



Submission on Initial Assessment Report on Application A576 – Pregnancy Health Advisory Labels on Alcoholic Beverages

To Food Standards Australia New Zealand
PO Box 10559
Wellington
New Zealand

Submission from:
Alcohol Healthwatch
PO Box 99407
Newmarket
09 5207037

Submission prepared by:
Christine Rogan
Email: christine@ahw.co.nz

Introduction

Alcohol Healthwatch is an independent charitable trust that works to reduce alcohol-related harms in New Zealand. We are contracted by the Ministry of Health to provide a range of services regionally and nationally, which include provision of evidence-based information on policy and practice, and co-ordination and public health expertise for inter-agency and community groups who work on alcohol issues.

As part of this work, Alcohol Healthwatch coordinates the Fetal Alcohol Network New Zealand (FANNZ), a network that consists of over 300 professionals from multiple sectors and families that are concerned about reducing the harm of Fetal Alcohol Spectrum Disorder¹. This submission follows consultation with the network on the topic of requiring an alcohol and pregnancy advisory label.

This submission will provide comment on the questions asked and provide other evidence-based information not included in the ALAC application that further support the application.

We welcome the opportunity to provide feedback.

¹ Fetal Alcohol Spectrum Disorder is an umbrella term used to describe a range of adverse effects that can result from consuming alcohol during pregnancy including Fetal Alcohol Syndrome, Partial FAS (PFAS), Alcohol-Related Neurodevelopmental Disorders (ARND) or Alcohol Related Birth Defects (ARBD), (Chudley et al, 2005). The use of the word 'fetal' or 'fetus' is not an Americanisation but is the Latin origin (Liggins Institute, 2005).

Alcohol Healthwatch summary position on application A576

- This submission strongly supports the Alcohol Advisory Council of New Zealand (ALAC) application A576, made on behalf of the New Zealand Government to require the prominent display of a pregnancy health advisory label on all alcoholic beverages.
- A pregnancy health advisory label on all alcoholic beverages is not only complimentary to other prevention strategies it is fundamental and foundational.
- A variation to the food standard 2.7.1 to label alcoholic beverages with a pregnancy health advisory label is fully consistent with the objectives in section 18 of the FSANZ Act.
- There have been significant increases in harmful drinking behaviour of women of childbearing age over the past decade and drinking during pregnancy is relatively common.
- Alcohol poses a significant health risk to the general population and accrues no health benefit from any level of consumption at any age.
- Alcohol exposure during pregnancy is a proven teratogen. Physical birth defects as well as central nervous system dysfunction and brain damage that are irrevocable over an individual's lifetime have been identified at variable levels and times of exposure.
- Exposing a tiny developing fetus to low levels of alcohol could not be deemed safe when evidence shows that adult women are at risk of harm at very low levels of consumption.
- Pharmaceutical products or other chemical agents that show *any* level of toxicity to developing fetuses or infants are not permitted to be used during pregnancy or breastfeeding.
- A health advisory label to avoid alcohol during pregnancy will consistently counter the stream of misinformation about the risk of drinking during pregnancy that confuse the public and undermine public health efforts and clinical advice.
- Given the proven link between alcohol and birth defects, there is no moral, ethical, legal or commercial justification for alcoholic beverages to continue being sold to the New Zealand and Australian public without the product displaying this important health information.

With no dose threshold or safe time to consume alcohol during pregnancy, women of childbearing age must be advised to avoid consuming alcohol when pregnant by all means possible. Fundamental to all efforts to reduce this risk, is a health advisory label that includes a pictorial image that is regulated to be prominently displayed on all alcoholic beverage containers as soon as possible.

There is no safe level of alcohol use for anyone

In the Western Pacific region, alcohol accounts for 5.5% of the burden of disease in addition to the substantial social and economic costs associated with harmful use (World Health Organisation, 2006).

A recent study published in The Lancet assessing the evidence of harm from the top 20 drugs of misuse, placed alcohol at number 5 on an objective rating scale, several rating points ahead of tobacco and other drugs such as marijuana and methamphetamine (Nutt et al, 2007).

However, few people understand that the risk to their health and safety begins at very low levels of consumption for adults and tend to overestimate the amount they think they can safely drink (NHMRC, 2007).

This is particularly a problem for women whose risk of acute and chronic harm from drinking is three times that for men drinking in a similar manner. For instance a recent prospective study of approximately 20,000 adults suggests that the risk of developing alcohol dependence begins at 1-7 drinks per week for women, whereas for men the risk is at 21- 41 drinks (Flensburg-Madsen et al, 2007).

