

## SUBMISSION TEMPLATE

### Policy options targeted consultation paper: *Pregnancy warning labels on packaged alcoholic beverages*

#### Overview

This submission template should be used to provide comments on the policy options targeted consultation paper: *Pregnancy warning labels on packaged alcoholic beverages*.

#### Contact Details

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<b>Date of submission:</b>	14 <sup>th</sup> June 2018

**If we require further information in relation to this submission, can we contact you?**  Yes  
No

#### Privacy

Personal information provided to the Food Regulation Standing Committee (FRSC) as part of the *Pregnancy warning labels on alcoholic beverages* public consultation will be dealt with in accordance with the Privacy Act 1988 (Cth) at [www.comlaw.gov.au](http://www.comlaw.gov.au) and the Australian Privacy Principles at [www.oaic.gov.au](http://www.oaic.gov.au). The Department of Health's Privacy Policy is available at <http://www.health.gov.au/internet/main/publishing.nsf/Content/privacy-policy>.

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If you consider that all or part of your submission should not be released, please make this clear when making your submission and indicate the grounds for withholding the information. Please provide two versions of the submission; one full version **with confidential information identified in red text**, and one with the confidential information removed.

A request made under the *Freedom of Information Act 1982* for access to a submission marked confidential will be determined in accordance with that Act.

**Do you want this submission to be treated as confidential?**  Yes  No

**If yes, please state why:**

## Submission Instructions

Submissions should be received by 5pm AEST on 14 June 2018. The Food Regulation Standing Committee reserves the right not to consider late submissions.

Please complete the attached template for your submission. Note that submissions may not be drawn upon in preparing the decision regulation impact statement (DRIS) to recommend a preferred policy option to the Australia and New Zealand Ministerial Forum on Food Regulation (the Forum) if they:

- are not supported by evidence;
- do not directly answer the questions in the Policy options targeted consultation paper; and/or
- do not use this template.

Please do not change the template.

Where possible, submissions should be lodged electronically. Please send your submission to: [FoodRegulationSecretariat@health.gov.au](mailto:FoodRegulationSecretariat@health.gov.au) with the title: *Submission in relation to pregnancy warning labels on packaged alcoholic beverages*.

OR mail to:

c/- MDP707  
GPO Box 9848  
Canberra ACT 2601

If you need to attach documents to support your submission, please make it clear which question/s they relate to.

## Consultation questions

Please insert your comments against the consultation questions below. These questions correspond to specific sections of the Consultation Paper. If you cannot answer the question or it doesn't apply, please write "nil response" or "not applicable".

**1:** Are these appropriate estimates of the proportion of pregnant women that drink alcoholic beverages? Do you have any additional data to show changes in drinking patterns during pregnancy over time? Please specify if your answers relate to Australia or New Zealand.

This relates to Australia.

The National Rural Health Alliance (NRHA) agrees that these are appropriate estimates of the proportions of pregnant women who drink alcohol during pregnancy. The Australian Institute of Health and Welfare (AIHW) proportions are more likely to be accurate for Australia at around 26% drinking after the first trimester.

In addition, the NRHA also draws on estimates outlined in the Australian Bureau of Statistics National Aboriginal and Torres Strait Islander social Survey 2014-2015.

- The report showed that 13% of Aboriginal and Torres Straits Islander women in remote areas drink alcohol during pregnancy, compared with 9% of Aboriginal and Torres Strait Islander women in non-remote areas (ABS NATSI Social Survey 2014-15 <http://abs.gov.au/AUSSTATS/abs@.nsf/DetailsPage/4714.02014-15?OpenDocument> Table 6.3.)
- The margins of error around these 2014-15 estimates were substantial, and they were considered to be not significantly different from the 2008 estimates of 19.7% and 19.3% in non-remote and remote areas respectively (ABS NATSI Social Survey 2014-15 <http://abs.gov.au/AUSSTATS/abs@.nsf/DetailsPage/4714.02014-15?OpenDocument> Table 6.3.)

Apart from the figures for Indigenous Australian women (which seem to be relatively imprecise and potentially not significantly different from the 26% for pregnant Australian women generally), we are unaware of any rural and remote specific figures for the proportion of pregnant women who drink alcoholic beverages.

