Submission to Food Standards Australian and New Zealand

PUBLIC CONSULTATION: PROPOSAL P1050, PREGNANCY WARNING LABELS ON ALCOHOLIC BEVERAGES

ALCOHOL BEVERAGES AUSTRALIA

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Executive Summary

Our submission draws your attention to a number of significant flaws in the DRIS which has in turn set the direction of P1050 and its recommendations. These include:

- The extent of FASD prevalence in Australia is overstated by a factor of between 100 and 500 (5% claimed v. 0.01% to 0.05% actual)
- The cost of a label change is understated by a factor of between 12 to 48 ($344.44 stated v. between $4,166 and $16,800 as actual)
- Erroneous 'government advice' ('pregnant women not consume any alcohol' v 'its safest not to drink')

We also believe the lack of consumer testing of the existing DrinkWise label against that being proposed is a major flaw, as is not testing the signal words 'pregnancy warning'.

Before any recommendation can be made that mandating a totally different form of warning will improve outcomes, it needs to be first proven that the existing voluntary initiative has failed to make an impact on the objective of the proposed regulation; or that a variation in message and layout would provide an additional 'net-benefit' that justifies the substantial costs involved. Considering that 98.8% of women either abstain or reduce their alcohol consumption when pregnant, an improvement from 96.6% in 2004, it is highly suggestive that the multi-faceted campaign by DrinkWise has had an impact.

These errors and flaws are of such significance that they have effectively undermined the Cost-Benefit Analysis that was undertaken in the DRIS which in turn gave guidance to FSANZ proposals.

Clearly the process to date is a departure from normal FSANZ independent review processes and would strongly point to the need for FSANZ to consider undertaking their own independent Consultation RIS in its prosecution of P1050.

Should this not be embraced, we respectfully submit that adopting the existing DrinkWise Australia style guide meets the Food Forum decision to introduce a "mandatory labelling standard for pregnancy warning labels on packaged alcoholic beverages" and does so in a way that better delivers on the Principles of Best Practice Regulation.

This provides flexibility across container size, is sympathetic to the overall label design, and doesn't impose additional costs on already compliant industry participants. It further recognises that many wine, beer and spirits are iconic products that represent Australia around the world.

By contrast, adopting the P1050 Proposal selects the highest-cost option, and creates a "Health Warning" that is significant larger and less flexible than other FSANZ warning label requirements.

The reasons we advocate for adopting the voluntary labelling scheme are there old: 1) to minimise excessive costs to industry (and thus potentially to consumers or farmers) and 2) because awareness of the potential harm of alcohol for pregnant women is already at very high levels in the community.

Against the weight of the above reasoning, should FSANZ still be of a mind to continue with a different approach, we encourage you to consider design changes that minimise regulatory burden. These include:

- The removal of the red line and text and allowing for colours other than black: most back labels are printed with only one or two colours to reduce costs. Additional colour imposes a high cost.
- The replacement of "Health Warning" with "Pregnancy Advice" or "Pregnancy Warning": this wording more closely aligns to the Food Forum regulatory goal and is more strongly supported in consumer testing - internal consumer research has previously indicated that more than 70% of women consider the signal words "Pregnancy Warning" (72.2%) more effective than "Health Warning" (24.5%).
- Review the need for text: the mandated French pictogram-only has achieved high levels of awareness and understanding among pregnant women
- If you do decide to require text, to use the NHMRC's wording "It's safest not to drink while pregnant": to ensure that the danger of unintended consequences arising from a total abstinence message is minimised and to remain consistent across all communication channels. [With the imminent completion of the NHMRC review of the Drinking Guidelines, it would also seem prudent to delay any label advice upon which to make recommendations, until it is known whether there will be a change in the Guidelines].
- Providing flexibility: allowing for the use of contrast to be sympathetic to overall label design
- Provide consistency with other FSANZ food and beverage warnings: Specify minimum font sizes that are consistent with other food safety warnings and with overseas countries.

About Alcohol Beverages Australia

ABA is the pan body representing the many industry manufacturers, distributors and retailers that operate legally and responsibly across Australia. Our role is to ensure that regulations are balanced so there is stability and certainty in the market to drive investment, while acknowledging and working with all stakeholders to minimise the harms associated with alcohol misuse.

ABA advocates for evidence-based regulation and policies which target specific at-risk groups as the most effective way of changing behaviour associated with alcohol harm.

Industry's Support of Pregnancy Warning Labels

ABA's members are genuinely committed to harm minimisation and providing accurate information regarding alcohol consumption and pregnancy.

As you would be aware, leaders in our industry have been voluntarily providing a range of drinking advice (including pregnancy) on their containers for over 30 years. Following the 2011 Blewett Review and the decision of the then Food Forum, these messages were confined to adhere to advice on Pregnancy alone. Through DrinkWise Australia, industry created a set of labelling guidelines and funded the multi-faceted campaign suggested in the original Blewett Review that provided a consistency of message through a number of communication channels all centred on the NHMRC advice.

The high uptake of the current pregnancy warning label by manufacturers is testament to the commitment industry has to reducing harm associated with FASD.

Despite the vast majority of products in the liquor shopper's basket already containing such labelling, we respect the decision of the Food Forum in its October 2018 to mandate this advice for the estimated 62,000 – 80,600 containers found for sale in Australian and New Zealand.

In addition to the DrinkWise pregnancy warning label scheme, DrinkWise has also developed a FASD Awareness Program. The program is extensive, incorporating broad-based and targeted awareness measures to ensure this important message reaches not just those women who are pregnant, planning a pregnancy or breastfeeding, but also friends and family supporting them.

The program includes educational videos featuring medical expert Dr Norman Swan, as well as posters and brochures in medical practices across Australia. These resources provide those who may be planning a pregnancy and expectant mothers with a timely reminder of the message and the importance of seeking further advice from medical professionals.

Complementing this multi-faceted campaign has been the production of a number of Point-of-Sale materials which have been utilised by retailers of alcoholic beverages.

As outlined within this submission ABA supports the mandating of the DrinkWise labelling scheme as the most effective means of achieving the primary purpose of P1050.

Effectiveness of the DrinkWise Labelling Scheme in Achieving the Objectives of P1050

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

Having properly considered the problem to be solved, the next requirement is to review potential options against the second Principle of Making Government Policy: *Regulation should only be imposed when it can be shown to offer an overall net benefit*.[1]

ABA submits that mandating the DrinkWise labelling scheme is the most effective way to achieve the primary and secondary objective of P1050 and that there is no justifiable evidence to suggest that the proposed FSANZ labelling design will provide any net benefit above and over the DrinkWise labelling scheme (which is multi-faceted and includes a wider range of retail Point-of-Sale materials and posters and brochures in medical practices).