The latest cancer research indicates that every unit of alcohol increases the risk of a woman developing breast cancer by 10% (Li et al, unpublished, 2007). At three standard drinks the risk of cancer is similar to the risk from smoking a packet of cigarettes.

Exposing a tiny developing fetus to low level of alcohol could not be deemed safe when evidence shows that adult women are at increased risk of harm at very low levels of consumption.

The issue of health benefits

The evidence about alcohol having health-giving properties is an important consideration in relation to health advisory statements for alcohol even though there are clearly no health benefits to a fetus. The alcohol industry and their associates have been and are likely to continue being vociferous in promoting the health benefits of alcohol as part of their opposition to this application. This is illustrated through recent media such as appeared in Capital Times Wine Press (16/01/08) reiterating the health benefits of moderate consumption and suggesting there is no risk from moderate consumption during pregnancy either. Another example is the Wine Federation of Australia media release (28.01.08) promoting health benefits in opposition to the draft Australian Alcohol Guidelines.

Equally important is that the issue of health benefits was also considered a valid and significant reason why the previous application A359 to ANZFA was declined. Indeed in the ANZFA Full Assessment Report in 2000, setting out the reasons for declining the application, reference to alcohol having health benefits was referred to 48 times in the 52 page report. Such emphasis was disproportionate to the reality and the evidence, even eight years ago.

As pointed out by the ALAC application A576 (page 2), *"no health benefit from the consumption of alcohol accrues to women of reproductive age"* which by implication suggests it accrues to others. However, the evidence that a health benefit from moderate consumption may accrue to anyone is now scientifically questionable.

New Zealand epidemiologists, who had previously advocated alcohol's protective effect, are now openly questioning that hypothesis (Jackson, 2007). This was precipitated by research including a large USA study that rigorously assessed confounding factors in data from 250,000 adults. The US researchers concluded:

'These findings suggest that some, if not all, of the health protective factors attributed to alcohol are more likely to be the result of residual or unmeasured confounding characteristics associated with increased CVD mortality' (Naimi et al, 2005). The confounding characteristics included social, behavioural and demographic factors, access to healthcare and other health related conditions. Those with multiple factors were progressively more likely to be non-drinkers.

Put another way, drinking in moderation is a sign of good health and lifestyle behaviour rather than a cause of good health.

Alcohol poses a significant health risk to the general population and accrues no health benefit from any level of consumption at any age.

Other health advice

Ideally, given the high level of media promotion of the health benefits and the drive to enhance the desirability of alcohol consumption that continually undermine harm prevention measures, alcoholic beverages should be required to carry a rotating set of health advisory statements relating to the wide range of causal risks to health and safety, as happens for tobacco and other chemical products.

Since that is not a consideration for this application, this submission will focus on answering the questions posed by the FSANZ report in relation to Application A 576.

Responses to Initial Assessment questions for public comment

- 1. What other strategies or programs are there in Australia or New Zealand (initiated by industry, public health, government, and consumer groups) to advise women of childbearing age of the risk of consuming alcohol when pregnant or if planning a pregnancy?***

The need for a health advisory statement to inform the public of a risk of harm from consumption should not be based on the success or otherwise of other efforts to convey the message. The absence of this foundational information on the product being consumed simply undermines any other efforts to inform the public of a risk to health. It is not about 'either/or' but 'both'. Therefore the only critical question to ask in response to this risk assessment is to establish whether all types of commercially available alcoholic beverages can cause harm to an unborn baby.

- 2. What information (from industry, public health, government and consumer groups) is available to women planning a pregnancy or pregnant women, about the risk of consuming alcohol?***

Whether there is an abundance or dearth of pamphlets or posters, for women about alcohol consumption during pregnancy, the product itself needs to convey the information first and foremost. This will enhance the ability of health professionals to engage with women on the topic. As pointed out above, the public is exposed to a large measure of promotional messages that send mixed messages. A health advisory statement on the product may be the only consistent health message that women and others around them are able to respond to.

- 3. What published and unpublished information is available that may provide answers to the risk assessment questions regarding FASD that will be addressed at Draft Assessment?***

As raised in the risk analysis discussion of the alcohol and pregnancy drinking guidelines by the NHMRC, pharmaceutical products or other chemical agents that show any level of toxicity to developing fetuses or infants are not permitted to be used during pregnancy or breastfeeding (NHMRC, 2007).

