FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

12 December 2007
[8-07]

INITIAL ASSESSMENT REPORT

APPLICATION A576

LABELLING OF ALCOHOLIC BEVERAGES WITH A PREGNANCY HEALTH ADVISORY LABEL

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 6 February 2008
SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL NOT BE CONSIDERED
(See 'Invitation for Public Submissions' for details)

For Information on matters relating to this Assessment Report or the assessment process generally, please refer to http://www.foodstandards.gov.au/standardsdevelopment/

Executive Summary

The Alcohol Advisory Council of New Zealand (ALAC) (the Applicant) lodged an Application with Food Standards Australia New Zealand (FSANZ) on 17 February 2006. The Application is seeking a variation to existing Standard 2.7.1 – Labelling of Alcoholic Beverages and Food Containing Alcohol, of the *Australia New Zealand Food Standards Code* (the Code), to require a health advisory label on alcoholic beverage containers advising of the risks of consuming alcohol when planning to become pregnant and during pregnancy. The Application was accompanied by a summary of findings of a review of recent research relating to drinking, pregnancy and labels.

This Initial Assessment Report is not an assessment of the merits of this Application, but rather it is an appraisal of whether the Application warrants further consideration according to criteria laid down in the *Food Standards Australia New Zealand Act* 1991 (FSANZ Act). It is the conclusion of this assessment that, having regard to the requirements of section 13 of the FSANZ Act, this Application should be accepted.

It is known that drinking alcohol during pregnancy can be associated with varying degrees of harm to the unborn child. Foetal Alcohol Spectrum Disorder (FASD) is an umbrella term used to describe the wide range of effects on the foetus from drinking alcohol during pregnancy.

This Report identifies the issues which need to be considered in order to proceed with the assessment of the Application. It also provides the general community with information to assist interested parties in preparing submissions.

In order to evaluate the merits of this Application, FSANZ needs to assess the evidence available which investigates the impact of low maternal alcohol consumption on the developing foetus. Data on the incidence of FASD, the drinking patterns of women of childbearing age and pregnant women in Australia and New Zealand, and their knowledge of the risks to the foetus associated with consuming alcohol during pregnancy also need to be considered as part of the risk assessment. Should the risk assessment indicate the need to evaluate risk management options, FSANZ will consider available data on the impact of advisory labels on alcoholic beverages on consumer awareness of the risk of drinking alcohol during pregnancy and subsequent behaviour, at Draft Assessment. The Applicant has emphasised that the introduction of health advisory labels is an essential part of a much wider public health strategy aimed at educating the community as a whole to increase awareness and minimise the risk of consuming alcohol during pregnancy.

If the Application is approved, suppliers will be required to place a label on alcoholic beverage containers advising consumers of the risks of consuming alcohol when planning to become pregnant and during pregnancy.

Purpose

The purpose of this Application is to seek a variation to existing Standard 2.7.1 to require a health advisory label on alcoholic beverage containers advising of the risks of consuming alcohol when planning to become pregnant and during pregnancy.

Reasons for Assessment

After considering the requirements for Initial Assessment as prescribed in section 13 of the FSANZ Act, FSANZ has decided to accept the Application for the following reasons:

- The Application seeks approval to require a health advisory label on alcoholic beverage containers advising of the risks of consuming alcohol when planning to become pregnant and during pregnancy. Such an approval, if accepted, would warrant a variation to the Code.

- There is currently no requirement in the Code for a health advisory label on alcoholic beverages advising of the risks of consuming alcohol when planning to become pregnant and during pregnancy.

- The Application is not so similar to any previous application that it ought not be accepted. FSANZ considers that Application A359, which requested that the warning statement 'This product contains alcohol. Alcohol is a dangerous drug' be placed on the label of alcoholic beverages, differs to the current Application which focuses on maternal alcohol consumption only. Application A306, which requested a warning about the possible risk of birth defects from alcohol consumption during pregnancy on alcoholic beverages, was withdrawn before being fully assessed.

- At this stage no other relevant matters are apparent.

Regulatory Options

FSANZ has identified two options that are available for proceeding with assessment of Application A576:

Option 1 – Maintain status quo

Under this option, the *status quo* would be maintained by not amending the Code to mandate the labelling of alcoholic beverages to advise of the risks of consuming alcohol when planning to become pregnant and during pregnancy.

Option 2 – Amend the Code to require a health advisory label on alcoholic beverage containers advising of the risk of consuming alcohol when planning to become pregnant and during pregnancy.

Option 2 would result in the mandatory labelling of alcoholic beverage containers with a health advisory label. The wording or format of the health advisory label, the level of alcohol (percentage of alcohol by volume) to which the labelling requirement would apply, any exemptions from the labelling requirement, and the standard of the Code in which the conditions would be located, would need to be determined.

Preliminary consideration of the impacts of these two options has been included under Section 8 of this Initial Assessment Report.

Consultation

The purpose of this Initial Assessment Report is to seek input from stakeholders in relation to the Application and to seek input on the likely regulatory impact at an early stage. At this stage FSANZ is seeking public comment to assist in assessing this Application and is particularly interested in receiving further information on the questions asked throughout this report, which are also presented at Attachment 1.

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INVITATION FOR PUBLIC SUBMISSIONS

FSANZ invites public comment on this Initial Assessment Report for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in preparing the Draft Assessment of this Application. Submissions should, where possible, address the objectives of FSANZ as set out in section 18 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 114 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. Submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222
www.foodstandards.gov.au

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942
www.foodstandards.govt.nz

Submissions need to be received by FSANZ by 6pm (Canberra time) 6 February 2008.

Submissions received after this date will not be considered, unless agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Questions relating to making submissions or the application process can be directed to the Standards Management Officer at the above address or by emailing slo@foodstandards.gov.au.

Assessment Reports are available for viewing and downloading from the FSANZ website. Alternatively, requests for paper copies of reports or other general inquiries can be directed to FSANZ's Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au.

INTRODUCTION

The Alcohol Advisory Council of New Zealand (ALAC) lodged an Application with FSANZ on 17 February 2006 to vary existing Standard 2.7.1 – Labelling of Alcoholic Beverages and Food Containing Alcohol, of the *Australia New Zealand Food Standards Code* (the Code). The purpose of the Application is to require a health advisory label on alcoholic beverage containers advising of the risks of consuming alcohol when planning to become pregnant and during pregnancy.

This Initial Assessment Report discusses the issues involved in the proposed amendment and seeks comment from stakeholders, particularly in relation to expected regulatory impact(s), to assist FSANZ in making an assessment of this Application.

1. Nature of the Application

1.1 The Applicant

ALAC was established in New Zealand in 1976 following a recommendation by the Royal Commission of Inquiry into the Sale of Liquor that a permanent council be established with the aim of encouraging responsible alcohol use and minimising misuse. ALAC's aims are pursued through policy advice, dissemination of information related to alcohol, research, community initiatives and treatment development. ALAC works with the media and other stakeholders to deliver messages on reducing alcohol related harm. ALAC is a Crown-owned entity.

1.2 Basis of the Application

The Applicant has proposed a variation to Standard 2.7.1 to require a health advisory label on alcoholic beverage containers advising of the risks of consuming alcohol when planning to become pregnant and during pregnancy. The actual wording or format of the health advisory label has not been proposed.

In its Application, ALAC states that alcohol consumption in pregnancy has the potential to harm the foetus at all stages of pregnancy and particularly in the early stages of pregnancy when the foetus is forming. Its view is that health advisory labels on alcohol beverage containers warning of the potential dangers of consuming alcohol when planning to become pregnant and during pregnancy are essential because:

- it is still a commonly held belief in both New Zealand and Australia that it is acceptable to have 'a couple of drinks', 'a couple of times a week';
- there is good evidence to show that health advisory labels will complement and enhance national strategies to raise awareness of the potential dangers of consuming alcohol when planning to become pregnant or during pregnancy;
- Foetal Alcohol Spectrum Disorder (FASD)/Foetal Alcohol Effects (FAE) is not a problem only for 'at risk' groups – there is strong evidence that FASD/FAE is fast becoming an issue for European, middle class women in full employment;
- no health benefits from the consumption of alcohol accrue to women of child-bearing age – benefits for women do not occur until after menopause;

- no level of alcohol consumption has been determined as completely low risk for the foetus; and
- consumers have a right to know the risks attached to consuming products.