However, we are aware that women living in rural/regional areas are slightly (5%-10%) more likely to drink alcohol at risky levels (in exceedance of the NHMRC guidelines - around 10% of women (<https://www.aihw.gov.au/reports/biomedical-risk-factors/risk-factors-to-health/data> table 3). Note that “drinking any alcohol”, and “drinking at risky levels” are different concepts.

We also note that women living in rural/regional areas are two to three times as likely to smoke in the second half of pregnancy, compared with those in major cities, with those in remote areas three to five times as likely to smoke during the second half of pregnancy (reference <https://www.aihw.gov.au/reports/mothers-babies/perinatal-data-visualisations/contents/data-visualisations> see antenatal period).

If this pattern for smoking during pregnancy also applies to drinking alcohol during pregnancy, then the proportion of women in rural and remote areas drinking during pregnancy (currently unknown or unpublished as far as we are aware) could be substantially higher than it is for pregnant women in major cities. This, combined with the higher fertility rate of women in rural and remote areas would make the burden of Fetal Alcohol Spectrum Disorder (FASD) on rural and remote dwelling Australians potentially higher than for other Australians.

We note that the health of babies and children is also influenced by the older males in their lives. We are aware that men living in rural and remote areas are 2-3 times more likely to drink alcohol at risky levels (in exceedance of the NHMRC guidelines) than their male counterparts in Major cities (<https://www.aihw.gov.au/reports/biomedical-risk-factors/risk-factors-to-health/data> table 3).

In this context it should also be noted that:

- Children living in rural/regional areas are 50% more likely, while children living in remote areas are three to four times more likely to be the subject of a child protection substantiation. (<https://www.aihw.gov.au/reports/child-protection/child-protection-australia-2015-16/data>).
- Children living in rural/regional areas are slightly more likely to be classified as vulnerable on one, two or more developmental domains, and in remote areas around twice as likely to be classified as vulnerable (<http://www.phidu.torrens.edu.au/social-health-atlases/data>).

While alcohol is not the only factor that can be associated with adverse outcomes for children, it is well known as a significant one.

The Australian Bureau of statistics does little health survey sampling (apart from ATSI surveys) in remote areas of Australia, and so we have little understanding of health risk factors for the broad population in those areas.

**2: Are these appropriate estimates of the prevalence and burden (including financial burden) of FASD in Australia and New Zealand? Please provide evidence to support your response.**

The National Rural Health Alliance agrees that these are appropriate estimates.

Rootzen et al 2016 suggests that geography and descent are key factors to consider when estimating FASD. In line with these findings, research undertaken in remote areas of Australia (as part of the Lililwan Project Collaboration 2012, referred to in the Consultation Paper), showed how small remote communities with high numbers of Aboriginal and Torres Strait Islander communities have higher prevalence of FASD.

Specifically: of children born in 2002-3 in Fitzroy Valley, Western Australia, 55% were exposed prenatally to alcohol (90% high risk). FASD was diagnosed in 1/5 (19%) amongst the highest rate worldwide.

In line with other research findings, children with FASD:

- had birth defects, learning, behavioural and academic difficulties, ADHD, speech and motor disorders
- Health needs and service use, including hospitalisation rates are high. These children have chronic complex disabilities requiring multi-disciplinary care but services are fragmented and health professionals scarce
- are vulnerable and many will face unemployment, contact with the justice system, and substance abuse

Additional data could be sourced from:

- Lange, S., Rovet, J., Rehm, J., (2017). Neurodevelopmental profile of Fetal Alcohol Spectrum Disorder: A systematic review. *BMC Psychology* 5: 22. doi 10.1186/s40359-017-0191-2
- Popova, S., Lange, S., Bekmuradov, D., Mihic, A., Rehm, J. (2011). Fetal Alcohol Spectrum Disorder prevalence estimates in correctional systems: A systematic literature review. *Canadian Journal of Public Health* 102(5), 336-340.
- Popova S, Lange S, Burd (2013) Cost of Fetal Alcohol Spectrum Disorder Diagnosis in Canada. . *PLoS ONE* 8(4): e60434. doi:10.1371/journal.pone.0060434
- Rootzen, S., Petere, G.J., Kok, G., Townend, D., Nijhuis, J., Curfs, L. (2016) Worldwide Prevalence of Fetal Alcohol Spectrum Disorders: A Systematic Literature Review Including Meta-Analysis. *Alcoholism: Clinical and Experimental Research*. 40 (1) pp.18-32
- Fitzpatrick, J.P. et al (2015). Prevalence of fetal alcohol syndrome in a population-based sample of children living in remote Australia: the Lililwan Project. *J Paediatr Child Health*. 2015 Apr;51(4):450-7. doi: 10.1111/jpc.12814
- Fitzpatrick, J.P. et al (2017) Prevalence and profile of Neurodevelopment and Fetal Alcohol Spectrum Disorder (FASD) amongst Australian Aboriginal children living in remote communities. *Res Dev Disabil*. 2017 Jun;65: 114-126. doi: 10.1016/j.ridd.2017.04.001
- Lupton, C., Burd L., Harwood, R.A., (2004) Cost of fetal alcohol spectrum disorders. *Am J Med Genet C Semin Med Genet*. 15;127C (1):42-50. – Estimated annual cost estimates for the United States range from \$75 million in 1984 to \$4.0 billion in 1998. Estimates of lifetime cost vary from \$596,000 in 1980 to \$1.4 million in 1988.

