

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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Date of submission: 14 June 2018

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

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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 with the title: *Submission in relation to pregnancy warning labels on packaged alcoholic beverages*.

OR mail to:

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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.

There are many and varying estimates of the proportion of pregnant women in Australia and New Zealand who continue to drink. In addition to the evidence already reviewed in the Consultation Paper, we note the following studies which suggest that drinking during pregnancy is still practiced by a not insignificant share of the Australian and New Zealand population:

- The National Drug Strategy Household Survey (NDSHS) 2016 found only 56 per cent of pregnant women reported that they abstained from drinking during pregnancy.¹
- According to FARE's national 2018 poll, 78 per cent of Australian women who have been pregnant and drank alcohol prior to becoming pregnant said that they stopped drinking altogether while they were pregnant. But this means that nearly 1 in 4 pregnant women in Australia continue to drink during pregnancy²
- The Growing up in New Zealand study report found that 71 percent of women drank alcohol before they knew they were pregnant. Of these women, two-thirds stopped once they knew they were pregnant. There were 5 patterns of drinking behaviours during pregnancy identified: 29 per cent did not drink; 43 per cent stopped early; 16 per cent stopped later; 10 per cent stopped/restarted; and 2 per cent drank through the pregnancy³.
- A 2017 study involving 1,403 pregnant women from Australian metropolitan areas found that 61 per cent of women consumed alcohol when they were conceiving but were still unaware that they were pregnant, though at least 88 per cent of these women either ceased or reduced alcohol consumption once they became aware of their pregnancy⁴. However, this research implies that the rate of alcohol-exposed pregnancies may be higher than previous estimates when the period prior to pregnancy recognition is taken into account.
- A 2017 survey of pregnant women in rural Western Australia found that approximately 20 per cent of women reported drinking alcohol during pregnancy⁵. Predominantly the drinkers were women from older age groups and smokers.

¹ Australian Institute of Health and Welfare (2017). National Drug Strategy Household Survey 2016: Detailed findings. (Canberra: Australian Government). p115.

² Annual Alcohol Poll 2018: Attitudes and Behaviours. Foundation for Alcohol Research and Education.

³ Growing up in NZ. Alcohol and Pregnancy - Understanding the New Zealand context. 2015. <http://www.superu.govt.nz/alcohol-and-pregnancy-understanding-new-zealand-context>.

⁴ McCormack C, Hutchinson D, Burns :L. et al. Prenatal Alcohol Consumption Between Conception and Recognition of Pregnancy. Alcohol Clin Exp Res. 2017 Feb;41(2):369-378.

⁵ Tearne E, Cox K, Giglia R. Patterns of Alcohol Intake of Pregnant and Lactating Women in Rural Western Australia. Matern Child Health J. 2017;21(11):2068-2077.

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.

As the Consultation Paper notes, there are no national data on the prevalence or burden of FASD in Australia and New Zealand, as children are not routinely screened for FASD in infancy or childhood though according to one estimate the prevalence may be as high as 2 per cent in Australia⁶. A 2010 report prepared for Food Standards Australia New Zealand estimated an incidence of 1 per cent of live births for Australia and New Zealand which equates to an additional AU\$66 million and NZ\$16 million cost per annum to Australian and New Zealand taxpayers respectively in terms of the cost of additional services required for new FASD births.⁷ Note that this is a significant under-estimate which does not include the costs of managing existing FASD sufferers in the population.

Australian State prevalence data in 2013 from research also cited in the Consultation Paper indicated that birth prevalence rates of fetal alcohol syndrome (FAS) (which is a subset of FASD) was between 0.01 and 0.68 per 1000 live births⁸. According to research summarised by the Telethon Kids Institute there is an estimated birth prevalence rate of FAS in Western Australia of 0.3 per 1000 births but this is acknowledged to be an underestimate⁹.

We are aware of more recent estimates of rates of FAS and FASD in specific Australian jurisdictions. For instance:

- A study of the prevalence of FASD in youth detention in Australia found that 89 per cent of 99 youths (aged 13-17) had at least one domain of severe neurodevelopmental impairment and at least 36 per cent were diagnosed with FASD¹⁰.
- The diagnosis rate of FASD is as high as 194.4 per 1000 for Aboriginal Australian children living in the Fitzroy Valley, Western Australia.¹¹

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.

