



NEW ZEALAND WINE

P U R E D I S C O V E R Y

SUBMISSION ON

PROPOSAL P1050 - PREGNANCY WARNING LABELS ON ALCOHOLIC BEVERAGES ("FSANZ Proposal")

A. Name and contact details (position, address, telephone number, and email address):

- Chief Executive Officer, New Zealand Winegrowers
- Level 3, 52 Symonds Street, Grafton, Auckland
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B. For organisations, the level at which the submission was authorised:

- Chief Executive Officer

C. Summary:

New Zealand Winegrowers (NZW) provides strategic leadership for the New Zealand wine industry and represents the interests of all of New Zealand's 1,400 wineries and independent grape growers.

NZW:

- **Fully supports** the reduction of harmful drinking and efforts to reduce the incidence of FASD.
- **Fully supports** advising women not to drink alcohol during pregnancy, and the provision of scientifically accurate information about the risks of doing so.
- **Accepts** the decision of the Ministerial Forum on Food Regulation to mandate pregnancy warning labels, but must insist that any such labels be implemented on the basis of sound evidence, and in a manner that does not result in unjustified cost for producers.
- **Submits** that FSANZ is proposing a warning statement that goes beyond both the best available scientific evidence and the Ministry of Health's advisory guidelines. It is improper for FSANZ to do so. FSANZ should instead propose a statement that is based on the best available scientific evidence:
 - FSANZ has a duty of care based on its enabling legislation to ensure code content is accurate and is based on the "best available scientific evidence".
 - The use of the absolute words "any amount" in the proposed warning statement does not meet that standard because the best available scientific evidence does not establish that "any amount" of alcohol (for example, one molecule) causes harm. That evidence instead

reveals considerable uncertainty about the effects and risks of low levels of consumption, and therefore the prudent risk-based public health approach in New Zealand has been to recommend that pregnant women not consume any alcohol. NZW supports this approach.

- **Submits** that because the statement that “any amount” of alcohol can cause harm is not supported by the best available scientific evidence, **mandating its use would be in breach** of New Zealand’s obligations under Article 5(1) of the *Agreement on the Requirements for Wine Labelling* between World Wine Trade Group member states, which requires that “in any circumstance in which [a signatory state] regulates wine labelling, all information on a label shall be ... accurate, truthful, and not misleading to the consumer”.
- **Submits that the FSANZ Proposal is invalid**, because it is not a proposal of the kind that was evaluated in the cost/benefit analysis in the Food Regulation Standing Committee Decision Regulation Impact Statement (**DRIS**) 2018 used to justify the imposition of mandatory pregnancy warning labelling. As such, the FSANZ Proposal is improper and cannot form a basis for adoption of the measure proposed.
 - The cost/benefit analysis in the DRIS justified the labelling measure by calculating the value of assumed behaviour changes that will result from the warning labels proposed by FSANZ. All of the benefits that were valued arise from avoided incidence of FASD harm – and all were assumed to occur because of changed drinking behaviour by pregnant women, as a direct result of the warning labels.
 - However, both the DRIS and the FSANZ consultation paper expressly acknowledge that labels alone are not shown to influence behaviour (See section D, below).
 - To get around this problem, the FSANZ consultation frames the purpose of the labels as merely being to “convey” information (rather than to change behaviour) and expressly does not consider the effectiveness of the proposed warning statement at changing behaviour. Consistent with this, FSANZ made no attempt to consumer-test whether the proposed warning statement actually has any behaviour-changing effect.
 - **Collectively, the DRIS and the FSANZ proposal cannot have it both ways:** either
 - the labels **are intended** to change behaviour (as assumed and valued in the DRIS), in which case FSANZ must obtain and rely on evidence of the labels’ effectiveness at changing behaviour – which they have failed to do; **or**
 - the labels **are not intended** to change behaviour, but only intended to convey information (as asserted by the FSANZ Proposal), in which case only the value of providing information, not the value of any resulting changes in behaviour, should have been taken into account in the DRIS.
- **Submits** that the signal words “**HEALTH WARNING**” should be removed or replaced by ‘Pregnancy Warning’, ‘Pregnancy Advice’ or other wording consistent with the purpose of the warning. There is no precedent and little rationale provided for introducing the use of “**HEALTH WARNING**” on food in New Zealand and no reliance by FSANZ on material evidence supporting its use, colour or all-caps requirements.
- **Requests** that the size of the label be aligned with the current voluntary size requirements which are well understood and will cause least disruption for industry.
- **Subject to the next paragraph, supports** the proposed transitional period of two years from the date of the change, and the exemption for ‘stock in trade’ (ie all product that is already packaged and labelled) at that date.
- **Strongly submits** that if any additional beverage alcohol label changes are mandated or introduced during the transition period, the implementation period for these proposed changes should be extended to match the timing for the additional changes.