**3:** Do you have evidence that the voluntary initiative to place pregnancy warning labels on packaged alcoholic beverages has resulted in changes to the prevalence of FASD, or pregnant women drinking alcohol, in Australia or New Zealand? Please provide evidence to justify your position.

The NRHA is unaware of evidence that the voluntary initiative to place pregnancy warning labels on packaged alcoholic beverages has resulted in changes to the prevalence of FASD, or pregnant women drinking alcohol, in Australia or New Zealand.

**4.** Variation in labelling coverage and consistency, and some consumer misunderstanding associated with the current voluntary pregnancy warning labels in Australia and New Zealand were identified as reasons for possible regulatory or non-regulatory actions in relation to pregnancy warning labels on alcoholic beverages.

Are there any other issues with the current voluntary labelling scheme that justify regulatory or non-regulatory actions? Please provide evidence with your response.

The NRHA opinion is that the impact of the warning message is undermined when placed next to wording like ‘Drink wise’, ‘Enjoy responsibly’, or ‘drink responsibly’. Clarity, legibility, size, colour and placement of message and warnings are important. The health warning labels needs to be in a prominent position on alcohol containers.

Sources:

Martin-Moreno J, Harris M, Breda J, Møller L, Alfonso-Sanchez J, Gorgojo L. Enhanced labelling on alcoholic drinks: reviewing the evidence to guide alcohol policy. *Eur J Public Health*. 2013;23(6):1082-7

Pettigrew S, Biagioni N, Daube M, Stafford J, Jones SC, Chikritzhs T. Reverse engineering a “responsible drinking” campaign to assess strategic intent. *Addiction*. 2016;111:1107–13.

Smith KC, Cukier S, Jernigan DH. Defining strategies for promoting product through “drink responsibly” messages in magazine ads for beer, spirits and alcopops. *Drug Alcohol Depend*. 2014;142:168–73.

Smith SW, Atkin CK, Roznowski J. (2009) Are Drink Responsibly alcohol campaigns strategically ambiguous? *Health Commun.*;20:91–9.

Wilkinson C, Allsop S, Cail D, Chikritzhs T, Daube M, Kirby G, Mattick R (2009). Report 1 Alcohol Warning Labels: Evidence of effectiveness on risky alcohol consumption and short term outcomes. Prepared for the Food Standards Australia New Zealand. Accessed 4 March 2014 at: [http://www.foodstandards.gov.au/code/applications/documents/Curtin%20University%20of%20Technology\\_Alcohol%20Warning%20Labels.pdf](http://www.foodstandards.gov.au/code/applications/documents/Curtin%20University%20of%20Technology_Alcohol%20Warning%20Labels.pdf)

**5:** Has industry undertaken any evaluation on the voluntary pregnancy warning labels? If so, please provide information on the results from these evaluations.

The NRHA is not aware of any Industry evaluation on voluntary pregnancy warning labels.

6: Considering the potential policy options to progress pregnancy labelling on alcoholic beverages and address the implementation issues:

a) Are there additional pros, cons, and risks associated with these options presented that have not been identified? Please provide evidence to support your response.

The NRHA believes that there are additional risks of maintaining the voluntary self-regulation approach.

