

**6 October 2022**

**216-22**

**Call for submissions – 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. FSANZ has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [current calls for public comment and how to make a submission](https://www.foodstandards.gov.au/code/changes/Pages/Documents-for-public-comment.aspx).

All submissions on applications and proposals will be published on our website. We will not publish material that we accept as confidential. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1982*. Submissions will be published as soon as possible after the end of the submission period.

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Submissions should be made in writing; be marked clearly with the word ‘Submission’. You also need to include the correct application or proposal number and name. Electronic submissions can be made through the FSANZ website via the link [how to make a submission.](http://www.foodstandards.gov.au/code/changes/Pages/Documents-for-public-comment.aspx) You can also email your submission to submissions@foodstandards.gov.au. FSANZ also accepts submissions in hard copy to our Australia and/or New Zealand offices.

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

**DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 16 November 2022**

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making a submission or application and proposal processes can be sent to standards.management@foodstandards.gov.au.

Submissions in hard copy may be sent to the following addresses:

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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 beverages[[1]](#footnote-2). 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 mark[[2]](#footnote-3) 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 the 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 and have reduced effectiveness.



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. 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 concludes that given the technical issues and costs associated with the existing requirements for the pregnancy warning mark, an alternative pregnancy warning mark should be permitted for CC outer packaging of more than one individual unit of a prescribed alcoholic beverage, when a post-print printing process is used. FSANZ is proposing:

* the existing minimum size of type for the signal words and statement and the pictogram diameter be increased by around 25%
* the text, pictogram and border be in the single colour black
* the background be the same colour as the CC outside liner (i.e. kraft brown, recycled brown or grey, or white).

This approach prescribes colour, contrast and an increased size, ensuring effectiveness of the pregnancy warning mark is maintained, whilst allowing industry to resolve technical misalignment issues for a very small proportion of packaging used for alcoholic beverages.

FSANZ proposes a transition period for a prescribed alcoholic beverage with a pregnancy warning mark on an outer package made of CC (as set out in the draft variation) commences on the date of gazettal 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.

FSANZ now seeks submissions to assist consideration of the draft variation to the Code.

# 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 beverages[[3]](#footnote-4)) a technical issue with printing the warning mark on CC packaging using a post-print (flexographic) printing process[[4]](#footnote-5) 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 advised 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 the post-print process; and
* 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 estimates individual alcoholic beverage producers use the 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

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

Standard 2.7.1 of the Code sets labelling requirements for alcoholic beverages and food containing alcohol. Standard 2.7.1[[5]](#footnote-6) and Standard 1.1.2 (Definitions used throughout the Code) were amended in 2020[[6]](#footnote-7) 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:

the pregnancy warning pictogram,

the signal words ‘Pregnancy Warning’ and

the statement ‘Alcohol can cause lifelong harm to your baby’,

all within a border.



 ***Individual unit*** means a container that:

1. is an innermost package; and
2. contains a beverage with more than 1.15% alcohol by volume.

Section 2.7.1—8 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 the pregnancy warning mark. The section requires the use of three colours (red, white and black) as follows:

* The background of the pregnancy warning mark 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 ‘PREGNANCY WARNING’ must be in the colour red.
* 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.

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 outside 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 after 1 August 2023. This exemption also applies to imported alcoholic beverages.

## 1.4 Reasons for accepting 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 is being assessed under the General Procedure in the FSANZ Act.

# 2 Summary of the assessment

## 2.1 Technical printing issues

FSANZ has assessed the technical issues associated with printing the pregnancy warning mark on CC using the post-print process, based on information provided by the applicant and printers. FSANZ had detailed discussions with two printing companies that have sites in both Australia and New Zealand, and one Australian company. All companies contacted print on corrugated cardboard and have clients in the alcoholic beverage sector.

As discussed in section 1.2, issues with misalignment of the currently prescribed pregnancy warning mark can arise due to a margin of error for print registration when using the 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 +/- 2-3mm up to 5mm 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. The outside liner of the board (noting CC is made up of at least three layers) can be a brown colour (referred to as ‘kraft board’), brown or grey (referred to as ‘recycled’) or white. The current prescribed colours for the pregnancy warning mark requires the layering of three colours on the CC, 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) can lead to a net registration shift of up to 6mm as demonstrated in the example in Figure 2 below.



