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[235-23]

Approval report – Application A1256

Colour of pregnancy warning labels for corrugated cardboard packaging

Food Standards Australia New Zealand (FSANZ) has assessed an application made by the Brewers Association of New Zealand seeking to amend the Australia New Zealand Food Standards Code (the Code) to permit pregnancy warning labels on corrugated cardboard packaging used for multiple individual units of alcoholic beverages to be in a single colour on a contrasting background.

On 6 October 2022, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received 38 (including one late) submissions.

FSANZ approved the draft variation on 15 March 2023. The Food Ministers' Meeting¹ was notified of FSANZ's decision on 20 March 2023.

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

¹ Formerly referred to as the Australia and New Zealand Ministerial Forum on Food Regulation

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Executive summary

The Brewers Association of New Zealand applied to Food Standards Australia New Zealand (FSANZ) to amend the Australia New Zealand Food Standards Code (the Code) to permit pregnancy warning labels on corrugated cardboard (CC) packaging used for the outer package of multiple individual units of alcoholic beverages to be in a single colour on a contrasting background.

On 31 July 2020, the Code was amended to include new requirements for pregnancy warning labelling on packaged alcoholic beverages, developed under Proposal P1050 – Pregnancy warning labels on alcoholic beverages². Businesses have to implement these requirements from 1 August 2023. Since the Code was amended, the alcohol industry in Australia and New Zealand have identified a technical issue with the printing of the pregnancy warning mark³ on CC packaging when using a post-print (flexographic) printing process.

The existing provisions in the Code require a pregnancy warning mark to be in three colours - red, black and white. Most CC packaging used for alcoholic beverages is printed using a post-print process which can result in a misalignment of the elements in the warning mark due to the three-colour requirement (see example below), making the label difficult to read thereby reducing effectiveness and risking non-compliance.



The applicant states the misalignment issue affects CC outer packaging primarily used for larger multi-packs of beer, cider and pre-mixed drinks (e.g. 12, 16, 18 and 24 packs) as well as wine (6 and 12 bottle cases). They estimate 8% of beer and cider, 9.5% of wine and 12.5% of pre-mixed drinks are in CC packaging at the retail point of sale i.e. most CC packaging is removed prior to retail sale. The applicant also notes that given the producer does not control a retail display, the pregnancy warning mark has to be printed on all outer CC packaging.

The purpose of the requested amendment is to provide an alternative pregnancy warning mark for CC outer packaging of more than one individual unit of a prescribed alcoholic beverage, when a post-print printing process is used. No other aspects of the pregnancy warning labelling requirements are in scope of the application.

FSANZ has undertaken an assessment of the requested amendment to the pregnancy warning mark in relation to the technical printing issue. In doing this assessment we considered information provided by printers and drew on the consumer evidence included in Proposal P1050, specifically in relation to the impact of the requested amendment on label effectiveness. FSANZ is satisfied the P1050 evidence is the best available evidence.

FSANZ concluded that given a misaligned label could reduce readability and effectiveness of the pregnancy warning mark, and risk non-compliance with existing requirements, permitting an alternative pregnancy warning mark will maintain effectiveness of pregnancy warning labelling.

² [Proposal P1050 – Pregnancy warning labels on alcoholic beverages](#)

³ In the Code, a *pregnancy warning mark* is comprised of the pregnancy warning pictogram, the signal words 'Pregnancy Warning' and the statement 'Alcohol can cause lifelong harm to your baby'. This term is used subsequently throughout the report.

Following assessment and the preparation of a draft variation, FSANZ called for submissions about the draft variation on 6 October 2022 for a six-week consultation period. FSANZ received 38 submissions (24 from industry, eight from public health/consumer groups, five from government and one academic), including one late submission. Submitter views varied with public health, academic and consumer submitters not supporting the draft variation, most industry submitters supporting it and government submitters having mixed views.

Based on the assessment and having considered submitter views and other relevant considerations set out in this report, FSANZ approved an amended draft variation to the Code to permit an alternative pregnancy warning mark. The alternative pregnancy warning mark can only be used on CC outer packages for retail sale that are printed using a post-print process and contain more than one individual unit of a prescribed alcoholic beverage. FSANZ amended the draft variation to correct a typographical error.

The approved draft variation amends Standard 2.7.1 of the Code to permit the use of an alternative pregnancy warning mark with the following requirements:

- the signal words, statement, pictogram and border must be in the single colour black
- the background must be the same colour as the CC outside liner (i.e. brown, grey or white).
- minimum size of type for the signal words of 4.4 mm
- minimum size of type for the statement of 3.4 mm
- minimum pictogram diameter of 14 mm.

This approach prescribes colour, contrast and an increased label size compared with the existing size requirements for outer packaging, ensuring effectiveness of the pregnancy warning mark is maintained. An alternative pregnancy warning mark will enable industry to resolve technical misalignment issues for a specific type of packaging in a cost-effective manner (i.e. post-printed CC outer packaging of more than one individual unit of an alcoholic beverage) and consistently comply with the Code.

The transition period for a prescribed alcoholic beverage with a pregnancy warning mark on an outer package made of CC (as set out in the approved draft variation) commences on the date of gazettal of the approved draft variation and ends on 1 February 2024. Additionally, such prescribed alcoholic beverages packaged and labelled before the end of the transition period (i.e. before 2 February 2024) may be sold without the pregnancy warning mark. The end of the transition period for pregnancy warning labels for all non-CC packaging and individual alcoholic beverage containers remains at 31 July 2023.

1 Introduction

1.1 The Applicant

The applicant is the Brewers Association of New Zealand, an incorporated society representing the interests of brewers in New Zealand.

The application is supported by Visy Industries (Australia & New Zealand), New Zealand Brewers Guild, Brewers Association of Australia, Australian Grape and Wine, New Zealand Winegrowers, Spirits New Zealand, Spirits and Cocktails Australia and Asahi Beverages Ltd (Australia).

1.2 The Application

The applicant is seeking to amend Standard 2.7.1 (Labelling of alcoholic beverages and food containing alcohol) of the Australia New Zealand Food Standards Code (the Code), to permit pregnancy warning labels on corrugated cardboard (CC) packaging used for the outer package of multiple individual units of alcoholic beverages to be in a single colour on a contrasting background.

Since the gazettal of the requirements for pregnancy warning labels in July 2020 (from Proposal P1050 – Pregnancy warning labels on alcoholic beverages⁴) a technical issue with printing the warning mark on CC packaging using a post-print (flexographic) printing process⁵ has been identified.

Three colours (black, red and white) are currently prescribed for the pregnancy warning mark. The applicant states that misalignment of the warning mark occurs when using the standard post-print printing process on CC. A misaligned mark (see Figure 1 below) can be difficult to read and have reduced effectiveness. The applicant states misalignment is due to a +/-3 mm margin of error for print registration for each colour (i.e. each colour is printed directly onto the board in a sequential manner). According to the applicant, the requested amendment would resolve this technical issue. The applicant also advises that options currently available to resolve the misalignment issue are not practical or feasible.



Figure 1: Example of a misaligned pregnancy warning mark

The scope of the application is limited to the pregnancy warning mark on CC packaging as follows:

- the CC packaging material consists of at least three layers (outside liner, fluted medium, inside liner); and
- the CC packaging is in the form of a box or carton; and
- the pregnancy warning mark on the CC packaging is printed using a post-print process; and

⁴ [Proposal P1050 – Pregnancy warning labels on alcoholic beverages](#)

⁵ A post-print (flexographic) printing process means the pregnancy warning mark is printed directly on to the outside liner of corrugated cardboard packaging using flexible raised image printing plates.

- the CC packaging contains multiple individual units of a prescribed alcoholic beverage, each of which is labelled with the warning label as required by Standard 2.7.1; and
- the individual units of the prescribed alcoholic beverage cannot be consumed without removing them from the CC packaging.

No other pregnancy warning labelling requirements are being reviewed in the context of this application.

The applicant states the misalignment issue affects CC outer packages that are primarily used for larger multi-packs of beer, cider and pre-mixed drinks (e.g. 12, 16, 18 and 24 packs) as well as wine (6 and 12 bottle cases).

The applicant states individual alcoholic beverage producers use a post-print process for the majority of their CC packaging. They estimate 8% of beer and cider, 9.5% of wine and 12.5% of pre-mixed drinks are in CC packaging at the retail point of sale i.e. most CC packaging is used for transportation, not retail point of sale. The applicant therefore claims the proposed amendment to the colour requirements would have a very minor impact on potential purchaser and/or consumer attention to the pregnancy warning mark.

1.3 The current Standard

Subsection 1.1.1—10(8) of the Code provides that food for sale must comply with all relevant labelling requirements in the Code.

Standard 2.7.1⁶ of the Code sets out labelling requirements for alcoholic beverages and food containing alcohol. Standard 2.7.1 and Standard 1.1.2 (Definitions used throughout the Code) were amended in 2020⁷ to require a packaged *prescribed alcoholic beverage* to display a pregnancy warning label.

Standard 1.1.2 provides that a ***prescribed alcoholic beverage*** is 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
- (a) does not include a beverage that:
 - (i) is sold for retail sale; and
 - (ii) is packaged in the presence of the purchaser.

Standard 1.1.2 also provides the following definitions for the purposes of Standard 2.7.1:

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.

⁶ [Standard 2.7.1 – Labelling of alcoholic beverages and food containing alcohol](#)

⁷ For further information see [Proposal P1050 – Pregnancy warning labels on alcoholic beverages](#)



Individual unit means a container that:

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

Subsection 2.7.1—8(2) generally provides that a prescribed alcoholic beverage that has more than one layer of packaging must display a *pregnancy warning label on its outer package.

Section 2.7.1—10 sets out that a prescribed alcoholic beverage containing more than one individual unit (as defined above) must display a pregnancy warning mark on its outer package and the size requirements for that label. The required size of the pregnancy warning mark is as follows:

- size of the pictogram: at least 11 mm in diameter
- size of type of the signal words 'PREGNANCY WARNING': at least 3.5 mm
- size of type of the statement 'Alcohol can cause lifelong harm to your baby': at least 2.7 mm.

Section 2.7.1—12 sets out the required form for pregnancy warning labels, including the pregnancy warning mark. The section requires the use of three colours (red, white and black) as follows:

- The background of the pregnancy warning label must be in the colour white.
- The circle and strikethrough of the pictogram must be in the colour red.
- The silhouette of a pregnant woman of the pictogram must be in the colour black.
- The signal words of the pregnancy warning mark 'PREGNANCY WARNING' must be in the colour red.
- The statement of the pregnancy warning mark 'Alcohol can cause lifelong harm to your baby' must be in the colour black.
- The border of the pregnancy warning mark must be in the colour black.

Section 2.7.1—12 also sets out other requirements, including bolding of the signal words, typeface, the use of capital letters (signal words) and sentence case (statement) and the clear space surrounding the outside of the border of the pregnancy warning mark.