As Dr John Whitehall, Director of Neonatology at Townsville Hospital in Queensland, writing in the Medical Journal of Australia (2007), points out, normal public health and safety standards applied to other environmental toxins that cause developmental abnormalities needs to apply to alcohol. He points out the importance of additional caution when a toxicity database is incomplete. Dr Whitehall quite rightly questions why alcohol should not be subject to these standards when it is one of the most teratogenic agents affecting humans.

Alcohol is a proven teratogen. It is a substance that can lead to deviations in cell development during the course of prenatal development down to the lowest possible measurable level (Stratton et al, Eds, 1996). No other risk assessment needs to be considered. To set a different standard of proof or criteria for alcohol, would need to be robustly justified in any risk assessment about safety and harm.

The brain and central nervous system is particularly sensitive to the teratogenic effects of ethanol and no known threshold of exposure at which harm does not occur has been identified. Alcohol consumption throughout pregnancy is a risk to development down to the lowest measurable level (Sampson et al, 2000).

Because the brain and central nervous system continues to develop throughout pregnancy and beyond, there is no safe time to consume alcohol throughout the developmental period. There is also currently no way to predict who is at increased risk, at what dose or stage of development and under what circumstance (Streissguth et al, 1993; Jacobsen & Jacobsen 2007).

During the second trimester, nerve cells are developing at a rate of approximately 250,000 a minute. It takes the average healthy adult approximately one hour to detoxify one unit of alcohol from the blood stream. During exposure alcohol can interfere with the genetically programmed chemical/hormonal regulation of the proliferation and migration of cells, exposing every cell to possible damage and loss of potential if they migrate to the wrong destination.

Neurodevelopment depends on the patterned migration and growth of cells and cell-to cell interactions such as the ability of cell molecules to adhere and this can be affected by ethanol (Greenberg, 2003). *"Given the critical role of Cell Adhesion Molecules (CAMs) in guiding brain development, it is not surprising that impaired dysfunction of CAMs should result in neurodevelopmental disorders"*. This is one mechanism known to be associated with ethanol exposure at a cellular level.

When ethanol enters the blood stream, millions of developing cells are placed at risk of adverse development by exposure to ethanol's neurotoxic effects and while this may be mitigated by factors such as genes, it is not possible to predict individual susceptibility and outcomes (Jacobsen & Jacobsen, 2007; Wilkemeyer, 2003). Changes in cellular activity have been found down to the lowest measurable level (Stratton et al, 1996; Sampson et al, 2000).

Research of this nature is in its early stages. Some of the reviews of literature that include many older studies have serious limitations. The NHMRC include meta-analysis of data eg Henderson, (2007) which suggests a threshold effect of around 8

drinks a week. However as the NHMRC importantly point out that the review did not address developmental, cognitive or behaviour outcomes – the very development that is most sensitive and vulnerable to the detrimental and debilitating effects of ethanol and a key reason why there is a need to protect a fetus from exposure, as they now recognise.

4. What other data are available regarding alcohol consumption by women of childbearing age and during pregnancy in Australia and New Zealand?

In a survey of women of reproductive age, 50% believed women can safely consume alcohol in moderation during pregnancy (Parackal, et al, 2006).

Drinking alcohol during pregnancy is a critical aspect of a wider health issue relating to women's recent drinking behaviour. A New Zealand study of drinking behaviour in two time periods - 1995 and 2003 of patients attending general practices, found that heavy and problematic drinking by females aged 16-24 years had significantly increased between those two time periods (Goodyear Smith et al, 2004). The difference over that time for young males was non-significant. This study finding backs up national population studies pointed out in the ALAC application.

There has been a steady and significant cultural change in female alcohol use over the last decade. This has been precipitated by the liberalisation of liquor laws resulting in increased availability and social acceptability of drinking such as having wine available in supermarkets, as well as the development of premix 'ready to drink' (RTDs) alcoholic beverages purposely designed in taste, colour and style to appeal to young women. There is also a trend toward the alcohol strength of these products increasing.

RTD sales are driving a significant rise in per capita consumption. *"An increase in spirit-based drinks was the leading contributor to a new high in the total volume of alcohol available for consumption in the December 2006 year. The volume of spirit-based drinks has increased every year since 1996"* (Statistics NZ, 2007²).

There has been a corresponding increase in the New Zealand birth rate. In 2007, 62,360 births were registered in New Zealand, up 5.5 percent from 2006 (Statistics NZ, 2007). Half of all births occur for women under 30 years.