- **Supports** the recognition that the producer should have the ability to place the label on any part of the package.
- **Very strongly submits that** standard for pregnancy labelling needs to be expressly limited in application to only wine intended for New Zealand and Australia (refer section 2.6 of FSANZ Proposal), because the exemption for exports in section 14(2A) of the Wine Act is not broad enough to cover key wine export markets (such as the UK) where universal, but technically voluntary, pregnancy labelling is required. As a result, New Zealand winemakers will be required to place two pregnancy warnings on exports to some markets. Use of the NZ label overseas may also give rise to regulatory issues in export markets.

Comments to specified sections of the FSANZ Proposal:

D. Literature review on the effectiveness of warning labels (section 3.1.1 of FSANZ Proposal)

- NZW **questions FSANZ's reliance on the literature review** given that the FSANZ commissioned peer review of the literature review will not be part of the public consultation process. [page 12]
- NZW **notes** that the literature review draws only weak conclusions regarding how effective the warning statement design is as best at conveying the government advice: "The research findings are not definitive in terms of what statements would work best in Australia and New Zealand". [Page 12] Most of the literature reviewed did not relate to warning statements in respect of alcohol.
- The **literature review should have considered effectiveness of warning labels to change behaviour** as part of broader public health programmes, so the FSANZ Proposal could be evaluated properly [See section M, below]. FSANZ defined "effectiveness" of a warning statement in a very limited way, such that it relates only to effectiveness at "conveying" government advice not to drink alcohol during pregnancy, rather than effectiveness at achieving any behaviour change outcome that could have a health impact. This allowed FSANZ to commission the literature review only on the "effectiveness" of warning labels to "convey the government advice".
 - The literature review itself explicitly noted "[i]t is generally accepted that where alcohol warnings labels have been introduced, they have had limited impact on consumption behaviour" [page 7].
 - Similarly, the DRIS states:

"...pregnancy warning labels, as an isolated intervention, have not been found to change behaviours in relation to alcohol consumption during pregnancy. **It is widely recognised that pregnancy warning labels need to be complemented by broader activates and targeted interventions** that aim to promote behaviour change, reduce the proportion of women who drink alcohol during pregnancy and ultimately prevent FASD." [page 2]
 - Similar findings are noted in the FSANZ Proposal at paragraph 3.1.1.4.
- Despite these limitations noted above, the FSANZ Proposal and the literature review contain essentially no information on, or assessment of, "broader activities and targeted interventions" within NZ government policies that might – or might not – make the proposed measures effective to achieve health outcomes. The only nod in this direction is at pages 54-44 of the FSANZ Proposal, which notes FSANZ's *expectation* of such other public health measures. With respect, an *expectation* should not be relied on to justify this measure and cannot constitute a

basis to conclude that any change in harmful drinking behaviour will occur, or that these specific labelling changes will make any measurable impact or difference.

E. Consumer testing of warning statements (section 3.1.2)

- NZW **does not support** the conclusion of the consumer testing of warning statements and the identification of the preferred option for pregnancy warning labelling.
- NZW **strongly opposes** the inclusion of the words '**HEALTH WARNING**' and the use of the colour red, and other mandatory design requirements in relation to these words, none of which were consumer tested.
- No alternatives to '**HEALTH WARNING**' were tested, for example "Pregnancy Warning" – which would appear to align much more closely to the mandate given to FSANZ to develop and test a pregnancy warning statement, and which may be perceived as more relevant by pregnant women.
- The DRIS justifies imposition of a mandatory warning statement on the basis of behaviour change resulting from the label change (ie on the basis of assumed reduced harmful drinking by pregnant women, resulting in lower incidence of FASD, which is valued). Given this, any consumer testing of the proposal ought have been designed to measure behaviour change resulting from the label change. It did not. The consumer testing therefore does not inform the choice of statement in a way that conforms with the requirements of the DRIS, and therefore FSANZ does not have a sufficient basis to recommend this warning statement. [For more detail, refer Section M]
- We also note that even on its own terms, the consumer testing was equivocal: "For New Zealand no single statement consistently had the highest mean scores" [FSANZ Proposal, page 23].
- NZW is concerned that there has not been a peer review of the consumer testing design and conclusions – something that NZW asked to occur. In particular, we are concerned:
 - that the consumer testing was designed to measure effectiveness of conveying information rather than behaviour change; and
 - that FSANZ's *prompted* consumer testing of the warning statement options may be inappropriate as a means of measuring effectiveness a warning statement that, in practice, will only be viewed *passively* in a consumer purchasing context.