- Option 1a: Voluntary - status quo – without an incentive or the requirement to put labels on alcohol, the lack of prominence currently given to the labels and limited use of text and pictogram together are unlikely to change (see Siggins Miller, 2017).
- Option 1b: Voluntary - self-regulated by industry – there is a risk in allowing industry to continue to self-regulate and there is evidence to show that they have been unreliable in the past. A code of practice would need to be developed independently of the industry to ensure ethical and legal adherence and no conflict of interest (see Petticrew et al, 2017).
- Option 1c: Voluntary – with government style guide. There is a risk that companies may not elect to be signatories to the agreement. For example, there are many companies who are not signatories of the Alcohol Beverages Advertising Code (ABAC).
- **Option 2- Option 2: Mandatory – with government developed label**  
The NRHA believes that Option 2 is the only option that will provide the coverage, consistency, prominence, and consumer awareness and understanding for the warning label to be effective.

Sources:

Alcohol Beverages Advertising Code (ABAC). <http://www.abac.org.au/about/signatories/>

Petticrew et al (2017). How alcohol industry organisations mislead the public about alcohol and cancer. *Drug and Alcohol Review* 37(3), 293-303. <https://doi.org/10.1111/dar.12>

Siggins Miller (2017) Second evaluation of the voluntary labelling initiative to place pregnancy health warnings on alcohol products: Final report. Canberra: Commonwealth of Australia Department of Health). 596

b) Are there other potential policy options that could be implemented, and if so, what are the pros, cons and risks associated with these alternate approaches? Please provide evidence to support your response.

It is the NRHA's position is that only Option 2 a mandatory scheme (with government developed label) will overcome the significant conflict of interest, ensure compliance across the industry and consistent warning label.

Although there has been an increase in the number of market share products that have warning labels, only 48 per cent of all products have some form of warning (as outlined in the consultation paper pg.19).

It is the NRHA's view that the voluntary scheme has not been effective at communicating a clear and consistent message that pregnant women should not drink alcohol.

7: Which option offers the best opportunity to ensure that coverage of the pregnancy warning labelling is high across all types of packaged alcoholic beverages, the pregnancy warning labels are consistent with government recommendations and are seen and understood by the target audiences? Please justify your response.

It is the NRHA's position is that only Option 2 a mandatory scheme with government developed label and regulation will be effective in coverage, consistency, prominence, and consumer awareness and understanding required for the warning label to be effective. Left to industry to self-regulate has resulted in too much variation and misunderstanding of the message by consumers.

The Global Drug Survey 2018 also strongly supports the mandatory use of health warnings.

**Coverage**- evidence outlined in the Consultation paper from New Zealand in 2014 and 2016 reported that reasons why pregnancy warning labels were not adopted was that they were not mandatory and that they would only comply with mandatory labelling requirements (Consultation paper pg 21).

**Consistency**- the mandatory use of a consistent message to reduce misunderstanding and improve message uptake that is used by the whole industry is the only way this will be achieved. Consistency of warning labels/ application of a mandatory warning scheme increases awareness and aids effectiveness.

Sources:

Global Drug Survey 2018 <https://www.globaldrugsurvey.com/>

Stockwell, T.R. (2006). A review of research into the impacts of alcohol warning labels on attitudes and behaviour. British Columbia, Canada: Centre of Addictions Research of BC, University of Victoria.

Retrieved 14/05/2018 from:

<https://dspace.library.uvic.ca/bitstream/handle/1828/4785/Alcohol%20Warning%20Labels%202006.pdf?sequence=1>

Sambrook Research International (2009). A review of the science base to support the development of health warnings for tobacco packages. A report prepared for European Commission, Directorate General for Health and Consumers. Retrieved 14/05/2018 from:

[http://ec.europa.eu/health/tobacco/docs/warnings\\_report\\_en.pdf](http://ec.europa.eu/health/tobacco/docs/warnings_report_en.pdf)

**8:** Do you support the use of a pictogram? If so, do you have views on what pictogram should be used (e.g. pregnant woman holding beer glass or wine glass), and also, what colour/s should be used, and why? Do you have any views on size, contrast, and position on the package? Please provide research or evidence to support your views.

