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Supporting document 3

Addendum to Alcohol Warning Label Survey Report by Roy Morgan Research

Prepared by Food Standards Australia New Zealand

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1. Introduction

This is an addendum to the report prepared by Roy Morgan entitled *Alcohol warning label survey report, 20 September 2019*. The original report was prepared by Roy Morgan, who were commissioned by Food Standards Australia New Zealand (FSANZ) to implement a survey and analyse collected data. The report was released as Supporting Document 2 (SD2) to the Call for Submissions for Proposal 1050 Pregnancy warning labels on alcoholic beverages.

This addendum provides additional information to assist the interpretation of the original report. The additional information has been added following the peer review of the original report.

The topics covered are:

- Peer review
- Ethical review
- Sampling
- Selection of statements tested.

2. Peer review

FSANZ typically undertakes independent external peer review of its substantive social and behavioural evidence inputs for the standards development process. In normal circumstances this would take place on a draft final report to inform and assist in finalising the ultimate report, which would then be made public. In this instance, the peer review took place simultaneously with the release of the Call for Submissions document for Proposal 1050. This addendum to the original report provides additional information as suggested through the peer review process.

3. Ethical review

The National Statement on Ethical Conduct in Human Research (NHMRC, 2018) sets national standards for the use by individuals, institutions and organisations conducting human research, including research undertaken by government agencies, for Australia. This survey falls within the scope of human research covered by the National Statement.

The National Statement requires that human research involving more than low risk be reviewed by an appropriately constituted Human Research Ethics Committee (HREC). Research is of low risk where the only foreseeable risk is one of discomfort. Where the risk is more serious than discomfort the research is not low risk (see section 2.1.6 - NHMRC, 2018). Discomfort can involve body and/or mind and includes minor side-effects such as anxiety induced by an interview or survey.

In New Zealand health and disability research much be reviewed by one of the four statutory Health and Disability Ethics Committees (HDEC). The scope of HDEC review is limited¹ and this survey fell outside the scope of the HDEC. Additional ethical guidance is provided in the Royal Society of New Zealand Code of Professional Standards and Ethics in Science,

¹ Limited to participants recruited as consumers of health and/or disability services; relative/caregiver of consumers of health and/or disability services; volunteers in clinical trials; where human tissues are collected, used or stored; use or disclosure of health information.

Technology and the Humanities (Royal Society of New Zealand, 2019). The Royal Society's Code is to support its members to follow ethical behaviour, though it also provides a guide to other researchers and institutions. Part 2 of the Royal Society's Code sets out ethical values and principles that underpin research. The values and principles outlined are commensurate with the NHMRC Guidelines – however the NHMRC Guidelines have been expanded and detailed to a greater degree than the Royal Society's Code. The Royal Society's Code covers all science, technology and humanities research, rather than just research involving human participants, consequently it is at a higher level of abstraction. However, their values and principles are commensurate with the NHMRC Statement and through satisfying the NHMRC Statement, we will also be satisfying the values and principles of the Royal Society's Code.

An internal risk assessment of the research proposed identified a number of risks that were considered higher than low risk. Consequently a formal HREC review was sought.

FSANZ entered into an agreement with Bellberry Ltd to provide ethical review services. Bellberry Ltd operates several HRECs constituted in accordance with the National Statement and are registered and certified with the NHMRC. FSANZ's research was reviewed by Bellberry Human Research Ethics Committee A (EC00372).

The review process involves the presentation of a research protocol for review by the HREC. The protocol described the research and approach and justified the benefit of the research against any potential risks identified. Strategies for the management of identified risks are required. The protocol included detailed information against the 7 elements identified in the National Statement:

- Element 1: Research scope, aims, themes, questions and methods
- Element 2: Recruitment
- Element 3: Consent
- Element 4: Collection, use and management of data and information
- Element 5: Communication of research findings or results to participants
- Element 6: Dissemination of project outputs and outcomes
- Element 7: After the project.

Additionally the protocol detailed specific considerations for women who are pregnant, children and young people, Aboriginal and Torres Strait Islander peoples, and people in other countries.

Following initial consideration by the HREC additional information was required or clarified in some areas. During the ethical review process we made the decision to change the survey sample from 16-45 years of age to 18-45 years of age. This removed 16 and 17 years olds from the survey. As this demographic are adolescents and under the legal drinking age of 18 in both countries we initially planned to seek parental/guardian permission for their child's participation in the survey. Given the possible priming of drinking behaviour in adolescents and the practicalities of obtaining parental/guardian permission prior to inviting participation in the survey we decided to use an entirely adult sample.

Bellberry HREC A (EC00372) met on the 15 May 2019 and approved the project on 5 Jun 2019 (Application No. 2019-04-323).

4. Sampling

4.1 Māori and Pacific peoples

We achieved a count of 100 Māori and 41 Pacific Islanders aged 18-45 years in the survey sample. As a share of the weighted sample, this represents 11.1% and 3.5% for Māori and Pacific Islanders respectively. Māori represented approximately 15.5% of the estimated resident population of 18-45 year old New Zealanders in 2017. The sample was not weighted for ethnicity and these groups are underrepresented in the final weighted sample.

The Māori and Pacific Islander sample of 141 provided a robust sample for reporting of their responses across the six key measures, for the four tested warning statements (See Appendix B of main report). The sample is not large enough for further disaggregation within this group. Four Māori women of child bearing age were included in the 15 cognitive interviews undertaken in New Zealand.