5. Are there any other data available on the incidence of FAS/FASD in Australia or New Zealand?

There is currently no research in New Zealand to accurately estimate the extent of FASD as a public health issue for a number of reasons. FASD is not routinely screened in infancy and early childhood meaning that many children born with FASD remain undiagnosed which can lead to misclassifications and further harm. Children without the presenting features of the full syndrome are unlikely to be assessed.

Clinicians in Australia and New Zealand are at the present time poorly equipped to

² Compare this to trend statistics on tobacco which do carry health warning labels, *"During the December 2006 year, the number of cigarettes available for consumption was virtually unchanged from the 2005 year. The number peaked at 6.3 billion in 1977. Levels were generally above 6 billion until 1984, but have been below 2.5 billion for the last four years"* (Statistics NZ, 2007).

identify this disability or to associate a range of presenting disorder and birth defects with possible prenatal exposure to alcohol. It is therefore not at all surprising that trying to establish prevalence in Australia and New Zealand is unrealistic. If an FASD is not recognised it is not counted and therefore by definition is deemed not to exist as an alcohol-related disorder. This however, does not mean that the problems are not being experienced and that the impact is not being felt by families and community and the service providers they encounter.

The occurrence of FASD is likely to be as significant as has been found in other developed countries where the consumption of alcohol is normalised and where prevalence studies have begun to take place in populations of children and adults.

Overseas studies estimate that Fetal Alcohol Spectrum Disorder, which includes FAS, collectively affects 1 in 100 (1%) live births (May and Gossage, 2001). However, more recent epidemiological studies have found the numbers of individuals affected to be much higher in some communities. For instance a well controlled prevalence study, carried out in a random sample of Italian primary schools to ascertain the prevalence and characteristics of FASD, found the rate of Fetal Alcohol Syndrome to be 7.4/1000, with an overall rate of 3.5% for Fetal Alcohol Spectrum Disorders (May et al, 2006).

In Australia and New Zealand, there has never been an investment made at a Government level to train health professionals to identify, accurately diagnose and assess FASD against recognised protocols. Based on consumption levels and patterns of drinking and numbers of women continuing to consume alcohol during pregnancy and a comparison with prevalence studies from elsewhere, a reasonable assumption would be that the numbers in Australia and New Zealand will be substantial.

It is of significant concern that a decision about whether to place a health advisory label on a toxic product might be based on the numbers or likelihood of being born affected. For instance, should the numbers affected have been a deciding factor in the FSANZ decision to add folate to food products to reduce (as opposed to prevent) the risk of neural tube defect?

As you see in appendix 1 and 2 a caffeine warning has been placed on a Vodka RTD that has an alcohol content of 7%. The evidence that caffeine can adversely and permanently damage an unborn baby is highly questionable. Even the most recent research suggesting a link between caffeine and miscarriage is being seriously disputed by other researchers (Butterworth, 2008). The decision to warn against caffeine consumption during pregnancy on caffeinated beverages could not have been justified on research about the numbers of babies born affected.

6. *Are there any other data available relating to the level of awareness amongst women of childbearing age of the risk of consuming alcohol when planning to become pregnant and during pregnancy in Australia and New Zealand?*

See response to question 4. The risk of prenatal alcohol exposure is likely to be more accurately estimated if it is based on pre-conception levels of drinking by women of reproductive age, rather than how much women who are already pregnant report consuming. The reason being that many pregnancies are unscheduled and confirmation of pregnancy often does not occur until the pregnancy is already advanced. A health advisory statement on bottles of alcohol is an important way to

prompt a woman thinking about their possible pregnancy status when socialising with alcohol and therefore have a chance to moderate the intake until that status is known.

7. *Do you think a health advisory statement about the risk of consuming alcohol when planning to become pregnant and during pregnancy on all alcoholic beverage containers should be required? Why/why not?*

Yes most definitely for all the reasons stated above: A mandatory health advisory label including a pictorial image prominently displayed on the product container is essential for public health and safety because of:

- proven risk of birth defects and fetal alcohol syndrome associated with binge or heavy consumption
- evidence of central nervous system sensitivity to ethanol damage at low levels of consumption
- no known lowest dose threshold
- no safe time to consume alcohol during pregnancy for normal brain development
- a right the public has to be informed and reminded about the product they are consuming at the time of consumption
- a need for this fundamental information to act as a support base for other public health efforts and to counter the stream of media and other misinformation.