In establishing this position, ABA consider five fundamental issues as follows:

1. Is there any evidence to demonstrate that the current DrinkWise pregnancy warning labelling scheme is not already working to achieve the primary objective of P1050?
2. Is there evidence that moving away from the current DrinkWise pregnancy warning labelling scheme could have a negative impact on pregnant women?
3. Is there any evidence that the proposed labelling scheme will achieve the primary objective of P1050 more effectively than the current DrinkWise labelling scheme?
4. Can we be certain that there will be no unintended consequences arising from P1050's proposed labels?
5. Does the proposed mandatory label provide enough benefit when compared to the DrinkWise label to justify the significant cost to industry, which would be passed onto consumers or borne through the agricultural supply chain?

The response to each of these questions are outlined in detail in Section One below, while Section Two responds to the Proposal and the DRIS from which it was guided. Section Three outlines concerns over the Literature Review. Section Four focuses on survey effectiveness and introduces new evidence from an industry survey showing a compelling case for using 'pregnancy warning' over 'health warning' should a text-based solution be put forward in the final recommendation.

[1] Australian Government, *The Australian Government Guide to Regulation* (2014)

SECTION ONE – EFFECTIVENESS OF DRINKWISE INITIATIVE IN MEETING REGULATORY OBJECTIVES

Q1: Is there any evidence to demonstrate that the current DrinkWise pregnancy warning labelling scheme is not already working to achieve the primary objective of P1050?

No, the evidence clearly shows that the current DrinkWise labelling scheme is working, a fact which has been highlighted throughout the P1050 process.

The DRIS outlines the primary role of the P1050 process as follows:

> "The primary objective of pregnancy warning labels on packaged alcoholic beverages is to provide a clear and easy to understand trigger to remind pregnant women, at both the point of sale and the potential point of consumption, to not drink alcohol. FASD is prevented if women choose not to drink alcohol when pregnant and pregnancy warning labels complement broader FASD prevention initiatives."

The DrinkWise initiative is a multi-faceted approach that includes educational videos featuring medical expert Dr Norman Swan, as well as posters and brochures in medical practices across Australia, and the production of Point-of-Sale materials (shelf-talkers, floor decals, brochures) which have been utilised by retailers of alcoholic beverages.

The pattern of behaviour among pregnant women in Australia indicates that DrinkWise initiative is providing a trigger to remind women not to drink while pregnant and that there are high levels of awareness amongst women of the harms associated with alcohol consumption during pregnancy.

These patterns of behaviour are examined in Section 2, Alcohol Consumption in Pregnant Women in Australia with key points as follows:

- 74.8% of pregnant women completely abstained from drinking alcohol upon knowing they were pregnant.
- 98.8% of pregnant women either abstained from drinking alcohol or decreased their consumption (96.6% in 2007).
- 55.6% of pregnant women did not consume alcohol when pregnant – this represents a 39% increase in the proportion of pregnant women who abstained from consuming alcohol since 2007.
- 43.2% of pregnant women consumed less alcohol compared to when they were not pregnant – in 2007 this figure was at 56.6% which shows that more pregnant women are abstaining from alcohol altogether instead of decreasing their consumption.

There have also been significant improvements in awareness among pregnant women (the target audience of the Objective) of the DrinkWise labelling initiative over time.

Study	Year	Prompted Awareness
Siggins Miller	2014	26.3%
Siggins Miller	2017	32.5%
Quantum Market Research	2019	56%

It can be anticipated that mandating the existing initiative to all beverage containers will lead to further improvements in awareness levels.

Q2: Is there evidence that moving away from the current DrinkWise pregnancy warning label scheme could have a negative impact on pregnant women?

Yes – best practice when it comes to public health messaging is consistency; moving away from the current scheme means that consistency is lost and pregnant women may become confused in turn, and consequently less likely to follow the advice.

When designing a health campaign, the World Health Organisation (WHO) is clear that consistency in messaging is key. The *WHO Strategic Communications Framework for Effective Communication* states that:

> *Presenting a consistent message from multiple sources increases the likelihood of action.*

Current Australian government advice in the Australian Guidelines to Reduce Health Risks from Drinking Alcohol (the Guidelines) is:

> *"For women who are pregnant or planning a pregnancy, not drinking is the safest option".*

In relation to FASD, the Guidelines go on to state:

> *Health professionals should highlight that:*
>
> - *the risk is higher with high alcohol intake, including episodic intoxication*
> - *the risk appears to be low with low level intake*
> - *it is impossible to determine how maternal and fetal factors will alter risk in the individual.*

The Guidelines are clear in terms of the general advice that it's safest not to drink while pregnant and also provide clear guidance for health professional on communicating with pregnant women the risks of alcohol consumption during pregnancy. At no point do the Guidelines provide the advice that "any amount of alcohol can harm your baby".

The proposed warning label contains the following wording:

> *Any amount of alcohol can harm your baby.*

The proposed message is inconsistent with:

- general advice in the Guidelines,
- guidance provided to health professionals in the Guidelines,
- advice from federal, state and territory Governments, and
- advice from health professionals to pregnant women.

The DrinkWise labelling scheme was developed with best practice in mind. For this reason the official Government advice was adopted in the label, ensuring consistent messages are given to pregnant women from a variety of sources. A move away from a consistent message has the potential to confuse women and make it less likely for them to follow the advice.

The Decision Regulation Impact Statement has taken a position that is not in line with the present evidence-base concerning drinking while pregnant and is different to the existing Drinking Guidelines that state “it is safest not to drink while pregnant”.

Such an approach is also inconsistent with the original Blewett labelling recommendation which called for a multi-faceted campaign – as presently being undertaken by DrinkWise. It would potentially create a range of different Government messages, leading to confusion to the consumer who may, for example, be getting conflicting messaged on their label to what is being provided by medical professionals giving advice to pregnant or breastfeeding women.

ABA considers that extreme options have been preferred without legal justification or indeed entitlement. A mandatory labelling system employing the modalities of wordings and pictograms proposed goes far beyond what is required, especially when the benefits and efficiencies of an industry initiative are properly measured.

In the ABA’s opinion, the clear Ministerial direction provided to FSANZ in its Communique has been re-interpreted in the DRIS by ‘advice’ that is inconsistent with all other “Government Advice”.