The NRHA supports the use of the current pictogram. However, as per research conducted by the European Commission (2011) the following needs to be addressed to ensure the message is clear and understood:

- Label clutter should be avoided: warning labels should not be obscured by surrounding information.
- Location: warnings on the front of alcohol container are more noticeable than those in any other place.
- Orientation: horizontal placement increases noticeability.
- Contrast: a strong foreground-background contrast is more effective in drawing attention.
- Colour: the specific colour used is less important than the colour combination. However, the NRHA supports the use of Red for the warning label which is supported by research findings by Siggins Miller (2014 and 2017).
- Pictorials: attract attention. If paired with written warnings, they may be better remembered.
- Signal icons: the red triangle for instance helps to identify warning- related information. The text “Government warning” functioned as a signal helping to identify the warning. Texts with a shorter signal (such as “warning” as a single word) are less noticeable. The NRHA would support the wording “health warning” (Victorian Health Promotion Foundation 2009).
- Border: the area should be large enough to ensure that the text could be read.
- When text is used, font size needs to be an appropriate size and not smaller than 11pt to be able to attract attention (Fuchs et al 2008).

Sources:

European Commission 2011. Health warnings and responsibility messages on alcoholic beverages – a review of practices in Europe. From:

[http://ec.europa.eu/chafea/projects/database/fileref/20081205\\_oth-03\\_en\\_ps\\_health\\_warnings\\_and\\_responsibility\\_messages\\_on\\_alcoholic\\_beverages.pdf](http://ec.europa.eu/chafea/projects/database/fileref/20081205_oth-03_en_ps_health_warnings_and_responsibility_messages_on_alcoholic_beverages.pdf)

Fuchs J, Heyer T, Langenhan D, Hippus M. Influence of font sizes on the readability and comprehensibility of package inserts. *Pharm Ind.* 2008;70(5):584-92)

Siggins Miller (2014). Evaluation of the voluntary labelling initiative to place pregnancy health warnings on alcohol products. Canberra: Commonwealth of Australia Department of Health.

Siggins Miller (2017). Second evaluation of the voluntary labelling initiative to place pregnancy health warnings on alcohol products: Final report. Canberra: Commonwealth of Australia Department of Health.

Victorian Health Promotion Foundation (2009). Alcohol health information labels: Report of qualitative research into health information labels on alcoholic beverages, Carlton South, Australia.

**9:** Do you support the use of warning text on a label? Why or why not? Do you have views on what text should be used, and if so, what is it? Do you support the use of warning messages already used in other markets? Please provide research or evidence to support your views.

The NRHA's position is that the use of warning text is supported however, it is unclear if the current wording is effective enough to relay the warning message.

The Victorian Health Promotion Foundation (Victorian Health Promotion Foundation, 2009) research found that the use of the words "Health Warning" may be more effective in raising a health warning message.

Sources:

Victorian Health Promotion Foundation (2009). Alcohol health information labels: Report of qualitative research into health information labels on alcoholic beverages, Carlton South, Australia.

Thomson LM, Vandenberg B, Fitzgerald JL. An exploratory study of drinkers views of health information and warning labels on alcohol containers. *Drug Alcohol Rev* 2012;31:240–247

**10:** Do you have views on what colour should be used for text, and whether green should be permitted? Do you have any views on size, contrast, and position on the package? Please provide research or evidence to support your views.

In line with the above responses and reiterated again here:

- Label clutter should be avoided: warning labels should not be obscured by surrounding information.
- Location: warnings on the front of alcohol container are more noticeable than those in any other place.
- Orientation: horizontal placement increases noticeability.
- Contrast: a strong foreground-background contrast is more effective in drawing attention.
- Colour: the specific colour used is less important than the colour combination. However, the NRHA supports the use of Red for the warning label as outlined above.
- Pictorials: attract attention. If paired with written warnings, they may be better remembered.
- Signal icons: the red triangle for instance helps to identify warning- related information. The text "Government warning" functioned as a signal helping to identify the warning. Texts with a shorter signal (such as "warning" as a single word) are less noticeable. The NRHA would support the wording "health warning" (Victorian Health Promotion Foundation 2009).
- Border: the area should be large enough to ensure that the text could be read.

(Sourced from: European Commission 2011. Health warnings and responsibility messages on alcoholic beverages – a review of practices in Europe. From:

[http://ec.europa.eu/chafea/projects/database/filerefer/20081205\\_oth-03\\_en\\_ps\\_health\\_warnings\\_and\\_responsibility\\_messages\\_on\\_alcoholic\\_beverages.pdf](http://ec.europa.eu/chafea/projects/database/filerefer/20081205_oth-03_en_ps_health_warnings_and_responsibility_messages_on_alcoholic_beverages.pdf) )

**11:** Should both the text and the pictogram be required on the label, or just one of the two options? Please justify your response.