A label would have three primary purposes: to inform, to remind and to reinforce health promotion. Anecdotal evidence suggests that a label may be the only consistent message that some people receive, particularly those who are not well connected to healthcare services.

8. *What further evidence is available about the use and/or effectiveness of a health advisory statement on alcoholic beverage containers regarding the risk of consuming alcohol when planning to become pregnant and during pregnancy?*

It is simply impossible to measure the use and/or effectiveness of a health advisory statement on alcoholic beverages in New Zealand and Australia since they have never existed here.

The experiences from the USA where most studies have been carried out may present some learning, however may not translate adequately. The USA government warnings in small print, not in contrasted colours and are usually obscured on the back or neck of the container and without any accompanying pictorial image. Appendix 1 & 2 provide examples of the USA warning appearing on wine products from Australia and New Zealand that are destined for export to that market.

Basic to the success or otherwise of a health warning is whether people notice them. Experiments on how quickly people could locate the typical alcohol warning label in the USA, indicates that that government warning is not noticeable (Agostinelli and Grube, 2002). Hence they are not likely to be very effective.

However, what evidence there has been on effectiveness, suggests that even at this very inadequate level of warning the awareness of consumers improved, as pointed out in the ALAC application.

It is commonly argued by industry groups that consumers are already adequately informed. As the authors of a large scale study of the effectiveness of warnings on cigarette packet point out, that argument is false (Hammond et al, 2005). The findings from an international study of 10,000 smokers in 4 countries assessing the effectiveness of tobacco warnings indicates, there are gaps in smoker's knowledge even in the most highly educated countries and those who noticed the warnings were significantly more likely to endorse the health risk of smoking. The study showed that health warnings on packaging are a prominent source of information.

A label will additionally provide a foundation for other public health education efforts such as an advertising campaign or posters where alcohol is sold. Mandating a pregnancy and alcohol health advisory label for New Zealand and Australia citizens, is the beginning not the end of prevention efforts as demonstrated in the USA. Subsequent to mandating a health advisory statement in 1989, approximately 67 bills relating to FASD prevention and intervention and a host of projects and programme have been introduced (SAMHA, 2006). Nineteen US states and the District of Columbia so far have enacted laws requiring warning posters be displayed at the point of sale.

9. What wording for a statement about the risk of consuming alcohol when planning to become pregnant and during pregnancy would be appropriate on an alcoholic beverage container to raise awareness in pregnant women and women planning to become pregnant?

Regardless of the wording, the inclusion of a pictorial image is essential. The pictorial example provided in appendix 3 is a good example of combining text and imagery. The meaning is clear and easily understood regardless of the ability to read or understand English.

The design and placement must be determined by FSANZ, not left to industry discretion.

Consultation with birth mothers who have been at risk of alcohol consumption during pregnancy is essential during the content development stage.

10. What further evidence is relevant to the wording of such a statement, such as its likely effectiveness or appeal to women of childbearing age and/or understanding of the statement by women of childbearing age?

According to evidence in regard to tobacco warnings internationally, warnings that are graphic, larger and more comprehensive in content are more effective in communicating the health risk of smoking (Hammond et al, 2005).

However, pregnancy is a very sensitive issue and the wording and the graphic needs to be empowering rather than graphically horrifying. The example in appendix 3 achieves that aim.

11. What are the advantages and disadvantages of a written statement compared with a pictorial image for conveying the risks of consuming alcohol when planning a pregnancy and during pregnancy?

As discussed above a picture is far more effective than text alone (EnviroNics Research Group, 1999).

Both a written and a pictorial label should be required to be displayed together so the advice can be understood at a glance regardless of levels of literacy and to appeal to different learning styles.

12. What percentage of alcohol by volume should be used to determine which alcoholic beverages are to carry an advisory statement, if required?

Ideally, given this is an amendment to inform the public of the risk of consuming alcohol during pregnancy and there is no established safe level of consumption of alcohol, every alcoholic beverage should be required to carry the warning label.

13. What is the likely impact on consumers, industry, and/or government if the status quo was maintained?

Maintaining the status quo is not justifiable. The status quo is ill-informed consumers, unsupported health promotion efforts and accordingly the continuation of a higher risk of preventable birth defects. The application to amend the code as per the application is at the request of the New Zealand Government because of the significant cost to society from not acting accordingly (See Minister's press release in Appendix 4). This has been a New Zealand Government directive since 2003, when it supported a request from the then Parliamentary Health Select Committee.