It is also emphasised in the Application that the introduction of health advisory labels is an essential part of a much wider public health strategy aimed at educating the community as a whole to increase awareness and minimise the risk of consuming alcohol during pregnancy.

The Application was accompanied by a summary of findings of a review of recent research relating to drinking, pregnancy and labels. Copies of the references quoted in the Application have been provided to FSANZ.

1.3 Scope of the Application

The Applicant has requested a health advisory label be required on 'alcoholic beverage containers'. 'Alcoholic beverage' and 'containers' are not defined in the Code and therefore appropriate definitions or descriptions of these terms would need to be considered as part of the assessment of this Application.

The percentage of alcohol by volume could be used to define the scope of 'alcoholic beverage'. Clause 2 of Standard 2.7.1 requires declaration of alcohol by volume on the label of a package of food, and this clause states requirements for both 0.5% and 1.15% alcohol by volume. Under Clause 3 of Standard 2.7.1, standard drink labelling is required on the label of a package of a beverage that contains more than 0.5% alcohol by volume.

'Package' (as defined in Standard 1.1.1 of the Code) may adequately replace the use of the word 'container' as referred to in the Application. The definition of 'package' refers to 'any container or wrapper in or by which food intended for sale is wholly or partly encased, covered, enclosed, contained or packaged…'.

1.4 Background to the Application

As outlined in the Application, in the year 2000, the New Zealand House of Representatives received a petition requesting the House legislate that all alcoholic beverages in New Zealand carry health and safety messages including the warning that drinking alcohol during pregnancy can cause birth defects. This petition was referred to the Health Select Committee who considered the literature provided and recommended that mandatory warning labels be placed on all types of alcoholic liquor reminding women of the dangers of drinking alcohol while pregnant. The Health Select Committee also recommended that the labels be supported by a range of health promotion and education initiatives and research (House of Representatives Health Committee, 2002). In February 2003, the New Zealand Government agreed in-principle to health advisory labels advising of the potential dangers of drinking alcohol when planning to become pregnant and while pregnant on alcoholic beverage containers. Subsequently, ALAC prepared the appropriate application, which was supported by the New Zealand Ministry of Health.

A proposal for industry to voluntarily place advisory labels regarding the consumption of alcohol during pregnancy on alcohol beverage containers, was put to representatives from the New Zealand alcohol industry by the Associate Minister of Health in March 2005. At this meeting voluntary labelling was generally rejected by industry.

However, industry put forward an alternative approach of placing a website address on labels which consumers could use to find out information regarding alcohol consumption during pregnancy and when planning a pregnancy.

1.5 Approach to assessment of the Application

In order to evaluate the merits of this Application, FSANZ must take account of certain factors. The initial process will involve a risk assessment of:

- the available evidence which investigates the impact of low maternal alcohol consumption on the developing foetus; and
- the data on the incidence of FASD, the drinking patterns of women of childbearing age and pregnant women in Australia and New Zealand, and their knowledge of the risks to the foetus associated with consuming alcohol during pregnancy.

Should this risk assessment indicate the need to evaluate risk management options, FSANZ will take this Application through to a full Draft Assessment, which will include:

- consideration of available data on the impact of advisory labels on alcoholic beverages on consumer awareness of the risk of drinking alcohol during pregnancy and subsequent behaviour;
- consideration of other factors such as the need for minimum effective legislation, desirability of an efficient and internationally competitive food industry, the impact on consistency with trade agreements and international standards, and Australia's and New Zealand's obligations under the World Trade Organization; and
- a benefit cost analysis to determine whether changes to the Code would result in a net public benefit.

Should the risk assessment not support the use of a health advisory statement on alcoholic beverage containers about the risks of alcohol consumption before and during pregnancy, then FSANZ would present the rationale for this outcome in a Draft Assessment Report.

2. The Issue / Problem

The Applicant is seeking a variation to the Code to require a health advisory label on alcoholic beverage containers advising of the risk of consuming alcohol when planning to become pregnant and during pregnancy. The issue, according to the Applicant, is that alcohol consumption in pregnancy has the potential to harm the foetus, and that women do not know of this risk, or, if they do, they could benefit from a reminder of the risk at the time of planning to drink alcohol.

Currently, there is no mandatory requirement in the Code for such an advisory statement on alcoholic beverage containers.

3. Background

3.1 Foetal alcohol syndrome and associated terminology

Drinking alcohol during pregnancy has been associated with varying degrees of harm to the unborn child. These effects may include physical, mental, behavioural and/or learning disabilities with possible life long implications. FASD is an umbrella term used to describe harm to the foetus as a result of maternal alcohol consumption during pregnancy. This group of disorders encompasses foetal alcohol syndrome (FAS), alcohol-related birth defects and alcohol-related neurodevelopment disorders (Health Canada, 2006). FAS represents the most severe type of harm and includes characteristic physical abnormalities, growth retardation and neurological dysfunction with development delay (NHMRC, 2001). The term FASD is not intended for use in a clinical diagnosis.

Although the Application also refers to FAE, it is noted that in much of the recent literature the term 'FAE' has been replaced with 'alcohol-related birth defects' and 'alcohol-related neurodevelopment disorders'. With alcohol-related birth defects, certain alcohol-related physical abnormalities are present but not the facial features associated with FAS. Alcohol-related neurodevelopment disorder is characterised by alcohol-related mental defects without the facial defects and growth deficiency of FAS (May and Gossage, 2001).

3.2 Current standard

Standard 2.7.1 was gazetted in 2000 and became fully enforceable in Australia and New Zealand following a two-year transition period. The Standard provides the labelling requirements for alcoholic beverages and food containing alcohol.

Standard 1.2.3 – Mandatory Warnings and Advisory Statements and Declarations sets out the mandatory advisory statements and declarations that must be made in relation to certain foods or foods containing certain substances.

There are currently no requirements in either of these standards for health advisory labels on alcoholic beverages or food containing alcohol. Although the purpose of the Application refers to varying Standard 2.7.1, FSANZ would determine the most appropriate standard for the conditions at Draft Assessment, should assessment of the Application determine the need for a variation to the Code.

3.3 Historical background

3.3.1 Application A306

Application A306 was received by the then National Food Authority (now FSANZ) in March 1996, from the Australian National Council of Women. T his Application sought to require a warning to women about the possible risk of birth defects from alcohol consumption during pregnancy, on labels of alcoholic beverages. Submissions were received in response to the Information Summary that was released in June 1996. However, the Application was subsequently withdrawn at the end of that year due to an impending review of the Australian alcohol guidelines.

3.3.2 Application A359

Application A359, previously considered by the then Australia New Zealand Food Authority (now FSANZ), sought to require that all alcoholic beverages be labelled with the following warning statement - 'This product contains alcohol. Alcohol is a dangerous drug.' A Full Assessment of Application A359 was made and in July 2000, Application A359 was rejected (http://www.foodstandards.gov.au/standardsdevelopment/applications/applicationa359label953.cfm). A summary of the Statement of Reasons and ALAC's response is in Table 1.

ALAC has provided a summary of findings from recent research as at 2005, under the issues raised by FSANZ when rejecting Application A359 in 1999, in order to provide support for the acceptance of its Application. FSANZ considers that the current Application differs sufficiently to the broad approach taken under the previous Application A359, by focusing on FASD and maternal alcohol consumption only.