The above requirements operate subject to transitional arrangements put in place by Proposal P1050. These are as follows:

- From 31 July 2020 to 31 July 2023, an alcoholic beverage can comply with either the Code as in force as if the above requirements had not taken effect, or with the Code including the above-mentioned requirements.
- From 1 August 2023, all alcoholic beverages will need to comply with the above requirements (i.e. have the pregnancy warning label), except for those subject to the exemption below.
- An alcoholic beverage packaged and labelled before 1 August 2023 (i.e. compliant with either the Code as in force without the above requirements i.e. not carry the mandatory pregnancy warning label, or with the Code as in force with the above requirements i.e. carry the mandatory pregnancy warning label) will be deemed compliant with the Code

if sold from 1 August 2023. This exemption also applies to imported alcoholic beverages.

1.4 Reasons for accepting the Application

The application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the *Food Standards Australia New Zealand 1991* (the FSANZ Act)
- it related to a matter that warranted the variation of a food regulatory measure.

1.5 Procedure for assessment

The application was assessed under the General Procedure in the FSANZ Act.

1.6 Decision

For reasons set out in this report, FSANZ decided to approve a draft variation amending the Code to permit an alternative pregnancy warning mark for CC outer packaging of more than one individual unit of a prescribed alcoholic beverage, when a post-print printing process is used.

The draft variation as proposed following assessment was approved with one amendment required to correct a typographical error. The approved draft variation takes effect on gazettal. The approved draft variation is at Attachment A.

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

The draft variation on which submissions were sought is at Attachment C.

2 Summary of the finding

2.1 Summary of issues raised in submissions

FSANZ sought public comment on the proposed draft variation to the Code in the Call for Submissions (CFS) report from 6 October 2022 to 16 November 2022. A total of 38 submissions⁸ (including one late submission) were received: 24 from industry, eight from public health/consumer groups, five from government and one academic.

A summary of issues raised by submitters and FSANZ's response are presented in Table 1.

Public health, academic and consumer submitters did not support the alternative pregnancy warning mark proposed to address the technical printing issue. Key views included that sufficient evidence of the problem was not provided to justify an alternative label, the proposed alternative label could reduce label effectiveness, and that any increased costs for industry in printing the three-colour label on CC packaging could be passed onto consumers (see Table 1 for further details).

⁸ Submissions are published on the FSANZ website at [A1256 - Colour of pregnancy warning labels for corrugated cardboard packaging \(foodstandards.gov.au\)](https://www.foodstandards.gov.au/1256-colour-of-pregnancy-warning-labels-for-corrugated-cardboard-packaging)

Most industry submitters supported the proposed alternative pregnancy warning mark for the following key reasons:

- the application is about a minor technical issue only affecting labelling of products in post-printed CC outer packaging at the point of retail sale
- the proposed alternative label is a practical solution to address technical printing issues
- the impact of the proposed alternative label on consumers will be minor given the small percentage of alcoholic beverages that are actually sold in post-printed CC outer packaging in New Zealand and Australia and given the warning labels on individual units and other types of outer packaging will be in the three colours
- with the 25% increase in size of type and pictogram diameter and the mandated colour contrast the impact of the alternative label on consumers in relation to visibility and consumer attention will be minor
- flexibility with the background colour avoids producers having to use white CC because of the need to avoid smudging that would arise from printing a white background
- available technical solutions for addressing the printing issue are either impractical and/or uneconomic, and would grossly outweigh any perceived adverse impacts of adopting an alternative, compromise solution such as the one proposed.

Some industry submissions were unclear as to their support for the proposed alternative label. Furthermore, mandating the colour black and an increased size for the proposed alternative label were not supported by all industry submitters (see Table 1).

Government submitters had mixed views. While one government submitter supported the proposed alternative label, others did not. Key views for not supporting the alternative label included that further clarification and information about the problem was needed, the impact on overall label effectiveness and associated trade-offs should be considered noting the removal of the colour red would undermine the labels' effectiveness, and the proposed alternative label may compromise the objectives of Proposal P1050 (see Table 1 for further details).

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

Issue	Raised by	FSANZ response
General comments about the application		
<p>Concerned with information and statements made in the application. For example, references to previous industry P1050 submissions (e.g. about cost, opposition to prescribed colour) in the application are not relevant to the application.</p>	<p>Foundation for Alcohol Research and Education (FARE) George Institute</p>	<p>FSANZ has undertaken its own assessment of the application based on information provided by third-party printers, and the consumer literature review that informed Proposal P1050 specifically in relation to the impact of the requested amendment on label effectiveness. We note some of the information provided in the application was not relevant to our assessment.</p>
Evidence supporting the technical printing problem		
<p>It is not clear how many labels will be misaligned, the extent to which they will be misaligned or how either of these factors will impact overall efficacy of the design.</p>	<p>Victorian Department of Health and the Victorian Department of Jobs, Precincts and Regions</p>	<p>Specific information on the number of labels which will be misaligned, and the extent of misalignment is not available. As further detailed in section 2.2.1 of this report, whilst it is acknowledged misalignment will not be evident on every CC package, it is difficult to predict the incidence or extent of the misalignment within the margin of error (i.e. $\pm 2\text{-}5\text{ mm}$). There are also variances in printing machines used across the industry, with older machines generally having greater misalignment issues.</p> <p>As discussed in section 2.2.2, consumers need to be able to read and understand a warning label for it to be effective. FSANZ considers a misaligned label could impact the readability, and therefore the effectiveness, of the label.</p> <p>A misaligned label also risks non-compliance with existing pregnancy warning label requirements. General legibility provisions (section 1.2.1—24 of the Code) also require the label to be legible.</p>
<p>Requests examples of printing the warning labels at varying sizes to determine the degree of misalignment.</p>	<p>Department of Health, Tasmania</p>	<p>FSANZ has received details of larger labels from printers. See sections 2.2.1 and 2.3.1 for further discussion.</p>

Issue	Raised by	FSANZ response
<p>Need to independently establish how many CC cartons are on retail display, to be able to assert that it's only a small proportion. Also need the breakdown on proportion of products in CC at retail by place of purchase. 10% or more of product does not constitute a very small proportion of the large alcohol market.</p>	<p>FARE Cancer Council Australia Alcohol Healthwatch Health New Zealand</p>	<p>It is not possible for FSANZ to establish the exact number of CC cartons on retail display by place of purchase. The applicant has sought data from its members and other parties to determine estimated percentages of wine, beer, cider and pre-mixed drinks that are in CC's at the point of retail sale as detailed in section 1.2. Industry submitters have confirmed that most wine is removed from the CC outer package before being sold (see section 2.3.3). The estimated percentages cannot be averaged to 10% of the whole alcohol market as they are based on the proportion of each category of alcoholic beverages which have different sale volumes (beer being the highest) and does not include spirits (which are not packaged in CC outer packaging).</p> <p>The scope of the approved draft variation is also limited to post-printed CC outer packaging with more than one individual unit. Any other printing process used on CC outer packaging (e.g. pre-print or digital), any other type of outer packaging material which is not CC, and all other types of packages (including individual units within a CC outer package), will still require the existing three-colour pregnancy warning label.</p>
<p>There is a lack of independent verification from impartial CC manufacturers on the technical practicality of adapting the printing to permit legible three colour printing.</p> <p>Scope of application</p>	<p>Fetal Alcohol Spectrum Disorder Care Action Network (FASD-CAN)</p>	<p>FSANZ has had extensive discussions with a range of printers on the technical issues involved. See section 2.2.1 for further details.</p>
<p>Limiting use of the alternative label could stifle printing and packaging innovation and will result in inconsistent rules for different types of cardboard with potential challenges for compliance and enforcement officials. All outer packaging used for more than one individual unit should be permitted this flexibility to encourage consistency and support innovation.</p>	<p>NZFGC Australian Grape & Wine</p>	<p>The scope of the application is to address a specific technical issue for post-printed CC outer packaging. Consideration of other outer packaging is out of scope.</p> <p>Enforcement officials have the option of seeking information about compliance from alcoholic beverage producers.</p>

Issue	Raised by	FSANZ response
<p>Seeks clarity that cardboard packaging used for cask wine is out of scope of the application as cask wine contains only one individual unit. Also assume the same situation applies to spirits when they are packaged in bottles with an outside layer of cardboard packaging.</p>	<p>New South Wales Food Authority (NSWFA)</p>	<p>The approved draft variation (Attachment A) applies to CC packaging (not all cardboard packaging) used as an outer package for retail sale which contains more than one individual unit of a prescribed alcoholic beverage. It does not apply to an outer package that includes only one <i>individual unit</i> (see section 1.3 for definition) as is the case for cask wine.</p>
<p>Colour, contrast and size of warning label</p> <p>Further substantiation of the conclusion that the proposed change will not lead to an overall decrease in the effectiveness of the labels on CC outer packaging is required to justify a move from current requirements.</p> <p>Concerned the amendment proposes to trade colour for size, without a clear and compelling scientific rationale. Any trade-offs between legibility, attention and warning recognition need be made clearer.</p> <p>Do not support removing the colour red from the warning label. Consumers recognise red as a colour to indicate warning. Evidence used for P1050 indicated colours should be prescribed and include red. In the review, FSANZ's assessment said that removal of the colour red would undermine the labels effectiveness.</p>	<p>Victorian Department of Health and the Victorian Department of Jobs, Precincts and Regions Alcohol Healthwatch FASD-CAN Health New Zealand New Zealand College of Midwives Alcohol Healthwatch George Institute Cancer Council Australia Department of Health, Tasmania</p>	<p>FSANZ's assessment is based on the consumer literature review that informed Proposal P1050. As discussed in sections 2.2.2 and 2.3.2, the review shows that the use of the colour red in the warning label has advantages over the colour black for attention and recognition of a warning. It also indicates that multiple design elements can be used in varying combinations to enhance noticeability of warning labels e.g. a larger black and white warning may be as noticeable as a smaller red warning; and that this provides some degree of flexibility in design options to optimise the level of attention a warning receives. In FSANZ's review of P1050, we stated the colour red in the design should be maintained for label effectiveness and that if red was removed, a significantly larger label than currently proposed would be required to maintain noticeability. This assessment was based on consideration of the broad range of packaging types and package sizes for alcoholic beverages.</p> <p>FSANZ has assessed the application based on new information received since the P1050 assessment about misalignment issues for a particular type of outer packaging. FSANZ has therefore re-assessed the P1050 consumer evidence in the context of the newly identified misalignment issues. FSANZ has approved the draft variation to maintain the effectiveness of the pregnancy warning mark on post-printed CC packaging. The permitted alternative pregnancy warning mark resolves misalignment issues to ensure the label remains legible for consumers, while the size of the label has been increased to attract attention and offset the loss of the colour red. This approach ensures that industry can effectively and consistently comply with the Code. See further discussion in section 2.3. Consumers will continue to see the three-colour pregnancy warning mark on the majority of prescribed alcoholic beverage packaging, including the individual units inside the CC outer package.</p>