Any cost incurred to change the code to require this health advisory statement simply pales into insignificance when considering that every case of FASD that is not prevented places an enormous financial burden on taxpayers through requiring extra health, education and social support services. The burden on affected families and individuals is simply indescribable.

The USA estimates the life-time health-care costs for one individual with Fetal Alcohol Syndrome to be at least US\$1.4 million (Lupton et al, 2004).

In Canada, using an estimated life-time care cost of \$1 million per person, the calculation for FAS alone costs Canadian taxpayers an extra \$4 billion every year across all systems (Clarren, 2007). This estimate is based on the annual Canadian birth rate and an FAS prevalence rate of 1 per 1000 live births (4,000 babies born with FAS). This figure is cumulative as it is additional to the cost of those already born with FASD.

"It would be my belief that that is very conservative in all ways. The rates of FAS and FASD are undoubtedly far higher than 1/1000 and the cost per person over a lifetime is not clearly known but might be much higher as well in both outgoing costs to the person and decreased income and taxes paid." (Personal correspondence with Professor Sterling Clarren, 8/04/07).

Given that alcohol manufacturers appear willing to already label alcohol beverages for other jurisdictions (see appendix 1 & 2) there is no reasonable argument that would preclude this measure being taken for the domestic markets of Australia and New Zealand.

Continuing with the status quo leaves the alcohol industry at risk of litigation. It was a successful legal challenge against the alcohol industry, mounted by a handful of angry birth mothers who had not been advised to abstain from drinking during pregnancy in the North of France that led to the mandatory government warning in France, as discussed in the FSANZ report.

Any cost that is passed on to consumers is likely to be negligible. However, any increase in the overall price of alcohol is to be encouraged as a public health benefit. Although usually achieved through an increase in excise taxation, a rise in the price of alcohol is one of the most effective ways to reduce overall alcohol-related harm, particularly among price sensitive young people (Babor et al, 2003).

14. How would labelling alcoholic beverages compare in terms of effectiveness and cost-effectiveness with other public health measures to inform pregnant women of the risks of alcohol consumption during pregnancy?

Health advisory information conveyed via packaging is arguably the cheapest and most cost-effective way to raise awareness and inform - as demonstrated in the USA and the tobacco labelling experience – the job for which they are intended.

However, as raised previously in this submission, there is no justifiable reason to compare the effectiveness or otherwise of other public health measures as a basis on which to decide. Comparisons between one intervention and another is simply not feasible when each intervention is designed to do a different job or the same job in a different manner or setting. No one intervention could be expected to achieve all that is possible.

What would be more useful to determine in this context, is whether an intervention is effective at doing what it is aimed to do in conjunction with other measure and whether it adds positively to the overall aim. Research on the success of awareness raising measures suggest that it is the way in which the message, the source and the audience factors interact that is the important consideration (Agostinelli & Grub, 2002).

A health advisory label advising the public that there is a risk of harm from consuming alcohol during pregnancy is not a comparable 'either/or' issue. It is a stand alone issue. The sale and supply of alcohol is regulated because of its links to significant harm. Continuing the sale of this marketed food commodity in the absence of important health related risk information, does not meet the important principle of informed choice, something that the public appears to increasingly demand.

Changing the status quo in support of Application A576 is about FSANZ acting appropriately and responsibly - morally, ethically and legally – to ensure the public is advised of a significant and preventable risk that is inherent in all alcohol available for consumption. What is done from there onwards is up to others.

References

Agostinelli G and Gurbe J (2002). *Alcohol Counter-advertising and the media: A review of recent research*. National Institute on Alcohol and Alcoholism of the National Institute of Health. <http://pubs.niaaa.nih.gov/publications/arh26-1/15-21.htm>

Babor T, Caetano R, Casswell S, Edwards G, Giesbrecht N, Graham K, Grube J, Gruenewald P, Hill L, Holder H, Homel R, Osterberg E, Rehm J, Room R and Rossow I (2003) *Alcohol: No Ordinary Commodity*. Oxford University Press.

Butterworth T (2008). *Coffee and Miscarriage: Jitters or Junk?*

<http://thestatsblog.wordpress.com/2008/01/22/coffee-and-miscarriage-jitters-or-junk/>

Chudley A, Conry J, Cook J, Look C, Rosales T and LeBlanc N. (2005) Fetal alcohol spectrum disorder: Canadian guidelines for diagnosis. *Canadian Medical Association Journal*; 172 (5 Supplement):S1-S21.