As the Consultation Paper notes, due to the difficulties in estimating the prevalence of FASD (discussed above), there is no high-quality evidence available to determine whether the voluntary initiative to place pregnancy warning labels on packaged alcoholic beverages has resulted in changes to the prevalence of FASD in Australia or New Zealand.

⁶ McLean S, McDougall S. 2014. 'Fetal alcohol spectrum disorders Current issues in awareness, prevention and intervention' Australian Institute of Family Studies. Australian Government.

⁷ 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.

⁸ Burns L, Breen C, Bower C, et al. Counting fetal alcohol spectrum disorder in Australia: the evidence and the challenges. *Drug Alcohol Rev.* 2013 Sep;32(5):461-7.

⁹ Telethon Kids Institution. Research topic: Fetal Alcohol Spectrum Disorder. <https://www.telethonkids.org.au/our-research/research-topics/fetal-alcohol-spectrum-disorder-fasd/>

¹⁰ Bower C, Watkins RE, Mutch RC, et al. Fetal alcohol spectrum disorder and youth justice: a prevalence study among young people sentenced to detention in Western Australia. *BMJ Open.* 2018;8(2):e019605.

¹¹ Fitzpatrick JP, Latimer J, Olson HC, et al. Prevalence and profile of Neurodevelopment and Fetal Alcohol Spectrum Disorder (FASD) amongst Australian Aboriginal children living in remote communities. *Res Dev Disabil.* 2017;65:114-126.

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.

There is evidence from Australia¹² and New Zealand¹³ that voluntary initiatives to place alcohol warning labels in general (whether with pregnancy or other warnings) will not be effective in raising public awareness about the harms of alcohol use due to poor recall and awareness. For instance, a 2015 study of drinkers in the 18 to 45 year old group found low rates of recall and awareness of the 'Get the facts' logo which directs drinkers to a DrinkWise website.¹⁴ In particular, recall of the warning labels was 16 per cent at best, recognition of the logo was around 25 per cent while only 7.3 per cent of respondents had visited the website.

There is also evidence that such voluntary initiatives do not typically result in high coverage:

- As indicated in the consultation paper, the coverage of pregnancy health warning labels on alcoholic beverages was 48 per cent in 2017, under the current voluntary initiative¹⁵ and this adoption rate may fall if monitoring and evaluation activities were to stop.
- Additionally, 2014 and 2016 NZ surveys of the alcohol industry reported that one of the key reasons for some producers not adopting warning labels was because these labels were not mandatory¹⁶. These aforementioned surveys also found a wide variation in the pregnancy warning messages placed on alcoholic beverages¹⁷. This lack of consistency is likely to reduce the effectiveness of the messaging.

Last but not least there is an inherent conflict of interest associated with the current voluntary approach to pregnancy warning labels because it results in consumers being directed towards browsing alcohol industry websites in order to receive a 'warning' message. In the process of doing so, the clarity and impact of the warning message may be undermined by its collocation with messages promoting consumption such as 'Cheers', 'Drink wise', 'Enjoy responsibly', or 'drink responsibly'.

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

Not applicable.

¹² Coomber K, Martino F, Barbour IR, Mayshak R, Miller PG. Do consumers "Get the facts"? A survey of alcohol warning label recognition in Australia. BMC Public Health. 2015;15:816.

¹³ Rout J, Hannan T. 2016. Consumer awareness and understanding of alcohol pregnancy warning labels. Wellington: Health Promotion Agency

¹⁴ Coomber K, Martino F, Barbour IR, Mayshak R, Miller PG. Do consumers "Get the facts"? A survey of alcohol warning label recognition in Australia. BMC Public Health. 2015;15:816.