Issue	Raised by	FSANZ response
<p>Research from the George Institute demonstrated presentation modifications, in particular the use of colour, can make a significant difference to the way consumers respond to and retain information.</p>	<p>George Institute</p>	<p>FSANZ notes the research from the George Institute supports the importance of considering label colour in relation to effectiveness. The consumer literature review that informed Proposal P1050 also discussed the importance of colour as one of multiple design elements influencing noticeability and understanding of warning labels. As discussed above, following assessment of the newly identified misalignment issues since P1050, FSANZ has approved the draft variation in order to maintain the effectiveness of the pregnancy warning mark for post-printed CC packaging.</p>
<p>Will there always be sufficient contrast between the colour black and the permitted background colours of the CC?</p>	<p>NSWFA</p>	<p>As demonstrated by the examples provided in section 2.3.2, the colour black does contrast against the permitted background colours of the CC.</p>
<p>The default colour of the proposed alternative label should be red, with an option of black to maximise contrast against the predominant colour of the packaging. Packaging is often multi-coloured and in some cases black labelling may not stand out from background packaging colour. Mock ups with current CC packaging should be used to determine whether black colour is optimal.</p>	<p>FASD-CAN</p>	<p>The approved draft variation requires the background of the alternative pregnancy warning mark to be in the colour of the outside liner made of kraft, recycled or white paper. As noted above, the examples in section 2.3.2 show the colour black does contrast against the background colours of the CC outside liner.</p> <p>As discussed in section 2.3.2, a red colour on a brown or grey CC background colour may not result in good contrast and legibility given the specific shade of red is not prescribed.</p>
<p>The requirements to have specific colours on outer cartons is incredibly limiting. Given the physical printing limitations for cartons and the fact that the label will appear on both the clusters and can/bottle it seems reasonable that it could either be left off the carton or the colours could be flexible to fit within the design.</p>	<p>Moon Dog Brewing</p>	<p>As further discussed in section 2.3.2, the colour of the alternative pregnancy warning mark for post-printed CC outer packages is prescribed to ensure legibility and noticeability and prevent consumer confusion.</p> <p>As discussed in P1050, the primary objective of the pregnancy warning label as identified in policy advice provided by food ministers, is to provide a clear and easy to understand trigger to remind pregnant women, <u>at both the point of sale and the potential point of consumption, not to drink alcohol</u>. FSANZ determined that requiring the warning label on outer packages sold for retail sale is consistent with this policy advice. The policy intent is not being reviewed as part of this application. See section 1.2 of the P1050 Approval Report for further details.</p>

Issue	Raised by	FSANZ response
<p>Size needs to be considered in relation to other displayed information on the package. Concerned visibility will be reduced.</p>	<p>Alcohol Healthwatch</p>	<p>The size of other displayed information on the package is generally not prescribed (other than for warning statements) so a consistent comparison to existing information on the label is not possible. FSANZ has increased the size of type of the signal words and statement and the pictogram diameter relative to existing pregnancy warning label size requirements.</p>
<p>A size increase will produce a substantially larger increase in label surface area. An estimation of the total size increase should have been provided. The proposed size increase seems to be a disproportionate response to the potential loss of attention to the label. Any loss of attention will be negligible noting the primary target of the original policy was the point of consumption rather than the point of sale and that all other warning labels will be in the three colours.</p>	<p>Lion</p>	<p>The label surface area is increased by approximately 50%, noting that as the specific font type, letter spacing and dimensions of the black border are not prescribed, the percentage increase in label surface area will vary. See section 2.3.2 for an example of the larger alternative pregnancy warning mark compared with the existing label for outer packaging.</p> <p>As discussed in section 2.3.2, the increased size is prescribed to offset the loss of the colour red and maintain the label effectiveness.</p> <p>As noted above, the primary objective of the pregnancy warning label was 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.</p>
<p>Options for responding to the technical printing problem</p>	<p>Options for responding to the technical printing problem</p>	
<p>Require the three-colour label on CC packaging. Alcohol producers would pay the increased costs of printing, which they can pass on to consumers.</p>	<p>FARE George Institute Cancer Council Australia</p>	<p>See section 2.5.1.1 on the consideration of costs and benefits.</p>
<p>Require a larger three-colour warning label to mitigate the misalignment problem. How much larger would the label need to be? Additional costs could be passed on to the consumer.</p>	<p>Health New Zealand Consumer New Zealand Alcohol Healthwatch Cancer Council Australia</p>	<p>See section 2.2.1 for details of label size examples needed to reduce or remove the misalignment issue. Additionally, due to variances in printing machines used across the industry, the increased size required to reduce the appearance of the misalignment would vary.</p>
<p>There are examples of the three-colour warning label on the bottom of CC packaging in the marketplace. While not ideal location, there seems no reason why size cannot be increased to reduce misalignment.</p>	<p>FARE George Institute New Zealand College of Midwives Department of Health, Tasmania</p>	

Issue	Raised by	FSANZ response
<p>Require the printing of 'NOT FOR RETAIL DISPLAY' label on all post-printed CC packaging, noting such a labelled product would still be legally suitable for retail sale. The proposed alternative label would be required while compliance data are gathered.</p>	<p>FARE George Institute Cancer Council Australia</p>	<p>The Code does not prescribe when a package of food can or cannot be displayed for retail sale. If a food is for retail sale, or can be sold for retail sale, it is up to the food supplier to ensure it complies with all relevant requirements in the Code e.g. being labelled in accordance with the Code.</p>
<p>Are there alternative three-colour designs that could address the problem? (e.g. increase the size of white background around the red warning text).</p>	<p>Victorian Department of Health and the Victorian Department of Jobs, Precincts and Regions</p>	<p>FSANZ has considered other colour design options to address the misalignment issues as discussed in section 2.3.2.</p> <p>Increasing the size of the white background would not resolve the misalignment and smudging issues associated with printing another colour on a printed white background; or resolve misalignment of the intersection of the red strikethrough over the black silhouette (see section 2.2.1).</p>
<p>If other options for maintaining the colour red are not viable, front of pack labelling for the proposed alternative label should be explored so it is visible to consumers pre-purchase.</p>	<p>NSWFA Department of Health, Tasmania</p>	<p>FSANZ considered the issue of location and orientation of the pregnancy warning label under P1050. It was decided not to prescribe these elements for a number of reasons including providing flexibility for industry and noting no other countries prescribe location (see section 3.3.6 of P1050 Approval Report). FSANZ considers this decision is appropriate to maintain, noting the increased size of the warning label to offset the loss of the colour red.</p>
<p>It is not clear why the 'trapping' method using one colour (red pictogram) on a white background is not worth pursuing.</p> <p>Costs</p>	<p>Department of Health, Tasmania</p>	<p>See section 2.2.1. The 'trapping' approach can still lead to misalignment as it is difficult to position the pregnancy warning mark exactly in the correct position.</p>
<p>If it cannot be demonstrated that the proposed alternative label will be equally effective, information needs to be presented regarding the costs savings to industry associated with the proposed change to enable ministers to make a fully informed decision regarding the trade-off between cost and effectiveness.</p>	<p>Victorian Department of Health and the Victorian Department of Jobs, Precincts and Regions</p>	<p>See section 2.5.1.1 for discussion of costs and benefits and sections 2.2.2 and 2.2.3 for discussion of label effectiveness. Additional costs to industry for resolving the misalignment issue with the options currently available to them (without a change to the Code) are not able to be specifically quantified. However, the applicant has provided estimates (see pages 18/19 of the application) and FSANZ has confirmed with printers that the approved alternative pregnancy mark will provide a cost-saving compared with the three-colour label on CC packaging because alternative printing processes or over-stickering a label are more expensive on a per unit basis.</p>

Issue	Raised by	FSANZ response
<p>The costs associated with FASD greatly outweigh any increased costs of printing the three-colour warning label on CC packaging.</p> <p>A detailed cost-benefit analysis would need to be conducted with all possible options explored to justify any consideration of compromising P1050 requirements.</p> <p>The application has not provided specific enough implementation cost evidence for FSANZ to update a cost-benefit to justify this amendment. It provides 'low / medium / high' range of setup and print costs, and example costs from a specific business, but does not indicate how many packaging units the per-unit cost applies to. The alcohol industry also has the ability to pass any increased cost onto the distributor or end consumer.</p>	<p>Alcohol Healthwatch Cancer Council Australia FARE</p>	<p>Noting the limited scope of the approved draft variation it is not appropriate to update the P1050 cost-benefit analysis to justify this amendment. The frame of the reference for the consideration of costs and benefits is moving from the current status quo position of requiring the three-colour pregnancy warning label for all packaging types to potentially allowing an alternative format for a specific type of packaging.</p> <p>As discussed above, FSANZ considers that permitting an alternative pregnancy warning mark for post-printed CC outer packaging will ensure legibility for consumers and maintain label effectiveness while enabling industry to effectively and consistently comply with the Code.</p> <p>Refer to section 2.5.1.1 for discussion of costs and benefits.</p>
<p>Prescribing black for the warning label will significantly increase printing costs for CC packaging currently produced in a single colour, which may not be black. Introducing a second colour may also replicate the technical issues the application seeks to resolve. A more pragmatic approach would be to take the approach the applicant sought, that is the warning label be in a single colour on a contrasting background.</p>	<p>Diageo</p>	<p>The costs associated with prescribing colours was considered in Proposal P1050 and is not within the scope of this application. In the context of this application, the status quo is the existing three-colour warning label. See comment above.</p> <p>As further discussed in section 2.3.2, the single colour black is prescribed for the alternative warning mark to ensure it contrasts against the permitted background colours. This is an important design factor for a warning label to be effective. The single colour requirement of black addresses the misalignment issue.</p>

Issue	Raised by	FSANZ response
<p>Use of CC packaging</p> <p>With the increase in online sales and alcohol retailers, there may be an increased use of CC packaging and therefore the proposed amendment may not have a minor impact on consumer attention to the warning label.</p> <p>Other factors that may result in increased use of CC packaging:</p> <ul style="list-style-type: none"> - increased role of sustainability in driving consumer decisions - increased use of large package sizes by industry <p>Proposed amendments to the warning label need to be future-proofed should the industry decide to move towards more CC packaging.</p>	<p>Alcohol Healthwatch Department of Health, Tasmania Health New Zealand</p>	<p>The approved draft variation is limited to CC outer packaging for retail sale that is printed using a post-print process only. Other printing methods used on CC outer packaging (e.g. pre-print or digital), other outer packaging which is not CC, and all other types of packages including the individual units within a CC outer package, would still require the three-colour pregnancy warning label. Outer packaging used only for transportation (e.g. to transport alcoholic beverages to another site or to a consumer) and not retail sale, does not need to display the pregnancy warning label (See Q & A at Pregnancy warning labels on alcoholic beverages (foodstandards.gov.au)).</p> <p>FSANZ considers that most producers currently using non-CC outer packaging, or using other printing processes on CC packaging, would be unlikely to switch to CC outer packaging with a post-print finish. As further discussed in section 2.3.3, this is due to design limitations of the post-print process and additional bulk of CC packaging.</p>
<p>Transition Period</p> <p>Proposed transition period not supported and should not be extended beyond 1 August 2023 because:</p> <ul style="list-style-type: none"> - the transition period for pregnancy warning labels has already been extended to three years - industry has already had time to address the labelling requirement - presence of unlabelled packages from 1 August 2023 will dilute the warning message. <p>While the preference is to maintain the transition period ending 1 August 2023, the proposed transition period of 1 February 2024 should not be further extended.</p>	<p>Health New Zealand FASD-CAN Alcohol Healthwatch</p>	<p>FSANZ considers it is appropriate to give industry time to implement the pregnancy warning labelling requirements using the alternative label. Given the Food Ministers' Meeting (FMM) has 60 days to consider FSANZ's decision, industry may not have certainty about labelling requirements until approximately 6 weeks before 1 August 2023. Six weeks is not sufficient time for industry to implement the alternative label on CC packaging from 1 August 2023 should they choose to do so.</p>

