Submission to Food Standards Australia New Zealand

On

Proposal P1050 – Pregnancy Warning Labels on Alcoholic Beverages

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25 October 2019

Brewers Association of New Zealand Inc., PO Box 25526, Wellington 6146, New Zealand.

1. About us: The Brewers Association of New Zealand

1.1 The Brewers Association of New Zealand (BANZ) represents major New Zealand brewers and has a core purpose of celebrating beer, its contribution to the economy and to social wellbeing through responsible consumption.

1.2 Our members (Lion New Zealand and DB Breweries Ltd) produce approximately 82% of the beer brewed in New Zealand. The brewing industry is a major contributor to the ongoing success of the New Zealand economy – the grain to glass value chain was worth $2.3 billion in the year ending March 2017. There are at least 214 commercial brewing operations throughout New Zealand[1] and the brewing industry contributes over $645 million to GDP.

1.3 Our core principles include:

a) Drinking beer can add to an adult's enjoyment of life, and as a lower alcohol and natural product, can be part of a balanced lifestyle when enjoyed in moderation.

b) Beer plays a positive role in our society and the economy due to its important role in the agricultural, brewing, tourism and hospitality sectors, as well as our culture and heritage.

c) supporting targeted efforts by industry, government and the community to reduce alcohol misuse; and

d) Brewers Association members as responsible New Zealand entities play an important role in minimising the negative effects of Foetal Alcohol Spectrum Disorder (FASD) and are committed to targeted interventions to do so.

1.4 This submission has been prepared on behalf of the Brewers Association of New Zealand by Dylan Firth, Executive Director of the Brewers Association. He can be contacted on 027 6888 488 and dylan.firth@brewers.org.nz

[1] NZIER Report – Brewing in New Zealand

2. Introductory Comments

2.1 BANZ acknowledges that FASD is a preventable but incurable condition caused by foetal exposure to alcohol in the womb. While awareness of FASD is on the rise in New Zealand better targeted initiatives can be made to improve the public knowledge of this issue.

2.2 We note that based on available evidence pregnant women in New Zealand are drinking less. However, it is clear more needs to be done.

2.3 While it makes sense for the industry to continue and build upon the awareness work it is already doing, as demonstrated through pregnancy warning labelling and initiatives like the Cheers! 'No alcohol means no Risk' campaigns, the beer sector is also open to partnering with government, health groups, community groups, clinicians and GPs, as appropriate, to assist with further informing and educating pregnant women and women who may be preparing for pregnancy, as well as the general community, about FASD.

2.4 BANZ supports targeted interventions where the outcomes can be truly identified as having a positive impact. However, BANZ is cautious about implementing mandatory measures that are based on weak or less than adequate data and where other options are available and accepted as more appropriate by many parties involved. It has been proven on a multitude of occasions that labelling alone is not effective[2].

2.5 It would be remiss of BANZ not to mention the alcohol beverages industry has been proactive and undertaken a range of initiatives and measures to reduce alcohol related harm in the community. Through the voluntary uptake of labelling on beer from BANZ members on all their alcoholic beer products through to in-store and social media campaigns such as the recent Cheers Safer Pregnancy initiative.

2.6 The Safer Pregnancy initiative funded by BANZ members along with Pernod Ricard has been utilised in a three phase video message delivered through social media and YouTube. To date we have had over 165,000 views.

2.7 To this end, BANZ highlights the ongoing investment and initiatives along with existing tight controls on marketing of alcohol which shows the industry's commitment to the promotion of responsible and appropriate alcohol consumption. We believe these activities are important because the research consensus on the impact of warning and advice labels is that while such labels can raise awareness of an issue, they do not change drinking behaviour in and of themselves[34].

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[2]Food Regulation Standing Committee Decision Regulation Impact Statement (2018) Pregnancy warning labels on packaged alcoholic beverages, pp 2.

[3] T Stockwell, A Review of Research into the Impacts of Alcohol Warning Labels on Attitudes and Behaviour, Centre for Addictions research of BC, University of Victoria, Canada, 2006, http://www.uvic.ca/research/centres/carbc/assets/docs/report-impacts-alcohol-warning-labels.pdf

[4] T Babor, R Caetano, S Casswell, G Edwards, N Giesbrecht, K Graham, J Grube, P Grunewald, L Hill, H Holder, R Homel, E Osterberg, J Rehm, R Room and I Rossow, Alcohol: no ordinary commodity – research and public policy, Oxford University Press, Oxford, 2003.

2.8 The alcohol industry's commitment to ongoing investment in voluntary initiatives in labelling and other areas demonstrates the industry's desire to promote the appropriate and responsible consumption of alcohol.

2.9 Finally, BANZ consistently advocates for alignment between all proposed labelling changes. Currently, industry is faced with possible changes to labels relating to pregnancy, sugar, carbohydrate content, allergens, and nutrition panel information. Without alignment, the non-streamlined nature of multitude of current and upcoming proposed changes will burden industry with significant and unnecessary cost.

2.10 BANZ implores FSANZ to work towards alignment across the consultations. Further, BANZ requests that FSANZ communicates with other government sectors such as MfE who are currently undertaking a design for possible container deposit/Return schemes which would require further label changes.

2.11 This submission should be read in conjunction with BANZ members DB Breweries and Lion New Zealand's submission. This will provide greater detail on individual business costs and impact.

3. Departure from Policy Guideline process

3.1 BANZ is concerned that this Proposal is the result of a flawed process in which FSANZ has not been able to properly fulfil its responsibilities under the Food Standards Australia New Zealand Act 1991 (the FSANZ Act). In the absence of formal Policy Guideline from the Forum, FSANZ has erroneously and almost exclusively relied upon the DRIS in substitution for the performance of its own functions under the FSANZ Act. The result is that it appears FSANZ has failed to take a full view of the evidence or weigh all of the relevant considerations appropriately.

4. The role of the Forum in initiating a new food standard

4.1 The food regulatory system in Australia and New Zealand depends upon a division of responsibilities between the body known as the Australia and New Zealand Ministerial Forum on Food Regulation (the Forum) and FSANZ. In simple terms, the Forum is responsible for setting out food policy and FSANZ is responsible for developing food regulatory measures to implement such policy.

4.2 The Forum does not have a generalised mandate to direct FSANZ to develop food standards or to dictate their content. Its role and powers in relation to FSANZ, and FSANZ's obligations in respect of the Forum, are circumscribed by the terms of the Food Regulation Agreement and the FSANZ Act.

4.3 When the Forum wishes FSANZ to undertake the process of developing a standard, the correct procedure is for the Forum to formulate a Policy Guideline. Section 3(a)(ii) of the Food Regulation Agreement states that the Forum has responsibility for "the development of policy guidelines for setting domestic food standards".