This has effectively resulted in FSANZ being told “what to do”, rather than what is best to do.

Advice from Australian governments at both the federal and state levels follow that of the NHMRC Guidelines[2]:

Source	Government Advice
Department of Health DRIS 2019	Pregnant women not consume any alcohol. If a pregnant woman consumes alcohol (of any type), it can cause damage to the developing fetus
FSANZ Proposed Warning Label	Any amount of alcohol can harm your baby
Department of Health (sourced 25 Oct 2019) https://www.health.gov.au/health-topics/alcohol/alcohol-throughout-life/alcohol-during-pregnancy-and-breastfeeding	If you're pregnant, breastfeeding or planning to have a baby, the safest option is to not drink alcohol at all.
NHMRC https://www.nhmrc.gov.au/about-us/publications/australian-guidelines-reduce-health-risks-drinking-alcohol	For women who are pregnant or planning a pregnancy, not drinking is the safest option.
Victorian Government https://www.betterhealth.vic.gov.au/health/healthyliving/Alcohol-and-pregnancy	It is safest not to drink alcohol while you are pregnant.
NSW Government https://www.health.nsw.gov.au/kidsfamilies/MCFhealth/Factsheets/alcohol-in-pregnancy.pdf	For women who are pregnant or planning a pregnancy, not drinking is the safest option
QLD Government https://www.health.qld.gov.au/__data/assets/pdf_file/0022/463720/alcohol-use.pdf	If you are pregnant, planning a pregnancy or breastfeeding it is safest NOT to drink alcohol.
NT Government https://nt.gov.au/wellbeing/pregnancy-birthing-and-child-health/fetal-alcohol-spectrum-disorder	The safest option is to avoid alcohol if you are pregnant or trying to get pregnant.
SA Government https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/health+topics/health+conditions+prevention+and+treatment/alcohol/alcohol+and+pregnancy	For women who are pregnant or planning a pregnancy, not drinking is the safest option.

[2] NSW: https://www.gethealthynsw.com.au/healthier-you/reduce-alcohol/
QLD: https://www.health.qld.gov.au/__data/assets/pdf_file/0025/444634/drugandalcohol.pdf
NT: https://www.healthywa.wa.gov.au/Articles/J_M/Lifestyle-and-planning-to-get-pregnant
SA: https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/health+topics/health+conditions+prevention+and+treatment/alcohol/alcohol+and+pregnancy#targetText=Pregnancy%20and%20breastfeeding%20%E2%80%93%20Maternal%20alcohol,drinking%20is%20the%20safest%20option.
TAS: http://www.drinkthing.tas.gov.au/alcohol/did_you_know
Vic: https://www.betterhealth.vic.gov.au/health/ConditionsAndTreatments/fetal-alcohol-spectrum-disorder-fasd

WA Government https://healthywa.wa.gov.au/Articles/F_I/Is-it-safe-to-use-drugs-or-drink-alcohol-when-pregnant	The safest option for your baby is for you to not take any drugs or drink any alcohol if you are pregnant.
TAS Government https://www.dhhs.tas.gov.au/publichealth/community_nutrition/health_and_community_workers/pregnancy_and_early_childhood_0-5/resources_for_child_and_family_health_nurses/alcohol	If you are pregnant, the safest option is not to drink any alcohol.
ACT Government	[Not able to source ACT Government advice]
Health Direct (All Governments) https://www.healthdirect.gov.au/fetal-alcohol-spectrum-disorders	If you're planning a pregnancy or know you are pregnant, avoiding alcohol altogether is the best way to prevent FASD.

Advice from health professionals and FASD experts also follow that of the Guidelines that is safest not to drink while pregnant. Organisations that provide this advice include:

- NOFASD[3]
- FASD Hub Australia[4]
- Royal Australian College of General Practitioners[5]
- Royal Australian and New Zealand College of Obstetricians and Gynaecologists[6]

ABA is extremely concerned that FSANZ has interpreted the DRIS 'advice' as requiring it to bypass a proper consideration of the evidence on the wording on labels, and on the efficacy of labelling against the Cost-Benefit of a change to the existing voluntary initiative.

Instead, the predetermined "goal" of the process has been to implement mandatory labelling in a manner that ignores both the effectiveness of labelling, in the context of the uptake of labelling information by consumers and existing community awareness, and the need to reliably and adequately inform consumers in the wording used. Separate 'advice' in the DRIS should not have been allowed to pre-empt the independent evaluation of the evidence by FSANZ.

Considering that the NHMRC is presently reviewing the Drinking Guidelines, it is astonishing that the DRIS 'advice' pre-empts what the conclusions of that review might be; and to overrule what FSANZ may have determined through its own review of the evidence.

[3] https://www.nofasd.org.au/latest-news/national-alcohol-guidelines/
[4] https://www.fasdhub.org.au/fasd-information/understanding-fasd/alcohol-in-pregnancy-questions/
[5] https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/red-book/preventive-activities-prior-to-pregnancy
[6] https://ranzcog.edu.au/womens-health/patient-information-resources/planning-for-pregnancy

Q3. Is there any evidence that the proposed labelling scheme will achieve the primary objective of P1050 more effectively than the current DrinkWise labelling scheme?

No – there is no evidence to suggest that the proposed labelling scheme will be any more effective in achieve the primary objective of P1050.

No evidence in the P1050 process to date has been presented to establish that the proposed labelling scheme will achieve the primary objective of P1050 more effectively when compared to the current DrinkWise labelling scheme.

While the literature review has endeavoured to make a case for the elements used in the proposed labelling, there is a clear lack of evidence to support the case. The studies presented in the literature review lacked sufficient relevancy to the subject matter of pregnancy warning labels on alcoholic beverages in Australia and New Zealand.

Full consideration of the literature review can be found in sections 10, 11 and 12 below.

There was no testing of the existing DrinkWise voluntary labelling initiative when FSANZ undertook consumer testing of a its totally new "HEALTH WARNING" label design, meaning that no contemporaneous and comparative information was obtained.

FSANZ Proposal	Current DrinkWise Initiative
	

Q4. Is there a possibility of unintended consequences arising from P1050's proposed labels?

Yes – the policy application of P1050 has not been sufficiently considered at any point in the P1050 process. As such, unintended consequences have not been contemplated.

The literature review was based on a rigid framework that looked at very specific definitions of the elements needed to make an effective label. By taking such a narrow view of the literature, the literature review has not been able to capture the evidence relating to

unintended consequences of the proposed labelling scheme. The issue of unintended consequences is considered fully in Section 3.