Issue	Raised by	FSANZ response
<p>Proposed transition period for variation from A1256 supported by wine, beer and spirits sectors, however if there is a delay with gazettal, the transition period may need to be reviewed as a full six months is needed.</p>	<p>New Zealand Food Safety Saint Clair Wines Estate Wineworks Group Brewers Association of Australia Rose Family Estate Australian Grape & Wine Constellation Brands Independent Brewers New Zealand Winegrowers Spirits New Zealand</p>	<p>Should there be a delay in gazettal, for example if the FMM requests a review of the application, FSANZ would consider adjusting the transitional arrangements for CC packaging covered by the application.</p>
<p>Proposed transition period not supported and should be extended because:</p> <ul style="list-style-type: none"> - a transition period of 12 months from date of gazettal would provide certainty if gazettal is delayed - implementing the pregnancy warning label on CC packaging would take 9-12 months, therefore suggest the transition period is extended to 31 July 2024 to give certainty. - the proposed 6 month extension to the original transition period is not realistic and would impact ability to resource current business operations. A minimum of 12 months is required. 	<p>NZFGC Diageo Lion</p>	<p>FSANZ has decided the transition period for the pregnancy warning mark printed using a post-print process on CC packaging used for retail sale will commence on the date of gazettal and end on 1 February 2024. See section 3 for further details.</p> <p>As noted above, FSANZ would consider adjusting the transitional arrangements for CC packaging covered by the application if there was a delay in gazettal.</p>

2.2 Summary of assessment

2.2.1 Technical printing issues

FSANZ has assessed the technical issues associated with printing the pregnancy warning mark on CC using a post-print process, based on information provided by the applicant and printers. FSANZ has undertaken significant third-party information gathering across the printing industry in Australia and New Zealand. During assessment, FSANZ had several detailed discussions with two printing companies that have sites in both Australia and New Zealand, and one Australian company. We have since had discussions with two additional printers in New Zealand to further confirm the technical issues as described below.

Issues with misalignment of the currently prescribed pregnancy warning mark can arise due to a margin of error for print registration when using a post-print process on CC, and movement of the board through the printer. According to information from the applicant and some printers, the margin of error can range from ± 2 - 5 mm for some printing machines. One printer also identified warping of the CC (related to the moisture content in the CC) as the main reason for misalignment, in addition to the print registration margin of error.

The misalignment is a key issue for the post-print printing process where the colour is printed directly onto the CC using one printing plate per colour. The outside liner of the board (noting CC is made up of at least three layers) can be made of kraft, recycled or white paper, the colours of which are brown, grey or white. The current prescribed colours for the pregnancy warning mark requires the layering of three colours on the CC using three plates, or two if a white outside liner is used (as this achieves the prescribed white background). Therefore, the margin of error for each colour pass (around ± 2 – 5mm depending on the machine) can lead to a net registration shift. Figure 2 below provides an example of a misaligned label based on a ± 3 mm margin of error.



Figure 2: Example of a misaligned pregnancy warning mark

A key issue, as shown above, is misalignment of the intersection of the red strikethrough over the black silhouette due to the registration shift. However, the different coloured wording (red and black) can also be misaligned (see example in Figure 3 below also based on a ± 3 mm margin of error).



Figure 3: Example of misaligned pictogram and wording within the pregnancy warning mark

Whilst the applicant and printers acknowledged that misalignment will not be evident on every CC package, it is difficult to predict the incidence or extent of the misalignment within

the margin of error. One printer noted that they get close to 90% strikethrough (coloured red) movement of varying amounts in a printing run.

In response to comments from public health submitters about the need for more evidence about the technical problem, FSANZ discussed printing the three-colour warning label with additional printers. Printers confirmed misalignment occurs when printing the three-colour warning label on CC with the most commonly used post-print process. Printers across the two countries have flexographic printing machines of varying ages. Many printing companies have older machines (e.g. 30-40 years old) that result in greater misalignment of label elements. A few companies have newer machines (less than 5 years) which are capable of printing the three-colour warning label with no misalignment issues. Some printers using the post-print process may also be able to use subsidiary processes (e.g. clay coating) which also reduces registration errors. However, most commonly older machines are used for the post-print process and therefore misalignment frequently occurs when printing the warning label on CC packaging.

About half of the industry submitters specifically confirmed the misalignment issue when using a post-print process for CC packaging. Submitters maintained the post-print (flexographic) printing process is a cost-effective print method used across the industry, but that as the alignment of plates for each colour is not precise, printing fine details when multiple colours are close together, is near impossible. It was stated that much effort has gone into resolving the misalignment issue, but they have concluded there is no technical solution for printing the label legibly and consistently when post-print is used on CC packaging. In addition, they considered it would not be practical, feasible or sustainable to change all product lines to alternative packaging types or printing methods.

Misalignment is not an issue with other printing processes, such as pre-print (flexographic, lithographic) or digital printing. Digital printing has no registration issues but is expensive, generally only suitable for short print runs and not widely available in the industry. Pre-print processes involve printing onto paper which is then laminated onto the outside liner. The registration margin of error is much less compared with post-print at approximately ≤ 0.5 mm as the movement of paper through the printer is more tightly controlled. However, according to the applicant and printers consulted, these printing processes have higher associated costs for both set up and printing and can have run-size limitations. FSANZ has confirmed with printers that pre-print machinery is not available in New Zealand and so alcoholic beverage producers in New Zealand would have to source pre-printed graphics offshore with additional transportation costs and lead-times.

According to the applicant and printers, other options currently available to resolve the misalignment issue are not practical or feasible. Corrugated cardboard is primarily used as outer packaging for larger multi-packs of alcoholic beverages (e.g. 12 to 24 packs of beer, 6 and 12 bottles of wine). The strength, durability, protection and light weight attributes, and cheaper cost, makes CC irreplaceable as outer packaging for heavy and fragile products. The applicant and submitters claimed it is not feasible in terms of costs and practicality to over-sticker every CC box. This would introduce a major step in the packaging process which may not be able to be automated. Another option is to increase the size of the pregnancy warning mark on the package to reduce the appearance of the misalignment (this is possible under the current provisions of Standard 2.7.1 which only set a minimum size requirement). However, printers have advised a substantially larger label may still not completely resolve the misalignment. Since assessment, an example provided with a larger surface area of 165% compared with existing requirements did not completely resolve the misalignment issues. Another example with a 2171% increase in surface area was required to resolve misalignment.

Another potential option discussed by the applicant is for the pregnancy warning mark to be in a single colour on a white background. Based on information from the applicant and printers, FSANZ understands there are two approaches that theoretically could be used to print the pregnancy warning mark in a single colour on a printed white background when using the post-print process. A block of white could be printed and dried before printing the pregnancy warning mark on top, or space for the warning label could be left within the printed white block so that the warning label is printed directly on the CC (a stencil or 'trapping' approach). The 'trapping' approach requires printing the white background as the first colour, leaving a 'trap' (clear space) for the text and pictogram. A further colour pass would then be required to print the text and pictogram of the label.

Both approaches have technical issues. For the first approach, printers have advised that when printing a block of white colour on a brown CC liner, beige typically results making it difficult to achieve the white background for the warning label. It can also be difficult to have sufficient drying time between the printing of the white block and the pregnancy warning mark resulting in smudging. In addition, due to the margin of error for the two colours, misalignment can still occur resulting in white showing outside the border of the pregnancy warning mark or the colour of the CC liner showing within the border of the pregnancy warning mark. A thicker border around the pregnancy warning mark could be used to manage the latter misalignment issue (but not the smudging issue). Water based inks are used in the post-print process which require a longer drying time than alcohol-based inks. For the second 'trapping' approach, while smudging would not occur, the pregnancy warning mark could still be misaligned as with the registration margin of error (i.e. $\pm 2-5$ mm), it is difficult to position the pregnancy warning mark exactly in the correct position. Misalignment would potentially be most noticeable in the pictogram.

2.2.2 Summary of consumer evidence that informed pregnancy warning label design in Proposal P1050, relevant to the application

2.2.2.1 Overview

FSANZ's design of the pregnancy warning label in Proposal P1050 was informed by a consumer literature review on warning label effectiveness (FSANZ, 2020). The discussion below is a summary of the evidence presented in the literature review.

To be effective, a warning label has to be noticed. After noticing a warning, the consumer needs to read and understand the content of the message. The effectiveness of warning labels is influenced by a range of design factors. These design factors can be manipulated to enhance both the noticeability and comprehension of warning labels. These design factors include colour, contrast and size.

In FSANZ's final design, the signal words ('PREGNANCY WARNING') are in red text because evidence suggests that red signal words capture attention and convey a warning more than black signal words. The warning statement ('alcohol can cause lifelong harm to your baby') is in black text to provide a distinction with the red signal words. The circle and diagonal strikethrough of the pictorial are also in red because evidence suggests that this makes the pictorial more noticeable in contrast to other colours, and also helps consumers to recognise the pictorial is a warning. The silhouette of the pregnant woman holding a drinking glass is in black to provide adequate contrast with the circle and diagonal strikethrough, and is consistent with the existing consumer evidence which has primarily tested red and black pictorials. The background of the warning label is white to produce adequate contrast and ensure legibility of the label.

Multiple design elements (including colour and size) can be used in varying combinations to enhance the noticeability of warning labels. For example, a larger black and white warning may be as noticeable as a smaller red warning. This provides some degree of flexibility in design options to optimise the level of attention a warning receives. However, it should also be considered that some colour combinations may produce contrast that is difficult to read. Additionally, the colour green should be avoided as green generally conveys permission rather than prohibition, which may be confusing within the context of a warning label.

A more detailed description of the consumer evidence from FSANZ (2020) is provided below.

2.2.2.2 Colour and contrast

Colour has been used in warnings to enhance effectiveness both in terms of attention and comprehension. Some colour combinations produce contrast that is difficult to read (e.g. yellow on white) and legibility is reduced when the contrast between characters and the background is low. Dark lettering on a white background, or vice versa, rather than similar shades of a similar colour, has been recommended to enhance legibility (Wogalter & Leonard, 1999).