4.4 In turn, Section 18(2)(e) of the FSANZ Act requires FSANZ to have regard to any written policy guidelines formulated by the Forum when developing food regulatory measures. This is the only input from the Forum that FSANZ is required by law to take into account when developing a food regulatory measure.[5]

4.5 Typically, a formal Policy Guideline is a brief statement of policy. It is clear that a Policy Guideline should respect the statutory roles of the Forum and FSANZ. The Forum's own guidance states:

The Policy Guideline needs to be clear, comprehensive and consistent but should not be so prescriptive that it specifies the details of standards to FSANZ, and therefore cause potential conflict with the procedures that FSANZ undertakes in developing food standards.

4.6 The Forum has a well-established process that should be followed to arrive at a Policy Guideline.[6] The process that has been followed by the Forum in the present case does not adhere to the publicly notified process of establishing a Policy Guideline.

4.7 Once a policy outcome has been properly identified, the established procedure for the formulation of a Policy Guideline is set out on the Forum's website. It can be summarized as follows:

- a working group of the FRSC prepares an options paper including a regulatory impact statement;
- the FRSC reviews the options paper and makes a recommendation;
- the recommendation is put before the Forum for consideration;
- if the recommendation is to develop a standard, a Policy Guideline is then developed;
- the Policy Guideline must then be considered and approved by the Forum.

5. Failure to formulate a Policy Guideline

5.1 In the present case, it appears that the necessary process of developing and considering a Policy Guideline has been skipped. The DRIS operates as an options paper with a regulatory impact statement. But it does not appear in form or process to be a formal Policy Guideline in itself.

5.2 In the October 2018 meeting of the Forum, the Forum simply noted the DRIS and proceeded to request to prepare a food standard. It did not request the preparation of a Policy Guideline, and its decision was not in itself a Policy Guideline. The relevant text from the Forum's Communiqué of 11 October 2018 reads as follows:

The Forum noted a Decision Regulation Impact Statement (DRIS) with four options for progressing pregnancy warning labels on packaged alcoholic beverages. The DRIS was prepared by the Food Regulation Standing Committee and took into account stakeholder views provided through a targeted stakeholder consultation in May and June 2018 and further research, modelling and evidence gathering.

The Forum agreed that, based on the evidence, a mandatory labelling standard for pregnancy warning labels on packaged alcoholic beverages should be developed and should

[5] Section 18(2)(e) FSANZ Act.
[6] https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/steps-in-the-policy-framework

include a pictogram and relevant warning statement. The Forum requested Food Standards Australia New Zealand (FSANZ) develop this mandatory labelling standard as a priority and that the work be completed expeditiously.

The Forum recognised the efforts of a large segment of the sector, including many small businesses, in voluntarily adopting pregnancy labelling. In recognition of these efforts, the Forum called for comprehensive consultation and appropriate transition timelines and stock-in-trade exemptions on new arrangements.

5.3 There is nothing in the form of this decision to suggest that it is intended as a formal Policy Guideline. It has not been published as a Policy Guideline by FSANZ on its website, as is required by the FSANZ Act for any Policy Guideline to be taken into account in the development of food regulatory measures.[7] FSANZ itself noted in the Call for Submissions that there was no Policy Guidance relevant to this Proposal.

5.4 As a result of this departure from due process, there is significant uncertainty as to FSANZ's obligations in respect of the Forum's request, the nature of the policy that FSANZ is required to follow, and the information that FSANZ is required to take into account. In our view, many of the failings of the Call for Submissions flow from the failure of the Forum to adhere to established processes, respect the division of labour between the Forum and FSANZ, and to provide FSANZ with clear policy guidelines.

6. FSANZ reliance on the DRIS

6.1 The difficulties created by the absence of a Policy Guideline are evident from the first introductory pages of the Call for Submissions. No reference is made to a Policy Guideline, because none has been formulated. Instead there are references to the Forum's decision of October 2018 and the DRIS. Paragraph 1.3 begins with the words "The DRIS provides policy advice to FSANZ […]". Further of, at page 51 of the Call for Submissions, it is stated:

"There are no specific policy guidelines formulated by the Forum which apply to this proposal, however, the DRIS provides ministerial policy advice to FSANZ."
FSANZ considers the proposed mandatory pregnancy warning label is consistent with the objectives and advice in the DRIS."

6.2 While FSANZ might well be attempting to make the best of the situation that they have been presented with by the Forum, that does not alter the fact that the DRIS has no formal status as policy advice to FSANZ and is not binding upon FSANZ.

6.3 The DRIS is prepared by the FRSC which, pursuant to the Food Regulation Agreement, is supposed to coordinate policy advice to the Forum – i.e. not directly to FSANZ. To the extent that such advice must be taken into account by FSANZ, it is through the mechanism of a Policy Guideline formulated by the Forum.

6.4 It is clear from the legislation that policy advice from the FRSC to the Forum, such as the DRIS, cannot in itself determine the scope of FSANZ's activities in developing a food standard. Nor can it dictate the content of such standards – which is in any event outside of the Forum's mandate even if correctly formulated as a Policy Guideline. FSANZ is required by

[7] Section 18(3) FSANZ Act

law to undertake these activities for itself and it should not abdicate its responsibilities by inappropriate reliance on the DRIS.

6.5 Section 18(1) of the FSANZ Act requires FSANZ to pursue the following objectives (in descending priority order) of the Authority in developing or reviewing food regulatory measures and variations of food regulatory measures:

a) the protection of public health and safety; and
b) the provision of adequate information relating to food to enable consumers to make informed choices; and
c) the prevention of misleading or deceptive conduct.

6.6 Section 18(2) requires that FSANZ must also have regard to the following:

a) the need for standards to be based on risk analysis using the best available scientific evidence;
b) the promotion of consistency between domestic and international food standards;
c) the desirability of an efficient and internationally competitive food industry;
d) the promotion of fair trading in food;
e) any written policy guidelines formulated by the Forum on Food Regulation for the purposes of this paragraph and notified to the Authority.

6.7 Section 18(3A) states that policy guidelines formulated by the Forum must not be inconsistent with the objectives set out section 18(1).

6.8 In other words, written Policy Guidelines from the Forum are the only input from the Forum to which FSANZ is legally required to have regard. Additionally, such Policy Guidelines are only one of a range of factors that must be taken into account by FSANZ and should not be given any greater or less weight that such other factors.

6.9 It should also be taken into account that the recommendations of the DRIS were only noted and not specifically adopted by the Forum. The recommendations and advice in the DRIS go considerably further than the request made by the Forum to FSANZ (whatever its actual status). The Forum only asked FSANZ to develop a mandatory labelling standard for pregnancy warning labels on packaged alcoholic beverages as a priority and expeditiously. It did not ask FSANZ to adhere to the DRIS as binding policy advice.

6.10 Nevertheless, FSANZ has placed the DRIS at the centre of its process, allowing it to determine the scope of the proposal.[8] The Call for Submissions appears to approach the DRIS as if it were a binding document to which FSANZ was obliged to have regard, leading it to predetermine several issues that FSANZ is required to consider for itself.