The NRHA's position is that both text and pictogram should be mandatory requirements of the warning label. In addition, the labels should include the signal word 'Health Warning'.

Sources:

European Commission 2011. Health warnings and responsibility messages on alcoholic beverages – a review of practices in Europe. From: [http://ec.europa.eu/chafea/projects/database/fileref/20081205\\_oth-03\\_en\\_ps\\_health\\_warnings\\_and\\_responsibility\\_messages\\_on\\_alcoholic\\_beverages.pdf](http://ec.europa.eu/chafea/projects/database/fileref/20081205_oth-03_en_ps_health_warnings_and_responsibility_messages_on_alcoholic_beverages.pdf)

Victorian Health Promotion Foundation (2009). Alcohol health information labels: Report of qualitative research into health information labels on alcoholic beverages, Carlton South, Australia.

Thomson LM, Vandenberg B, Fitzgerald JL. An exploratory study of drinkers views of health information and warning labels on alcohol containers. *Drug Alcohol Rev* 2012;31:240–247

**12:** Are you aware of any consumer research on understanding and interpretation of the current DrinkWise pictogram and/or text? What about other examples of pictogram and/or text?

NRHA is aware that FARE (Foundation for Alcohol Research and Education) has recently completed research on alcohol and pregnancy labels. However, the results are yet to be published.

**13: Describe the value of pregnancy warning labels. Please provide evidence to support your views.**

Preventing, controlling and reducing risks and improving health is a function and regulated mandate of government. Each Australian State and Territory has a Public Health Act that states this.

What is known:

- Alcohol is known to be a teratogen – a substance that can harm an unborn baby.
- Fetal alcohol syndrome (FAS) is an identifiable teratogenic cause of mental retardation, neurological deficit, mental disorders, and developmental disabilities. (Lupton, Burd & Harwood, 2004).
- The lifetime cost of care for a person with FAS in 2002 in the United States was estimated to be \$2 million, resulting in a total annual cost for FAS in the United States of more than \$4 billion (Lupton, Burd & Harwood, 2004, AIHW 2015).
- FASD and its long term chronic and irreversible disabilities are entirely preventable if alcohol is not consumed during pregnancy (AIHW 2015).
- Health warnings can raise awareness of health risks from alcohol (Global Drug Survey 2018), promote supportive cultural attitudes and discussion about harmful effects of alcohol and benefits of not drinking when pregnant by pregnant woman and other community members (Peadon et al 2011, Savic et al 2016,) and reinforce the National Health and Medical Research Council (NHMRC) guidelines that not drinking alcohol during pregnancy is the safest option (NHMRC 2009).
- If warning labels are effectively used awareness of alcohol related harm would increase and the incidence of drinking alcohol related in pregnancy decrease (Stockwell 2006) and prevalence of FASD would reduce (Health Technology Analysts 2010).

Sources:

AIHW (2015). Fetal alcohol spectrum disorders: a review of interventions for prevention and management in Indigenous communities. Resource sheet no. 36 prepared by the Closing the Gap Clearinghouse. From : <https://www.aihw.gov.au/getmedia/778f54f3-5618-428f-a094-40c347ed3c7f/ctgc-rs36.pdf.aspx?inline=true>

Health Technology Analysts Pty Ltd (2010). Fetal Alcohol Spectrum Disorder (FASD): Exploratory economic analysis of different prevention strategies in Australia and New Zealand. Food Standards Australia New Zealand. pp ix-x.

Lupton,C., Burd L., Harwood, RA., (2004) Cost of fetal alcohol spectrum disorders. Am J Med Genet C Semin Med Genet.15;127C(1):42-50

Peadon,E., Payne,J., Henley,n., D'Antoine,h., Bartu,A., O'Leary,C., Bower,C., Elliott,EJ.(2011). Attitudes and behaviour predict women's intention to drink alcohol during pregnancy: the challenge for health professionals.

Savic, M., Room, R., Mugavin, J., Pennay, A. & Livingston, M. (2016) Defining 'drinking culture': a critical review of its meaning and connotation in social research on alcohol problems, Drugs: Education, Prevention and Policy.