The consumer evidence indicates that the colour red attracts attention and also enhances recognition of a label being a warning. Conversely, the colour green can be ambiguous and confusing in the context of warnings. The available studies primarily used red and black labels. Some studies examined the colour of the warning statement, whereas other studies examined the colour of the pictorial. These studies are further described below.

Colour of the warning statement/signal words

Laughery et al. (1993) used an experimental design to test the influence of colour (red vs. black) of a text warning on alcohol products. The text warning was the standard US mandated alcohol warning⁹. Attention was measured by the time it took participants to accurately identify if the alcohol product included the warning. Participants more rapidly identified warnings when printed in red than when the warning was printed in black.

The literature review by Wilkinson et al. (2009) noted the importance of colour in the context of heuristic cues i.e. the use of learned knowledge structures in the form of simple decision rules to make judgements. In this context using a signal word (e.g. Warning) in the colour red serves as a cue to consumers which is perceived as implying a greater hazard than the equivalent signal word in black text (Zuckerman & Chaiken, 1998).

Colour of the pictorial

Rout and Hannan's (2016) cross-sectional online survey tested the standard pictogram¹⁰ in four colour options: duotone gold (circle and strikethrough in darker tone); duotone grey; monochrome green; and red and black (circle and strikethrough in red). A large majority of the total sample of young women (97%) and of women with children (98%) considered the red and black version of the pictogram looked most like a warning.

⁹ GOVERNMENT WARNING: (1) According to the Surgeon General, women should not drink alcoholic beverages during pregnancy because of the risk of birth defects. (2) Consumption of alcoholic beverages impairs your ability to drive a car or operate machinery, and may cause health problems.

¹⁰ The standard pictogram refers to a silhouette of a pregnant woman holding a drinking glass enclosed within a circle with a diagonal strikethrough.

Hall and Partners (2018) examined consumer understanding and interpretation of pregnancy warning labels using focus groups. When shown a duo-toned green pictogram (lighter green silhouette with darker green circle and diagonal strikethrough), participants felt that it would be prudent to avoid this colour as green generally signals permission, rather than prohibition. Participants also viewed a series of alternative pictograms. Four of the alternative pictograms used a red circle and diagonal strikethrough (with a black silhouette), the fifth used a more complex pictogram with several duller colours and no strikethrough. Participants highlighted the red colour as being eye catching and making the pictogram stand out. The colour red also conveyed danger. Participants did not draw the same conclusion for the more complex pictogram with no circle and diagonal strikethrough.

Pham et al. (2018) combined an online survey and eye tracking approach to measure the impacts of size and colour of warning labels on attention. The labels used were the standard pictogram (grey silhouette with black circle and diagonal strikethrough) with the black and white 'Get the facts DRINK WISE.ORG.AU' text-based logo. Three experimental conditions were tested: 1) colour: using a red circle and diagonal strikethrough in the pictogram and a red background in the logo; 2) size: increased size by 50% and 3) colour and size: incorporating both the colour changes and size increases. The control condition used a black and white pictogram and 'get the facts' logo in the standard size recommended in DrinkWise guidance. The control and experimental conditions were identical for both the survey and the eye tracking components of the study. Pham et al. (2018) reported a significant effect in the level of attention as measured by a self-report composite scale, with participants exposed to the colour and size condition reporting the highest level of attention compared to the smaller monochrome control. There was a trend of increasing attention from the control condition to the colour condition to the size condition and finally to the colour and size condition. However, it is unclear whether the differences between each condition were significant beyond that of the control and 'colour and size' condition¹¹. The eye tracking component of the study found that more participants (81%) looked at the warning in the colour and increased size condition compared with participants in the control condition (59%). Although there were no significant differences between the control and treatment groups in number or duration of eye fixations, the eye-tracking study was underpowered to detect anything but very large effects (sample sizes varied across the four groups from 11 to 17). Although Pham et al. (2018) did not sufficiently examine the independent effects of pictorial colour, findings from the previously described studies demonstrate that colour alone can increase the effectiveness of a warning label.

Summary regarding the statement and pictorial

A red warning statement/signal word can increase the reported level of attention that the warning receives and also implies a greater hazard than the equivalent signal word in black text. The use of a red circle and diagonal strikethrough in the pictogram was also considered more noticeable in contrast to other colours and also looked more like a warning. Conversely, use of the colour green may signal permission, rather than prohibition.

2.2.2.3 Size

Laughery and Wogalter (2016) noted that 'bigger is generally better', but qualify it is generally the size of the warning relative to other displayed information. Size also incorporates font

¹¹ The authors conducted a one-way analysis of variance (ANOVA) which showed that the different labels had a statistically significant effect on attention. However, the authors did not report post-hoc tests to identify where exactly the significant differences were. Therefore no conclusion can be made regarding significant differences among conditions beyond the 'colour and size' condition which had the greatest difference in mean attention score compared to the control. The reported confidence intervals also appear to be incorrect which casts doubt on the quality of this study.

size and the size of pictures or images used in the warning. There is a large research literature within advertising and marketing that have shown that large objects are more likely to be noticed, noticed more quickly and receive more attention than smaller objects (Peschel & Orquin, 2013). Studies have also explored the impact of size on warning label effectiveness.

As previously described, Pham et al. (2018) found that a 50% increase in warning label size coupled with using the colour red led to an increase in the noticeability of the warning. It is unclear whether the increase in size alone led to an increase in noticeability. The original size of the warning label in the control condition was the standard size recommended in DrinkWise guidance¹². The warning labels were presented alongside other on-label information.

Nevertheless, the effect of size alone on the effectiveness of warning labels is further supported by qualitative studies that found that the small size of warning labels was considered by participants to reduce the effectiveness of current voluntary warnings (Coomber et al., 2018; Jones & Gregory, 2010).

2.3 Risk management

In undertaking our assessment, FSANZ has re-assessed the consumer evidence that informed Proposal P1050 in the context of the newly identified misalignment issues detailed in section 2.2.1.

The risk management options available to FSANZ after assessment were to either:

- approve the draft variation that was set out in the earlier call for submissions
- amend and then approve that draft variation
- reject that draft variation.

For the reasons set out in this report, and having regard to all submissions received, FSANZ decided to approve the draft variation with an amendment required to correct a typographical error¹³ (Attachment A). The specific risk management considerations that were relevant to this decision are discussed below. We also had regard to other matters as outlined in section 2.5.

2.3.1 Permission for an alternative pregnancy warning mark

The applicant requested permission for pregnancy warning labels on CC packaging used for multiple individual units of alcoholic beverages to be in a single colour on a contrasting background to resolve technical misalignment issues. Given a misaligned label could reduce the readability and effectiveness of the pregnancy warning mark and risk non-compliance with existing requirements, FSANZ has approved the draft variation to permit an alternative pregnancy warning mark to maintain the effectiveness of the label. The scope of the approved draft variation is limited to post-printed CC outer packages containing more than one individual unit of an alcoholic beverage. The approved draft variation differs to that requested by the applicant to ensure the effectiveness of the label is maintained as detailed in the following sections.

¹² The DrinkWise style guide recommended a minimum height of 8 mm.

¹³ *After section 2.7.1—12* was added to Item 4.

Although some printers are able to print the existing three-colour pregnancy warning mark using the post-print process, misalignment frequently occurs on older machines which are commonly used across the industry (see discussion in section 2.2.1). The approved draft variation provides flexibility for industry to use the existing prescribed requirements or the alternative pregnancy warning mark for CC outer packages when a post-print process is used. This allows industry to effectively and consistently comply with the Code while ensuring legibility of the pregnancy warning mark for consumers.

FSANZ considers other options currently available to address the misalignment issues without changing the Code (e.g. changing packaging material or printing methods and machines), are not practical or would incur additional costs (see further discussion in sections 2.2.1 and 2.5.1.1). This includes increasing the size of the existing three-colour pregnancy warning mark. As detailed in section 2.2.1, while a larger label may reduce the appearance of the misalignment it may not be completely resolved, and therefore the label may still not be compliant with the Code. FSANZ considers that a considerably larger label to completely resolve the misalignment issue (e.g. 2171% increase in surface area compared with existing requirements) would be significantly disproportionate to the size requirements for other pregnancy warning labels. We also note that the size required to resolve misalignment would vary across the industry due to variations amongst flexographic printing machines (as discussed in section 2.2.1).

2.3.2 Colour, contrast and size

The applicant requested the pregnancy warning mark for CC outer packages be permitted in a single colour on a contrasting background (i.e. no colours prescribed). As noted in section 2.2.2, the current pregnancy warning mark was designed under Proposal P1050 in the context of design elements (such as colour and contrast) which serve to attract attention and enhance understanding of the label. The consumer evidence that informed Proposal P1050 indicated that some colour combinations can produce contrast that is difficult to read, and that the colour green can be confusing in the context of warnings. Policy advice previously provided to FSANZ¹⁴ also noted that the colour green should not be used due to potential confusion. While FSANZ agrees that a single colour on a contrasting background would help to resolve the misalignment issues, we consider it appropriate to prescribe the colour of the text (signal words and statement), pictogram and background to ensure legibility and noticeability and prevent consumer confusion.

FSANZ considered whether the colour white should be prescribed for the background. However, as noted in section 2.2.1, printing the colour white onto kraft or recycled CC raises technical issues of smudging or misalignment for some printers. This could reduce the readability and effectiveness of the pregnancy warning mark. Prescribing a white background could also require some manufacturers currently using kraft or recycled CC in a brown or grey colour to change to a white outside liner to meet these requirements, meaning further costs would be incurred (according to printer estimates, the white liner is 30-50% more expensive than kraft, and 60-90% more expensive than recycled liners). The approved draft variation therefore requires the background of the alternative pregnancy warning mark to be the same colour as the outside liner made of kraft, recycled or white paper (i.e. the colour of these liners are brown, grey or white).

FSANZ considered the following options for the colour of the text and pictogram of the alternative pregnancy warning mark, on the background colour of the outside liner:

- a) existing red and black colour requirements for the text and pictogram (as described in section 1.3)

¹⁴ [See section 1.3 in the Call for Submissions report for Proposal P1050](#)

- b) single colour black or single colour red for the whole pictogram (the silhouette, circle and strikethrough), red for the signal words 'PREGNANCY WARNING' and black for the statement 'Alcohol can cause lifelong harm to your baby'
- c) single colour red for the text and pictogram
- d) single colour black for the text and pictogram.

Option a) does not resolve the key misalignment issue of the red strikethrough intersecting with the black silhouette (as discussed in section 2.2.1) and was therefore not considered further as a viable option. Option b) would require the whole pictogram to be in the single colour black or the single colour red to resolve the intersecting red strikethrough and black silhouette misalignment issue. Under this option, the signal words would remain in the colour red and the warning statement would remain in the colour black. Options c) and d) are single colour options which would also resolve the misalignment issue associated with printing the two colours red and black.

