram and pregnancy warning mark.

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

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

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

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

For example:

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

Subsection 2.7.1—11(2) provides that, the pregnancy warning label required by subsection 2.7.1—11(1) must comply with any corresponding size requirements listed in columns 3, 4 and 5 of the table to subsection 2.7.1—11(3). The size requirements that apply depend on the liquid volume of the individual unit.

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

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

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

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

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

### ***Transitional arrangements***

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

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

Clause 4 provides two transitional arrangements. First, there is a general transitional arrangement where during a three 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 – Approved draft variation to the Australia New Zealand Food Standards Code on which review was requested



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

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

Dated [To be completed by Delegate]

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

**Note:**

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

## 1 Name

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

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

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

## 3 Commencement

The variation commences on the date of gazettal.

## 4 Effect of the variations made by this instrument

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

### Schedule

#### Standard 1.1.2

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

**individual unit** means a container that:

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

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

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

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



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



**prescribed alcoholic beverage** means a beverage that

- (c) has more than 1.15% alcohol by volume; and
- (d) either:

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

### Standard 1.2.1

[2] Standard 1.2.1 is varied by

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

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

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

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

**Note 1** See also section 1.2.1—24

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

### Standard 2.7.1

[3] Standard 2.7.1 is varied by

[3.1] inserting after Note 2 to Standard 2.7.1

## Division 1 Preliminary

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

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

**individual unit** means a container that:

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

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

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

- (d) the pregnancy warning pictogram,
- (e) the signal words “Health Warning” and
- (f) the statement “Alcohol can cause lifelong harm to your baby”,

all within a border.



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



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

- (c) has more than 1.15% alcohol by volume; and
- (d) either:
  - (i) is for retail sale; or
  - (ii) is sold as suitable for retail sale without any further processing, packaging or labelling; and

- (c) does not include a beverage that:
  - (i) is sold for retail sale; and
  - (ii) is packaged in the presence of the purchaser

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

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

[3.3] inserting after section 2.7.1—2

## **Division 2 Requisite statements**

[3.4] inserting after section 2.7.1—4

## **Division 3 Restricted representations**

[3.5] inserting after section 2.7.1—7

## **Division 4 Pregnancy warning labels**

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

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

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

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

**Pregnancy warning label required**

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

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

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

**Pregnancy warning label required**

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

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

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

corresponding size requirements listed in Columns 3 and 4 of the table to subsection (3).

- (3) The table to this subsection is:

**Pregnancy warning label required**

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

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

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