Figure 2: Example of a misaligned pictogram within the pregnancy warning mark

A key issue, as shown above, is 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).



 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.

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, these printing processes have higher associated costs for both set up and printing and can have run-size limitations.

According to the applicant and printers, other options currently available to resolve the misalignment issue are not practical or feasible. The CC 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 the CC irreplaceable as outer packaging for heavy and fragile products. The applicant also states that it is not feasible in terms of costs and practicality to over-sticker every CC box. This would introduce a major step in the printing 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, the misalignment would not be completely resolved and the size would need to be substantially larger for the misalignment not to be obvious. This would be significantly disproportionate to the size of pregnancy warning labels on other packages.

Another potential option discussed by the applicant is for the pregnancy warning mark to be in a single colour on a white background. This would require a change to the Code. 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 a ‘kraft’ or ‘recycled’ liner is used) 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).

Both approaches have technical issues. For the first approach, it can 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 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, 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 Summary of consumer evidence that informed pregnancy warning label design in Proposal P1050, relevant to the application

### 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 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.

### *2.2.2.1* *Colour of the warning statement/signal words*

Loughery 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 warning[[7]](#footnote-8). 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).

### *2.2.2.2 Colour of the pictorial*

Rout and Hannan’s (2016) cross-sectional online survey tested the standard pictogram[[8]](#footnote-9) 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.

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’ condition[[9]](#footnote-10). 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.

### *2.2.2.3 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.

### 2.2.3 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 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 guidance[[10]](#footnote-11). 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

FSANZ has considered the requested amendment to the pregnancy warning mark in the context of the technical issues and consumer evidence. We have also had regard to other matters as outlined in section 2.5.

### 2.3.1 Approach

Given the technical issues and costs associated with the existing prescribed pregnancy warning mark (see section 2.1), FSANZ proposes to permit an alternative pregnancy warning mark when the post-print process is used on CC outer packages containing more than one individual unit of an alcoholic beverage. FSANZ considers a misaligned label could reduce the readability and effectiveness of the pregnancy warning mark, and risk potential non-compliance with the current standard. This proposed pregnancy warning mark will be an alternative to the existing prescribed requirements (i.e. either can be used for these CC outer packages when a post-print process is used). Other options currently available to industry (e.g. changing packaging material or printing process as discussed in section 2.1) are not practical or would incur further costs. However, we have further considered the colour and contrast requested by the applicant, along with size of the alternative pregnancy warning mark, as discussed in section 2.3.2.

### 2.3.2 Colour, contrast and size

The applicant has 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, the pregnancy warning mark was designed 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 indicates 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 FSANZ[[11]](#footnote-12) 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 will help to resolve the current misalignment issues, we consider it appropriate to prescribe the single colour and the background colour to ensure legibility and noticeability and prevent consumer confusion.

FSANZ has considered whether the colour white should be prescribed for the background. However, as noted in section 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 white could therefore force some manufacturers currently using kraft or recycled CC to change to a white outside liner to meet the background 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). FSANZ therefore proposes to require the background of the alternative pregnancy warning mark to be the same colour as the outside liner (i.e. either white, brown or grey as described in section 2.1).

FSANZ proposes to prescribe the single colour as black for the alternative pregnancy warning mark on the background colour (white, brown or grey). This approach ensures consistency in colour and contrast and avoids colour combinations that are difficult to read (e.g. yellow on white) or confusing to consumers (e.g. green). While the colour red has advantages over black in regard to attention and recognition of a warning and would contrast well with a white outside liner, it may not contrast as well as the colour black when the outside liner is brown or grey (noting 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 (section 2.2.2). The colour black is therefore prescribed to ensure contrast against each of the three background colours (white, brown or grey). Given the circle, strikethrough and the silhouette of the pregnant woman in the pictogram will be the single colour black, a clear space will be required to be displayed either side of the strikethrough to ensure both the strikethrough and the silhouette are clearly legible (see Figure 4 below). The pictogram, signal words and statement of the pictogram otherwise remain the same to support consumer understanding of the pregnancy warning mark.