As identified by the consumer evidence (section 2.2.2), the colour red in options b) and c) has advantages over the single colour black in option d) in relation to attention and recognition of a warning. The red colour would also contrast well with a white outside liner. However, the colour red may not contrast as well as the colour black when the outside liner is brown or grey in colour given the specific shade of red is not prescribed. To be effective, the label has to be noticed and be legible. Consumer evidence indicates that legibility is reduced when the contrast between characters and the background is low. The approved draft variation therefore requires the single colour black for the text and pictogram (option d) above) to ensure contrast and legibility against the permitted background colours. Figure 4 below provides examples of the colour black on different kraft and recycled outside liner backgrounds.



Figure 4: Examples of colour and contrast of text, pictogram and border of the alternative pregnancy warning mark

Given the circle, strikethrough and silhouette of the pregnant woman in the pictogram will be the single colour black, the approved draft variation requires a clear space to be displayed either side of the strikethrough to ensure both the strikethrough and the silhouette are clearly legible (see example in Figure 5 below). The pictogram, signal words and statement of the pictogram otherwise remain the same as the existing requirements to support consumer understanding of the pregnancy warning mark.



Figure 5: Colour of text, pictogram and border of the alternative pregnancy warning mark

To offset reduced effectiveness from not having red in the warning label, FSANZ has increased the minimum size of the diameter of the pictogram and size of type of the signal words and warning statement of the alternative pregnancy warning mark by around 25%. This equates to an increase in label surface area of approximately 50%, noting this will vary given the specific font type, letter spacing and border size are not prescribed. While the colour red increases the attention and noticeability of warning labels, consumer evidence indicates that attracting attention can also be achieved through label size and that multiple design elements can be used in varying combinations to enhance the noticeability of warning labels (e.g. a larger black and white label may be as noticeable as a smaller red warning). This provides some degree of flexibility in design options to optimise the level of attention a warning receives. Noting the application is limited to specific CC outer packaging for more than one individual unit compared with existing requirements which apply more broadly to outer packages, FSANZ considers that increasing the size of the alternative pregnancy warning mark is an appropriate design element to maintain noticeability. In determining the increased size, we have taken into account the varying sizes of the CC outer packages label space. The alternative pregnancy warning mark size requirements prescribed in the approved draft variation compared with the existing size requirements are set out in Table 2, with label examples provided below in Figure 6.

Table 2: Minimum size requirements of existing and alternative pregnancy warning mark

Existing minimum size for pregnancy warning mark for outer package with more than one individual unit	Minimum size for alternative pregnancy warning mark for post-printed CC outer package with more than one individual unit
Pictogram 11 mm diameter	Pictogram 14 mm diameter
Size of type of the signal words 3.5 mm	Size of type of the signal words 4.4 mm
Size of type of the statement 2.7 mm	Size of type of the statement 3.4 mm



Existing minimum size requirements



Larger alternative pregnancy warning mark

Figure 6: Examples of the pregnancy warning mark using existing minimum size requirements for outer packaging and the larger alternative pregnancy warning mark

2.3.3 Application of pregnancy warning mark

The approved draft variation limits the permitted use of the alternative pregnancy warning mark for CC that is:

- printed using the post-print (flexographic) printing process; and
- used as an outer package for retail sale that contains more than one individual unit.

As discussed in section 2.2.1, technical issues only arise due to the post-print process used for CC (and not other printing processes or other packaging materials). Also, this type of cardboard is primarily used as an outer package for multiple individual units of alcoholic beverages and not single individual units.

FSANZ acknowledges it is possible producers that are currently using non-CC outer packaging could switch to CC outer packaging to use the alternative pregnancy warning mark. However, we consider such a change in packaging material is likely to be limited. As noted above, the scope of the approved draft variation is specific to CC outer packaging that is printed using the post-print process. This printing process has restricted design options (i.e. 3-5 colours maximum) and a lower quality printing finish compared with other printing processes. As described by the applicant, producers have likely already decided to use non-CC outer packaging or a pre-print process for CC packaging to give a premium finish. Further, CCs add bulk to a product which would also affect packaging lines, storage space and shelf space. There would be other business decisions to consider in making a change to post-printed CC outer packaging, noting such a change would affect all label elements not just the pregnancy warning mark.

The applicant estimates only a small percentage of beer and cider, wine and pre-mixed products are in a CC outer package at the point of retail sale¹⁵ as this package is typically removed prior to sale (see section 1.2). Since assessment, the applicant has confirmed that spirits are not packaged in CC outer packaging. Industry submitters also confirmed that most wine is removed from CC outer packaging before being sold. In addition, the labels of individual units contained inside the CC outer package will display the existing three-colour pregnancy warning mark. Similarly, any other printing process used for CC outer packaging (e.g. pre-print or digital) and any other outer packaging material used (e.g. solid fibre board), will continue to require the existing three-colour pregnancy warning mark. Consumers will therefore see the three-colour pregnancy warning mark on the majority of prescribed alcoholic beverages either at the point of retail sale, or at the point of consumption. The impact and scope of the proposed amendment is therefore limited.

¹⁵ The applicant estimates around 8% of beer and cider, 9.5% of wine and 12.5% of pre-mixed drinks are in CC packaging at retail point of sale.

2.3.4 Summary of alternative pregnancy warning mark requirements

In summary, the approved draft variation requires the following design and application for the alternative pregnancy warning mark.

Label elements prescribed:



- The background of the pregnancy warning mark must be the same colour as the CC outside liner made of kraft, recycled or white paper (i.e. brown, grey, or white).
- The circle and strikethrough of the pictogram must be in the colour black.
- The strikethrough of the pictogram must be displayed with a clear space on either side of the strikethrough so both the strikethrough and silhouette of a pregnant woman are clearly legible.
- The silhouette of a pregnant woman on the pictogram must be in the colour black.
- The signal words 'PREGNANCY WARNING' must be in the colour black.
- The statement 'Alcohol can cause lifelong harm to your baby' must be in the colour black.
- The border of the pregnancy warning mark must be in the colour black.

Note: The font type requirements for the pregnancy warning mark will be the same as those currently prescribed in section 2.7.1—12 (e.g. bold, capitalised or sentence case, etc.).

Minimum size requirements:

- Pictogram 14 mm diameter
- Size of type of the signal words 4.4 mm
- Size of type of the statement 3.4 mm

Note: There must be a 3 mm clear space outside the border of the pregnancy warning mark (the same as currently prescribed in section 2.7.1—12).

Application of alternative pregnancy warning mark:

- The alternative pregnancy warning mark may only be used on CC outer packaging instead of the existing prescribed label when the:
 - pregnancy warning mark is printed on CC using a post-print (flexographic) printing process; and
 - the CC is used as an outer package for retail sale or sold as suitable for retail sale and contains more than one individual unit of a prescribed alcoholic beverage.

2.3.5 Risk management conclusion

Based on the above assessment and other considerations outlined in section 2.5 below, FSANZ has decided to approve a draft variation to the Code to permit an alternative pregnancy warning mark when the post-print printing process is used on CC outer packages containing more than one individual unit of an alcoholic beverage.

The approved draft variation differs to that requested by the applicant to maintain the effectiveness of the pregnancy warning mark whilst allowing industry using post-printed CC outer packaging some flexibility to effectively and consistently comply with the Code.

2.4 Risk communication

2.4.1 Consultation

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

FSANZ developed and applied a standard communication strategy to this application. The call for submissions was notified via the Food Standards Notification Circular, media release, FSANZ's social media channels and Food Standards News.

The process by which FSANZ approaches standards development matters is open, accountable, consultative and transparent. Public submissions were called to obtain the views of interested parties on issues raised by the application and the impacts of regulatory options. FSANZ acknowledges the time taken by individuals and organisations to make submissions on this application.

The draft variation was considered for approval by the FSANZ Board having regard to all submissions made during the call for submissions period.

2.5 FSANZ Act assessment requirements

2.5.1 Section 29

2.5.1.1 Consideration of costs and benefits

The Office of Impact Analysis (OIA)¹⁶ granted FSANZ an exemption from the requirement to develop a Regulation Impact Statement (RIS) for this application (correspondence dated 23 August 2022, OIA ID OBPR22-03128). This exemption was provided as the OIA assessed the proposed change was unlikely to have a more than minor regulatory impact on consumers, businesses and government. As such, the preparation of a RIS is not required.

FSANZ, however, has given consideration to the potential costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act considerations. The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 29 (2)(a)).

The purpose of this consideration is to determine if the community, government, and industry as a whole is likely to benefit, on balance, from a move from the status quo. This analysis considers three options:

¹⁶ Formerly known as the Office of Best Practice Regulation (OBPR)

- Option 1: Status quo – no change to requirements in Standard 2.7.1
- Option 2: Amend Code requirements as requested by the applicant (pregnancy warning mark on CC packaging used for multiple individual units of alcoholic beverages in a single colour on a contrasting background)
- Option 3: Amend Code requirements as requested by the applicant with modifications to mitigate the loss of three prescribed colours.

FSANZ is of the view that no other realistic food regulatory measures exist.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measure and, in fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the likely positives and negatives of moving away from the status quo by the second and third options.

FSANZ has undertaken significant third-party information gathering across the printing industry in Australia and New Zealand to confirm the existence of this technical issue and the costs associated with overcoming it. The objective of any change is to allow industry a more cost effective and efficient way to achieve compliance. However, any alternative path to achieving compliance must maintain the efficacy of the labelling. The labelling requirement has been put in place to assist with reducing the prevalence of Foetal Alcohol Spectrum Disorder which causes lifelong disability to individuals and significant costs to the community as a whole. Not maintaining the efficacy may result in unacceptable costs to individuals and the community as a whole. As a result, option 2 has been excluded from further analysis as it would result in a loss of efficacy (see sections 2.2.2 and 2.3.2).

Option 3 gives the alcohol industry an alternative set of requirements to achieve compliance that maintains the efficacy of the labelling. Consultation across the printing industry has established that significant cost savings can occur for industry with this option. Appropriate transitional arrangements are proposed to support these potential savings.

Costs and benefits of permitting the alternative pregnancy warning mark

Changing the printing process (e.g. to pre-print process) to avoid the technical issues associated with printing the pregnancy warning mark on CC using the post-print process (i.e. option 1) would not only increase the ongoing printing costs but could also lead to printers having to purchase new machinery or alcoholic beverage producers (particularly those in New Zealand) having to use the pre-print process offshore with additional transportation costs and lead-times. Changing the packaging material or over-stickering would also incur costs and not be as practical as CC for the larger package sizes (see section 2.2.1). FSANZ considers the approved draft variation maintains effectiveness of pregnancy warning labelling while enabling industry to resolve technical misalignment issues for a specific type of packaging (i.e. post-printed CC outer packaging of more than one individual unit of an alcoholic beverage).

Advice from the printing industry is that increasing the size of type and pictogram diameter by about 25% might lead to a small increase in cost due to an increased percentage of the box being covered in ink. However, this would be more than offset by the cost saved by not having to change printing method or packaging type, by not requiring the warning label to be on a printed (white) background and permitting the warning label to be in a single black colour. Therefore, the proposed change is likely to lead to significant cost savings to industry if industry participants decide to satisfy these alternative requirements to achieve compliance.