6.11 One particularly concerning example is in relation to label design. FSANZ appears to have taken directly from the DRIS the proposition that a highly prescriptive approach should be taken to label design elements. Label design is a matter of detail which is squarely within FSANZ's remit and should not be dictated by the Forum – and certainly not by reliance upon the DRIS.

[8] Section 1.5

6.12 FSANZ reliance upon the DRIS led to the establishment of a principle for label design elements as follows: *Principle 1: Have regard to policy advice in the DRIS provided to FSANZ, with particular reference to the recommendations related to warning label design*.[9]

6.13 FSANZ then went on to adopt the recommendations in the DRIS on design labelling elements. On almost every one of these recommendations, the scientific evidence in FSANZ's own literature review is weak, irrelevant or in some cases non-existent. However, in the absence of an adequate scientific basis, FSANZ has relied upon the DRIS as determinative, as illustrated by the table below.

DRIS "Principle"	**FSANZ Literature Review**	**FSANZ Consumer Survey**	**FSANZ Proposal**
Use short warning messages and words such as 'Warning' or 'Health Warning' to indicate it is a warning label.	No studies of specific relevance identified. Extrapolation from general studies only.	Only tested the words HEALTH WARNING.	Signal words: HEALTH WARNING
Warning label should be separated from other information such as 'enjoy in moderation', e.g. placed in a box, clear space used around the warning label.	No evidence about separation or clear space. Only low quality experimental evidence regarding wide, coloured borders.	Not tested.	3mm clear space border required.
Contrasting colours are used. The colour green should not be used as it can cause confusion while the colour red receives the most attention and is readily associated with being a warning.	No studies indicate that colour green should not be used. Insufficient evidential basis to suggest that red colour is the only effective colour or more effective than other colours / combinations.	Not tested.	HEALTH WARNING, circle and strikethrough must be in red. Background must be in white.

7. Prescriptive approach to label design

7.1 BANZ is concerned about the implications of the prescriptive approach taken in relation to the design of the label. As noted above, this design appears to have been dictated by an incorrect reliance upon the DRIS rather than adherence to the existing design principles embodied in the Food Standards Code.

7.2 The unusual nature and level of prescription around the specified label design elements greatly increase the cost to businesses whose operations are designed around the normal provisions of the Code. Yet the departure from the norm is barely acknowledged, let alone justified.

[9] Call for Submissions p.26.

7.3 The normal approach taken in the Food Standards Code towards labelling has been to balance flexibility with the need to communicate information to the consumer. This is embodied in the General Legibility Requirements set out in Standard 1.2.4-24 as follows:

> *If this Code requires a word, statement, expression or design to be contained, written or set out on a label—any words must be in English and any word, statement, expression or design must, wherever occurring:*
> *(a) be legible; and*
> *(b) be prominent so as to contrast distinctly with the background of the label.*

7.4 In short, as long as mandatory label information is legible, prominent and contrasting, producers, importers and retailers generally have flexibility as to how they present such information. No font size, type, colour or position is prescribed. This is extremely important to food producers in order to be able to manage costs.

7.5 A small number of warning statements are prescribed in relation to specific foods. For these statements, a form of wording and minimum font size are specified. But there is no requirement for a signal word, a box, a border, a position on the label, a specific font or capitalisation or any specifications as to colour.

7.6 In some cases, the risk that the existing warning labels refer to is significantly more immediate that FASD – such as the risk of fatal hypoallergenic reaction to the consumption of royal jelly – and the label is the only source of information on that specific risk in relation to that particular product. The risk of FASD is extremely serious, but equally so are the other risks managed by the existing standards governing warning statements. It is difficult to objectively understand why a public health warning should be treated as inherently more important than a food safety warning.

7.7 The motivation for a prescriptive approach to label design elements appears to be the prioritisation of "attention" as the key criterion for the effectiveness of the warning label. FSANZ states in its Literature Review that:

> *Attracting the attention of women, and the general community, is a necessary initial step in the process of attending to, and acting upon, a pregnancy warning label. The warning label competes with other visual elements on the label, and needs to cut-through in order to attract attention of the consumer.*

7.8 This is a step beyond the general principle of legibility that applies to other mandatory label information, including warning statements. Again, it can be questioned why it is more important for this message to gain attention than any other warning or advisory statements.

7.9 The focus on "attention" for the pregnancy warning tends to lose sight of the fact that the warning label is not intended to be the sole source of information for pregnant women or the community on this point. It is only intended to be a trigger.

7.10 This is not to say that "attention" is unimportant. It is simply to say that taking an over-prescriptive approach in order to gain a small amount of additional "attention" must be balanced against: the cost of the measures proposed; the weakness of the evidence supporting many of the proposed design elements; and the intended function of the warning as a trigger rather than as the sole source of information.

8. Use of signal words

8.1 A key example of the inherent problems with the Proposal is the requirement for the use of the signal words HEALTH WARNING. The proposed use of signal words is itself a departure from the existing requirements of the Code by mandating:

- the use of the two specific words HEALTH WARNING;
- the use of capitals;
- the requirement to present the words in the colour red.

8.2 There were no studies identified in the FSANZ Literature Review that tested this precise form of words specifically in the context of pregnancy warning labels. Rather, the choice of words is based on an extrapolation by FSANZ from general studies. However, beyond establishing in broad terms that signal words can help attract attention, the actual findings of the general studies are equivocal and do not appear to provide a solid evidential foundation for this choice of words.

8.3 Indeed, Hassan and Shiu in their recent systemic review of the efficacy of alcohol warning labels not diverging findings regarding signal words and conclude that: "[…] different target populations may perceive the use of signal words and qualifiers differently and further research is needed to clarify the effective use of signal words and qualifiers."[10]

8.4 Similarly, there is nothing in the research that clearly justifies the use of capitalisation. As for the use of colour for the signal words, reliance appears to be place on what is essentially a hypothesis in Wilkinson et al. (2009). It is also important to note that the consumer testing carried out by FSANZ did not test the use of colours.

8.5 It could be questioned whether FSANZ, in considering a third party application for a label change that departed dramatically from the existing requirements of the Code, would be prepared to do so on the basis of such equivocal evidence.

9. Colour, contrast and border

9.1 The FSANZ Proposal mandates a 3-colour label – red and black on a white background – with a border of clear space around the outer box. This is one of the most potentially costly aspects of the proposal for businesses.

9.2 These requirements are completely unprecedented in the Food Standards Code. The only justification for their inclusion is the fact that recommendations along these lines appear in the DRIS – although as above it is not for the FRSC to dictate to FSANZ the details of the food standards that it proposes.