F. Pictogram (section 3.2.2.2)

- NZW **supports** the continued use of the pictogram that has been successfully utilised in voluntary labelling initiatives, as it now an internationally and domestically recognised image for advising against alcohol consumption during pregnancy.
- Given the importance the government is placing on the pictogram, we now look forward to the Health Promotion Agency incorporating it into all of its pregnancy-related activities, as industry has been asking it to do for many years.

G. Warning statement (section 3.2.2.3)

NZW has long supported efforts to encourage pregnant women not to drink, including through voluntary labelling, its activities through the *Cheers!* programme, and industry efforts to encourage the Health Promotion Agency to use the internationally accepted pregnancy warning symbol in its campaigns. These activities align with the New Zealand Ministry of Health's current risk-based advice to pregnant women that:

- “[T]here is no known safe amount of alcohol to drink during pregnancy”¹; and
- “Alcohol is not recommended. Your baby is sensitive to alcohol. The full effects of alcohol on your baby are unknown. Alcohol, even in small amounts, will enter the baby’s bloodstream, so whatever the mother drinks, the baby is having too. Alcohol could affect the development of your baby, especially of his/her brain.”²

NZW **supports** the use of the statement “Its safest not to drink while pregnant” which is factually correct, supported by the best available scientific evidence, and aligns with the Ministry of Health’s advice. Other warning statements, such as “Alcohol can harm your baby” or “Don’t drink when pregnant” would also be supported by the best available scientific evidence. As noted above [see section E], in the consumer testing for New Zealand no single statement consistently had the highest mean scores”, so it is equally open to FSANZ to recommend selection of a factually accurate message.

NZW **does not support** the proposed option of the wording statement on the basis that:

- the wording, imagery and restrictive use of one mandated shade of red are not shown to be a proportionate or effective measure to protect public health, and are not justified by the evidence on which FSANZ relies.
- FSANZ has a statutory duty in its enabling legislation to ensure code content is accurate and reflects the “best available scientific evidence”. Its proposal to use the words “any amount” of alcohol does not meet that standard. It is not within FSANZ’s mandate to propose the use of a factually inaccurate warning statement on the basis that the ends justify the means, even if it believes it is following a policy direction to do so.
 - The FSANZ Proposal (page 13) cites the Australian health guidelines that “the risk of harm to the developing fetus is ... likely to be low if a woman has consumed only small amounts of alcohol (such as one or two drinks per week) before she knew she was pregnant or during pregnancy.” They then go on to state that uncertainties mean it is not possible to identify a *safe* limit. As any scientist or logician will attest, lack of evidence that there is a safe limit for a substance is not the same as affirmatively establishing that no amount is safe.
 - The proposed statement goes beyond the New Zealand government’s risk-based advice, and beyond the best available scientific evidence, to state much more specifically that “any amount of alcohol” can harm a baby.
 - In order to be satisfied that the warning statement “Any amount of alcohol can harm your baby” is able to be used, FSANZ must have relied on best available scientific evidence to conclude that consumption of any amount of an alcohol-containing food (no matter how small) will lead to harm. Any such evidence has not been disclosed as part of this consultation, and we are not aware of any such evidence. However, if that were true, then the same logic would apply equally to all foods and medicines that contain any amount of alcohol. This includes a wide range of foods (consumed in potentially significant quantities by pregnant women) including:
 - most foods containing natural food extracts (such as vanilla essence);
 - fermented foods (such as soy sauce and bread);
 - fresh fruits (such as oranges and bananas); and