¹⁵ Food regulation standing committee policy options targeted consultation paper: Pregnancy warning labels on packaged alcoholic beverages. May 2018. Page19

¹⁶ Food regulation standing committee policy options targeted consultation paper: Pregnancy warning labels on packaged alcoholic beverages. May 2018. Page21

¹⁷ Food regulation standing committee policy options targeted consultation paper: Pregnancy warning labels on packaged alcoholic beverages. May 2018. Page21

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.

In addition to those pros, cons and risks listed in the consultation paper, we note the following additional points:

- While option 2 (the mandatory option) allegedly creates an additional regulatory burden, and will require a compliance monitoring scheme, even the current voluntary approach which has resulted in less than half of alcoholic beverages being covered by warning labels is driven by industry awareness of monitoring and evaluation activities¹⁸ and this adoption rate is likely to fall if current monitoring and evaluation were to stop or be reduced. Thus, the current system is therefore hardly costless while yielding a less than adequate return. Spending marginally more on compliance monitoring under a mandatory scheme should be regarded as a worthwhile investment if it leads to more complete coverage. We also note that there is already mandatory alcohol labelling for other purposes (e.g. of alcohol concentration and the number of standard drinks) such that the costs of monitoring an additional component of the label are unlikely to be substantial.
- The fundamental flaw underlying all the voluntary options from 1(a) to 1(c) is that the remaining issues of low coverage rates, poor compliance rates, and inconsistency of messaging will remain unresolved given the widespread evidence for the unreliability of a self-regulatory approach in other areas of alcohol harm reduction policy. For example, a recent systematic review of international approaches to industry self-regulation of alcohol marketing concluded that violations of the content guidelines within these codes were highly prevalent.¹⁹ The credibility and effectiveness of sanctions embedded in these industry codes is also highly questionable. A study of the effectiveness of compliance and complaint procedures in industry self-regulation codes for alcohol marketing in the UK, Europe, US, Canada and Australia concluded that current alcohol industry marketing complaint processes were ineffective at removing potentially harmful content.²⁰ In the light of this evidence of failed industry self-regulation published by distinguished researchers in a high quality peer-reviewed health journal, the RACP believes it is essential to introduce a more robust approach.

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.

Nil response

¹⁸ Food regulation standing committee policy options targeted consultation paper: Pregnancy warning labels on packaged alcoholic beverages. May 2018. Page 19

¹⁹ Noel JK, Babor TF, Robaina K. Industry self-regulation of alcohol marketing: a systematic review of content and exposure research. *Addiction*. 2017 Jan;112 Suppl 1:28-50.

²⁰ Noel, J. K., and Babor, T. F. (2017) Does industry self-regulation protect young people from exposure to alcohol marketing? A review of compliance and complaint studies. *Addiction*, 112: 51–56.

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.

In terms of **coverage**, as indicated in the consultation paper, the coverage of pregnancy health warning labels on alcoholic beverages was 48 per cent in 2017, under the current voluntary initiative²¹. Some of these labels are printed in ways making them difficult to interpret (7mm in several cases, or printed in colours that cannot be seen in normal daylight)²². This level of adoption may fall if monitoring and evaluation activities were to stop. Indeed, 2014 and 2016 NZ surveys of the alcohol industry reported that one of the key reasons for some producers not adopting warning labels was because these labels were not mandatory²³. The surveys also found a wide range of pregnancy warning messages placed on alcoholic beverages²⁴. A UK study revealed that under a voluntary labelling approach, one third of alcohol products sampled did not have any health warning messages on their labels, while those carrying a health warning label were found to alter the tone or the meaning of the intended health messages²⁵.

Consistency of messaging is important with research indicating that it increases awareness and aids effectiveness.²⁶ Consistency is unlikely to be achieved under a voluntary scheme where alcohol producers can implement whatever they see fit even if there is a standardised government recommended message available.

²¹ Food regulation standing committee policy options targeted consultation paper: Pregnancy warning labels on packaged alcoholic beverages. May 2018. Page19

²² Examples include the Montrose sparkling white and Coldstream Hills chardonnay 2014 labels.

²³ Food regulation standing committee policy options targeted consultation paper: Pregnancy warning labels on packaged alcoholic beverages. May 2018. Page21.