Clarren S (2007). The Western and Northern Canadian Approach to Diagnostic, Intervention and Prevention Research. *Plenary Session at the 2nd International Conference on Fetal Alcohol Spectrum Disorder: Research Policy and Practice Around the World*. Inter-professional Continuing Education, University of British Columbia.

Environic Research Group (1999). *Qualitative (focus group) report regarding health warning labels and images on cigarette packages*. Health Canada, Ottawa.

Li Y et al (2007). Alcohol increases breast cancer risk. WebMed News. European Cancer Conference, Barcelona, Spain, Sept. 23-27. *News release* <http://www.medicinenet.com/script/main/art.asp?articlekey=84174>

Flensburg-Madsen T, Knop J, Mortensen E, Beker U and Gronbaek M (2007). Amount of alcohol consumption and risk of developing alcoholism in men and women. *Alcohol and Alcoholism*, 42(5):442-447.

Goodyear-Smith f, McCormick R, Paton-Simpson G and Brighthouse S (2004). *Changes in Drinking Behaviour Detected in Auckland General Practice Patients Between 1995 and 2003: Public Research Summary*. Goodfellow Unit, Department of General Practice and Primary Health Care, University of Auckland.

Greenberg (2003). Linking acquired neurodevelopmental disorders to defects in cell adhesion. *Proceedings of the National Academy of Sciences*. U S A. 2003 July 8; 100(14): 8043–8044.

Hammond D, Fong G, McNeill A, Borland R & Cummings K (2006). Effectiveness of cigarette labels in informing smokers about the risks of smoking: findings from the International Tobacco Control (ITC) Four Country Survey. *Tobacco Control*: 15 (Supplement 3); iii19-iii25.

Jackson R (2007). Alcohol and ischaemic heart disease: probably no free lunch. *The Lancet*, 366: 1911-1912.

Jacobsen S and Jacobsen L (2007). Biomarkers and Effect Modifiers of Fetal Alcohol Spectrum Disorder: Findings from Detroit and Cape Town. *Plenary Session at the 2nd International Conference on Fetal Alcohol Spectrum Disorder: Research Policy and Practice Around the World*. Inter-professional Continuing Education, University of British Columbia.

Liggins Institute (2005) *Dialogue*: Newsletter of the Liggins Institute November. University of Auckland.

Lupton C, Burd L and Harwood R (2004) Cost of Fetal Alcohol Spectrum Disorders. *American Journal of Medical Genetics*, 15:127 C(1):42-50.

May P, Fiorentino J, Gossage P, Kalberg W, Hoyme E, Robinson L, Coraile G, Jones K, Campo M, Tarani L, Romeo M, Kodituwakku P, Deiana L, Buckley D and Ceccanti M (2006). Epidemiology of FASD in a Province in Italy: Prevalence and Characteristics of Children in a Random Sample of Schools. *Alcoholism: Clinical and Experimental Research*, 30(9):1562-1575.

Naimi T, Brown D, Brewer R, Giles W, Mensah G, Serdula M, Mokdad A, Hungerford D, Lando J, Naimi S, Stroup D. (2005) Cardiovascular risk factors and confounders among non-drinking and moderate-drinking U.S. adults. *American Journal Preventive Medicine*, 29(3):243.

National Health and Medical Research Council (2007). Australian Alcohol Guidelines for Low-risk Drinking: Draft for public consultation.

Nutt D, King L, Saulsbury W and Blakemore C (2007) Development of a rational scale to assess the harm of drugs of potential misuse. *The Lancet*, 369:1047-1053.

Parackal S, Parackal M, Ferguson E & Harraway J (2006). Report on Awareness of the Effects of Alcohol Use During Pregnancy Among New Zealand Women of Childbearing Age. *Submitted to the Alcohol Advisory Council & Ministry of Health*.

SAMHSA (2006) Fetal Alcohol Spectrum Disorders Legislation by State 2005-2006 Legislative sessions. *Substance Abuse and Mental Health Services Mental Health Services Administration: Fetal Alcohol Spectrum Disorder Center of Excellence*.

Sampson P, Streissguth A, Bookstein F and Barr H (2000). On Categorization in Analysis of Alcohol Teratogenesis. *Environmental Health Perspectives*, Volume 108.