Table 1: Summary of Statement of Reasons for rejection of Application A359 and response from ALAC

Statement of reasons	Summary of ALAC response
Scientific evidence indicates that health advisory labels are not effective in changing behaviour of 'at-risk' groups	• Labelling on alcoholic beverage containers will contribute to an overarching strategy to address FASD. • There now seems to be two distinct profiles of 'at-risk' women, including middle class European women. • Many women report that they continue to drink because of misperceptions about how much alcohol intake is acceptable and how much harm it can cause.
Simple, accurate warning statements would be difficult to devise, given the complexity of the issues and the benefits of moderate consumption	• The current Application addresses a single issue for which there is clear evidence of potential harm, not a broad approach as suggested under Application A359. • The need for a balancing message about the possible health benefits of alcohol does not apply. The latest evidence shows there are no health benefits in drinking alcohol before middle age.
Alcohol consumption and alcohol-related harm are trending down in Australia and New Zealand	• The downward trend in alcohol consumption identified in 1999 has not been realised and the most current and credible research available shows that alcohol consumption in women of child bearing age has increased.
Public health strategies aimed at reducing alcohol-related harm are already implemented in Australia and New Zealand	• New Zealand and Australia have implemented drug strategies that tend to focus on reducing drink driving or underage drinking through health promotion initiatives, community action programs and social marketing campaigns. • Health advisory labels can be put into place quite quickly and cost effectively compared to other initiatives which will take some time and significant resources to develop and implement.

Statement of reasons	Summary of ALAC response
Alcohol is regarded as having health benefits when consumed at low to moderate levels	• This issue is not directly relevant to the Application (A576). A message advising of the potential dangers of drinking alcohol during pregnancy does not bring any particular responsibility to also provide information about the potential to gain health benefits. • Such an approach could undermine the benefits of the proposal. • Such benefits do not accrue to women of child-bearing age.
The available literature suggests that 'there was no evidence that light drinking by pregnant women harms the foetus'	• A review of evidence available in 2004 supported the conclusion that alcohol consumption during pregnancy can have a direct harmful effect on a foetus, although it is not possible to specific exactly how much alcohol is required for this harm to occur. • Some studies suggest that even very light drinking can have an effect on foetal development.

3.4 International perspective

There is no international consensus on the use of warning labels on alcoholic beverages nor consistency of format and/or wording. Some countries prescribe warning labels for alcoholic beverages regarding pregnancy; these are the USA, Colombia, South Korea (Stockwell, 2006), and more recently, France, Finland and South Africa. In Japan, some brewers voluntarily label with messages warning about drinking during pregnancy (Stockwell, 2006).

At least another 13 countries require health warning labels on alcoholic beverages, but not specifically in relation to pregnancy. There is no consistency amongst these countries regarding the required wording, however, most are general statements such as 'Alcohol abuse is harmful to your health'.

There are no specific Codex standards in relation to labelling of alcoholic beverages.

3.4.1 United States of America (US)

Since 1989, all alcoholic beverage containers sold or distributed in the US have been required to bear the following statement:

> *GOVERNMENT WARNING: (1) According to the Surgeon General, women should not drink alcoholic beverages during pregnancy because of the risk of birth defects.*
>
> *(2) Consumption of alcoholic beverages impairs your ability to drive a car or operate machinery, and may cause health problems.*

The enactment of this legislation and associated public concern was driven by mounting scientific evidence of the harmful effects of alcohol, including FAS. The risk of birth defects was given priority in the warning statement due to concern for potential harm to innocent infants by maternal drinking of even small amounts of alcohol. It was acknowledged that the lowest safe level of alcohol consumption for preventing FAS was not known and this led to the recommendation that the only safe level of drinking during pregnancy is complete abstention (Kaskutas, 1995).

3.4.2 Europe

3.4.2.1 European Union

The European Union (EU) Parliament has recently decided not to require standard EU-wide legislation for alcoholic drinks to carry warning labels (including for pregnant women). Instead, Member States are urged to develop their own requirements with respect to warning labels on alcoholic beverages.

3.4.2.2 France

France has recently implemented a requirement for all containers of alcoholic beverages to have at least one of two health messages:

- a statement indicating that consuming alcoholic beverages during pregnancy, even in small quantities, can have serious effects on the health of the child;
- the following logo:

The use of this labelling has been mandatory from 3 October 2007 (allowing for a one year transition period). This labelling measure is part of a larger action program to reduce the occurrence of FAS.

It has been noted by the French authorities that the data available do not allow scientists to define a threshold under which alcohol consumption by pregnant women would be risk free for the child. Therefore, French health authorities recommend that women totally abstain from drinking alcohol during pregnancy.

3.4.2.3 Finland

Finland has recently proposed that the packaging of alcoholic beverages carry a general warning regarding the harmful effects of alcohol on health and a special warning regarding the risk of foetal damage due to alcohol. The final details regarding this requirement are yet to be determined. The mandatory warning regarding the risk of foetal damage has been proposed as part of a broader range of measures aimed at decreasing the detrimental effects caused by alcoholic substances, including a more general warning label about the health hazards of alcohol. The rationale for requiring warnings about both the general hazards of alcohol and the risk of foetal damage was that if the warning label is restricted to the risk of alcohol during pregnancy, it might direct attention to use of alcohol by women in a way which could increase the feeling of shame or increase the threshold for seeking help. It was therefore considered that warning labelling and supporting information should pay attention to the risks specific to both women and men.

3.4.2.4 United Kingdom

In the United Kingdom, warning labels on alcohol regarding pregnancy are not mandated. The government has recently released a document entitled 'Safe. Sensible. Social. The next steps in the National Alcohol Strategy' (Department of Health et al, 2007). This document reviews progress since the publication of the Alcohol Harm Reduction Strategy for England (2004) and outlines further national and local action to achieve long-term reductions in alcohol-related ill health and crime.

The document includes the advice that pregnant women or women trying to conceive should avoid drinking alcohol, and if they do choose to drink, to protect the baby they should not drink more than 1-2 units of alcohol once or twice a week and should not get drunk. This advice is based on a literature review completed in 2006 which found some evidence that binge drinking can affect the development of the nervous system in the foetus (Gray and Henderson, 2006). However, low to moderate consumption during pregnancy was not found to have any adverse effects on the baby. It was recognised that there was a risk that it would be difficult to interpret guidance based on this information in terms of the amount it would be safe to drink when pregnant, and therefore it was decided to strengthen the wording of the advice to women.

The government is encouraging the alcohol industry to include sensible drinking information for pregnant women on labels, such as 'Avoid alcohol if pregnant or trying to conceive', as part of the overall sensible drinking message. It is intended that consultation will be carried out in 2008 to determine the use of such messages by industry and to evaluate the need for legislation on alcohol labelling regarding pregnancy.

3.4.3 Canada

Health advisory or warning labels are not required in Canada and there are no proposals for such a requirement at this time. However, since February 2005, licensed establishments in Ontario have been required to display specific warning signs about the risk of alcohol use in pregnancy (Dell and Roberts, 2005).

The Public Health Agency of Canada (2005) recommends that women who are trying to get pregnant or are pregnant already, stop drinking alcohol. It states that there is no safe amount or safe time to drink alcohol during pregnancy.

3.4.4 South Africa

In South Africa, new regulations have recently been published requiring that containers of alcoholic beverages display messages highlighting the negative effects of alcohol consumption. There are numerous messages required including 'drinking during pregnancy can be harmful to your unborn baby'.

3.4.5 International industry approaches

Pernod Ricard, who claim to be one of the world's largest operators in the wine and spirits market, has announced that a warning regarding the health risks for pregnant women will progressively be added to their wine and spirit brands sold across the European Union during 2007.

This labelling initiative has been proposed as a result of the requirement in France for the 'pregnant women' logo, which will enable Pernod Ricard to communicate the warning message more widely (Pernod Ricard website). Pernod Ricard owns some major alcohol brands in Australia and New Zealand including Montana and Jacob's Creek.