9.3 Proposal P1050 proposes the mandatory use of three colours – black, white, and red PANTONE 485 – for the pregnancy warning label. This is a much more prescribed method of design than previously directed by FSANZ. Especially as it different from what is prescribed by the food standards code General Legibility Requirements set out in Standard 1.2.4-24 which are as follows:

[10] Hassan & Shiu (2018) at p.16.

If this Code requires a word, statement, expression or design to be contained, written or set out on a label—any words must be in English and any word, statement, expression or design must, wherever occurring:

(a) be legible; and

(b) be prominent so as to contrast distinctly with the background of the label.

9.4 This requires any mandatory label information to be prominent, legible and contrasting (as well as meeting the minimum font size requirements set out at Standard 1.2.1-25). But there are no further requirements with regard to colour.

9.5 Mandated colours have the potential to be counter-productive as they may be less visible for products with a red colour scheme. A contrasting, bordered message will still fulfil the function of the proposed warning label as a trigger without an unnecessary departure from existing regulatory practices.

9.6 The justification for a mandated colour is given to attract attention and reinforce the warning nature of the message. It is the view of BANZ that a focus solely on attracting attention but ignoring other considerations does not take into account other functions of the proposed warning statement as a trigger. The most important factor and focus of the design criteria should be the reinforcement of the message over the need to garner immediate attention.

9.7 BANZ believes that viewing the warning label design as a single issue without taking into account other mandatory messaging and advisory statements may reduce the impact and effectiveness of these. When there are multiple mandatory warning and advisory statements specified in the Food Standards Code. There should be no reason for one to be elevate as more important over another. They all deal with serious risks or conditions and should be taken as equally important. Such a significant departure in FSANZ existing practice risks opening the floodgates requests for the mandating of colours for all warning and advisory labels at great cost and disruption to the food sector.

9.8 Overall, the Literature review does not establish that the proposed red-white-black colour combination will give a significant measurable benefit over and above a legible and contrasting warning in other colour combinations such as would justify the additional cost of implementing such a measure. It is particularly notable that there are no studies at all directly related to the mandatory white background and only one study in relation to the clear space border which does not support this as an effective measure.

10. Content of warning statement

10.1 BANZ is concerned that the content of the mandatory warning statement – “Any amount of alcohol can harm your baby” – is scientifically incorrect and may cause undue distress and worry to expectant mothers.

10.2 The content of the mandatory warning statement is unequivocal: it says that any amount of alcohol can be harmful to a baby. However, this statement does not reflect the current state of scientific evidence and even the DRIS does not go so far as to make such a claim. Government authorities cited in the DRIS take the precautionary position that it is not possible to determine a safe level of alcohol consumption for pregnant women and therefore women should not drink while pregnant. Conversely, it is noted that the pictogram alone does accurately portray the Government’s recommendation.

10.3 The precautionary position taken by Government authorities, and many alcohol producers, is very far from establishing a scientific basis for the proposition that any amount of alcohol can cause harm to an unborn child. Indeed, the weight of scientific evidence suggests that low and infrequent consumption is likely to carry a low risk, and there is no evidence that extremely low levels of consumption are harmful. Of course, BANZ does not advocate for such studies to be used to support pregnant woman consuming alcohol while pregnant, but rather they represent evidence contradicting the messaging set out in the proposed warning statement.

10.4 BANZ believes that it is outside of FSANZ's mandate to propose a statement that is scientifically inaccurate. FSANZ is required by law to base standards on the best available scientific evidence.

10.5 In reality, the absolute zero approach implied by the proposed statement is practically unachievable because alcohol can be present in trace amounts in a wide range of common foods such as juices and brewed soft drinks to vinegars to confectionary which may be consumed during pregnancy. The fact that FSANZ has not required mandatory pregnancy labelling on products between 0.5% and 1.15% alcohol by volume is an implicit acknowledgement by FSANZ that it is not accurate to say that any amount of alcohol can harm an unborn baby.

10.6 BANZ is further concerned about the process by which FSANZ arrived at its proposed statement. FSANZ took the approach that the pregnancy warning label must include a statement to convey a message that reflects Government advice not to consume any alcohol during pregnancy. Putting to one side the fact that the Forum did not specifically direct FSANZ to take this approach, FSANZ itself has adopted a process that has resulted in an outcome that goes beyond Government advice.

10.7 FSANZ selected 4 statements for consumer testing; the DrinkWise statement and three other statements:

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

10.8 Two of the four statements were scientifically incorrect. None of the statements included the actual government advice – i.e. don't drink when pregnant.

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

10.10 Participants were required to allocate meanings from a list of prompted choices in order to determine comprehension. Not surprisingly, the two statements framed in the most absolute (but inaccurate) term tended to correlate with the with the prompted choices framed in the most absolute terms. This testing provides no meaningful information about the unprompted understanding of these messages. Indeed, while it may not have been the intention, this methodology was inevitably going to work against the less dramatically worded DrinkWise statement.

10.11 Testing the inaccurate statements against criteria for believability, credibility and convincingness equally provides no useful information. The fact that a statement is believable, credible or convincing has no relevance if that statement is not scientifically accurate or whether it results in behavioural change, or further, whether it results in increased behavioural change than the pictogram alone.

11. Cost Benefit Analysis.

11.1 Firstly, it is the view of BANZ that the undertaking a reliable Cost Benefit Analysis is highly difficult, given the assumed impact of the effectiveness is almost impossible to establish. Furthermore, we believe that the assumptions made in the positive impact of label effectiveness through the break-even principle – which is used in absence of actual rates of change – is inappropriate when evidence in the literature review acknowledges the limited impact of warning label effectiveness.

11.2 In short actual measures could be used, but they may show a lower benefit of changes to labels than through using the break-even principle.

11.3 In a normal cost benefit analysis, the expected rate of change in FASD occurrence would drive the analysis and the benefits calculated. However, rates of FASD occurrence, and more particularly the effect of warning labelling in changing those rates, are not known.

11.4 BANZ also believes the cost of label changes used to determine a cost/benefit solution does not reflect true costs nor do the costs assess the business impact for small, medium and large producers.

11.5 This is particularly so if a mandated red colour is used along with the 3mm exclusion zone. Industry-supplied figures from previous consultations do not reflect the impact of such factors.

11.6 In undertaking a review of the Cost Benefit Analysis, BANZ saw it prudent to seek external advice on the process which FSANZ undertook and information it used to come to the conclusions produced in the discussion document. Therefore, we have engaged the New Zealand Institute of Economic Research (NZIER) to assess the provided Cost Benefit Analysis. This document can be seen as attachment A.

11.7 The assessment by NZIER provides the broad summary of FSANZ's Cost Benefit Analysis as the following:

11.7.1 Overall the FSANZ analysis has been done correctly but not very comprehensively. The principal drivers of the analysis are the compliance costs for industry in changing labels, which may be on the low side and do not distinguish, quantitatively or qualitatively, the different impacts on firms of different sizes; and the value of benefit in avoiding new FASD cases. The different scenarios do not give much sense of how changes in inputs vary the results, as each scenario differs from the others in multiple ways.