Q5. Does the proposed mandatory label provide enough benefit when compared to the DrinkWise label to justify the significant cost to the consumer?

The cost-per-SKU for the proposed label change is a matter of contention with estimates ranging from $4,166 in the most recent FZANZ proposal, to the 2008 Pricewaterhouse Coopers report for FSANZ which identified an approximate average cost of $9k-10k, through to the $16.8k we have identified with our members. Regardless of what is an accurate number, it is clear that any of these scenarios imposes significant costs that are likely to be passed onto consumers at a time of weak economic and wage growth, or create additional pressures to find savings through the agricultural and processing supply chain:

	62,000 SKUs	*80,600 SKUs*
At $4,166 a SKU	**$258.29m**	**$335.78m**
At $10,000 a SKU	**$620.00m**	**$806.00m**
At $16,800 a SKU	**$1.042b**	**$1.354b**

To put this in perspective, for a small craft brewer who would typically create over 25 SKUs a year, this translates into a ~$250,000 cost to their business. For a large winemaker or brewer with 200 SKU's, this will be a ~$2million cost to their business.

At a time when all Governments are seeking to encourage business investment and stimulate economic and wage growth, these significant compliance costs represent a major redirection of funds away from investment opportunities.

Considering that if the DrinkWise labelling scheme was mandated there would be considerably lower cost to be passed onto the consumer, it is important to consider then if the proposed labelling scheme provides sufficient additional benefit, if any, to justify this cost. With 98.8 percent of pregnant women either abstaining from alcohol or decreasing the amount they drink while pregnant it's clear that there is no case to be able to imply that the proposed labelling scheme will provide this additional benefit.

SECTION 2 – SUBMISSIONS TO P1050

1. Interpretation of Government Advice on Alcohol Consumption During Pregnancy

Key points:

- *ABA accepts the NHMRC's advice regarding alcohol consumption during pregnancy as the official government advice.*
- *The NHMRC Guidelines advice is "for women who are pregnant or planning a pregnancy, not drinking is the safest option."*
- *The DRIS, Roy Morgan Research and all other documents associated with P1050 have characterised the government advice as "not to consume any alcohol during pregnancy".*
- *There is a misalignment between the actual government advice as provided by NHMRC and the interpretation of the advice within P1050.*
- *The misinterpretation of government advice has meant that core issues of P1050 have been measured against the incorrect advice and tainted the outcome of DRIS and the advice provided on pregnancy warning labels.*

The Call for Submissions – Proposal P1050 states that:

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

Current Australian government advice in the Australian Guidelines to Reduce Health Risks from Drinking Alcohol (the Guidelines) is:

> *"For women who are pregnant or planning a pregnancy, not drinking is the safest option".*

The Guidelines go on to say:

> *While there is convincing evidence linking chronic or intermittent high-level alcohol intake with harms, including adverse pregnancy outcomes and FASD, there remains uncertainty about the potential for harm to the fetus if a woman drinks low levels of alcohol during pregnancy. It is important that all women of child-bearing age are aware, before they consider pregnancy, of both this uncertainty and the potential risks of harm, so they can make informed decisions about drinking in pregnancy.*

It is clear that the official advice places importance on women of child-bearing age being fully aware of BOTH the uncertainty of the potential harm to the fetus at low levels of

alcohol consumption during pregnancy as well as potential risk of harm. This is why the Guidelines have carefully crafted the advice that for women who are pregnant or planning a pregnancy, not drinking is the safest option.

The fact that the entirety of the P1050 has been based on supposed Government advice not to consume alcohol during pregnancy invalidates the entirety of the related documentation. Most importantly, this has affected the wording and the structure of the Roy Morgan consumer testing. The effects on the consumer testing is further considered below.

2. Alcohol Consumption Amongst Pregnant Women in Australia

Key points:

- *Evidence from official Australian government data suggests that the current awareness of government advice that it is safest not to drink while pregnant is high. However, this has not been acknowledged in the P1050 process.*
- *Once women become aware that they are pregnant, the overwhelming majority cease consuming alcohol.*
- *98.8% of pregnant women in Australia either abstain from drinking alcohol or decrease their consumption indicating a high awareness that it is safest not to drink while pregnant.*
- *74.8% of pregnant women completely abstained from drinking alcohol upon knowing they were pregnant*
- *Of the women that did consume alcohol when pregnant, 97.3% consume 1-2 drinks on any single occasion and 81% consumed alcohol on a monthly or less basis.*

The data from the National Drug Strategy Household Survey (NDSHS) undertaken by the Australian Institute of Health and Welfare (AIHW) has more than 24,000 participants and provides, amongst other information, insight into the behaviour of pregnant women when it comes to alcohol.

The information from the NDSHS shows that awareness that it is safest not to drink while pregnant is high amongst Australian women as their behaviours indicate an overwhelming trend towards both abstinence and reduction in alcohol consumption during pregnancy.

The key points from the NDSHS includes:

- 74.8% of pregnant women completely abstained from drinking alcohol upon knowing they were pregnant.
- 98.8% of pregnant women either abstained from drinking alcohol or decreased their consumption (96.6% in 2007).
- 55.6% of pregnant women did not consume alcohol when pregnant – this represents a 39% increase in the proportion of pregnant women who abstained from consuming alcohol since 2007.

- 43.2% of pregnant women consumed less alcohol compared to when they were not pregnant – in 2007 this figure was at 56.6% which shows that more pregnant women are abstaining from alcohol altogether instead of decreasing their consumption.

The NDSHS also provides the following data in relation to drinking patterns during pregnancy:

- 97.3% of pregnant women consumed a maximum of 1-2 drinks during each drinking occasion (95.8% in 2013).
- A large majority (81%) consume alcohol on a monthly or less basis (77.9% in 2013).

This data clearly demonstrates high levels of awareness when it comes to alcohol consumption and pregnancy. As the intent of P1050 is "to provide a clear and easy to understand trigger to remind pregnant women, at both the point of sale and the potential point of consumption, to not drink alcohol", the outcomes of mandating the pregnancy label as proposed it likely to be negligible as awareness levels are already at 98.8%.

There have also been significant improvements in awareness among pregnant women (the target audience of the Objective) of the DrinkWise labelling initiative over time.

Study	**Year**	**Prompted Awareness**
Siggins Miller	2014	26.3%
Siggins Miller	2017	32.5%
Quantum Market Research	2019	56%

By comparison, the 2007 mandated French pictogram has awareness levels of 66.1% (Dumas et al 2018). For the DrinkWise voluntary initiative to have achieved similar levels of awareness to a mandated French pictogram in a five-year shorter time frame is testament to its success in raising awareness with the target audience.