The efficacy of labelling will be maintained, alerting consumers about the risks of drinking

alcohol during pregnancy and enabling them to make an informed choice.

Beyond making compliance officers aware of the alternative requirements that can be satisfied to achieve compliance, the Government is unlikely to encounter any additional costs.

Conclusions from cost benefit considerations

FSANZ's assessment is that the direct and indirect benefits that would arise from option 3 most likely outweigh the associated costs.

2.5.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than the approved draft variation.

2.5.1.3 Any relevant New Zealand standards

The relevant standards apply in both Australia and New Zealand. There are no relevant New Zealand Standards.

2.5.1.4 Any other relevant matters

Other relevant matters are considered below.

2.5.2. Subsection 18(1)

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

2.5.2.1 Protection of public health and safety

The approved alternative pregnancy warning mark for use only under specific circumstances as described in section 2.3, will maintain the effectiveness of the warning label whilst enabling industry to resolve technical misalignment issues for a specific type of packaging (i.e. post-printed CC outer packaging of more than one individual unit of an alcoholic beverage). Similar to the warning label on individual units of alcoholic beverages and other (non CC) packaging, the alternative pregnancy warning mark 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.

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

The approved alternative pregnancy warning mark will maintain a noticeable and understandable warning on alcoholic beverages packaged in CC (meeting the specific conditions described in section 2.3) to alert consumers about the risks of drinking alcohol during pregnancy and enable them to make an informed choice.

2.5.2.3 The prevention of misleading or deceptive conduct

FSANZ has not identified any issues relevant to this matter.

2.5.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

FSANZ used the best available evidence in the assessment. FSANZ drew on the evidence review prepared for Proposal P1050 to support the assessment and the consideration of options to address the technical printing issue and maintain label effectiveness. FSANZ is satisfied the P1050 evidence is the best available evidence. The applicant submitted information on the technical printing issue and FSANZ obtained additional evidence from printers in Australia and New Zealand.

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

FSANZ is unaware of international food standards directly relevant to this application.

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

FSANZ does not anticipate a significant impact on efficiency and international competition. The approved draft variation will also provide an alternative pregnancy warning mark for producers exporting alcoholic beverages in CC packaging to Australia and New Zealand (providing the packaging meets the conditions for use of the alternative pregnancy warning mark).

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

FSANZ has not identified any issues relevant to this matter.

- **any written policy guidelines formulated by the Food Ministers' Meeting**

There are no specific policy guidelines formulated and notified by the Australia and New Zealand Ministerial Forum on Food Regulation (the Forum¹⁷) under paragraph 18(2)(e) of the FSANZ Act which apply to this application. However, FSANZ has had regard to policy advice provided by the Forum for Proposal P1050 (see section 2.3.2).

3 Transitional arrangements

FSANZ has decided the transition period for the pregnancy warning mark printed using a post-print process on CC packaging used for retail sale (and meeting the requirements of clause 4(2) of the variation) will commence on the date of gazettal and end on 1 February 2024. Additionally, alcoholic beverages in such packaging and labelled before the end of the transition period (i.e. before 2 February 2024) may be sold without the pregnancy warning mark.

FSANZ considered a 12 month transition period from the date of gazettal. However, given industry has been moving towards implementing pregnancy warning labelling requirements since July 2020, providing an additional period of about seven months from the date of gazettal to 1 February 2024 for producers who package alcoholic beverages in CC (and meet all other requirements in the approved draft variation) should be sufficient. Commencing the transition period on the date of gazettal of the approved draft variation and ending it when the transition period for P1050 ends on 31 July 2023 would not give producers sufficient time to meet the requirements in the approved draft variation for product packaged and labelled from 1 August 2023, should they choose to use the alternative

¹⁷ Now known as the Food Ministers' Meeting

pregnancy warning mark.

Alcoholic beverages in CC packaging (as set out in the approved draft variation) that are labelled before the end of the transition period (i.e. before 2 February 2024) will be able to be sold without the pregnancy warning mark. This is a similar approach to that applied to all prescribed alcoholic beverages under Proposal P1050. The approach aims to reduce the need for re-labelling and recognises alcoholic beverages with a slow market turnover.

4 Implementation

FSANZ expects to update the information on its website¹⁸ to assist implementation of the pregnancy warning labelling requirements and include the approved alternative pregnancy warning mark in the suite of downloadable labels. Transitional arrangements will be covered.

5 Monitoring and evaluation

The proposed labelling change would be captured under the monitoring and evaluation activities proposed under Proposal P1050¹⁹.

6 References

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¹⁸ Information and downloadable pregnancy warning labels are available at [Pregnancy warning labels on alcoholic beverages \(foodstandards.gov.au\)](https://www.foodstandards.gov.au)

¹⁹ See section 9 in the [P1050 Approval Report](#).

- [andunderstanding-of-alcohol-pregnancy-warning-labels](#)
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Attachments

- A. Approved draft variation to the *Australia New Zealand Food Standards Code*
- B. Explanatory Statement
- C. Draft variation to the *Australia New Zealand Food Standards Code* (call for submissions)

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



Food Standards (Application A1256 – Colour of pregnancy warning labels for corrugated cardboard packaging) Variation

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

Dated [To be completed by Delegate]

[Insert Delegate's name and position]

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 (Application A1256 – Colour of pregnancy warning labels for corrugated cardboard packaging) Variation*.

2 Variation to a standard in the Australia New Zealand Food Standards Code

The Schedule varies a Standard 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) This clause applies to a food product that is an alcoholic beverage:
 - (a) that is required by subsection 2.7.1—10(1) of the Code to display a pregnancy warning mark on its outer package; and
 - (b) to which subsection 2.7.1—13(2) of the Code applies.
- (3) During the transition period, the food product may be sold if the product complies with one of the following:
 - (a) the Code as in force without the pregnancy warning label amendments; or
 - (b) the Code as amended by the pregnancy warning label amendments.
- (4) The food product may be sold after the transition period if:
 - (a) the product complies with the Code as amended by the pregnancy warning label amendments; or
 - (b) both the following apply:
 - (i) the product was packaged and labelled before 2 February 2024; and
 - (ii) the labelling on the product's outer package complies with the Code as in force without the pregnancy warning label amendments.
- (5) This clause does not limit clause 4 of the *Food Standards (Proposal P1050 – Pregnancy warning labels on alcoholic beverages) Variation*.
- (6) For the purposes of this clause:
 - (a) the **pregnancy warning label amendments** means the variations made by both of the following:
 - (i) this instrument; and
 - (ii) the *Food Standards (Proposal P1050 – Pregnancy warning labels on alcoholic beverages) Variation*;
 - (b) the **transition period** means the period commencing on this instrument's date of commencement and ending on 1 February 2024.

Schedule

Standard 2.7.1

[1] After subsection 2.7.1—10(2)

Insert

- (2A) Subsection (2) does not apply to a *pregnancy warning mark to which section 2.7.1—13 applies.

[2] Subsection 2.7.1—12(1)

Omit "A", substitute "Subject to subsection (10), a".

[3] After subsection 2.7.1—12(9)

Insert

- (10) This section does not apply to a *pregnancy warning mark to which section 2.7.1—13 applies.

[4] After section 2.7.1—12

Insert:

2.7.1—13 Optional pregnancy warning mark for corrugated cardboard outer packaging

- (1) This section applies to a *pregnancy warning mark that:
- (a) is required by subsection 2.7.1—10(1) to be displayed on the outer package of a *prescribed alcoholic beverage; and
 - (b) is displayed on a *prescribed alcoholic beverage to which subsection (2) applies; and
 - (c) has been printed on the outer package of the *prescribed alcoholic beverage using a post-print (flexographic) printing process; and
 - (d) complies with this section.
- (2) This subsection applies to a *prescribed alcoholic beverage that has:
- (a) packaging that includes more than one *individual unit; and
 - (b) an outer package that:
 - (i) is made of corrugated cardboard; and
 - (ii) has an outside liner made of kraft, recycled or white paper.
- (3) The *pregnancy warning pictogram must be at least 14mm in diameter.
- (4) The *size of type of the signal words of the *pregnancy warning mark must be at least 4.4 mm.
- (5) The *size of type of the statement of the *pregnancy warning mark must be at least 3.4 mm.
- (6) The background of the *pregnancy warning mark must be in the same colour as the outside liner.
- Note** Subparagraph 2.7.1—13(2)(b)(ii) requires the outside liner to be made of kraft, recycled or white paper, the colours of which are brown, grey or white.
- (7) The circle and strikethrough of the *pregnancy warning pictogram must be in the colour black.
- (8) The silhouette of a pregnant woman on the *pregnancy warning pictogram must be in the colour black.
- (9) The strikethrough of the *pregnancy warning pictogram must be displayed with a clear space on either side of the strikethrough so both the strikethrough and silhouette of a pregnant woman on the *pregnancy warning pictogram are clearly legible.
- (10) The signal words of the *pregnancy warning mark must be:
- (a) in the colour black; and
 - (b) in bold font; and
 - (c) in a sans-serif typeface; and
 - (d) in capital letters; and
 - (e) in English.
- (11) 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.

- (12) The border of the *pregnancy warning mark must be in the colour black.
- (13) 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.
- (14) The *pregnancy warning mark must be displayed as a whole and without modification.
- (15) In this section, a **post-print (flexographic) printing process** means the pregnancy warning mark is printed directly on to the outside liner of corrugated cardboard packaging using flexible raised image printing plates.

Attachment B – Explanatory Statement

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1256 – Colour of pregnancy warning labels for corrugated cardboard packaging) Variation

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 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

The Authority accepted Application A1256 which seeks approval for pregnancy warning labels on corrugated cardboard packaging containing multiple individual units of alcoholic beverages to be in a single colour on a contrasting background. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation – *the Food Standards (Application A1256 – Colour of pregnancy warning labels for corrugated cardboard packaging) Variation*.

Following consideration by the Food Ministers' Meeting (FMM), section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the approved draft variation.

2. Variation is a legislative instrument

The approved draft variation is a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and is publicly available on the Federal Register of Legislation (www.legislation.gov.au).

This instrument is not subject to the disallowance or sunset provisions of the *Legislation Act 2003*. Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunset if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunset legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the FMM. The FMM is established under the Food Regulation Agreement and the international agreement between Australia and New Zealand, and consists of New Zealand,

Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

The Authority has approved a draft variation to amend Standard 2.7.1 of the Code to permit the use of an alternative pregnancy warning mark for corrugated cardboard outer packaging of certain prescribed alcoholic beverages in specified circumstances.

4. Documents incorporated by reference

The approved draft variation does not incorporate any documents by reference.

5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1256 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 6 October 2022 for a six-week consultation period.