Stockwell, T.R. (2006). A review of research into the impacts of alcohol warning labels on attitudes and behaviour. British Columbia, Canada: Centre of Addictions Research of BC, University of Victoria. Retrieved 14/05/2018 from: <https://dspace.library.uvic.ca/bitstream/handle/1828/4785/Alcohol%20Warning%20Labels%202006.pdf?sequence=1>

**14: Which is the option that is likely to achieve the highest coverage, comprehension and consistency? Please provide evidence with your response.**

As outlined in question 7 and reiterated again here:

It is the NRHA's position is that only Option 2 a mandatory scheme with government developed label and regulation will be effective in coverage, consistency, prominence, and consumer awareness and understanding required for the warning label to be effective.

Left to industry to self-regulate has resulted in too much variation and misunderstanding of the message by consumers.

The Global Drug Survey 2018 also strongly supports the mandatory use of health warnings.

**Coverage-** evidence from New Zealand in 2014 and 2016 reported that reasons given for not adopting the voluntary pregnancy warning labels was that they only comply with mandatory labelling requirements therefore would only put labels on alcohol if mandatory (Consultation paper pg. 21) .

**Consistency-** the mandatory use of a consistent message to reduce misunderstanding and improve message uptake a consistent appropriate message that is used by the whole industry is the only way this will be achieved. Consistency of warning labels/ application of a mandatory warning scheme increases awareness and aids effectiveness.

Sources:

Global Drug Survey 2018 <https://www.globaldrugsurvey.com/>

Stockwell, T.R. (2006). A review of research into the impacts of alcohol warning labels on attitudes and behaviour. British Columbia, Canada: Centre of Addictions Research of BC, University of Victoria.

Retrieved 14/05/2018 from:

<https://dspace.library.uvic.ca/bitstream/handle/1828/4785/Alcohol%20Warning%20Labels%202006.pdf?sequence=1>

Sambrook Research International (2009). A review of the science base to support the development of health warnings for tobacco packages. A report prepared for European Commission, Directorate General for Health and Consumers. Retrieved 14/05/2018 from:

[http://ec.europa.eu/health/tobacco/docs/warnings\\_report\\_en.pdf](http://ec.europa.eu/health/tobacco/docs/warnings_report_en.pdf)

**15: Which option is likely to achieve the objective of the greatest level of awareness amongst the target audiences about the need for pregnant women to not drink alcohol? What evidence supports your position?**

As outlined in question 7 and 14 is reiterated again here:

It is the NRHA's position is that only Option 2 a mandatory scheme with government developed label and regulation will be effective in coverage, consistency, prominence, and consumer awareness and understanding required for the warning label to be effective.

Left to industry to self-regulate has resulted in too much variation and misunderstanding of the message by consumers. Introduction of mandatory alcohol warning labels in the USA shows that awareness levels of the messages subsequently increased (Stockwell 2006)

Sources:

Stockwell, T.R. (2006). A review of research into the impacts of alcohol warning labels on attitudes and behaviour. British Columbia, Canada: Centre of Addictions Research of BC, University of Victoria.

Retrieved 14/05/2018 from:

<https://dspace.library.uvic.ca/bitstream/handle/1828/4785/Alcohol%20Warning%20Labels%202006.pdf?sequence=1>

**16:** More information is required on the benefits of each of the regulatory options. Do you have any information on the benefits associated with each option in relation to social, economic or health impacts for individuals and the community? Please provide evidence with your response.

The NRHA has no further additional information other than what has been presented above.

**17:** To better predict cost to industry associated with each option, can you provide further information that could inform the cost to industry associated with each of these approaches, particularly costings from a New Zealand industry perspective? Please provide evidence to support your response.

The NRHA has no further additional information other than what has been presented above. However, it is the NRHA's understanding that companies already change their labels regularly.

**18:** For Australia, is the estimated cost of \$340 AUD per SKU appropriate for the cost of the label changes? To what extent do these cost estimates capture the likely impacts on smaller producers? Should the cost estimates be adjusted upwards to capture disproportionate impacts on smaller producers?

Above, the NRHA has no further additional information other than what has been presented above. However, it is the NRHA's understanding that companies already change their labels regularly.

**19:** Is the number of active SKUs used in the cost estimation appropriate? What proportion of SKUs on the market is from smaller producers?

Not applicable – the NRHA has no expertise in this area.

**20:** Should there be exemptions or other accommodations (such as longer transition periods) made for boutique or bespoke producers, to minimise the regulatory burden? If so, what exemptions or other accommodations do you suggest?

The NRHA's opinion that as alcohol is a known teratogen, there should be no variation, exemption or accommodations.