It is worth noting high levels of awareness among French women and recognition of what the pictogram means. This has been achieved without prescribing a text-based solution and probably would warrant further examination in a Consultation RIS or in the final FSANZ recommendation.

It can be anticipated that mandating the existing DrinkWise initiative to all beverage containers will lead to further improvements in awareness levels.

3. Consultation with Industry

Key Points

- *More timely and meaningful consultation with industry may have assisted in avoiding some of the inconsistencies and issues presented in this consultation draft.*
- *ABA acknowledges the need for P1050 to be considered expeditiously, however, meaningful stakeholder engagement should not be overlooked.*
- *The current consultation period of three weeks is insufficient to provide fully considered input into the process, particularly for ABA as we must consider both the feasibility of the label, costs and the evidence.*

Consultation with Industry to Date

ABA acknowledges there has been significant time placed into the consideration and development of P1050 by Government. P1050 concerns a complex, multifaceted issue with a large and varied stakeholder holder groups.

While ABA appreciates the instances in which industry were acknowledged, there were instances where more meaningful and timely consultation with industry could have been undertaken. Should the consultation with industry occurred prior to key decisions being made, some of the shortcoming of the P1050 process may have been avoided.

An example of this is the consumer testing. Industry was not consulted on any aspect of the consumer testing of the labels. Had we been consulted prior to the consumer testing process being developed the issues outlined in under the heading below may have been avoided.

Current Consultation Period

ABA submits that the three-week consultation period is insufficient to allow for meaningful review and input into the labelling process. While we understand that the Food Forum has asked that P1050 be considered expeditiously, we do not believe that this was intended to come at the cost of stakeholder consultation.

The three-week time line for consultation is particularly short considering this is first time that FSANZ has released the literature review, final costing model and market research. The three-week period is also contrary to guidance provided by the Office of Best Practice Regulation which stipulates at least 30 to 60 days for effective consultation.[7]

[7] https://www.pmc.gov.au/resource-centre/regulation/best-practice-consultation-guidance-note

4. Beverages to Carry the Pregnancy Warning Label

ABA supports the proposed approach as pregnancy warning labels being required on packaged beverages with more than 1.15% alcohol by volume.

5. Transitional Arrangements

Unopened alcohol products can have considerably long shelf lives especially when compared to other consumables. This is reflected in the product life cycle of alcoholic beverages and results in large amounts of stock in trade at any one time.

Given that some alcoholic beverages do not have expiry dates it is therefore more appropriate to provide a 5-year transition period to cater for the potentially large stock in trade issues the industry will face.

The Proposal would also benefit from an acknowledgement that adopting the voluntary DrinkWise initiative would provide a shorter path to achieving broad industry compliance. While a Consultation RIS could explore this further, the industry may be in a position to commit to a shorter time frame should mandating the existing voluntary initiative be supported.

6. Cost-Benefit Analysis has been flawed, which has undermined the DRIS and its recommendations that then underpinned FSANZ proposals

ABA submits that there have been a number of crucial flaws in the development of the cost benefit analysis. These flaws go the fundamental basis involved in the development of the cost analysis and include:

- The cost benefit analysis has not properly been formulated to provide a clear indicator of costs and benefits for a range of label options.
- An unfounded assumption that warning labels will reduce instances of FASD.
- Selective use of evidence in modelling the incidence of FASD.
- Lack of credible evidence for the base figures of incidence of FASD in Australia.

These issues go to the heart of developing accurate costing. Without these issues being addressed, the costing system used cannot be used as part of the decision-making process in P1050.

A high standard of public health protection should be provided to all Australians. Equally, FSANZ must maintain “an effective, transparent and accountable regulatory framework within which the food industry can work efficiently”. The evidence of community awareness

of the risks of alcohol in pregnancy supports a labelling system that is familiar and does not impose unnecessary costs on the industry.

It needs to be stressed that mandated regulation imposes significant costs.

The cost-per-SKU for the proposed label change is a matter of contention with estimates ranging from $4,166 in the most recent FZANZ proposal, to the 2008 Pricewaterhouse Coopers report for FSANZ which identified an approximate average cost of $9k-10k, through to the $16.8k we have identified with our members. Regardless of what is an accurate number, it is clear that any of these scenarios imposes significant costs that are likely to be passed onto consumers at a time of weak economic and wage growth, or create additional pressures to find savings through the agricultural and processing supply chain:

	62,000 SKUs	*80,600 SKUs*
At $4,166 a SKU	**$258.29m**	**$335.78m**
At $10,000 a SKU	**$620.00m**	**$806.00m**
At $16,800 a SKU	**$1.042b**	**$1.354b**

To put this in perspective, for a small craft brewer who would typically create over 25 SKUs a year, this translates into a ~$250,000 cost to their business. For a large winemaker or brewer with 200 SKU's, this will be a ~$2million cost to their business.

Also, the cost of the new scheme to industry has been weighed against the economic impact of foetal alcohol spectrum disorder (FASD) year on year. This is a departure from the principles of Minimum Effective Regulation adopted by COAG and endorsed by the Forum.

We would question why responsible consumers (through industry costs) are effectively paying to implement a labelling initiative likely to deliver any significant change to the 1.2% of pregnant women who continue to drink at risky levels during pregnancy, when the drivers for this behaviour are complex social and cultural issues.

At a time when all Governments are seeking to encourage business investment and stimulate economic and wage growth, these significant compliance costs represent a major redirection of funds away from investment opportunities.

ABA welcomes that FSANZ introduced some rigour into consideration of costs, compared to that encompassed by the DRIS, but we are concerned that it has not extended to the next logical conclusion - which is for FSANZ to conduct its own Consultation and Decision RIS process armed with this new knowledge.

Clearly the Cost-Benefit analysis undertaken by the Department of Health which used the discredited Siggins-Millers cost of $344.44 per label is now totally flawed and cannot be relied upon by Ministers to make a decision.

In light of this, ABA does not accept the concept that wholesale change in labelling is required, and disagrees with many of the financial details presented in the DRIS which has

then underpinned the direction given to FSANZ. A new Consultation RIS process will allow the independent FSANZ to consider these properly and free from poor methodology and process.

As part of Best-Practice Regulation it would now appear the only responsible course of action is for FSANZ and Ministers to reconsider the full range of feasible policy options, and their benefits and costs be properly re-considered.