11.7.2 None of the scenarios strictly conform to a break-even analysis, in which the Present Value of Net benefits should be zero or as close as practically possible. For the Base case

scenario the A$7.5 million NPV makes little difference: with a zero NPV the analysis breaks even with about 221 avoided FASD cases per year, instead of 225 as in the FSANZ paper. The FSANZ Worst case scenario is even closer to its break-even point.

11.7.3 The Best case scenario is the least conforming of all, having a sizeable net present value of A$93 million. All its input settings favour a better result than the other scenarios, with a much higher value per FASD case avoided, the lowest assumed number of affected SKUs, the lowest unit cost per SKU and a lower discount rate. We have not been able to replicate the results of the Best case scenario on the information in the FSANZ paper.

11.7.4 A break-even analysis identifies how many beneficial outcomes (avoided FASD cases) are required to match the costs of the regulation. The FSANZ results show low percentage reductions in FASD births would suffice, but it does not answer the question of how effective the labelling is at changing behaviour that would reduce alcohol exposure of babies before birth.

11.7.5 The low break-even result of the FSANZ analysis is partly a function of the accumulation of benefits over time and the long 20 year time-frame, which requires fewer cases of avoided FSANZ and/or lower values attached to each avoided case, than would occur with a shorter timeframe. As the effect of new information campaigns, such as label changes, tends to decline over time, so too would the avoidance of new FASD cases.

11.7.6 Twenty years is a long period over which to attribute improved behaviour to a single label change. As FSANZ has used a 10 year time-frame in past assessments of labelling proposals (e.g. on energy labelling of packaged alcohol in 2015), such a shorter time-frame could be more appropriate to apply to P 1050.

11.7.7 When we shorten the period of analysis to 10 years, the true break-even would need 707 FASD cases avoided in that time. The shorter period would require a little over 3 times the avoided cases as the 20 year period. It would also lift those cases from 1.3% of total FASD cases per year at 20 years to around 4.2% of annual cases over the 10 year period, outside the 0.2%-3.2% range of case reduction observed by FSANZ as within the range observed in other countries.

12. Conclusion

12.1 As highlighted earlier, BANZ is not opposed to fair, reasonable and most importantly effective measures in the reduction of harmful use of alcohol, especially in relation to FASD. The core arguments made by BANZ on the proposal for mandatory pregnancy warning labels and their design, centre around the process in which FSANZ reached the proposed design and wording. Primarily using the DRIS as a policy guidance base. Also, the focus on recognition over behaviour change. BANZ believes there is a lack of evidential basis on the proposed designs effectiveness in making these behaviour changes.

12.2 BANZ acknowledges that changes to the design, in partnership with appropriate process and evidence would be acceptable to those affected by them. But in this instance we believe there are some deficiencies.

12.3 Given this, BANZ would ask that the use of mandatory red, black and whites colour be changed to the use of contrasting colour. That the wording HEALTH WARNING be amended to 'pregnancy warning' and as expressed by the evidence internationally. The content of the wording be changed to reflect the evidence, which does not state that 'any amount of alcohol can harm your baby'.

13. Transitional Arrangements

13.1 The current proposal suggests a 2 year transition for pregnancy warning labels to be applied to alcoholic beverages. BANZ are concerned this will not allow the incorporation of any further required changes which may be enacted for other labelling changes that are expected over the next 6 to 12 months. Ideally if industry can manage this all in one change, the overall cost to the sector would be significantly decreased.

13.2 BANZ proposes that any 2 year transition period for pregnancy warning labels be caveated with a condition that allows for this. This would be in the form of a conditions allowing that in the event of additional requirements for label changes occurring over and above pregnancy warning labels and falling within the 2 year transitional period, those affected products may extend the transition period to align with that of the new label change transition period.

14. Notes on P150 Literature review

14.1 The Brewers Association also makes the point that in its assessment of relevant literature on the effects of warning labels and the impact of warning labels on consumption during pregnancy FSANZ has not taken into account the following pieces of research as part of this process.

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NZIER
NEW ZEALAND INSTITUTE OF ECONOMIC RESEARCH

Review of cost and benefit assessment of FSANZ proposal P1050

The net benefits of pregnancy warning labels on packaged alcohol

NZIER report to New Zealand Brewers' Association

October 2019

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Authorship

This paper was prepared at NZIER by .

It was quality approved by

Registered office: Level 13, Willeston House, 22–28 Willeston St | PO Box 3479, Wellington 6140
Auckland office: Ground Floor, 70 Shortland St, Auckland
Tel 0800 220 090 or +64 4 472 1880 | econ@nzier.org.nz | www.nzier.org.nz

Key points

This report provides an independent review of the consideration of costs and benefits in the FSANZ call for submissions on Proposal P 1050 on pregnancy warning labels for alcoholic beverages. The purpose of P 1050 is to reduce the frequency of childbirths affected by Fetal Alcohol Spectrum Disorder (FASD), which can cause life-long detriment to well-being for affected children and increased costs on social support services.

The FSANZ consideration of costs and benefits for P 1050 conforms to a simplified cost benefit analysis (CBA) procedure. **Costs are confined to industry costs of changing labels** that would be incurred at the start of implementation of the regulation. **Benefits are the avoided costs of dealing with cases of FASD** achieved from a reduction in pregnant women's consumption of alcohol attributable to warning labels. The avoided costs accumulate over time.

The FSANZ results suggest very small proportionate reductions in new FASD cases per year would be required to produce benefits that outweigh the costs of the regulation. They present three scenarios, Worst case, Base case (most likely) and Best case, but these are not very informative of how robust results are to changes in individual assumptions, other things held constant (Table 1).

Table 1 Summary of FSANZ CBA results and key inputs

		Worst Case	Base Case	Best Case
Benefit	PV$	615,814,904	358,801,611	351,604,741
Cost	PV$	611,107,875	351,319,011	258,336,031
Net benefit	**PV$**	**4,707,029**	**7,482,600**	**93,270,877**
Change in FASD #/year		**555**	**225**	**35**
Change in FASD %		**3.2%**	**1.3%**	**0.2%**
Discount rate		7.0%	4.0%	3.0%
Industry cost $/SKU		7,575	4,924	4,166
Affected SKU #		80,592	71,223	61,853
Cost of FASD $/year		13,847	13,847	79,280

Source: NZIER, drawing from FSANZ (2019), Table 13 and Attachment I

The FSANZ analysis uses a break-even analysis to identify how many beneficial outcomes (new FASD cases avoided) are required to match the costs incurred, because there is insufficient evidence to predict the change in the rate of FASD cases that can be attributed to warning labels. Break-even analysis is a recognised variant of CBA that is commonly used when the rate of change caused by a proposal is indeterminate.