²⁴ Food regulation standing committee policy options targeted consultation paper: Pregnancy warning labels on packaged alcoholic beverages. May 2018. Page21.

²⁵ Eurocare, European Alcohol Policy Alliance (2009). *Labelling Initiatives: A Brief Summary of Health Warning Labels on Alcoholic Beverages*. pp 10-12.

²⁶ Sambrook Research International. [A review of the science base to support the development of health warnings for tobacco packages](https://ec.europa.eu/health/sites/health/files/tobacco/docs/warnings_report_en.pdf).2009. https://ec.europa.eu/health/sites/health/files/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 RACP supports the use of a pictogram **in addition to** an effective text, as part of mandatory requirements for pregnancy warning labels in Australia and New Zealand. The key strength of the combined approach of pictogram and text is that it can make the relationship between alcohol consumption, pregnancy and harm to the unborn child clearer and starker to consumers

Evidence of the value of a pictorial approach includes the following:

- As outline in the consultation paper, a 2016 NZ study shows that without visual prompting, most people are unable to recall existing pregnancy warning labels²⁷.
- Pictorial health warning labels have also been found to arouse a higher level of fear and intentions to reduce and quit alcohol consumption among those who are exposed to such labels²⁸. This finding is consistent with the research on tobacco warning labels.²⁹ The evidence from research on tobacco health warning labels finds that depicting graphic effects to illustrate pregnancy risks is particularly effective among women of reproductive age.³⁰

There is also growing evidence of synergies between pictograms and text in effectively conveying intended messages and increasing recalls rates. For example:

- In the case of tobacco warning labels, evidence consistently shows that graphic warning labels that combine textual warnings with emotionally salient images can facilitate recall of the information on textual warnings³¹.
- Both pictorial and text-only alcohol health warning labels are associated with reduced speed of alcohol consumption. This suggests both forms of warning have complementary impacts in changing drinking behaviour³².

In terms of design features, both a recent World Health Organisation report on alcohol labelling and a report prepared for the European Commission make very similar recommendations for effective health warning labels about using large bold print, high contrast, colour and borders, and the importance of size^{33,34}. It is important to specify these characteristics, as current examples of wine labels reveal some warning labels printed in colours that are unreadable in normal daylight.

27 Rout, J. Hannan, T. 'Consumer awareness and understanding of alcohol pregnancy warning labels.' Wellington: Health Promotion Agency. 2016.

28 Wigg S, Stafford LD. Health Warnings on Alcoholic Beverages: Perceptions of the Health Risks and Intentions towards Alcohol Consumption. Ptitto M, ed. PLoS ONE. 2016;11(4):e0153027. .

29 Schneider S, Gadinger M, Fischer A. Does the effect go up in smoke? A randomized controlled trial of pictorial warnings on cigarette packaging. Patient education and counseling. 2012;86(1):77–83

30 Kollath-Cattano C, Osman A, Thrasher JF. Evaluating the perceived effectiveness of pregnancy-related cigarette package health warning labels among different gender/age groups. Addict Behav. 2017;66:33-40.

31 Wang AL, Shi Z, Fairchild VP, et al. Emotional salience of the image component facilitates recall of the text of cigarette warning labels. *Eur J Public Health*. 2018 Apr 26.

32 Stafford, Lorenzo D. "Alcohol health warnings can influence the speed of consumption". *Journal of public health* (0943-1853), 25 (2):147-154.

33 World Health Organization (2017). Alcohol labelling: A discussion document on policy options. Copenhagen: Denmark. Retrieved 21/05/2018 from:

http://www.euro.who.int/__data/assets/pdf_file/0006/343806/WH07_Alcohol_Labelling_full_v3.pdf?ua=1 9 (accessed June 2018);

34 Sambrook Research International. [A review of the science base to support the development of health warnings for tobacco packages](https://ec.europa.eu/health/sites/health/files/tobacco/docs/warnings_report_en.pdf).2009. https://ec.europa.eu/health/sites/health/files/tobacco/docs/warnings_report_en.pdf

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.