3.5 Alcohol policies, strategies and guidelines

3.5.1 New Zealand

3.5.1.1 New Zealand National Drug Policy

New Zealand's *National Drug Policy 2007 - 2012* sets out the New Zealand Government's policy for alcohol, tobacco, illegal and other drugs. The overarching goal of the National Drug Policy is to prevent and reduce the health, social and economic harms that are linked to tobacco, alcohol, illegal and other drug use. One of the specific objectives under this policy is 'to reduce harm to individuals, families and communities from the risky consumption of alcohol' (Ministry of Health, 2007a).

3.5.1.2 New Zealand National Alcohol Strategy

The Government's *National Alcohol Strategy 2000-2003* sits under the National Drug Policy. The National Alcohol Strategy provides more detail on how to achieve the alcohol-related targets that are identified in the National Drug Policy. The National Alcohol Strategy lists 'effects on unborn children' as one of the most significant types of alcohol-related harm (ALAC and Ministry of Health, 2001).

A number of Demand Reduction Strategies are identified in this document. These are designed to prevent alcohol-related harm from occurring by ensuring that those who choose to drink do so in a responsible manner. One of the Demand Reduction Strategies identified to help achieve the objective of providing consumers with accurate and clear information on alcoholic drink containers is to 'Support further examination of the benefits and costs of including additional product information on alcoholic drink containers (e.g. health warnings).'

Targets for monitoring against the outcome of 'reduction in the prevalence of drinking among pregnant women and women planning pregnancy' were not identified in this document due to the lack of baseline data (ALAC and Ministry of Health, 2001).

A review of the *National Alcohol Strategy* was completed in September 2007. Recommendations from the review are being considered in the development of the National Alcohol Action Plan which will replace the *National Alcohol Strategy.* The National Alcohol Action Plan is scheduled to be completed by mid-2008.

3.5.1.3 New Zealand Food and Nutrition Guidelines

The Food and Nutrition Guidelines for Healthy Pregnant and Breastfeeding Women (Ministry of Health, 2006) include the recommendation that it is best not to drink alcohol during pregnancy.

3.5.1.4 Action Plan to address FASD in New Zealand

Information provided to FSANZ by ALAC subsequent to the receipt of the Application has indicated that the Interagency Committee for Drug Policy has agreed that a working group develop a whole of government action plan to address FASD. The approach is to develop a broad Child and Maternal Health Action Plan which is intended to be focused on FASD but will consider other drugs under each action. It is anticipated that a draft Action Plan will be completed by early 2008 and following public consultation, is expected to be completed mid-2008. This Action Plan will sit under the National Drug Policy. The Application states that health advisory labels will form an important strand of this Action Plan involving education of the community as a whole and women of child-bearing age as well as their health professionals, partners, families and friends.

3.5.*2* *Australia*

3.5.2.1 Australia National Alcohol Strategy

Australia's *National Alcohol Strategy 2006 – 2009* is a plan for action developed through collaboration between Australian Governments, non-government and industry partners and the broader community (Ministerial Council on Drug Strategy, 2006). It outlines priority areas for coordinated action to develop drinking cultures that support a reduction in alcohol-related harm in Australia. The National Alcohol Strategy reflects Australia's *National Drug Strategy: Australia's integrated framework 2004-2009* and also supports the *National Drug Strategy Aboriginal and Torres Strait Islander Peoples Complementary Action Plan 2003-2006.*

The National Alcohol Strategy identifies FAS as a particular health concern and states that 'While the evidence suggests that the birth prevalence of foetal alcohol syndrome (FAS) is relatively small in Australia, the condition is a particular issue of concern in Aboriginal and Torres Strait Islander communities.' It is noted that better and more consistent data and evidence are needed about the full range of alcohol-related birth defects, so that specific interventions can be well informed.

A number of actions in response to the alcohol-related health issues are recommended in the National Alcohol Strategy. Those actions relating specifically to FAS are as follows (Section 3D: support whole-of-community initiatives to reduce alcohol related health problems):

- As part of the cyclical review of the Australian Alcohol Guidelines:
    - consider any special needs for population sub-groups – pregnant women, young people, Aboriginal and Torres Strait Islander peoples, older people, and people who have experienced alcohol dependence.
- Support consistent data collection on Foetal Alcohol Spectrum Disorders in the general population and in high risk groups.
- Monitor developments in Australia and overseas to address the problem of Foetal Alcohol Spectrum Disorders and identify best practice approaches to reduce its incidence, particularly in Aboriginal and Torres Strait Islander communities (Ministerial Council on Drug Strategy, 2006).

3.5.2.2 Australian alcohol guidelines

The current *Australian Alcohol Guidelines: Health Risks and Benefits* (NHMRC, 2001) were developed by a working party convened by the National Health and Medical Research Council (NHMRC) and in collaboration with the Population and Health Division of the Department of Health and Aging. The Alcohol Guidelines 11.1 to 11.4 are aimed at women who are pregnant or might soon become pregnant. These specific guidelines are:

> *Women who are pregnant or might soon become pregnant:*
>
> *11.1 may consider not drinking at all;*
> *11.2 most importantly, should never become intoxicated;*
> *11.3 if they choose to drink, over a week, should have less than 7 standard drinks, AND, on any one day, no more than 2 standard drinks (spread over at least two hours);*
> *11.4 should note that the risk is highest in the earlier stages of pregnancy, including the time from conception to the first missed period.* (NHMRC, 2001)

The current guidelines were issued in 2001 and are in the process of being revised. A draft of the revised guidelines – *Australian Alcohol Guidelines for Low-risk Drinking*, was released for public consultation on 13 October 2007 (NHMRC, 2007). This consultation document can be found on the NHMRC website (www.nhmrc.gov.au). Refer to Section 5.1 for further information on the evidence base for this review. FSANZ will consider the revised guidelines during the assessment of this Application.

Guideline 3 of the draft *Australian Alcohol Guidelines for Low-risk Drinking* is aimed at women who are pregnant, are planning a pregnancy or are breastfeeding. The guideline is as follows:

Guideline 3 **For women who are pregnant, are planning a pregnancy or are breastfeeding**
3.1 Not drinking is the safest option.

As noted in the draft consultation document, this guideline is more conservative than the comparable 2001 guidelines outlined above.

The draft *Australian Alcohol Guidelines for Low-risk Drinking* are intended to provide a resource for a wide range of groups and individuals including health professionals, community groups, industry, professional organisations, schools and educational organisations. They will also inform policy makers, planners, decision makers and those responsible for providing alcohol, who have a broader responsibility to the community and whose decisions may influence the health of communities. The document is not primarily aimed at the general public and other booklets and fact sheets will be produced to help the general public to understand and implement the guidelines (NHMRC, 2007).

3.5.2.3 Dietary Guidelines for Australian Adults

The Dietary Guidelines for Australian Adults do not specifically include recommendations for pregnant women.

The Guide to Healthy Eating document notes that some authorities recommend total abstinence when pregnant or planning a pregnancy, however, this recommendation has not been incorporated into the actual dietary guidelines (NHMRC, 2003).

3.5.2.4 Strategies to address FASD in Australia

Under the Inter-Governmental Committee on Drugs, a working party comprised of jurisdictional representatives has been established to advise the Ministerial Council on Drug Strategy on the issue of FASD. The FASD Working Party has the following key areas of activity:

- current research and literature addressing FASD;
- clinical responses to FASD; and
- prevention approaches to address FASD, particularly in indigenous communities.

Current activities of the Working Party include:

- providing input into the review of the Australian Alcohol Guidelines;
- development of a National Drug Strategy monograph on FASD for consideration by the Intergovernmental Committee on Drugs; and
- planning a National Workshop on FASD to be held mid-2008.

It was noted in the Application that the Alcohol and other Drugs Council of Australia (a national, non-government organisation aimed at preventing or reducing harms caused by alcohol and other drugs) had formed a partnership with ALAC and other Australian organisations to carry out a project to provide an evidence base to support policy development in respect of alcohol beverage labelling in Australia and New Zealand. ALAC has now reported that this project is not going ahead.