None of the scenarios strictly conform to a break-even analysis, in which the Net Present Value of Net benefits should be zero or close to zero. For the Base case

scenario the A$7.5 million NPV makes little difference: when NPV is zero the analysis breaks even with about 221 avoided FASD cases per year, instead of 225 as in the FSANZ paper. The FSANZ Worst case scenario is even closer to its break-even point.

The Best case scenario is the least conforming of all, having a sizeable net present value of A$93 million. All its input settings favour a better result than the other scenarios, with a much higher value per FASD case avoided, the lowest assumed number of affected SKUs affected, the lowest unit cost per SKU and a lower discount rate. We have not been able to replicate the results of the Best case scenario on the information in the FSANZ paper.

Break-even analysis does not answer the question of how effective the labelling is in changing consumption behaviour that reduces alcohol exposure of babies before birth, but it does illustrate the amount of effect required to justify the regulation's cost.

Assumptions around the cost of changing labels may understate the total cost. Small producers face higher costs for labelling changes per SKU, but the FSANZ cost assumptions do not distinguish between costs for different types of opertions.

Timing delay of future labelling change will see costs rise. Future labelling changes are explicitly included in the FSANZ assumptions, and result in a reduction in the average cost per SKU used in their analysis. If other labelling changes should be delayed the cost of the P1050 regulation would rise and require more FASD cases avoided to break even.

The value of benefits appears to be at the lower end of estimates in other literature. However, it is also unclear how that value relates to the mix of mild, moderate and high severity FASD that occurs among new births.

Twenty-year time frame is a long period over which to attribute benefits to label changes. The benefits of FASD cases avoided accumulate over time in the FSANZ analysis, so the 20 year timeframe means break-even requires fewer cases of avoided FSANZ and/or lower values attached to each avoided case, than would occur with a shorter 10 year timeframe, which FSANZ have used in assessments of other past labelling proposals. As the effect of new information campaigns, such as label changes, tends to decline over time as people become used to them, a shorter timeframe could be more appropriate in this case.

To illustrate the effect of this, we have replicated the results of the Base case scenario and recalculated break-even, holding all inputs unchanged except for the number of FASD cases which adjusts in the calculation. **Shortening the period of analysis to 10 years would require 707 FASD cases avoided to break even, a little over 3 times the avoided cases in the 20 year period.** It would also lift those cases from 1.3% of total FASD cases per year at 20 years to around 4.2% of annual cases over the 10 year period.

Contents

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Tables

1 Introduction

This report provides an independent review of the consideration of costs and benefits in the FSANZ call for submissions on Proposal P 1050 on pregnancy warning labels for alcoholic beverages. The consideration of costs and benefits is included in section 3.4.1 on pages 42-51 of the FSANZ document, plus the attachments on pages 97 and 98.

The document describes how the FSANZ Act requires FSANZ to have regard to whether costs that would arise from a proposed measure outweigh the direct and indirect benefits to the community, government, or industry arising from implementation of that proposal. The FSANZ Act does not specify use of cost benefit analysis, which is a long-established economic procedure for assessing, in monetary terms, whether benefits of an action outweigh its costs. But it is a logical framework to apply to assessing proposed regulatory changes and is endorsed by the Australian Office of Best Practice Regulation.

This review proceeds by outlining the FSANZ consideration in general, comparing it against the requirements of a cost benefit analysis, and then examining in more detail specific issues regarding the consideration of costs and benefits.

2 General review

P 1050 is a FSANZ proposal requiring pregnancy warning labels on alcoholic beverage packaging. The problem that this regulation is intended to address, as described in the Decision Regulatory Impact Statement (DRIS September 2019), is that babies exposed to alcohol during pregnancy are more likely to be born prematurely and may suffer permanent damage to their brain and other critical organs, causing lifelong disability.

This is known as Fetal Alcohol Spectrum Disorder (FASD) and individuals with FASD have greater education and health needs, are more likely to have problems gaining employment and are at increased risk of breaking the law. This increases the financial costs borne by government agencies in fields including health, education, youth support and criminal justice, and also affects individuals and their families through lost productivity and income, raised morbidity and premature mortality.

The burden of FASD in Australia and New Zealand is difficult to estimate due to deficient data. It may affect 1-2% of the populations of the combined countries, but this may be conservative as up to 5% of babies have FASD in USA and Canada, countries with lower rates of alcohol drinking during pregnancy than in Australia and New Zealand.

For the FSANZ consideration, costs are primarily those of industry compliance, in meeting the new regulation and ensuring their products comply. The benefits arise from an assumed reduction in the incidence of FASD among newborns, the benefit of which is equated with reductions in lifetime costs for each FASD case avoided.

2.1 Framing the issue in cost benefit terms

Applying a standard cost benefit analysis (CBA) to the particulars of labelling alcoholic beverages with pregnancy warning labels involves comparing the likely outcome from a mandatory labelling intervention in both Australia and New Zealand against a counter-factual or projection of what would happen in the absence of such intervention. The critical parts of such analysis are:

- Identifying the changes in activity from the intervention occurring, and distinguishing between costs and beneficial effects that are additional to the counter-factual
- Quantifying the costs and benefits and when they occur, valuing them in dollar terms where feasible
- Allowing for the differences in timing of costs and benefits by converting them to present value terms through discounting at a chosen rate
- Applying sensitivity analysis to critical inputs and assumptions to test the robustness of the results.

In such a CBA, a positive net benefit over the period of analysis (NPV greater than zero) or a benefit cost ratio greater than 1 (Present value benefit/present value cost = 1 or more) are indications that benefits exceed costs and the proposal would be worthwhile.

A labelling intervention is likely to generate a number of compliance costs for affected industries and administrative costs for the regulatory agencies implementing it. The benefits stem from improved information for consumers that enable them to make better decisions and, in this case, reduce the risk of FASD in newborns, improving the lifetime prospects for these children and for their health, productivity and well-being.

To effect any change from the status quo, labelling needs to have a reading impact, raise awareness of an issue and cause some change of behaviour from what would have happened in the counter-factual without the new labelling.[1] Post-campaign surveys tend to show that labelling campaigns can be successful in getting noticed and raising awareness of an issue, but are much less conclusive in demonstrating lasting change of behaviour as a result. This is recognised in the Literature Review on the FSANZ website, which notes that there is "no strong evidence to suggest that where warning labels have been mandated there has been an impact on levels of consumption"[2].

2.2 The FSANZ consideration of costs and benefits

2.2.1 Costs

In the FSANZ consideration of costs and benefits, costs are primarily those for industry in making one-off adjustments to their packaging labels. These are driven off estimates of the number of stock keeping units (SKUs) needing their labels changed (assumed to 40,296 in Australia plus in New Zealand, where data are less complete, between a minimum of 21,557 to a maximum of 40,296). As the regulation would have a 2 year transition period,

[1] "Reading impact" refers to the ability to catch the eye of people so they read the contents; "awareness" refers to knowledge of the issue raised by the label; but effectiveness requires acting on awareness and changing behaviour to reduce the risk being targeted.