Figure 4: Proposed 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 proposes to increase the minimum size of the pictogram and size of type of the alternative pregnancy warning mark by around 25%. Consumer evidence indicates 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). While red increases the attention and noticeability of warning labels, attracting attention can also be achieved through warning size. In determining the increased size, FSANZ has taken into account the varying sizes of the CC outer packages label space. The proposed alternative pregnancy warning mark size requirements against the existing size requirements are set out in Table 1 below.

**Table 1:** Existing and proposed minimum size requirements for pregnancy warning mark

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

### 2.3.3 Application of pregnancy warning mark

FSANZ proposes to limit the permitted use of the alternative pregnancy warning mark to:

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

As discussed in section 2.1, technical issues arise due to the post-print process used for CC (and not other printing processes). Also, this type of cardboard is primarily used as an outer package for multiple individual units of alcoholic beverages. While it is possible producers that are currently using non-CC outer packages could switch to a CC outer package to use the alternative pregnancy warning mark, FSANZ considers this is unlikely to occur. The scope is limited to the post-print process which has limited colour 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.

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 sale[[12]](#footnote-13) as this package is typically removed prior to sale. In addition, the labels of individual units contained inside the outer package will display the existing three coloured pregnancy warning mark. Similarly, any other printing process used for CC (e.g. pre-print or digital) and any other outer package material used (e.g. solid fibre board), will continue to require the existing three coloured pregnancy warning mark. Consumers will therefore see the three coloured 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 to a very small proportion of packaging used for alcoholic beverages.

### 2.3.4 Summary of proposed approach for the alternative pregnancy warning mark

In summary, FSANZ proposes the following design and application for the alternative pregnancy warning mark.

The following label elements are proposed:



* The background of the pregnancy warning mark must be the same colour as the CC outside liner (i.e. kraft brown, recycled brown or 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 the CC using a post-print (flexographic) printing process; and
* CC is used as an outer package for more than one individual unit of a prescribed alcoholic beverage.

### 2.3.4 Risk management conclusion

Based on the above assessment and other considerations outlined in section 2.5 below, FSANZ’s proposed approach is to prepare a draft variation to amend the pregnancy warning mark requirements only when the post-print printing process is used on CC outer packages containing more than one individual unit of an alcoholic beverage.

The draft variation differs to that requested by the applicant to maintain the effectiveness of the pregnancy warning mark, whilst allowing industry to resolve technical misalignment issues for a very small proportion of packaging used for alcoholic beverages.

## 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.

All calls for submissions are notified via the Food Standards Notification Circular, media release, FSANZ’s social media tools and Food Standards News.

The process by which FSANZ considers standards development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of the public, including interested parties, on issues raised by the application and the impacts of regulatory options.

### 2.4.2 World Trade Organization (WTO)

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

FSANZ is unaware of international standards directly relevant to the amendment being sought in this application. Amending the Code to permit the pregnancy warning mark on CC packaging used for multiple individual units of alcoholic beverages to be in black on kraft, recycled or white CC, or in red, black and white as currently prescribed, is unlikely to have a significant effect on international trade. Therefore, a notification to the WTO under Australia’s and New Zealand’s obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

## 2.5 FSANZ Act assessment requirements

When assessing this application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 29 of the FSANZ Act:

### 2.5.1 Section 29

#### 2.5.1.1 Consideration of costs and benefits

The Office of Best Practice Regulation (OBPR) exempted FSANZ from the need to undertake a formal Regulation Impact Statement (RIS) in relation to the regulatory change proposed in response to this application (OBPR ID OBPR22-03128). The OBPR considers the proposed measure is unlikely to have a more than minor regulatory impact. 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:

* 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 of more than one individual unit 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, however information received may result in FSANZ arriving at a different outcome.

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 under this section as it would result in a loss of efficacy.