3.5.3 Australia and New Zealand

3.5.3.1 Royal Australian and New Zealand College of Obstetricians and Gynaecologists

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (New Zealand committee) has informed FSANZ that although it does not have a formal college statement regarding the consumption of alcohol during pregnancy, it does have general agreement that women should be advised not to drink alcohol in pregnancy, and that it does not advise a safe level of consumption.

3.5.3.2 Industry initiatives

FSANZ is not aware of the use of any voluntary advisory statements specifically relating to pregnancy on alcoholic beverages currently being sold in Australia or New Zealand.

A search of websites of a number of companies in the alcohol industry indicates that although some do not provide advice about responsible consumption of alcohol, others provide various levels of information, for example:

- Fosters 'beer and health' webpage has a number of links to websites such as the Australian Alcohol Guidelines but gives no advice specific to pregnancy; and

- DB Breweries 'social responsibility' webpage also does not specifically give advice about pregnancy but provides links to:

    - Drink Responsibly website – a Beer Wine and Spirits Council initiative representing the New Zealand alcohol industry. This website includes the recommendation 'don't drink while pregnant' (Beer Wine and Spirits Council no longer operates, however, this website still remains accessible); and
    - Drinking to Your Health brochure, which states it is never safe to drink alcohol when you are pregnant. This brochure was produced by the Beer, Wine and Spirits Council.

Other industry based initiatives include the:

- Australian Brewers Foundation, an independent body of the Australian Brewers Association, which promotes education on the responsible use of alcohol and research in to the relationship between alcohol and health; and
- DrinkWise Australia, an independent organisation funded by the liquor industry, which promotes change towards a more responsible drinking culture in Australia.

Questions:

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?

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?

4. Objectives

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 18 of the FSANZ Act. These are:

- the protection of public health and safety;

- the provision of adequate information relating to food to enable consumers to make informed choices; and

- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;

- the promotion of consistency between domestic and international food standards;

- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

The specific objective of this Application is to ensure that pregnant women are adequately informed of the risks of alcohol consumption in pregnancy by way of an amendment to the Code.

RISK ASSESSMENT

5. Key Risk Assessment Questions

5.1 Key risk assessment questions and risk assessment summary

The Applicant states that since Application A359 was rejected by FSANZ in 2000, new evidence has become available which indicates that pregnant women who consume low levels of alcohol are at risk of having babies with FASD. Although the Applicant did not specify the quantity of alcohol a 'low' intake represents, FSANZ has interpreted 'low' to mean less than the current Australian NHMRC recommendation for women who are pregnant or who might soon become pregnant, which is less than seven standard drinks over a week and no more than two standard drinks (20 g absolute alcohol) on any one day.

Since 2000 there have been a significant number of publications which report studies on alcohol use and outcomes resulting from exposure in pregnancy. As mentioned in section 3.5.2.2, the NHMRC is currently revising the *Australian Alcohol Guidelines* and, as part of this process, has recently conducted a systematic review of the recent literature (2000-2007) in relation to the effect of alcohol exposure during pregnancy and breast feeding (NHMRC, 2007, unpublished). The key points of the NHMRC analysis of the risks of drinking during pregnancy and breastfeeding have been provided in the draft *Australian Alcohol Guidelines for Low-risk Drinking* and include:

> *The relative risk of drinking during pregnancy or breastfeeding (compared to not drinking) has not been determined across a range of drinking levels. Hence, a safe ('no-effect') level has not been established on a population basis. Furthermore, individual factors mean that actual risks vary considerably from one person to another.*

It is noted in the draft *Australian Alcohol Guidelines for Low Risk Drinking* document that the most serious of the adverse pregnancy outcomes occur when pregnant women consume high levels of alcohol frequently, particularly during the first trimester. However, the effect of low to moderate alcohol consumption is the subject of current debate. It has been suggested that low to moderate intakes may result in adverse neurodevelopmental and behavioural outcomes.

Interpretation of the existing literature is hampered by methodological problems and predicting risk for an individual is difficult because of confounding factors such as nutrition and genetics, which can modify the effect of alcohol on the unborn child.

Hence, a 'no-effect' level has not been established and it is therefore impossible to set a 'safe' or 'no-risk' drinking level for pregnant and breastfeeding women to avoid harm to their unborn foetus or young baby (NHMRC, 2007).

Further comprehensive reviews of the foetal effects of prenatal alcohol exposure have been published from the UK. The report to the UK Department of Health (Gray and Henderson, 2006) did not find clear and robust evidence of poor outcome amongst women consuming low-to-moderate amounts of alcohol in pregnancy. Nevertheless it concluded that the evidence is probably not strong enough to rule out any risk. It also identified binge-drinking in pregnancy as a cause of concern in relation to poor neurodevelopmental outcomes. Significant gaps in the evidence base were acknowledged.

In June 2007, the British Medical Association Board of Science released a report *Fetal alcohol spectrum disorders: A guide for health care professionals*. It reviewed the evidence for a safe level of exposure to alcohol during pregnancy. Variability in the definitions of consumption levels, differences in the way drinking behaviour is characterised, methodological problems in the design and analysis of relevant studies and the effect of confounding factors are identified as reasons why it has been difficult to evaluate the effects of low-to-moderate drinking. It stated that 'the current evidence is not robust enough to exclude any risk from low-to-moderate levels and that evidence is continuing to emerge as to the possible effects of prenatal alcohol exposure at these levels'. It recommended that women who are pregnant or who are considering a pregnancy should be advised not to consume any alcohol.

In the Draft Assessment Report, FSANZ will review all of the evidence submitted by the applicant, together with all the available peer-reviewed literature and any information supplied by submitters, to consider the following questions as part of the risk assessment:

1. *What is the strength of evidence that intake of alcohol at less than two standard drinks per day causes foetal developmental effects?*

2. *Does the scientific evidence identify a threshold of alcohol intake for pregnant women above which foetal harm is likely to occur? What is the quality of this evidence?*

3. *What factors are likely to affect the impact of alcohol consumption on the foetus including:*

    - *binge-drinking compared with frequent smaller intakes*
    - *genetic differences*
    - *susceptible populations, e.g. people with diabetes?*

Question:

3. What published and unpublished information is available that may provide answers to the risk assessment questions (1 – 3 above) regarding FASD to be addressed at Draft Assessment?

The following questions address additional background information required for the risk assessment. A summary of key studies is provided in sections 5.2 to 5.4, however, a review of all relevant data will be presented at Draft Assessment.

4. *What is the incidence of FAS and FASD in New Zealand, Australia and internationally?*
5. *What is the reported level of alcohol consumption of women of childbearing age in New Zealand and Australia?*
6. *What is the level of awareness amongst women of childbearing age of the risk of consuming alcohol when planning to become pregnant and during pregnancy?*