Once the problem has been properly examined and a case for government intervention has been established, officers should identify the objectives for any intervention and consider all feasible options, of both a regulatory and non-regulatory nature, that could wholly or partly achieve these objectives. Working from an initial presumption against new or increased regulation, the overall goal is the effective and efficient achievement of the stated objectives. The 'status quo' and effectiveness of existing regulations should be considered as an option for meeting the objectives.

Technical Barriers to Trade

WTO rules state that "new measures must not introduce 'unnecessary trade costs' or barriers to trade, especially if the stated objective of the measure—such as protecting public health—could be achieved with a less costly alternative. In addition, governments must ensure that measures do not discriminate against foreign products (in favour of domestic producers)".

While Australia and New Zealand would be within their rights to argue for an exemption under public health grounds, it would need to prove the measure is both 'proportionate' and 'effective'.

We would contend that the proposed label design by FSANZ is the highest cost option available and therefore not 'proportionate'; and both the DRIS and P1050 clearly state that labelling is ineffective in changing behaviour of at-risk groups.

Australia, and to a greater extent, New Zealand, are both relatively small alcohol beverage markets globally. The Australian and New Zealand domestic industry will be in a favoured position to bear the one-off costs associated with a major label change, whereas overseas producers will need to create a country-specific label or undertake costly overstickering to export to the Australian and New Zealand market. The costs to those importers who currently use overstickering will be further multiplied by the printing costs associated with the coloured labels required by the proposals.

Regulatory Burden

The most recent Global Competitiveness Report[8] rated Australia 80th out of 141 countries globally on its score for "Burden of Government Regulation".

The vast majority of beer (~670 craft brewers), wine (~2,200 small winemakers), and spirit (~200 distilleries) producers are small or micro businesses. The burden of regulation falls more heavily on these smaller producers because the bulk of compliance costs are fixed costs, which apply irrespective of the size of the firm, and therefore account for a greater proportion of small firms' managerial and financial resources.

Constant changes to regulatory requirements also make it more difficult for business to plan and make sound investment decisions and may inhibit investment, with flow-on effects for productivity and profitability.

A change in labelling will require not just the costs involved in printing, but will require staff time, creative and design agency costs, checking and approval of plate changes to be compliant, updating of bottle/can shots, websites, etc.

7. Important to clarify goal: Is it raising awareness or changing behaviour?

Key Points

- *The DRIS acknowledges that pregnancy warning labels on alcohol beverages do not, in and of themselves, change the behaviour of pregnant women when it comes to alcohol consumption during pregnancy.*
- *DRIS does not provide any evidence to suggest that the proposed labelling scheme will be any more effective than the DrinkWise labelling scheme in changing the behaviour of pregnant women.*
- *Despite this, the cost-benefit analysis assumes that the proposed pregnancy labelling scheme will decrease the instances of FASD.*
- *While the industry supports pregnancy warning labels on alcoholic beverages, it is important to acknowledge their limitations in changing behaviours and to reflect that adequately in the cost-benefit analysis.*

There is clear acknowledgement in the DRIS that warning labels on alcoholic beverages do not, in and of themselves, change the behaviour of pregnant women when it comes to alcohol consumption.

The DRIS states:

> *It is recognised that health warning labels on alcohol, as an isolated intervention, do not lead to behaviour change.*

[8] http://www3.weforum.org/docs/WEF_TheGlobalCompetitivenessReport2019.pdf

The DRIS further indicates that this is a view widely held by public health, Governments, academia and industry:

> *Responses to the targeted consultation from the alcohol industry, public health, Governments and others (i.e. academics) offered a similar view that the value in pregnancy warning labels is in their role in communicating and raising awareness of the advice that pregnant women should not drink alcohol, and a that multifactorial approach is required to facilitate behaviour change.*

While the DRIS outlines the commitments of the Australian and New Zealand governments to undertake activities to complement pregnancy warning labels, there is still no evidence to suggest that the proposed labelling scheme as part of these activities will prevent the consumption of alcohol during pregnancy (particularly given that the message conveyed by the proposed labels is inconsistent with many of these other initiatives). Nor has there been any evidence to suggest that the proposed pregnancy warning label scheme will be more effective in reducing alcohol consumption amongst women than the DrinkWise labelling scheme.

Despite this, the cost benefit analysis assumes that with the introduction of the proposed pregnancy warning label scheme there will be a decrease in instances of FASD. While the industry supports pregnancy warning labels on alcoholic beverages, it is important to note their limitations in changing behaviours and assumptions that this will occur should not form the basis of the cost-benefit analysis.

8. Modelled Estimates of the Incidence of FASD – 2% is not the Minimum Rate of Incidence

Key Points

- *The model used in the DRIS to estimate the incidence of FASD relied on a starting point of 2% as the minimum incidence of FASD in Australia.*
- *The reference chain for the figure of 2% does not lead to a scientifically rigorous or publicly available source.*
- *Sources which are more scientifically robust indicate much lower incidences of FASD.*

The model used by the DRIS to estimate the incidence of FASD using a starting point of 2% as the minimum of incidence of FASD. The reference chain for this figure is as follows:

- The DRIS references this figure to a Child Family Community Australia (CFCA) paper titled *Fetal Alcohol Spectrum Disorders – Current issues in awareness, prevention and intervention.*
- The CFCA paper references the 2% figure to a House of Representatives Standing Committee paper titled *FASD: The Hidden Harm - Inquiry into the prevention, diagnosis and management of Fetal Alcohol Spectrum Disorders.*

- The House of Representatives Standing Committee paper in turn references a submission made by the Tasmanian Department of Health and Human Services[9]. This submission did not reference or provide any evidence to support the 2% number. This final report upon which the 2% estimate is based makes the following statement without any evidence to support the claim:
    - *It is thought that FASD is under diagnosed and under reported in Australia. A recent estimate is that at least two percent of all Australian babies are born with FASD annually.*

Clearly, chasing through footnotes to eventually find an unreferenced and non-peer reviewed claim of an 'estimate' is not an acceptable level of evidence or proof upon which to then create a Cost-Benefit analysis.

The scientific rigour of this reference chain is not robust, yet has then formed the basis for use as a 'base figure' for further modelling the incidence of FASD. By using the 2% figure without a scientifically sound basis brings the entire modelling of the incidence of FASD into question.