[2] FSANZ (2019) Pregnancy warning labels on packaged alcohol – a review of recent literature; page 6

FSANZ assumes most SKUs would have time to use up old stock and adopt new labels without relabelling (assuming most labelled stock has a shelf life of around 4-6 months).

FSANZ assumes warning symbols can be fitted on labels without increasing their size, with an average cost of A$7,575 for the one-off change to SKU labelling, derived from a simple average of a range of values they obtained from submissions. Label sizes are chosen for a various reasons and they have to carry branding material as well as product information for the benefit of the consumer, so there is also a cost (not quantified) if placing a new symbol on the label displaces or encroaches on the space for other information.

FSANZ also assumes that not all SKUs would face that full cost if the pregnancy label changes coincide with other regulatory labelling changes at the same time. Specifically, it assumes labelling costs would reduce by 70% if pregnancy warnings coincide with other label changes, which means a lower cost of A$2,272 faced by 50% of SKUs as a result. If the remaining 50% face the unadjusted average cost above, the average per SKU is A$4,924.

Imposing more than one regulatory requirement on a label at the same time compounds the encroachment of label space, and in some cases may force an increase in size of the label. The FSANZ assumptions about cost of label changes omit this possibility and may therefore be understating the cost of changes to industry.

FSANZ also includes costs for the industry-funded DrinkWise campaign due to a need to align messaging with the new labelling. This is comparatively small, at a one-off adjustment cost of A$650,000. Regulatory changes often also involve additional administrative costs for government's regulatory agencies to oversee the implementation and monitor compliance but these are not included in the consideration as they are anticipated to be performed as part of existing budgeted functions.

Treating administrative costs as within baseline (and hence not a cause of additional cost) would only be accurate if the staff and other resources involved had nothing else to do with their time, i.e. they have an opportunity cost of zero. This is unlikely to be the case. But the overall effect of this omission on this analysis is likely to be very small and not material to the result.

2.2.2 Benefits

FSANZ uses an average value of benefit per avoided case of FASD of A$13,487 per year, drawn from a Canadian study. This is the value attached to both the base case (assumed most likely) and the Worst Case scenario examined in the consideration. This figure is based on only "mild" cases of FASD being experienced. In a third "Best Case" scenario, FSANZ use a higher figure of A$76,002 per new case in Australia and A$92,395 in New Zealand, assuming an equal mix of mild, moderate and severe cases of FASD are avoided per year.

FSANZ claims these figures are understatements of full benefits, because the costs exclude some of those associated with FASD which are more difficult to predict, like future prison or juvenile justice costs. The analysis period is also confined to 20 years, so lifelong benefits beyond that time are not counted but would increase benefits beyond then, although their dollar value would be diminishingly small in present value terms the further into the future they fall.

In a normal cost benefit analysis the expected rate of change in FASD occurrence would drive the analysis and the benefits calculated. However, rates of FASD occurrence, and more particularly the effect of warning labelling in changing those rates, are not known.

Hence the FSANZ analysis uses break even analysis to find out how many new FASD cases, at a given value, would need to be avoided to achieve benefits over time that just equal the costs of the regulation. This is a common approach to analysis where the rates of change attributable to a new regulation are uncertain, but there is better knowledge about the value gain from such cases.

2.3 Analysis structure

The FSANZ consideration does include a simple cost benefit analysis, with discounted cash flows of costs and benefits. The costs of label adjustment are all incurred at the start of the analysis. The benefits occur sequentially each year and accumulate over time.

The cash flow analysis is conducted over 20 years and covers three scenarios: a Base case (assumed to be most likely) which applies a 4% discount rate; a worst case which assumes a higher cost and a higher discount rate (7%); and a Best case scenario which assumes a much higher benefit value and a lower discount rate (3%). While comparing worst, best and most likely scenarios is a common approach used in analysing proposals where outcomes may vary, varying multiple components across cases (unit cost, unit benefit, discount rate etc) tends to obscure the effect of any individual input variable and what precisely is driving result changes.

Results of the analysis are summarised in Table 13 of the call for submissions. The costs of each scenario are readily replicated from the information in the table. The benefits are more obscure and are only clearly intelligible with reference to the table in Attachment I.

By way of example, in the Base scenario in Attachment 1, benefits are calculated as the annual cost saving from avoided FASD cases, plus the cost savings from avoided cases in all previous years. That means an average of 225 fewer FASD cases a year saving an average of $13,847 per year for each year, results in $3.1 million a year throughout the analysis in constant dollar terms (without adjusting for inflation).[3] The exception to this is the first year, in which FSANZ assumes only 3 months of benefit are realised.

Thus, in year 1 the benefit in the Attachment 1 table is A$750,250, in year 2 A$3,901298 (A$0.78m + A$3.1m), in year 3 A$7,022,366 (A$0.78m + A$3.1m+ A$3.1m) and so on, accumulating to A$608 million after 20 years. When discounted at 4% over 20 years this has a present value of A$358.8 million, a little over the A$351.3 million costs identified in Table 13.

A break-even analysis looks at the point at which total costs equal total benefits, so this is only an approximate break-even, because the net benefit is not zero. This then leaves the question of whether the break even result is reasonable for likely to happen, which may be informed by the scale of change to current behaviour, but it is ultimately for decisions makers must make a judgement call when forming their decision.

FSANZ note these break-even results imply reductions in FASD cases of between 0.2% and 3.2%, which are within the ranges of percentage reductions observed in other countries.

[3] Inflation is commonly excluded from cost benefit analysis, as it is simply another variable that must be assumed in the forecast of future values and can be misleading in some circumstances.

3 Specific issues

3.1 Are costs assumed for FASD accurate?

The value attached to avoided cases of FASD has an important role in the FSANZ results. The figure of A$13,847 used in the Base and Worst case scenarios can be traced back to the DRIS (2019) and a specific Canadian study[4] which, referring to "mild" cases of FASD, excludes costs of crime and imprisonment which are associated with more severe FASD. Elsewhere the DRIS used much higher figures (around A$40,000-A$80,000) which, if used here, would make the benefits more valuable and reduce the number of FASD cases avoided that would be needed to break even.

Another study from the web cites a Dr Burd and colleagues, who undertook a review of 32 studies reporting on the cost of FASD, mainly from the US and Canada, to assess its worldwide impact. Twenty of those studies included only healthcare costs for people with FASD, but other studies included costs of residential care, special education, correction systems, productivity losses for caregivers and "intangible costs". Across all studies total costs per person were estimated to be US$23,000 per year for children and US$24,000 per year for adults.[5] This is similar to the assumed values used by FSANZ, after allowing for differences in coverage.