**21:** To better predict the proportion of products that would need to change their label to comply with any proposed change, information on the type of pictogram and text currently used is required. Do you have evidence of the proportion of alcohol products that are currently using the red pictogram, and what proportion of products are using an alternate pictogram (e.g. green)? Do you have evidence on the proportion of alcohol products that are currently using the beer glass pictogram, or the wine glass pictogram? Please specify which country (Australia or New Zealand) your evidence is based on.

The NRHA is not aware of any evidence to provide here.

**22:** What would be the cost per year for the industry to self-regulate? Please justify your response with hours of time, and number of staff required. Please specify which country (Australia or New Zealand) your evidence is based on.

Not applicable

**23:** For each of the options proposed, would the industry pass the costs associated with labelling changes on to the consumer? Please specify which country (Australia or New Zealand) your evidence is based on.

The NRHA does not know if industry would pass the costs associated with labelling to the consumer. However, if industry decided to do this, there is evidence to support an increase can decrease alcohol related harm.

Sources:

Wagenaar, A.C., Tobler, A.L., & Komro, K.A. (2010). Effects of alcohol tax and price policies on morbidity and mortality: a systematic review. *American Journal of Public Health* 100(11), 2270-2278. DOI: 10.2105/AJPH.2009.186007

**24:** If you identified an alternate policy option in question 5, please provide estimates of the cost to industry associated with this approach.

Not applicable

**25:** Based on the information presented in this paper, which regulatory/non-regulatory policy option do you consider offers the highest net benefit? Please justify your response.

Cost to industry appears to be an upfront cost of less than \$10million.

Benefit to the community is potentially as high. There are 311,000 births in Australia annually (ABS 2016), with the mothers of approximately 81,000 (26% of pregnant women) drinking alcohol throughout pregnancy, and with perhaps as many as 6,200 – 15,600 (2%-5% of) babies born each year with some level of fetal alcohol syndrome disorder (Burns et al 2013).

What is the cost to society (and to the affected individual) of FASD?

As one would imagine, the per capita costs for medical care, higher crime rate, incarceration, lost earnings etc for a totally preventable condition are high, with one estimate of around US\$2,000,000 lifetime cost per FASD affected individual (Popova et al 2011).

The Authors of one comprehensive review of the literature (Popova et al 2016) put the cost in Canada at around 1.8 million Canadian dollars per year (an average of approximately \$4,600 for every child born each year, or something like \$90,000 -\$230,000 per child born with FASD each year (depending on the prevalence of FASD in the community).

If these costs are applied to Australia (exchange rates are similar, but slightly fewer births occur 311,000 Australian versus 380,000 in Canada (Statistics Canada 2018), then the cost in Australia of FASD would be around A\$1.4 billion annually.

If introduction of mandatory labelling were to prevent only 1% of FASD cases in Australia, then the benefit would be around A\$14 million annually; greater than the one-off cost of introduction.

Sources:

ABS (2016) 3301.0 - Births, Australia, 2016. From :

<http://www.abs.gov.au/ausstats%5Ccabs@.nsf/0/8668A9A0D4B0156CCA25792F0016186A?Opendocument>

Burns, L., Breen, C., Bower, C. et al. (2013). Counting fetal alcohol spectrum disorder in Australia: the evidence and the challenges. *Drug Alcohol Rev.* 2013 Sep 32 (5):461-7. Doi: 10.1111/dar.12047. Epub 2013 Apr. 25. Review. PMID: 2361743

Popova, S., Stade, B., Bekmuradov, D., Lange, S., Rehm, J. (2011). What do we know about the economic impact of Fetal Alcohol Spectrum Disorder? A systematic literature review. *Alcohol and Alcoholism* 46(4), 490-497. doi.org/10.1093/alcalc/agr029

Popova, S., Lange, S., Burd, I., and Rehm J (2016) Burden and Social Cost of Fetal Alcohol Spectrum Disorders. *Oxford Handbooks Online* from:

<http://www.oxfordhandbooks.com/view/10.1093/oxfordhb/9780199935291.001.0001/oxfordhb-9780199935291-e-78?print=pdf>

Statistics Canada (2018) Live births and fetal deaths (stillbirths), by place of birth (hospital or non-hospital), from: <https://www150.statcan.gc.ca/t1/tbl1/en/tv.action?pid=1310042901>