The Office of Impact Analysis (OIA)²⁰ granted FSANZ an exemption from the requirement to develop a Regulation Impact Statement (RIS) for this application (correspondence dated 23 August 2022, OIA ID OBPR22-03128). This exemption was provided as the OIA assessed the proposed change was unlikely to have a more than minor regulatory impact on consumers, businesses and government.

6. 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 44 of the *Legislation Act 2003*.

7. Variation

The Schedule to the instrument varies Standard 2.7.1 of the Code.

Item [1] varies section 2.7.1—10 by inserting new subsection (2A) into that section. The new subsection provides that the pregnancy warning mark size requirements set by subsection 2.7.1—10(2) do not apply to a pregnancy warning mark to which section 2.7.1—13 applies.

Items [2] and [3] vary section 2.7.1—12 to allow for the different size, form and other requirements that new section 2.7.1—13 imposes for a pregnancy warning mark to which that new section applies.

Item [2] varies subsection 2.7.1—12(1) by replacing the word "A" where first occurring with the following text "Subject to subsection (10), a". This amendment provides that section 2.7.1—12 shall apply or operate subject to subsection 2.7.1—12(10).

Item [3] varies section 2.7.1—12 by inserting new subsection (10) into that section. The new subsection provides that section 2.7.1—12 does not apply to a pregnancy warning mark to which section 2.7.1—13 applies.

²⁰ Formerly known as the Office of Best Practice Regulation (OBPR)

Item [4] inserts a new section 2.7.1—13 after section 2.7.1—12.

The new section 2.7.1—13 provides for the use of an optional alternative pregnancy warning mark on the corrugated cardboard outer packaging of certain prescribed alcoholic beverages.

Subsection 2.7.1—13(1) provides that new section 2.7.1—13 applies to a pregnancy warning mark that:

- (a) is required by current subsection 2.7.1—10(1) to be displayed on the outer package of a prescribed alcoholic beverage; and
- (b) is displayed on a prescribed alcoholic beverage to which subsection 2.7.1—13(2) applies; and
- (c) has been printed on the outer package of that prescribed alcoholic beverage using a post-print (flexographic) printing process; and
- (d) complies with each requirement imposed by subsections 2.7.1—13(3) to (14).

If each of the above four conditions are not met, the alternative requirements provided in new section 2.7.1—13 for a pregnancy warning mark on corrugated cardboard outer package will not apply and cannot be used. In that case, the pregnancy warning mark must instead comply with the current requirements imposed by subsection 2.7.1—10(2) and section 2.7.1—12.

Subsection 2.7.1—13(2) states that it applies to a prescribed alcoholic beverage that has: packaging that includes more than one individual unit; and an outer package that is made of corrugated cardboard; and that the outer package has an outside liner made of kraft, recycled or white paper.

Subsection 2.7.1—13(3) requires that the pregnancy warning pictogram of the pregnancy warning mark must be at least 14 millimetres in diameter.

Subsection 2.7.1—13(4) requires that the size of type of the signal words of the pregnancy warning mark must be at least 4.4 millimetres.

Subsection 2.7.1—13(5) requires that the size of type of the statement of the pregnancy warning mark must be at least 3.4 millimetres.

Subsection 2.7.1—13(6) requires that the background of the pregnancy warning mark must be in the same colour as the outside liner. The Note to the subsection refers the reader to the requirement imposed by subparagraph 2.7.1—13(2)(b)(ii) that the outside liner be made of kraft, recycled or white paper, the colours of which are brown, grey or white.

Subsection 2.7.1—13(7) requires that the circle and strikethrough of the pregnancy warning pictogram must be in the colour black.

Subsection 2.7.1—13(8) requires that the silhouette of a pregnant woman on the pregnancy warning pictogram must be in the colour black.

Subsection 2.7.1—13(9) requires that the strikethrough of the pregnancy warning pictogram of the pregnancy warning mark must be displayed with a clear space on either side of the strikethrough so both the strikethrough and silhouette of a pregnant woman on the pictogram are clearly legible.

Subsection 2.7.1—13(10) prescribes the format of the signal words of the pregnancy warning mark (for example, colour, typography, English language).

Subsection 2.7.1—13(11) prescribes the format of the statement of the pregnancy warning mark (for example, colour, typography, English language).

Subsection 2.7.1—13(12) requires that the border of the pregnancy warning mark must be in the colour black.

Subsection 2.7.1—13(13) requires that the pregnancy warning mark must be displayed on the package with a clear space that: surrounds the outside of the border of the pregnancy warning mark; and is at least 3 millimetres in width.

Subsection 2.7.1—13(14) requires that the pregnancy warning mark must be displayed as a whole and without modification.

Subsection 2.7.1—13(15) defines the term 'post-print (flexographic) printing process' used in paragraph 2.7.1—13(1) to mean the process by which a pregnancy warning mark is printed directly on to the outside liner of corrugated cardboard packaging using flexible raised image printing plates.

Transitional arrangements

The approved draft variation commences or takes 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 does not apply to the amendments to the Code made by approved draft variation. See clause 4 of the instrument of variation.

Clause 4 provides two transitional arrangements for a prescribed alcoholic beverage that is required by subsection 2.7.1—10(1) of the Code to display a pregnancy warning mark on its outer package; and to which subsection 2.7.1—13(2) applies.

Subclause 4(3) provides an initial transitional arrangement that commences on the date of gazettal and ends on 1st February 2024. During this period, the prescribed alcoholic beverage can be sold if the product complies with either:

- the Code as in force without the amendments made by both the approved draft variation and the variations made by the *Food Standards (Proposal P1050 – Pregnancy warning labels on alcoholic beverages) Variation*; or
- the Code as in force and as amended by both the approved draft variation and the variations made by the *Food Standards (Proposal P1050 – Pregnancy warning labels on alcoholic beverages) Variation*.

Subclause 4(4) provides a second transitional arrangement that commences on and from 2 February 2024 and in which the prescribed alcoholic beverage can be sold if the product:

- complies with the Code as in force and as amended by both the approved draft variation and the variations made by the *Food Standards (Proposal P1050 – Pregnancy warning labels on alcoholic beverages) Variation*; or
- was packaged and labelled before 2 February 2024 and the labelling on its outer package complies with the Code as in force without the amendments by both the

approved draft variation and the variations made by the *Food Standards (Proposal P1050 – Pregnancy warning labels on alcoholic beverages) Variation*.

Subclause 4(5) preserves the operation of the clause 4 of the *Food Standards (Proposal P1050 – Pregnancy warning labels on alcoholic beverages) Variation*. That clause provides specific transitional arrangements, including a stock in trade provision, for prescribed alcoholic beverages. These include prescribed alcoholic beverages to which clause 4 of the *Food Standards (Application A1256 – Colour of pregnancy warning labels for corrugated cardboard packaging) Variation* applies.

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



Food Standards (Application A1256 – Colour of pregnancy warning labels for corrugated cardboard packaging) Variation

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

Dated [To be completed by Delegate]

[Insert Delegate's name and position]

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 (Application A1256 – Colour of pregnancy warning labels for corrugated cardboard packaging) Variation*.

2 Variation to a standard in the Australia New Zealand Food Standards Code

The Schedule varies a Standard 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) This clause applies to a food product that is an alcoholic beverage:
 - (a) that is required by subsection 2.7.1—10(1) of the Code to display a pregnancy warning mark on its outer package; and
 - (b) to which subsection 2.7.1—13(2) of the Code applies.
- (3) During the transition period, the food product may be sold if the product complies with one of the following:
 - (a) the Code as in force without the pregnancy warning label amendments; or
 - (b) the Code as amended by the pregnancy warning label amendments.
- (4) The food product may be sold after the transition period if:
 - (a) the product complies with the Code as amended by the pregnancy warning label amendments; or
 - (b) both the following apply:
 - (i) the product was packaged and labelled before 2 February 2024; and
 - (ii) the labelling on the product's outer package complies with the Code as in force without the pregnancy warning label amendments.
- (5) This clause does not limit clause 4 of the *Food Standards (Proposal P1050 – Pregnancy warning labels on alcoholic beverages) Variation*.
- (6) For the purposes of this clause:
 - (c) the **pregnancy warning label amendments** means the variations made by both of the following:
 - (ii) this instrument; and
 - (ii) the *Food Standards (Proposal P1050 – Pregnancy warning labels on alcoholic beverages) Variation*;
 - (d) the **transition period** means the period commencing on this instrument's date of commencement and ending on 1 February 2024.

Schedule

Standard 2.7.1

[1] After subsection 2.7.1—10(2)

Insert

- (2A) Subsection (2) does not apply to a *pregnancy warning mark to which section 2.7.1—13 applies.

[2] Subsection 2.7.1—12(1)

Omit "A", substitute "Subject to subsection (10), a".

[3] After subsection 2.7.1—12(9)

Insert

- (10) This section does not apply to a *pregnancy warning mark to which section 2.7.1—13 applies.

[4] **Insert:**

2.7.1—13 Optional pregnancy warning mark for corrugated cardboard outer packaging

- (1) This section applies to a *pregnancy warning mark that:
- (a) is required by subsection 2.7.1—10(1) to be displayed on the outer package of a *prescribed alcoholic beverage; and
 - (b) is displayed on a *prescribed alcoholic beverage to which subsection (2) applies; and
 - (c) has been printed on the outer package of the *prescribed alcoholic beverage using a post-print (flexographic) printing process; and
 - (d) complies with this section.
- (2) This subsection applies to a *prescribed alcoholic beverage that has:
- (a) packaging that includes more than one *individual unit; and
 - (b) an outer package that:
 - (i) is made of corrugated cardboard; and
 - (ii) has an outside liner made of kraft, recycled or white paper.
- (3) The *pregnancy warning pictogram must be at least 14mm in diameter.
- (4) The *size of type of the signal words of the *pregnancy warning mark must be at least 4.4 mm.
- (5) The *size of type of the statement of the *pregnancy warning mark must be at least 3.4 mm.
- (6) The background of the *pregnancy warning mark must be in the same colour as the outside liner.

Note

Subparagraph 2.7.1—13(2)(b)(ii) requires the outside liner to be made of kraft, recycled or white paper, the colours of which are brown, grey or white.

- (7) The circle and strikethrough of the *pregnancy warning pictogram must be in the colour black.
- (8) The silhouette of a pregnant woman on the *pregnancy warning pictogram must be in the colour black.
- (9) The strikethrough of the *pregnancy warning pictogram must be displayed with a clear space on either side of the strikethrough so both the strikethrough and silhouette of a pregnant woman on the *pregnancy warning pictogram are clearly legible.
- (10) The signal words of the *pregnancy warning mark must be:
- (a) in the colour black; and
 - (b) in bold font; and
 - (c) in a sans-serif typeface; and
 - (d) in capital letters; and
 - (e) in English.
- (11) 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.
- (12) The border of the *pregnancy warning mark must be in the colour black.

- (13) 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.
- (14) The *pregnancy warning mark must be displayed as a whole and without modification.
- (15) In this section, a **post-print (flexographic) printing process** means the pregnancy warning mark is printed directly on to the outside liner of corrugated cardboard packaging using flexible raised image printing plates.