Stratton K, Howe C and Frederick B, Eds. (1996). Fetal Alcohol Syndrome: Diagnosis, Epidemiology, Prevention and Treatment. *Institute of Medicine Division of Biobehavioural Sciences and Mental Disorders*, National Academy Press.

Streissguth A and Dehaene P (1993). Fetal Alcohol Syndrome in Twins of Alcoholic Mothers: Concordance of Diagnostic IQ. *American Journal of Medical Genetic*, 47:857-861.

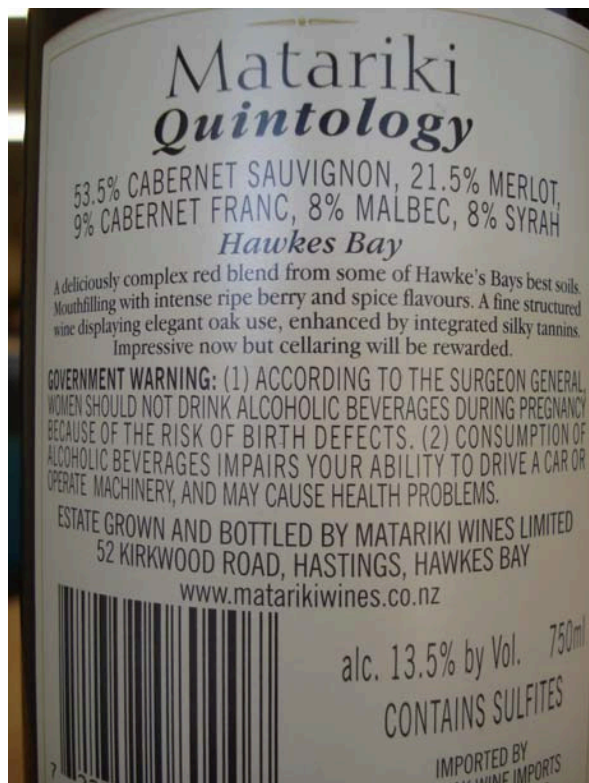
Wilkemeyer, M, Chen, S., Menkari, C, Brenneman, D, Sulik, K & Charness, M (2003). Differential effects of ethanol antagonism and neuroprotection in peptide fragment NAPVSIPQ prevention of ethanol-induced developmental toxicity. *Proceedings. National Academy of Sciences USA* 100, 8543-8548.

World Health Organisation (2007). *Draft Regional Strategy to Reduce Alcohol Related Harm*. Regional Office for the Western Pacific Regional Committee fifty-seventh Session, Auckland New Zealand.

Whitehall J (2007). National guidelines on alcohol use during pregnancy: a dissenting opinion. *Medical Journal of Australia*. Vol 186:1, 35-37.

Appendix 1

Australian and New Zealand produced wine with a Government warning required for the American market.



Appendix 2

An alcoholic ready to drink (RTD) product with a 7% alcohol content displaying health advisory statement for the caffeine it contains



Appendix 3

Label designed by the National Organisation for Fetal Alcohol Syndrome and Related Disorders (NOFASARD, 2007).



Appendix 4

Minister Welcomes Progress On Alcohol Warning Labels

Press Release by New Zealand Government at 4:37 pm, 13 Dec 2007

Associate Health Minister Damien O'Connor today welcomed progress on the proposal to place labels on alcoholic beverages informing women of the risks of drinking while pregnant.

Food Standards Australia New Zealand (FSANZ) yesterday released an assessment report on the Alcohol Advisory Council's (ALAC) application to amend the Food Standards Code so all containers of alcoholic beverages contain a warning label about the dangers of drinking during pregnancy. The report is to appraise whether ALAC's application warrants further consideration by FSANZ.

Mr O'Connor said the Government fully supports ALAC's application and he encourages individuals and organisations to comment on FSANZ's report.

"Fetal Alcohol Spectrum Disorder (FASD) can have life long and debilitating affects. It can result in permanent brain damage and can include a range of behavioural and physical disabilities. These disorders are fully preventable," said Mr O'Connor.

"The Government is concerned about this issue and is acting on it. We have already adopted a policy of recommending zero alcohol consumption for women who are pregnant or are considering becoming pregnant. There is no known safe level of alcohol use during pregnancy."

ALAC's application forms part of a whole of government approach to address FASD in New Zealand. Work is currently under way by the Inter-Agency Committee on Drugs to develop a broad action plan with a focus on FASD under the National Drug Policy 2007-2012.

The Ministry of Health will be providing a submission in support of ALAC's application to Food Standards Australia New Zealand.