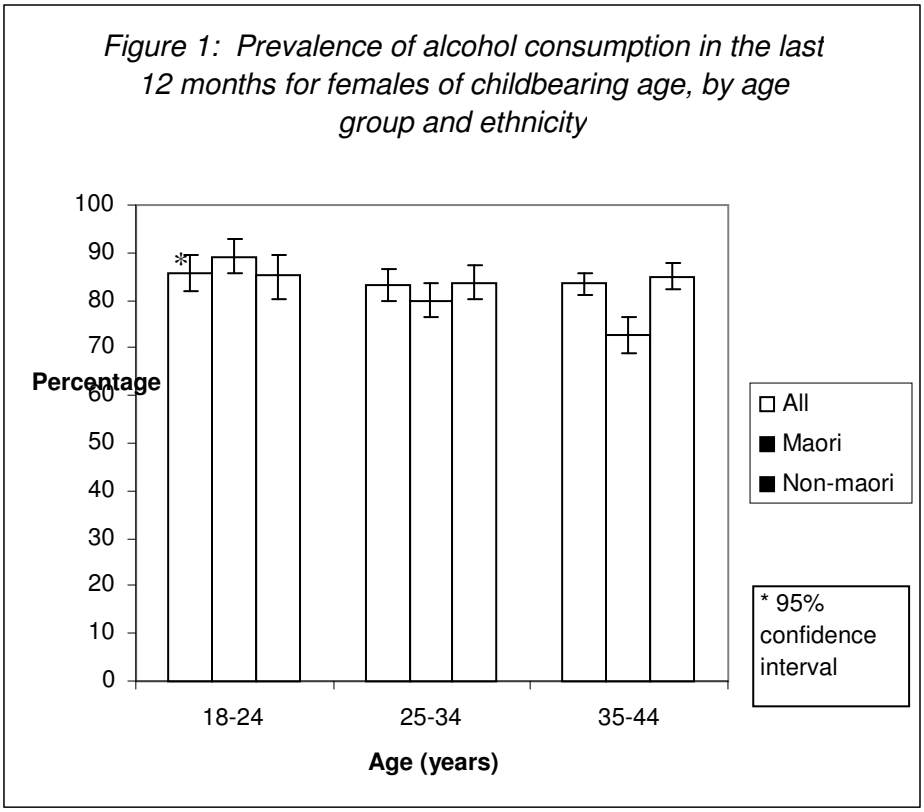
5.2 Reported levels of alcohol consumption by women of childbearing age

5.2.1 New Zealand

The results of the 2004 *Health Behaviours Survey – Alcohol Use*, provide the most detailed information on alcohol consumption and drinking patterns available in New Zealand (Ministry of Health, 2007b)[1]. However, limited data were collected about the consumption of alcohol by women during pregnancy.

Figure 1 indicates the prevalence of women of childbearing age (by age group and ethnicity) who had consumed alcohol in the 12 months prior to answering the survey. These were termed 'drinkers' in the survey. Typically, 80-85% of women in these age groups had consumed some alcohol in the previous 12 months. Fewer Maori women tended to consume alcohol compared with non-Maori women, except for those in the 18-24 year age group.

Figure 1: Prevalence of alcohol consumption in the last 12 months for females of childbearing age, by age group and ethnicity

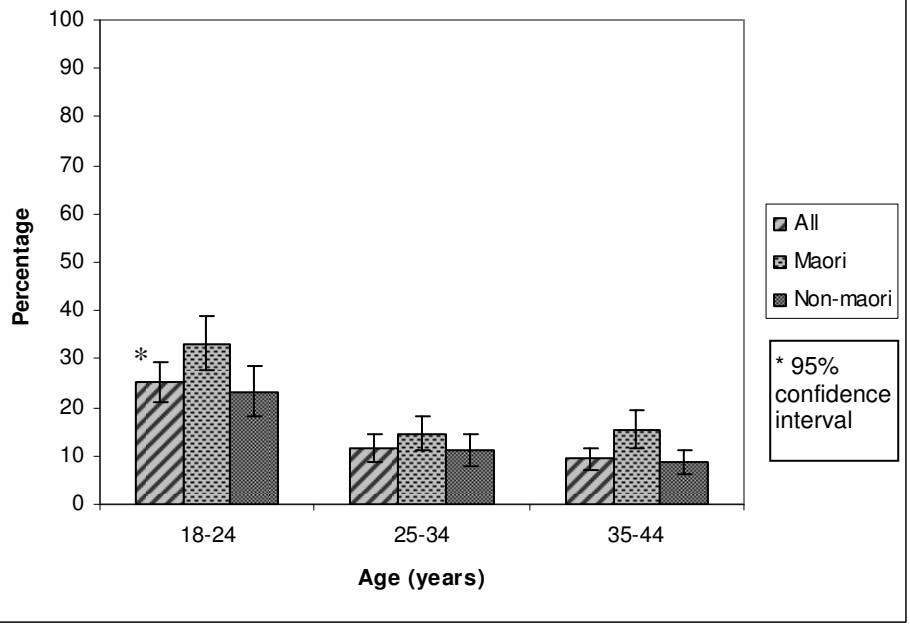


[1] This survey is part of the New Zealand Health Monitor programme, a co-ordinated cycle of population-based health-related surveys carried out by Public Health Intelligence (PHI). The target population for the 2004 survey was the New Zealand Population aged 12 – 65 years. The survey was a computer-assisted telephone interview carried out between September 2003 and August 2004, with a sample size of 9847 respondents. A stratified sample design was used, with increased sampling of Maori (n = 4387). Telephone numbers were randomly selected. The overall weighted response rate for the survey was 59%. Prevalence estimates reported from this survey represent the total New Zealand population.

There was a similar frequency of consuming alcohol reported for the three age groups, 18-24 years, 25-34 years, 35-44 years. Approximately 30% of all women (18-44 years) consumed alcohol less once a week, 40%, one to three times a week, 15%, four to six times a week and 10%, seven or more times a week. However, there was a markedly different drinking pattern in terms of the amount of alcohol consumed across the three age groups (Figure 2).

The prevalence of women 'drinkers' of childbearing age (by age group and ethnicity) who consumed large amounts of alcohol (more than four standard drinks) at least once a week is indicated in Figure 2. The data indicate that young women were more likely to consume large amounts of alcohol at least once a week compared with older women within the childbearing age group. In addition, Maori women were significantly more likely to consume large amounts of alcohol at least once a week compared with non-Maori women of childbearing age.

Figure 2: Prevalence of women 'drinkers' of childbearing age consuming large amounts of alcohol at least once a week, by age group and ethnicity



This survey found that of those who were pregnant at the time of the survey and who were 'drinkers' (n = 90), 82.4% had stopped all alcohol intake during the pregnancy and 13.3% were drinking a similar amount to prior to their pregnancy. Of those 'drinkers' who were planning a pregnancy at the time of the survey (n = 383) 79.2% had stopped all alcohol intake, while 7.1% were drinking a similar amount. There were no significant differences between Maori and non-Maori women for stopping alcohol intake, while planning a pregnancy or during a current pregnancy.

Planning for the next Alcohol and Drug Use survey by the Public Health Intelligence at the New Zealand Ministry of Health is currently under way and it is expected that this survey will be carried out later in 2007.

A survey to assess the awareness of women (n = 1256) aged 16 – 40 years about alcohol consumption in pregnancy, the effective and preferred sources of information on alcohol consumption in pregnancy and the prevalence of alcohol consumption in pregnancy was carried out in 2005 (Parackal *et al*., 2006)[2]. Information on the prevalence of alcohol consumption in pregnancy was collected retrospectively from women who had given birth in the five years prior to the survey and who were pregnant at the time of the survey. The survey found that of all the women (n = 552) who had had a baby in the previous five years or were currently pregnant:

- 53% (n = 291) reported to have had some alcohol in pregnancy. However, 40% (n = 219) reported having drunk some alcohol before they knew they were pregnant and stopped once they knew they were pregnant. The remaining 13% reported having consciously drunk some alcohol in pregnancy;
- 14% reported drinking alcohol 'more than once a week', 11% 'once a week', 13% 'once or twice a month' and 15% reported drinking alcohol 'less than once a month';
- 20% (n=109) reported to have binged at least once in pregnancy. However, most women (17%) reported to have binged only before they realized they were pregnant; and
- 5% reported to have binged once a week or more, 4% on 1-3 occasions per month and 10% on less than one occasion per month.

Women aged 16-24 years and women who were of European, Maori or Pacific Island ethnicity had higher odds of drinking prior to realizing they were pregnant than older women and women in the Asian/other ethnicity groups. However, when considering the whole duration of pregnancy, women in the 16-24 and 35-40 year age groups and who were of European, Maori or Pacific Island ethnicity had higher odds of consuming alcohol. The authors claim that unintentional alcohol consumption in the early stages of pregnancy is an important public health issue and that it may be prudent to educate all women of childbearing age. This is particularly important given that approximately 50% of pregnancies in New Zealand are unplanned (Schader and Corwin, 1999).