As indicated in the answer to question 8, the RACP supports the use of a pictogram in addition to an effective text, as part of mandatory requirements for pregnancy warning labels. We also recommend that existing text warning labels require revision to prevent misinterpretation and that it should refer directly to the risk of harm/damage to the fetus. There is obvious scope for improvement - for instance, the Health Promotion Agency of New Zealand's 2016 research paper reported that 38 per cent of consumers interpreted the DrinkWise text as meaning that you can drink alcohol in pregnancy. This suggests that the current text is not only far from clear in conveying its intended message, but is also sending the wrong message³⁵. Research shows that the effectiveness of warning messages can be increased by using simple, direct, personalised language while ambiguous or indirect health messages are unlikely to have any impacts^{36 37}. The RACP therefore recommends that new text should be developed by behaviour change experts and tested with the target audience, and those around the target audience that influence them, to ensure that it is readily comprehensible.

35 Rout, J. Hannan, T. 2016. 'Consumer awareness and understanding of alcohol pregnancy warning labels'. Wellington: Health Promotion Agency

36 Sambrook Research International. [A review of the science base to support the development of health warnings for tobacco packages](https://ec.europa.eu/health/sites/health/files/tobacco/docs/warnings_report_en.pdf).2009. https://ec.europa.eu/health/sites/health/files/tobacco/docs/warnings_report_en.pdf

37 Thomas G, Gonneau G, Poole N, et al. The effectiveness of alcohol warning labels in the prevention of Fetal Alcohol Spectrum Disorder: A brief review. *The International Journal of Alcohol and Drug Research*. 2014 Mar 19;3(1):91-103

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 terms of colour association with warning, the Australian³⁸ and New Zealand³⁹ evaluation reports found that red was a better choice to convey danger, while the use of green colour in this context was confusing, as indicated in the consultation paper⁴⁰.

Wine and other beverages are typically consumed in low-light settings such that labels must be readable in this setting.

With respect to the best design of the alcohol warning labels, a 2017 WHO report recommends that the visual impact of the label can be improved by employing large bold print, high contrast, colour, borders as well as pictorial symbols⁴¹.

This is broadly consistent with a number of key elements that have been identified to contribute to the effectiveness of tobacco warning labels which can also be taken into account when considering the evidence-based design of alcohol warning labels^{42 43}:

- Large warning labels are more easily noticed and read
- Warning labels on the front of packages allows greater recall rates
- Labels with direct, simple message are found to have greater impact
- Pictorial warning labels increase the accessibility to a greater target audience to a greater degree compared with text-only warning labels
- Colour pictures are more effective than black and white pictures.

Warning size also affects perceptions by reducing consumer based ratings for alcoholic beverages (i.e. reduces their appeal)^{44 45}. Based on the aforementioned evidence, the RACP recommends that the design should be informed by experts and by an engaged process of iterative pre-testing of messages and media with many segmented target audiences in social settings where alcoholic beverages are consumed. The duration of this engaged process must be long enough to allow for meaningful testing and feedback and the associated outcome measures should include comprehension, emotional engagement, recall and other relevant factors.

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

As explained in the responses to previous questions, the RACP supports the use of both warning pictograms and text to deliver the required health messages. However, their use should be in harmony to reinforce the intended messages. Our recommendation is supported by a study which shows that congruent messages will help process visual and textual information and improve recollection of label content⁴⁶.

³⁸ Siggins Miller. [Second evaluation of the voluntary labelling initiative to place pregnancy health warnings on alcohol products: Final report](#). Canberra: Commonwealth of Australia Department of Health.2017.

³⁹ Rout, J. Hannan, T. 'Consumer awareness and understanding of alcohol pregnancy warning labels'. Wellington: Health Promotion Agency. 2016

⁴⁰ Food regulation standing committee policy options targeted consultation paper: Pregnancy warning labels on packaged alcoholic beverages. May 2018. Page33

⁴¹ World Health Organization. Alcohol labelling: A discussion document on policy options. 2017.

http://www.euro.who.int/__data/assets/pdf_file/0006/343806/WH07_Alcohol_Labelling_full_v3.pdf?ua=1 9

⁴² Stafford, Lorenzo D. "Alcohol health warnings can influence the speed of consumption". *Journal of public health* (0943-1853), 25 (2), p. 147. 2017

⁴³ Thomas G, Gonneau G, Poole N, et al. The effectiveness of alcohol warning labels in the prevention of Fetal Alcohol Spectrum Disorder: A brief review. *The International Journal of Alcohol and Drug Research*. 2014 Mar 19;3(1):91-103.