9. Modelled Estimates of the Incidence of FASD – Selective Use of Evidence and poor methodology overstates incidence rates

Key Points

- *The DRIS attempts to model the incidence of FASD in Australia to compensate for data limitation.*
- *In modelling the data, the DRIS relied on a publication in The Lancet which provided international figures for the prevalence of drinking while pregnant and rates of FASD in different countries*
- *The DRIS note the prestige of The Lancet.*
- *The same publication in The Lancet places Australia's rate of FASD between 0.01 to 0.05%. However, this figure was not relied on by the DRIS in reporting the figure of FASD in Australia and modelling instead undertaken.*
- *The selective use of data from a publication raises concerns over the quality of the assessment of the evidence in the DRIS.*

The DRIS attempts to calculate the incidence of FASD in Australia in order to inform the costing analysis. The DRIS accepts that the "minimum" reported incidence of FASD in Australia and New Zealand are 2% and 1% respectively[10] (which as demonstrated above lacks any empirical or real evidence). The DRIS notes that certain stakeholders consider this to be an underestimate and that modelling is required to compensate for data limitations.

9 https://www.aph.gov.au/Parliamentary_Business/Committees/House_of_Representatives_Committees?url=spla/fasd/subs/sub006.pdf

10 Page 25 of the DRIS

The modelling process undertaken by the DRIS starts by considering the rate of alcohol consumption during pregnancy in Australia, New Zealand, Canada and the US. The figures are taken from a publication in The Lancet.[11] The DRIS notes that The Lancet is "the most prestigious health and medical journal".

What the DRIS fails to note is that the very same publication not only provides the rate of alcohol consumption during pregnancy across a number of countries but also the rates of FAS in those countries.

The publication places Australia's FAS rate at between 1 to <5 per 10 000 people (0.01% to <0.05%). The DRIS modelling estimates it to be 2-9% with the mid-point of 5% being adopted.

It seems illogical that the DRIS would praise this publication as being "the most prestigious health and medical journal" and accept half the data presented (alcohol consumption amounts) but ignore the other half (the rate of FAS). This raises serious concerns about the quality of the assessment of the evidence in the DRIS that has been relied on in making decisions regarding pregnancy warning labels.

Further, the DRIS uses errors of fact and extremely poor modelling methodology to claim a 5% FASD incidence rate.

- The DRIS claims that *Based on in-person assessments of school children, the United States Centres of Disease Control reports the prevalence of FASD in school children in United States could be between 1% and 5%.*
- Following the footnote actually shows the following statement from the CDC on FASD rates: *Using medical and other records, CDC studies have identified 0.2 to 1.5 infants with FAS for every 1,000 live births in certain areas of the United States. The most recent CDC study analysed medical and other records and found FAS in 0.3 out of 1,000 children from 7 to 9 years of age.* Translating these into percentages, the 0.2 to 1.5 per 1,000 equates to 0.02% to 0.15%, and the 0.3 equates to 0.03%
- They have then used these incorrect US figures, combined them with a comparison of rates of 'a drink during pregnancy' and created an estimate of FASD incidence of 5% in Australia.

When you compare this "modelling" of the entire population against known and reported rates among high-risk Indigenous Australians that have an incidence of FAS of between 1.87 to 4.7 per 1,000 births (equivalent to 0.187%-0.47%) (Burns et al., 2013), it really begins to stretch the credulity of their modelling and assumptions.

Clearly, the approach adopted in the DRIS and therefore the P1050 is not a scientifically valid method for estimating FASD rates in Australia, or to underpin further Cost-Benefit Analysis work.

[11] https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(17)30021-9/fulltext

10. No consistency of proposed design to other FSANZ warnings or internationally

We respectfully submit that adopting the existing DrinkWise Australia style guide fulfils the Food Forum resolution to introduce a "mandatory labelling standard for pregnancy warning labels on packaged alcoholic beverages".

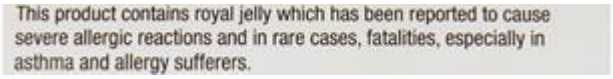
This provides flexibility across container size, is sympathetic to the overall label design, and doesn't impose additional costs on already compliant industry participants. It further recognises that many wine, beer and spirits are iconic products that represent Australia around the world.

The need for flexibility is important and has been somewhat acknowledged by FSANZ in its proposal, however, it is import that this matter is further explored through a Consultation RIS.

As the two examples below demonstrate, even though wine bottles have the ability to carry more label 'real estate', they don't always conform and hence need flexibility of mandated information:

By contrast, adopting the P1050 Proposal selects the highest-cost option, creates a "Health Warning" that is larger than the more important information on the label, being its alcohol

content and allergen information, and makes our world award winning beverages look more dangerous than products that can actually severely harm someone if consumed, such as royal jelly whose warning statement is text only and a minimum size of type of 3 mm (compared to the 9mm warning being proposed by FSANZ for pregnancy):



While we have made prior submissions about whether a text based message is necessary to achieve the regulatory goal, citingat the success of the French pictogram, if you do pursue a text message, it also diverges from the label design principles used in the United States which provide a lot more flexibility and sympathy to label size and design:

- Container Size Minimum Type Size Requirements
  - Over 3 litres: 3 mm
  - Over 237 ml and up to 3 litres: 2 mm
  - 237 ml or less: 1 mm
- Must be readily legible under ordinary conditions and appear on a contrasting background;
- Must appear separate and apart from all other label information

The reasons we advocate for mandating the current voluntary labelling scheme are two-fold: 1) to minimise excessive costs to industry (and thus potentially to consumers) and 2) because awareness of the potential harm of alcohol for pregnant women is already at very high levels in the community.

SECTION THREE: LITERATURE REVIEW

1. Structure of Literature Review and the principle of "Do No Harm"

Key Points

- *The literature review was based on a rigid framework.*
- *As a result, the literature review has not been able to capture the unintended consequences of the proposed labelling scheme.*
- *There is a real risk that the proposed wording of the label will result in undue stress on pregnant women.*

The literature review has used the framework outlined by Argo & Main.[12] ABA submits that by using this framework the literature review has not considered the possibility of unintended consequences as a result of P1050. It is important when any new initiative is introduced that the unintended consequences be seriously considered.

A great deal of research has been done in this area around abstinence-based messages, which is why the present NHMRC drinking guidelines are very carefully worded and have beed adopted in the existing voluntary initiative by industry: "*It is safest not to drink while pregnant*".