5.2.2 Australia

The inclusion of pregnancy and breastfeeding questions in the Australian 2004 National Drug Strategy Household Survey provided an opportunity to investigate the prevalence of alcohol consumption in pregnant and/or breastfeeding Australian women and compare this to all other Australian women of childbearing age. Of the women who reported being pregnant and/or breastfeeding in the previous 12 months, 47% reported drinking alcohol, compared with 85% of women of childbearing age who were not pregnant and/or breastfeeding (Wallace *et al.,* 2007).

[2] A cross-sectional baseline study was carried out across a nationally representative sample of 1256 women aged 16-40 years between October and December 2005. The sample was selected using stratification and random sampling procedures. The survey was carried out by Web Assisted Telephone Interviewing (WATI). Limitations of the retrospective collection of data include a possible failure to accurately recall information. The study was funded by ALAC and the New Zealand Ministry of Health. One of the purposes of the study was to collect baseline information prior to the implementation of the national alcohol strategy to reduce the prevalence of drinking among pregnant women and women planning pregnancy.

A postal survey of non-indigenous Western Australian women (n = 4839) was carried out during 1995 to 1997. The women were asked questions regarding the volume, frequency and type of alcoholic beverage they had consumed in the three months prior to pregnancy and during each trimester of their pregnancy. The study found that 58.7% of the women surveyed drank alcohol during at least one trimester of their pregnancy however, just over 40% reported that they did not drink any alcohol while pregnant. Of the women in the study, 46.7% had not planned their pregnancy and 79.8% reported drinking alcohol in the three months prior to their pregnancy. Approximately 10 to 14% of the women surveyed were drinking outside the 2001 Australian Alcohol Guidelines for pregnancy (see section 3.5.2.2) and 4.3% consumed five or more standard drinks on a typical drinking occasion at some stage during their pregnancy. In general, it was found that women reduced their average alcohol consumption and the number of standard drinks on a typical drinking occasion as their pregnancy progressed (Colvin *et al*., 2007).

A study conducted by Roy Morgan Research on behalf of The Salvation Army in 2005[3] found that of women aged 25–49 years who were mothers, 23% continued to drink during pregnancy. Those on a lower income were less likely to drink during pregnancy. For those where the income of the main earner in the household was less than $50,000, 21% consumed alcohol during pregnancy whereas for those in the over $70,000 bracket, 41% consumed alcohol.

Question:

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

5.3 Incidence of FAS and FASD

The incidence of FAS varies across populations. It is reported to be highest for African American groups in the United States, indigenous groups in the USA, Canada and Australia, and coloured/mixed races in South Africa (O'Leary, 2002). There are a number of problems encountered when trying to get a clear picture of the incidence of FAS. Accurate estimates depend on affected children being referred to paediatricians, determining alcohol exposure during pregnancy, considering the diagnosis of FAS and then making the diagnosis (NZPSU, 2001). In both Australia and New Zealand, there is currently no mechanism to collect data in relation to both FAS and other conditions under the broad category of FASD (DCPC, 2006; NZPSU, 2007).

5.3.1 New Zealand

There is little information about the incidence of FAS or FASD in New Zealand.

The New Zealand Paediatric Surveillance Unit collected data on the incidence of newly diagnosed FAS among children in paediatric care in New Zealand, over a 29-month period finishing in December 2001.

[3] This survey involved a phone interview of a total of 1296 Australians (including n=652 women) aged 14 yrs & over in July/August 2005. Respondents were asked about their average weekly drinking habits, the greatest number of standard drinks consumed in one session over the previous month, alcohol consumed during pregnancy and attitudes to the consumption of alcohol during pregnancy. Interpretation of the study results is limited due to FSANZ not having access to the full study methodology and results.

This study found a rate of 2.9 new cases per 100 000 children aged 0-14 years per year. The New Zealand Paediatric Surveillance Unit's Annual Report (2001) states that the reported incidence of FAS is considerably lower compared with estimates from other countries which probably reflects incomplete data collection in New Zealand. FAS is not currently under surveillance by the New Zealand Paediatric Surveillance Unit (NZPSU, 2007).

5.3.2 Australia

Figures for the Australian population as a whole are unknown. The National Perinatal Statistics Unit collects information on congenital malformations in Australia, however this does not include FAS (DCPC, 2006).

A recent study has attempted to establish the prevalence of FAS in Victoria through the Victorian Birth Defects Register.

This study found a prevalence of FAS of 0.006 per 1 000 live births. The prevalence increased to 0.03 per 1 000 live births when possible cases of FAS, cases with features of FAS but maternal alcohol use unknown, and cases where some low-level maternal alcohol use was reported, were included (Allen *et al*., 2007).

The birth defects register in Western Australia recorded an overall prevalence of FAS of 0.18 per 1 000 live births between 1980 and 1997. The West Australian birth defects register found that FAS is reported over 100 times more frequently in Aboriginal children, with an estimated figure of 2.76 per 1 000 live births (Bower *et al.,* 2000).

A postal survey of health professionals in Western Australia concluded that FAS is likely to be under-ascertained in Australia due to a lack of knowledge of FAS amongst health professionals (Payne *et al*., 2005).

The National Alcohol Strategy states that while the available evidence suggests that the birth prevalence of foetal alcohol syndrome is relatively small in Australia, the condition is a particular concern in Aboriginal and Torres Strait Islander communities (Ministerial Council on Drug Strategy, 2006).

5.3.3 International

The majority of literature and scientific evidence regarding the prevalence of FAS comes from studies carried out in the United States and Canada (DCPC, 2006). The prevalence of FAS in the United States has been estimated to be between 0.5 and 2 per 1 000 live births (May and Gossage, 2001).

Question:

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

5.4 Level of awareness amongst women of childbearing age of the risk of consuming alcohol when planning to become pregnant and during pregnancy

A study conducted by Roy Morgan Research on behalf of The Salvation Army in 2005 revealed that a considerable proportion of Australian women aged 14 years and over (63%) strongly agreed with the statement: 'drinking alcohol during pregnancy is dangerous to a baby's health' (Roy Morgan Research, 2005).[4] A further 23% of the sample indicated some level of agreement with the statement while 14% indicated a level of disagreement or neither agreement/disagreement.

Findings from a 2005 study, examining the opinions of New Zealand women on alcohol consumption in pregnancy (n=1256)[5], indicated that 76% of women believed that stopping alcohol consumption during pregnancy increased the chances of a healthy baby. This figure corresponds to the aforementioned 2005 Australian data (63%). However, half of the New Zealand women believed that up to one drink on a typical occasion during pregnancy was a safe level of consumption.

Forty per cent of the women believed that during pregnancy, women should abstain altogether from drinking alcohol (Parackal *et al*., 2006).

As reported in section 5.2.1, results from the 2004 New Zealand Health Behaviours Survey[6] reveal that 82% of 16-39 year old women surveyed reported abstaining from drinking alcohol during pregnancy, and 79% reported stopping alcohol consumption during the planning of a pregnancy. These data may serve as an indirect measure of awareness of the potential harms of drinking during pregnancy (New Zealand Ministry of Health, 2007b).

Should risk management options be considered at Draft Assessment, a review of the international literature on the awareness of women of childbearing age of the risk of consuming alcohol when pregnant or planning to become pregnant will be presented.

Question:

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?

[4] Refer to footnote 3 for methodology
[5] Refer to footnote 2 for methodology
[6] Refer to footnote 1 for methodology

RISK MANAGEMENT

6 Risk management issues

6.1 The impact of alcoholic beverage advisory/warning labels on consumer awareness of the risk of drinking alcohol during pregnancy and consumer behaviour

There are a number of studies which discuss the impact of warning labels on women's awareness of the effects of consuming alcohol during pregnancy and on alcohol consumption during pregnancy (Blume and Resor, 2007; Hankin *et al*., 1993; 1994; 1996; Greenfield *et al.*, 1993; Kaskutas *et al*., 1998; Kaskutas, 2000; MacKinnon *et al*., 1993; Hilton, 1993; Stockwell, 2006). The majority of the studies are from the USA and were published in the 1990s following the introduction of warning labels in 1989.