4.2 Aboriginal and Torres Strait Islander peoples

We did not collect any ethnicity data in the Australian survey and are unable to report on individual ethnicities, including Aboriginal and Torres Strait Islander peoples. Our previous experience with online surveys have had no success in attracting a representative sample of Aboriginal and Torres Strait Islander peoples.

FSANZ recognises the importance of including Aboriginal and Torres Strait Islander peoples in our projects. In this case, time and resource constraints did not permit the investment required to obtain a robust sample. Further, alcohol warning labels are one strategy in a suite of prevention measures for fetal alcohol spectrum disorder (FASD). Interventions for Aboriginal and Torres Strait Islander communities requires in-depth understanding of community dynamics and specifically designed programs.

4.3 Power limitations

The survey was designed with a focus on women of childbearing age and this group is overrepresented in the sample. Consequently analysis has been carried out separately for each sex. The sample who viewed each warning statement was approximately 200 females and 50 males. This sample provides good explanatory power for women of childbearing age. The level of explanatory power decreases as the sample size decreases.

Oversampling of Māori, Pacific Islanders, Aboriginal and Torres Strait Islander peoples would have enabled more robust analysis of responses by these ethnicities. Resource and timing constraints did not facilitate this oversampling. FSANZ notes that the proposed warning labels on alcohol are a population level intervention, and the results show that Māori and Pacific Islanders responded similarly to the New Zealand sample (See Appendix B of main report). Alcohol warning labels are one strategy in a suite of prevention measures for FASD. Other interventions are focussed at the individual level and are targeted to specific socio-demographic and cultural groups.

4.4 Representativeness

Quotas for respondents by age and sex and location by sex were used to create a sample that was representative by age and location within each country – noting that females were sampled at around 4 times the rate of males. Post-hoc weights were applied to ensure estimates given in the report are representative of the estimated resident population in each country.

Using an on-line panel as the source for the sample can introduce other biases. Individuals who are more highly educated, earn more income and from professional occupations are likely to be overrepresented in the survey sample.

5. Selection of Statements

The following discussion outlines the approach used to select the statements tested in the survey. Based on available research capacity and considerations of study design, the number of statements to be consumer tested was restricted to four. Given the statement *It's safest not to drink while pregnant* has been commonly used in the voluntary labelling initiative it was important to test this statement alongside alternative options..

A discussion document on alcohol labelling prepared by the World Health Organization (WHO, 2017) suggests four aspects of a warning message could be considered when developing an effective health warning:

- signal word to attract attention
- identification of the problem
- explanation of the consequences if exposed to the problem
- instructions for avoiding the problem.

Previous research has indicated the following principles may also help to enhance consumer understanding of a pregnancy warning label:

- directly refer to low levels of alcohol consumption
- avoid definitive language that harm will always occur
- use personalised language to increase relevance
- statement to be as short as possible.

The inclusion of the principle – directly referring to low levels of alcohol consumption – also reflects public health advice not to drink any alcohol during pregnancy.

FSANZ considers the proposed pictogram covers the principle relating to including instructions for avoiding the problem and so did not seek to include this aspect in the statement. Signal word(s) have been considered separately and were not tested in the survey.

FSANZ applied the remaining six principles above to a list of possible warning statements (see Attachment D of the Call for Submissions Report). Of the 35 statements in the list, the following statements best met the six principles:

- Drinking any alcohol can harm your unborn baby
- Any amount of alcohol may harm your unborn baby
- When pregnant, any alcohol can seriously damage your baby
- Any alcohol can harm your baby
- Any amount of alcohol can cause lifelong harm to your baby

The following statements were slightly adapted from those in the list to better meet the principles and were therefore also considered:

- Small amounts of alcohol can harm your unborn baby
- Drinking any alcohol may cause lifelong harm to your baby
- Any alcohol can harm your unborn baby

On the basis the word 'can' better reflects the evidence that alcohol consumption can cause FASD rather than 'may' cause, 'can' was preferred. Some of the above statements use the term 'unborn' baby and others do not. Given New Zealand and Australia consumer education materials tend not to use the term 'unborn' and to help reduce the number of words, it was decided to omit 'unborn' in the statements to be tested. We also considered 'drinking' to be redundant in the context of the warning label being placed on alcoholic beverages and the use of the pictogram alongside the statement.

Together with the statement used in the voluntary labelling initiative, the statements consumer tested were:

- It's safest not to drink while pregnant
- Any amount of alcohol can harm your baby
- Any amount of alcohol can cause lifelong harm to your baby
- Alcohol can harm your baby.

The shorter statement with no explicit reference to 'any amount' of alcohol was included to enable testing of the contribution 'any amount' has to consumer understanding of government advice not to drink any alcohol during pregnancy.

6. References

National Health and Medical Research Council (2018) *National statement on ethical conduct in human research 2007 (updated 2018)*. National Health and Medical Research Council, Canberra. <https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018> Accessed on 17 January 2020.

Royal Society of New Zealand (2019) *Code of professional standards and ethics in science, technology, and the humanities*. Royal Society of New Zealand, Wellington. <https://www.royalsociety.org.nz/who-we-are/our-rules-and-codes/code-of-professional-standards-and-ethics/code-of-professional-standards-and-ethics-in-science-technology-and-the-humanities> Accessed on 17 January 2020.

World Health Organization (WHO) (2017) *Alcohol labelling. A discussion document on policy options*. Available at <http://www.euro.who.int/en/health-topics/disease-prevention/alcohol-use/publications/2017/alcohol-labelling-a-discussion-document-on-policy-options-2017> Accessed on 12 September 2019.