To quote the national clinical guidelines for the management of drug use during pregnancy, birth and early development years of the newborn:

> *An abstinence-based approach is not recommended, in part because it could result in disproportionate anxiety among women with an unplanned pregnancy, many of whom consume before they know they are pregnant, but usually without harmful consequences for the infant. Anxiety about alcohol consumption has sometimes resulted in precipitous decisions to terminate a pregnancy.*

As outlined by the Public Health Agency of Canada:

> *The risk is that if women have been advised about alcohol and pregnancy solely through the health advisory label, upon discovering the pregnancy, women will immediately review their alcohol (and tobacco/drug) consumption in the previous one to two months. If the warning label states that the child could or may have been damaged, or is at risk of having neurological defects, this will likely create a sense of fear and guilt. This concern would be particularly acute for first time mothers, or those without strong social support networks, or with other drug dependencies.*[13]

[12] Argo, J. J., & Main, K. J. (2004). Meta-Analyses of the Effectiveness of Warning Labels. Journal of Public Policy & Marketing, 23(2), 193–208.

[13] *Public Health Agency of Canada. Research Update - Alcohol Use and Pregnancy, section 8.2. 2007*

It is important to recognise that these are not the assertions of industry, but are referenced to medical experts such as the Royal Australian College of Obstetricians and Gynaecologists [Reference: Abortion fear over no-alcohol in pregnancy advice. The Age, 15 November 2007], and the British Pregnancy Advisory Service.[14]

This highlights the importance of considering the pregnancy warning label holistically. That is, the wording must be considered for issues such as comprehension and believability but also for the potential of these unintended consequences. As such, ABA recommends that the current Government advice*, it's safest not to drink while pregnant*, be adopted as the wording for the pregnancy warning label.

2. Lack of compelling evidence has created "Best Guess" recommendations

Key Points

- *The studies presented in the literature review lacked sufficient relevancy to the subject matter of pregnancy warning labels on alcoholic beverages in Australia and New Zealand.*
- *Despite the lack of relevant literature conclusions relating to the form of the label are still drawn.*
- *This has led to outcomes such as the use of "Health Warning" being used in the label without sufficient evidence.*

ABA submits that the literature review lacks sufficient evidence that has been drawn from studies relating directly to pregnancy warning labels. Instead, the literature has been based on varying subject matters such as general stimuli and cancer warning labels.

The lack of evidentiary robustness in the 32 peer-reviewed empirical studies that were relied on by the literature review can be summarised thus:

- Less than 10% (2 studies) were rated as high study quality.
- Less than a half (14 studies) related to either Australia or New Zealand.
- Only 9 had a sample size of more than n=1000.
- Almost a third (10 studies) had a sample size less than 100 (lowest at n=22).
- Only 7 related directly to pregnancy warning labels on alcoholic beverages.

[14] https://www.independent.co.uk/life-style/health-and-families/health-news/media-scare-stories-over-drinking-during-pregnancy-are-causing-women-to-ask-for-abortions-9777827.html

It is also important to note the following issues regarding the 9 systematic and narrative reviews that were relied on by the literature review:

- None related directly to pregnancy warning labels on alcoholic beverages.
- Only 3 were published in the last decade.
- There was no citation provided for one study (Wilkinson & Room (2009)).

It is disappointing that the P1050 Proposal has not more strongly acknowledged that there is a lack of evidence to support aspects of the proposed label design, but instead attempted to retrofit literature in another domain to pregnancy warning labels. It is only from reading the supporting documents in detail that it is recognised that "A search of the literature for use of 'pregnancy warning' or 'pregnancy caution' did not locate any studies."

Further, the literature review clearly notes that the search "did not identify any studies that experimentally tested the impact of varying signal words on alcohol warning labels on level of attention attained". Despite this the literature review attempts to apply research on signal words in other areas to pregnancy warning labels.

This has resulted in the use of the signal words "Health Warning" being used in the proposed pregnancy warning label despite the obvious lack of evidence to support its use.

It is important to acknowledge the unique nature of a pregnancy warning label on alcoholic beverages. The reactions to pregnancy warning labels differ greatly to that of the reactions to the labels and stimuli used in some of the research in the literature review. As such, all findings in the literature review cannot be wholly transferable to the likely outcome for the label that has been proposed.

As such, ABA submits that there is no justification for the use of the term "Health Warning". As this is a pregnancy warning label the term that should be applied is "Pregnancy Warning".

SECTION FOUR - ALCOHOL WARNING LABEL SURVEY

Key Points

- *The consumer testing pre-empted major elements of the label, meaning that they were not included as a variable in testing.*
- *As the literature review does not provide sufficient evidence for those elements of the label there is a gap in the evidence base for the label.*
- *The Government advice on alcohol consumption during pregnancy was misrepresented in the consumer testing and cannot be relied upon as a benchmark for understanding.*

ABA submits that the consumer testing pre-empted major elements of the label such as:

- Every configuration had a large bolded "Health Warning" – something that had not been previously canvassed by the Ministerial Forum. Other options such as no signal words, or directly relevant signal words such as "Pregnancy Warning", were not tested.
- No different formats were used – including colours or border boxes.
- The DrinkWise labelling scheme (i.e. wording and format) was not tested.

While we understand that the literature review was intended to provide the evidence base for these elements of the pregnancy warning label, as outlined in the section above, the literature review does not have sufficient evidence to allow it to be relied upon. As such the consumer testing provided an opportunity to thoroughly test all aspects of the label providing a means to fill the evidence gap. Unfortunately, this opportunity was not fully utilised and the evidence gap on the elements of the label remains.

In addition, the questions and propositions put to the participants in the survey misinterpret Government advice on alcohol consumption during pregnancy as being not to consume alcohol during pregnancy. As outlined above, this is in fact not the Government's advice, instead it is that "for women who are pregnant or planning a pregnancy, not drinking is the safest option."

This has resulted in the entire premise of the consumer testing of wording to be based on an incorrect statement. As such, the consumer testing cannot be relied upon to test understanding of the label in comparison to Government advice.

In the short time available for consultation, industry was able to conduct a conduct consumer research to test "Pregnancy Warning" against "Health Warning". The target audience of Australian Females overwhelming selected "Pregnancy Warning" (72.2%) to "Health Warning" (24.5%) to the question *Please select the label that you consider best conveys the message that for women who are pregnant or planning a pregnancy, not drinking is the safest option.*

On this basis, and with respect to other gaps in the evidence, ABA maintains that The Forum cannot be fully satisfied that the proposed format and wording of the labels is optimal. Under those circumstances, you cannot proceed with an initiative that will demonstrably impact industry, entail uncertain consequences for pregnant women and contradict the majority of existing government and expert advice on the subject, all for an effect that the Forum itself admits that, in isolation, will not result in behaviour change.