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 costs saving 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

Advice from across the printing industry is that if the size of the warning is increased it 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 requiring the warning label to be on a printed (white) background and permitting the warning label to be in a single 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 proposed food regulatory measure developed or varied as a result of the application.

#### 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 only 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 alternative pregnancy warning mark for use only under specific circumstances as described in section 2.3 above, will maintain the effectiveness of the warning label whilst enabling industry to resolve technical misalignment issues for a very small proportion of packaging used for alcoholic beverages. As for 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 proposed alternative pregnancy warning mark would 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 has used the best available evidence in this 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 CC 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 any significant impact on efficiency and international competition. The proposed approach 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 Forum on Food Regulation**

There are no specific policy guidelines formulated and notified by the Australia and New Zealand Ministerial Forum on Food Regulation (the Forum[[13]](#footnote-14)) 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 Draft variation

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

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

## 3.1 Transitional arrangements

FSANZ has considered three options for transitional arrangements:

* applying the transitional arrangements for Proposal P1050 to the proposed draft variation (i.e. the transition period would be from the date of gazettal of the proposed draft variation to 31 July 2023);
* using the default transition period in the Code of 12 months beginning from the date of gazettal of the proposed draft variation (section 1.1.1—9);
* applying a transition period of an additional six months from 1 August 2023, that is, the transition period would commence on the date of gazettal and end on 1 February 2024.

Stock-in-trade exemptions have also been considered.

FSANZ proposes a transition period for a prescribed alcoholic beverage meeting the requirements of clause 4(2) of the variation only, commences on the date of gazettal and ends on 1 February 2024. FSANZ considers that given industry has been moving towards implementing pregnancy warning labelling requirements since July 2020, providing an additional six months (from 1 August 2023 to 1 February 2024) for producers who package alcoholic beverages in CC (and meet all other requirements in the draft variation) should be sufficient. Commencing the transition period on the date of gazettal of the 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 draft variation for product packaged and labelled from 1 August 2023, should they choose to use the alternative pregnancy warning mark.

FSANZ also proposes to apply a stock-in-trade provision for the labelling of prescribed alcoholic beverages warning mark on an outer package made of CC (as set out in the draft variation), similar to what was applied to all prescribed alcoholic beverages under Proposal P1050. This approach aims to reduce the need for re-labelling and recognises alcoholic beverages with a slow market turnover. Prescribed alcoholic beverages meeting the requirements of clause 4(2) of the variation only and which are packaged and labelled before the end of the transition period (i.e. before 2 February 2024) could therefore be sold without the pregnancy warning mark.

### 3.1.1 Implementation

FSANZ expects to update the information on its website[[14]](#footnote-15) that supports industry implementation of the pregnancy warning labelling requirements and include the proposed alternative pregnancy warning mark in the suite of downloadable labels.

### 3.1.2 Monitoring and evaluation

The proposed labelling change would be captured under the monitoring and evaluation activities proposed under Proposal P1050[[15]](#footnote-16).

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**Attachments**

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

B. Draft Explanatory Statement

## Attachment A – 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:

1. the **pregnancy warning label amendments** means the variations made by both of the following**:**
2. this instrument; and

(ii) the *Food Standards (Proposal P1050 – Pregnancy warning labels on alcoholic beverages) Variation*;

1. 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:

1. (a) is required by subsection 2.7.1—10(1) to be displayed on the outer package of a \*prescribed alcoholic beverage; and
2. (b) is displayed on a \*prescribed alcoholic beverage to which subsection (2) applies; and
3. (c) has been printed on the outer package of the \*prescribed alcoholic beverage using a post-print (flexographic) printing process; and
4. (d) complies with this section.

 (2) This subsection applies to a \*prescribed alcoholic beverage that has:

1. (a) packaging that includes more than one \*individual unit; and
2. (b) an outer package that:
3. (i) is made of corrugated cardboard; and
4. (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 – Draft Explanatory Statement

**1. Authority**

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

Division 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 used for 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 prepared a draft variation

**2. Variation will be a legislative instrument**

If approved, the draft variation would be a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and be publicly available on the Federal Register of Legislation ([www.legislation.gov.au](http://www.legislation.gov.au)).