¹ NZ Ministry of Health: *Alcohol and Pregnancy What you might not know* HE2523

² NZ Ministry of Health: *Eating for Healthy Pregnant Women* HE1805

- other popular beverages such as fruit juices, ginger beer and kombucha.
- If FSANZ is satisfied that this proposed warning statement is factually correct based on best available scientific evidence that consumption of any amount of alcohol by pregnant women needs to be regulated, then it would be logical for the same mandatory pregnancy health warning to be required on all foods containing any amount of alcohol so that the risk can be properly avoided. We are not suggesting that such labelling should now be required by FSANZ, as that is not our role, however we make this point to highlight the logical consequences of FSANZ's approach.
- There is a risk that the absolute but scientifically unsupported statement “any amount of alcohol can harm your baby” may incorrectly lead pregnant women to believe they have harmed their fetus by consuming a minute amount of alcohol, or inadvertently consuming alcohol. That could cause them unwarranted distress, or indeed lead to take other more serious consequences.
- **Additionally NZW notes** that because the warning statement that “any amount” of alcohol can cause harm is not supported by the best available scientific evidence, **mandating its use would be in breach** of New Zealand's obligations under Article 5(1) of the Agreement on the Requirements for Wine Labelling between World Wine Trade Group member states³, which requires that “in any circumstance in which [a signatory state] regulates wine labelling, all information on a label shall be ... accurate, truthful, and not misleading to the consumer”.

H. Design labelling elements (section 3.2.2.4)

See comments in Section I.

I. Summary of proposed pregnancy warning label design (section 3.2.2.5)

- NZW **supports** the use of the pictogram.
- NZW **opposes** the prescription of the colour red, and **very strongly opposes** the colour red being prescribed as Pantone 485. Other than asserting that the use of one colour will “help ensure consistency” the proposal contains only very weak evidence to support mandating the use of colour, no basis for mandating a single shade of red, no basis for mandating all-caps, and no consumer testing of any of those requirements.
- NZW **observes** that mandating the use of colour, and of one specific Pantone colour, will materially increase the cost of labelling, as it will inevitably be an additional colour to any colours already used on the label. Under the World Wine Trade Group *Agreement on the Requirements for Wine Labelling* (to which New Zealand is a party), the single field of vision concept has allowed for a simple “information label” containing product-specific information, which is typically produced using one single ink. The mandated use of red colour undercuts the simplicity of that approach. Mandating a specific Pantone shade further compounds the costs for any producer already using a different red on their label.
- NZW **does not** support the use of the words ‘HEALTH WARNING’ (see Sections E and G above)

³ New Zealand, Australia, USA, Canada, South Africa, Chile, Argentina, Georgia. Uruguay, the WWTG's newest member state, has not yet acceded to the Labelling Agreement.

- NZW **does not** support the use of the statement ‘Any amount of alcohol can harm your baby’ but supports use of a factually accurate statement (see Section G above)
- NZW **does not** support the use of a border (given that a reliance on contrast can be equally effective)
- NZW **does not** support the prescription of white as a background within the border
- NZW **recommends that** the size requirements for spacing and font size should remain as provided for by the current Drinkwise guidance, as that is well understood by industry, and will limit changes to design and printing. FSANZ has not provided any justification for why the proposed warning statement needs to be larger than other mandatory warnings, such as allergens warning statements.

J. Beverages to carry the pregnancy warning label (section 3.2.3)

- NZW **very strongly submits** that the standard for pregnancy labelling needs to be expressly limited in application to only wine intended for New Zealand and Australia (refer section 2.6 of FSANZ Proposal). In some export markets, pregnancy warning labelling is undertaken on a voluntary self-regulatory basis with Government endorsement. For example, in the UK, voluntary use of the Portman Group / Drinkaware label, which includes the pregnancy warning pictogram (at right) is near universal. In other markets, as in New Zealand, there is a commonly accepted voluntary label design.



Such non-mandatory measures in export

markets do not fall within the exemption in section 14(2A) of the Wine Act. Unless all wine exports (other than to Australia) are exempted from the proposed warning labelling, New Zealand wine exporters will, for many markets, be required in practice to include two health warning labels (the New Zealand label, and the non-regulated export market label), when no other country’s producers are subject to the same requirement. Additionally, in some export markets, the proposed New Zealand pregnancy warning label may be considered to be “health claim” and so trigger other regulatory controls.