A definitive answer on the value of FASD cases is beyond the scope of this review, but it would appear the values used in the FSANZ paper are on the conservative side compared to other estimates that have been made. However, the FSANZ paper could explain its choices more clearly, particularly with respect to the Best case scenario, where the value per FASD case avoided jumps to around $79, 280 per year on average across both countries, based on an even split between low, moderate and high severity FASD cases. If the incidence of FASD cases can be divided between low, moderate and high severity, presumably a weighted average severity and cost could be determined, but this has not apparently been done.

3.2 Are labelling costs fairly represented?

The FSANZ consideration uses an average relabelling cost of A$7575 per SKU, with weighted averages of A$4,924 when accounting for a proportion of SKUs incurring "mitigated costs" when done in conjunction with other label changes

We understand that earlier submissions to FSANZ from New Zealand Brewers have suggested label change costs in the range of $6,000 to over $11,000 per SKU for label changes alone (not including changes to outer wrappings or cartons). One member gave costs of $500 - $3,000 for design changes on a carton or wrap. These costs do not include administration, record keeping and FTE hours involved, all of which are variable depending on the details of the label change.

In view of this, the FSANZ study may be using compliance costs on the light side in terms of one-off costs of relabelling. We would expect relabelling to be more onerous for smaller

[4] Stade B, et al.. 2009. The burden of prenatal exposure to alcohol: REVISED measurement of cost. *Canadian Journal of Clinical Pharmacology*. 16(1): 91-102

[5] Wolters Kluwer Health (November 2018) High costs of fetal alcohol spectrum disorder; https://www.sciencedaily.com/releases/2018/11/181128154000.htm

producers than larger ones, as the fixed costs will be proportionately larger against their volume production. Figure 1 in the attachments to the FSANZ study indicates there is a broad spread of costs around the mean, and that some attempt to differentiate costs between small, medium and high volume producers would be informative of the distribution of potential impacts of compliance costs.

3.3 Are future label changes completely excluded in their assessment?

Future labelling changes are implicitly included in the FSANZ assessment, as is reflected in their calculation that 50% of SKUs are relieved of 70% of their relabelling cost because of an assumption that they share labelling costs with other regulatory changes. Which changes they are referring to is not specified.

An implication of this is that if those other changes get delayed longer than the 2 year transition window for P 1050, that discount would not apply and 100% of SKUs would face the full assumed cost of A$7575. This would increase the number of FASD cases avoided that would be needed to break even.

3.4 In the context of assumed costs, FSANZ are following their own criteria

We have not identified any FSANZ criteria against which to check their decision, which would require referring to other documents stating their criteria and perhaps their spreadsheet.

4 Overall assessment

The FSANZ consideration of costs and benefits for P 1050 conforms to a simplified CBA procedure. The use of a break-even analysis to identify how many beneficial outcomes are required to match the costs incurred is a recognised and common approach used when the rate of change caused by a proposal is indeterminate. It is appropriate in this case as there is no prior experience of introducing mandatory pregnancy warning labels for packaged alcohol in Australia and New Zealand.

In terms of the critical parts of cost benefit analysis identified above:

- Identifying the change in outcome attributable to the proposal, compared to the counter-factual: a counter-factual is not explicitly defined, but all costs and benefits are described as changes from what would otherwise happen
- Quantifying costs and benefits and when they occur: a narrow range of costs and benefits are quantified, but this is rather limited:
  - Costs are primarily one-off costs for industry incurred at the start of the regulation if it is applied; there are no costs for regulatory authorities to administer the regulation, although there will be an opportunity cost for such tax-funded resources.
- Allowing for differences in timing through discounting: this is done appropriately, although they could provide greater explanation and rationale on:

- the choice of discount rate and the use of different discount rates across scenarios, which makes them technically non-comparable
- The choice of 20 year analysis period, as results of break-even analysis vary with timeframe – analysis over a shorter period (say 10 years) would require more beneficial outcomes at a given value to break even, and that would be arguably more appropriate as the effects of new information campaigns such as labelling changes wear off over time as people become more used to them

- Applying sensitivity analysis to critical inputs: this is not currently done, except to the extent that different scenarios are examined – but as the scenarios differ in different variables (costs, benefits, discount rates) this is not a true sensitivity test that shows how sensitive results are to changes in single input variables while others are held constant (i.e. which variables are most critical to the results).

Overall the FSANZ analysis has been done correctly but not very comprehensively. The principal drivers of the analysis are the compliance costs for industry in changing labels, which may be on the low side and do not distinguish, quantitatively or qualitatively, the different impacts on firms of different sizes; and the value of benefit in avoiding new FASD cases. The different scenarios do not give much sense of how changes in inputs vary the results, as each scenario differs from the others in multiple ways.

None of the scenarios strictly conform to a break-even analysis, in which the Present Value of Net benefits should be zero or as close as practically possible. For the Base case scenario the A$7.5 million NPV makes little difference: with a zero NPV the analysis breaks even with about 221 avoided FASD cases per year, instead of 225 as in the FSANZ paper. The FSANZ Worst case scenario is even closer to its break-even point.

The Best case scenario is the least conforming of all, having a sizeable net present value of A$93 million. All its input settings favour a better result than the other scenarios, with a much higher value per FASD case avoided, the lowest assumed number of affected SKUs, the lowest unit cost per SKU and a lower discount rate. We have not been able to replicate the results of the Best case scenario on the information in the FSANZ paper.

A break-even analysis identifies how many beneficial outcomes (avoided FASD cases) are required to match the costs of the regulation. The FSANZ results show low percentage reductions in FASD births would suffice, but it does not answer the question of how effective the labelling is at changing behaviour that would reduce alcohol exposure of babies before birth.

The low break-even result of the FSANZ analysis is partly a function of the accumulation of benefits over time and the long 20 year time-frame, which requires fewer cases of avoided FSANZ and/or lower values attached to each avoided case, than would occur with a shorter timeframe. As the effect of new information campaigns, such as label changes, tends to decline over time, so too would the avoidance of new FASD cases.

Twenty years is a long period over which to attribute improved behaviour to a single label change. As FSANZ has used a 10 year time-frame in past assessments of labelling proposals (e.g. on energy labelling of packaged alcohol in 2015), such a shorter time-frame could be more appropriate to apply to P 1050.

To illustrate the effect of this, we have replicated the results of the Base case scenario from the table in Attachment I. Allowing for the number of FASD cases to change, but keeping all

other inputs unchanged, the true break-even with NPV=0 arises with about 221 FASD cases avoided over 20 years (a little lower than the 225 cases used in the FSANZ results).

When we shorten the period of analysis to 10 years, the true break-even would need 707 FASD cases avoided in that time. The shorter period would require a little over 3 times the avoided cases as the 20 year period. It would also lift those cases from 1.3% of total FASD cases per year at 20 years to around 4.2% of annual cases over the 10 year period, outside the 0.2%-3.2% range of case reduction observed by FSANZ as within the range observed in other countries.