If approved, this instrument would not be subject to the disallowance or sunsetting provisions of the *Legislation Act 2003.* Subsections44(1) and 54(1) of that Actprovide that a legislative instrument is not disallowable or subject to sunsetting 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 sunsetting legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Actgives 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 alsogives 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 Food Ministers Meeting (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 prepared the draft variation amending Standard 2.7.1 of the Code to permit an alternative pregnancy mark for corrugated cardboard outer packaging of more than one individual unit of a prescribed alcoholic beverage, when a post-print (flexographic) printing process is used, subject to certain conditions.

**4. Documents incorporated by reference**

The 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 will include one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary.

The Office of Best Practice Regulation (OBPR) granted FSANZ an exemption from the requirement to develop a Regulation Impact Statement (RIS) for this application (OBPR correspondence dated 23 August 2022, OBPR ID:22-03128). This exemption was provided as the OBPR assessed the currently proposed change is unlikely to have a more than minor regulatory impact on consumers, businesses and government.

**6. Statement of compatibility with human rights**

If approved, this instrument would be 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 will impose 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 will provide 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.

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

The stock-in-trade exemption provided by section 1.1.1—9 of Standard 1.1.1 will not apply to the above 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.

There is an initial transitional arrangement commencing on the date of gazettal and ending 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 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 draft variation and the variations made by the *Food Standards (Proposal P1050 – Pregnancy warning labels on alcoholic beverages) Variation*.

There is a second transitional arrangement commencing on and from 2 February 2024 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 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 draft variation and the variations made by the *Food Standards (Proposal P1050 – Pregnancy warning labels on alcoholic beverages) Variation.*

Subclause 4(2) 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, which include prescribed alcoholic beverages to which sub-clause 4(2) of the A1256 variation will apply.

1. [Proposal P1050 – Pregnancy warning labels on alcoholic beverages](https://www.foodstandards.gov.au/industry/labelling/Pages/pregnancy-warning-labels.aspx) [↑](#footnote-ref-2)
2. 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. [↑](#footnote-ref-3)
3. [Proposal P1050 – Pregnancy warning labels on alcoholic beverages](https://www.foodstandards.gov.au/code/proposals/Pages/P1050Pregnancywarninglabelsonalcoholicbeverages.aspx) [↑](#footnote-ref-4)
4. 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. [↑](#footnote-ref-5)
5. [Standard 2.7.1 – Labelling of alcoholic beverages and food containing alcohol](https://www.legislation.gov.au/Series/F2015L00469) [↑](#footnote-ref-6)
6. For further information see [Proposal P1050 – Pregnancy warning labels on alcoholic beverages](https://www.foodstandards.gov.au/code/proposals/Pages/P1050Pregnancywarninglabelsonalcoholicbeverages.aspx) [↑](#footnote-ref-7)
7. 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. [↑](#footnote-ref-8)
8. The standard pictogram refers to a silhouette of a pregnant woman holding a drinking glass enclosed within a circle with a diagonal strikethrough. [↑](#footnote-ref-9)
9. The authors conducted a one-way 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. [↑](#footnote-ref-10)
10. The DrinkWise style guide recommended a minimum height of 8mm. [↑](#footnote-ref-11)
11. [See section 1.3 in the Call for Submissions report for Proposal P1050](https://www.foodstandards.gov.au/code/proposals/Pages/P1050Pregnancywarninglabelsonalcoholicbeverages.aspx) [↑](#footnote-ref-12)
12. 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. [↑](#footnote-ref-13)
13. Now known as the Food Ministers’ Meeting [↑](#footnote-ref-14)
14. Information and downloadable pregnancy warning labels are available at [Pregnancy warning labels on alcoholic beverages (foodstandards.gov.au)](https://www.foodstandards.gov.au/industry/labelling/Pages/pregnancy-warning-labels.aspx) [↑](#footnote-ref-15)
15. See section 9 in the [P1050 Approval Report](https://www.foodstandards.gov.au/code/proposals/Pages/P1050Pregnancywarninglabelsonalcoholicbeverages.aspx). [↑](#footnote-ref-16)