- We consider that requiring pregnancy labelling for New Zealand exports other than to Australia would be outside the scope of the mandate for the consultation.
- NZW **reiterates** that FSANZ’s own logic requires the requirement to be extended to all foods containing “any” alcohol. (See Section G). However, with the caveats mentioned above in respect of impact, and lack of evidence, if this FSANZ Proposal is adopted, NZW **supports** the option to have the labelling requirements apply only to alcoholic beverages containing more than 1.15% ABV.

K. Application to different types of sales (section 3.2.4)

- NZW appreciates the work by FSANZ to work through the scenarios for sales requirements, and has no comment to make.

L. Application to different types of packages (section 3.2.5)

- NZW **does not support** the requirement for pregnancy labelling to be on the outer layer of packaging when the label on the packaged product is not clearly discernible through the outer packaging. Such packages are typically used for high value gifts.

- Wine Tourism is an increasing component of the businesses of our members. Cellar doors are a growing distribution channel. Wine purchased at a cellar door is often presented in gift packs or wooden presentation boxes. These are commonly packaged after the decision to purchase has been made.
- For the avoidance of doubt, NZW **opposes** the imposition of labelling on packaging such as paper bags to be used for the safe transportation of a bottle of wine from the point of purchase.

M. Consideration of costs and benefits (section 3.4.1.1 of FSANZ Proposal)

- **The consideration of costs and benefits in the pregnancy warning labelling proposal as a whole (ie both DRIS and the FSANZ Proposal) is invalid, for the following reasons.**
- The cost/benefit analysis in the DRIS justified the labelling measure by calculating the value of assumed behaviour changes that will result from the warning labels proposed by FSANZ. All of the benefits that are valued arise from assumed avoided incidence of FASD harm – and all occur because of changed drinking behaviour by pregnant women.
- However, both the DRIS and the FSANZ consultation paper expressly acknowledge that labels alone are not shown to influence behaviour (See section D, above).
- To get around this problem, the FSANZ consultation frames the purpose of the labels as merely being to “convey” information (rather than to change behaviour) and expressly does not consider the effectiveness of the proposed warning statement (either alone, or in conjunction with other initiatives) in terms of changing behaviour. Consistent with this, FSANZ made no attempt to consumer-test whether the proposed warning statement actually has any behaviour-changing effect.
- **Collectively, the DRIS and the FSANZ proposal cannot have it both ways:** either
 - the labels are intended to change behaviour (as assumed and valued in the DRIS), in which case FSANZ must obtain and rely on evidence of the labels’ effectiveness at changing behaviour – which they have failed to do; **or**
 - the labels are not intended to change behaviour, but only intended to convey information (as asserted by the FSANZ Proposal), in which case only the value of providing information, not the value of any resulting changes in behaviour, should have been taken into account in the DRIS.
- **This is a fundamental flaw that strikes at the heart of the FSANZ Proposal.** If the government wishes to include the value of the assumed health benefits resulting from behaviour change in its DRIS calculation of costs and benefits in order to justify imposition of a warning statement, it must require FSANZ to design a label that evidence shows will achieve that behaviour change, and evaluate the effectiveness of the proposed regulatory measure *as a behaviour change measure*.

N. Transitional arrangements (section 4.1 of FSANZ Proposal)

NZW:

- **Would prefer a longer transitional period, but can support** the proposed transitional period of two years from the date of the change, provided the change in the following paragraph is made.
- **Strongly submits** that if any additional beverage alcohol label changes are introduced during the transition period (whether proposed by FSANZ or other agencies), the implementation period for the currently proposed changes should then be extended to match the timing for

the additional changes. This recognises that other likely labelling changes are currently under development, and would allow those producers who have not already made label changes to implement all proposed changes at once.

- **Supports** the exemption for 'stock in trade' i.e. all product that is already packaged and labelled, at that date.
- **Supports** the recognition that the producer should have the ability to decide where to place the label

O. Draft variation to the Australia New Zealand Food Standards Code (Attachment A of FSANZ Proposal)

Consistent with comments above, NZW **does not support** the draft variation where it relates to the prescription of warning statement, wording, colour, border or spacing for the warning label.

P. Other comments (within the scope of P1050 – see section 1.5 of the FSANZ Proposal)

NZW has no other comments to make.