⁴⁴ Al-Hamdani M, Smith SM. Alcohol warning label perceptions: do warning sizes and plain packaging matter? *Journal of studies on alcohol and drugs*. 2016 Dec 11;78(1):79-87.

⁴⁵ Al-Hamdani M, Smith S. Alcohol warning label perceptions: Emerging evidence for alcohol policy. *Canadian Journal of Public Health/Revue Canadienne de Santé Publique*. 2015 Sep 1;106(6):e395-400.

⁴⁶ Lochbuehler K, Mercincavage M, Tang KZ, et al Effect of message congruency on attention and recall in pictorial health warning labels *Tobacco Control* 2018;27:266-271.

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?

The main research on this is by Coomber et al⁴⁷ cited in the consultation paper.

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

We start from the premise that alcohol is a teratogen – a substance that can harm an unborn baby. The consultation paper lists that other teratogens are either:

- completely banned from use in products which are designed to be consumed by people
- illegal
- only used when there is no better alternative, under medical supervision
- carry a warning label on packaging⁴⁸.

It follows that as a matter of consistency, alcohol should be treated the same way as other teratogens and managed in one of these four ways.

The RACP believes that pregnancy health warning labels have the potential to affect the perceptions about alcoholic beverages among the public. Peer pressure is an important promoting factor for alcohol consumption in pregnancy⁴⁹. It is likely that wider public knowledge about the harm will reduce drinking in pregnancy and subsequently reduce the prevalence and severity of FASD. The value of pregnancy labels in delivering information and education is being increasingly acknowledged; there is evidence showing that certain population groups such as young people and pregnant women are more conscious of alcohol warning labels. This underscores the importance of pregnancy warning labels as a product-based intervention⁵⁰. A review of studies of alcohol warning labels in general has found that recall was highest for the message regarding the risk of birth defects resulting from alcohol consumption during pregnancy⁵¹. Exposure to labels (whether pregnancy warnings or other warnings) was also found to stimulate conversations about the risks of alcohol consumption. A consistent label across beverage types can be helpful to convey the message that it is the alcohol content of the drink that is of concern, be they beers, wines or other types of beverages.

The effectiveness of pregnancy warning labels is of course contingent on attention, reading, comprehension, recall, judgement and behaviour change⁵². Research indicates that although alcohol warning labels alone are unlikely to change alcohol consumption during pregnancy, it can play a part in multifaceted FASD prevention strategies. They have been shown to increase awareness of the risks of drinking during pregnancy and may contribute to a shift in the drinking culture⁵³.

⁴⁷ Coomber K, Martino F, Barbour IR, Mayshak R, Miller PG. Do consumers “Get the facts”? A survey of alcohol warning label recognition in Australia. BMC Public Health. 2015;15:816

⁴⁸ Food Regulation Standing Committee (May 2018). Policy options targeted consultation paper: Pregnancy warning labels on package alcohol beverages. p24

⁴⁹ Testa, M., & Leonard, K. E. (1995). Social influences on drinking during pregnancy. Psychology of Addictive Behaviors, 9(4), 258-268.

⁵⁰ Tinawi G, Gray T, Knight T, et al. Highly deficient alcohol health warning labels in a high-income country with a voluntary system. Drug Alcohol Rev. 2018.

⁵¹ Stockwell TR. 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; 2006.

⁵² Sambrook Research International. [A review of the science base to support the development of health warnings for tobacco packages](#). 2009

⁵³ Thomas G, Gonneau G, Poole N, et al. The effectiveness of alcohol warning labels in the prevention of Fetal Alcohol Spectrum Disorder: A brief review. The International Journal of Alcohol and Drug Research. 2014 Mar 19;3(1):91-103

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

The RACP strongly supports the mandatory labelling option. Evidence supporting this view is outlined in the previous responses.

Further evidence from a 2018 NZ study found that voluntary pregnancy labels were varied and inconsistent within and across alcoholic beverages and that they are small in size relative to promotional components for example brand log⁵⁴. The study also concluded that warning text and intention of industry-led initiatives were unclear from the standpoint of public health and concluded that, to ensure sufficient consumer information, mandatory labelling initiatives should be put in place⁵⁵.

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?

The RACP strongly supports the mandatory labelling option. Evidence supporting this view is outlined in the previous responses.

In addition, as noted in the consultation paper, a cross-sectional survey conducted five years after the introduction of compulsory warning labels on drinking during pregnancy in France indicated that of 36,504 pregnant or postpartum women surveyed, 66.1 per cent of women and 77.3 per cent of drinkers had noticed the warning label⁵⁶. Of those who had noticed the label, almost all (98.6 per cent) thought the labels suggested abstinence during pregnancy. This study concluded that awareness of such warnings was high, though it also found that knowledge of specific risks associated with specific beverages was still poor which clearly suggests that even under a mandatory labelling system, careful thought needs to go into the formulation of appropriate standardised messages.

It is logical that a greater level of awareness will be achieved at a population level if a greater proportion of the population are exposed to it. Once the parameters of an effective message have been set, this is ultimately an issue of coverage and this is best achieved by mandatory labelling.

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.

Any financial costs of implementing a mandatory pregnancy warning label would be far outweighed by the social and health benefits for individuals and the community, realised through lower levels of FASD. Furthermore, it is possible that it would actually be a cost-saving measure given the additional costs to the taxpayer of additional resources needed to manage patients with FASD, as outlined in the response to question 2. The RACP believes the costs are likely to be modest as there is already mandatory labelling of alcoholic beverages; such that addition of a pregnancy warning would be a relatively modest change to an existing program.

⁵⁴ Tinawi G, Gray T, Knight T, et al. Highly deficient alcohol health warning labels in a high-income country with a voluntary system. *Drug Alcohol Rev.* 2018.

⁵⁵ Tinawi G, Gray T, Knight T, et al. Highly deficient alcohol health warning labels in a high-income country with a voluntary system. *Drug Alcohol Rev.* 2018.

⁵⁶ Dumas A, Toutain S, Hill C, Simmat-Durand L. Warning about drinking during pregnancy: lessons from the French experience. *Reproductive health.* 2018;15(1):20.

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.

Alcohol companies already change their labels on a frequent basis. Moreover, they are already required to apply health warning labels to products that are exported to countries with a mandatory warning label requirement. There is already mandatory labelling of alcoholic beverages requiring information about concentration and content of alcohol. Consequently, the cost to industry of implementing a pregnancy warning label is likely to be minimal. The main costs of labelling would be borne by government through a compliance monitoring scheme.

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?

Nil response

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

Nil response

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?

An appropriate transition period for the alcohol industry should be adopted to implement mandatory pregnancy warning labels. Variations to a mandatory requirement according to company size would create confusion and could be used to justify inaction or delayed compliance. The RACP strongly recommends that no other exemptions or accommodations should be made.

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.

Nil response

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.

The RACP has consistently argued that self-regulation has failed and should not be adopted.

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.

We do not know whether industry would pass the costs of labelling changes onto the consumer. The costs are likely to be minimal and may be further reduced by allowing a suitable transition time so that new requirements can be efficiently incorporated into the production of new labels.

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.

The RACP believes based on the evidence reviewed in previous responses that mandatory labelling initiative will produce the highest net benefit as compared with the other non-mandatory options. We are convinced that it will ensure broader application of standardised warning messages across the alcohol industry and the realisation of the primary and secondary objectives of warning labels set out in the consultation paper. Only a mandatory scheme can overcome the significant conflict of interest (that alcohol producers ultimately want to sell more alcohol) which has thus far prevented the alcohol industry from implementing an effective and consistent warning label scheme.