The Applicant considers that there is a sound body of evidence to show that health advisory labels can contribute to increasing awareness of the potential dangers of consuming alcohol when planning to become pregnant or during pregnancy. Health advisory labels are generally most effective in conjunction with national strategies aimed to raise awareness, both complementing and enhancing these initiatives (Parsons *et al*., 1994; Public Health Agency of Canada, 2006).

The Applicant does not claim that the presence of the health advisory label will directly lead to behavioural change and a reduction in alcohol consumption. There is acknowledgement that achieving behavioural change is a complex process consisting of a series of stages to which increasing awareness of an issue may contribute. The Applicant states that a commonly stated limitation in studies is the lack of ability to demonstrate reduced consumption of alcohol as a direct result of exposure to health advisory labels on containers (MacKinnon *et al.*, 2001; Engs, 1989).

However, the Applicant emphasises the importance of any increases in awareness of the risks of consuming alcohol during planning for pregnancy and during pregnancy, to which labelling may contribute.

Arguments supporting the use of health advisory statements relating to pregnancy on labels provided by the applicant include:

- relative ease of implementation, if a two-year transition period is adopted;
- the efficiency and effectiveness of the labelling statement when complemented by other initiatives;
- ability to reach large numbers of people and potential to raise awareness in various populations;
- high public acceptance of and support for such information on labels (Greenfield *et al.,* 1993; Haines and Stockwell, 2003; Hilton and Kaskutas, 1991; Australian Institute of Health and Welfare, 2002; Roy Morgan Research, 2006);

- consumer recognition of the USA warning label (Hankin *et al.,* 1993; Parker *et al*., 1994; Barrett *et al*., 1993; Scammon *et al*., 1991; Kaskutas, 2000, MacKinnon *et al*., 2000) and increased awareness of the risk of consuming alcohol during pregnancy (Greenfield *et al*., 1993; Hankin *et al*., 1993; 1994; 1996; MacKinnon *et al*., 1993; Hilton, 1993; Kaskutas and Graves, 1994); and
- consumers' right to know about the possible harmful effects of consuming alcohol during pregnancy (Haines and Stockwell, 2003).

A number of issues associated with the use of health advisory statements on alcoholic products have been discussed in the literature including:

- the presentation of statements influencing effectiveness (e.g. statement wording and length, font size, orientation, visibility, positioning) (MacKinnon, 1993; Malouff *et al*., 1993; Adams, 1993);
- the merits of targeting the health advisory statement to high-risk groups of women (e.g. previously abused alcohol) as compared to the general population of women of child-bearing age (Hankin, 2002);
- the importance of targeting the statement to the intended audience in relation to social, cultural and demographic variables (Andrews *et al*., 1991; Smedley, 1998; Hankin *et al.,* 1996; Kaskutas and Greenfield, 1997);
- possible negative effect of statements e.g. labelling causing women to feel guilty about any alcohol consumed during pregnancy, the 'boomerang' effect (Abel, 1998) and possible political backlash with reduced public support for sensible drinking messages as government increases education initiatives (Parker *et al*., 1994);
- the lack of evidence of changed behaviour (Scammon *et al*., 1991; Stockwell, 2006; Murphy-Brennan and Oei, 1999; MacKinnon *et al*., 2000; International Center for Alcohol Policies, 1997), therefore this labelling strategy for reducing alcohol-related harms may not be appropriate (Stockley, 2001);
- the relationship between public support for warning labels and perceived policy effectiveness (Kaskutas, 1993);
- increased exposure and effect of familiarity of labels over time causing a reduction in both attention paid to label information, and associated impact on attitudes or behaviour (Greenfield and Kaskutas, 1998; Hankin *et al*., 1998; MacKinnon *et al*., 2000); and
- the need for label statements not to occur in isolation, but to be part of a broader education initiative (Kaskutas and Graves, 1994; Andrews and Netemeyer, 1996; Parsons *et al.,* 1994; Public Health Agency of Canada, 2006).

Questions:

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

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?

6.2 The wording of a health advisory statement and its use on alcoholic beverages

If, following public consultation and consideration of all available information, FSANZ's preferred option is to recommend a mandatory health advisory statement, then FSANZ will carry out research to investigate the most appropriate and effective wording to be used.

In addition, if the health advisory statement is to be required, it would need to be decided whether all alcoholic beverages should carry the statement or whether a subgroup of alcoholic beverages should be required to carry the statement, for example, beverages with a specified concentration of alcohol. Currently, standard drink labelling is required on beverages containing more than 0.5% alcohol by volume.

Questions:

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?

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?

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?

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

7. Options

FSANZ is currently considering two options for addressing this Application:

7.1 Option 1 – maintain *status quo*

Under this option, the *status quo* would be maintained by not amending the Code to mandate the labelling of alcoholic beverages to advise of the risks of consuming alcohol when planning to become pregnant and during pregnancy.

7.2 Option 2 – amend the Code to require a health advisory label on alcoholic beverage containers advising of the risk of consuming alcohol when planning to become pregnant and during pregnancy

Option 2 would result in the mandatory labelling of alcoholic beverage containers with a health advisory label. The wording or format of the health advisory label, the level of alcohol (percentage of alcohol by volume) to which the labelling requirement would apply, any exemptions from the labelling requirement, and the standard of the Code in which the conditions would be located, would need to be determined.

8. Impact Analysis

8.1 Affected parties

The parties likely to be affected by this Application are:

1. suppliers of alcoholic beverages, including alcoholic beverage manufacturers and importers (**industry**);

2. **consumers** of alcoholic beverages;

3. **Government** enforcement agencies of Australia States and Territories and New Zealand.

8.2 Benefit cost analysis

This analysis provides a preliminary assessment of the potential impacts of the regulatory options on the affected parties.

8.2.1 Consumers

It is unclear what effect maintaining the *status quo* will have on consumers of alcoholic beverages. The Applicant refers to recent research indicating a consumer motivation to want information about their food (Hurst, 2005). The possible benefits of Option 2 with disclosure of risks associated with consuming alcohol whilst planning pregnancy or during pregnancy, include increased consumer trust in the alcohol beverage industry, and meeting the consumer's 'right to know' of the potential dangers of consuming alcohol during any period of pregnancy (Stockwell and Single, 1997). All consumers could potentially see the advisory statement which may foster discussion of the issue in the broader community. A potential cost for consumers may arise if they are unnecessarily alarmed about alcohol already consumed either while planning pregnancy or during pregnancy. In addition, the cost of beverages may increase due to changes in labelling requirements.

It is also unclear what the most appropriate means is to ensure that pregnant women are adequately informed of the risks of consuming alcohol during pregnancy. Labelling of all alcoholic beverages would be one means of achieving this objective, but more targeted measures could be devised such as a promotion campaign targeted at young women.

8.2.2 Industry

The Applicant argues that the main cost to the Australian and New Zealand alcoholic beverage industries for Option 2 would be the one-off cost of labelling (i.e. design, marketing, new printing plates, etc.) and potential replacement of current labels. Other possible costs to the industry include enhanced quality assurance to ensure compliance to the Code and possible loss of existing label stocks.

The Applicant proposes a two-year transition period to mitigate the costs of any replacement labelling on existing stock (and loss of existing label stock). The issue of relabelling depends on shelf-life of stock, of which, wine products are estimated to be the products most profoundly affected by the change.

In addition to this transition period, the Applicant suggests to further mitigate the costs, that the timing of the label change coincides with the 'natural' labelling change that most alcohol beverage companies undergo every two years.

Mandatory labelling may have a major impact on international trade.

8.2.3 Government

Under Option 2, enforcement agencies in Australia and New Zealand would be responsible for enforcement of the proposed additional labelling.

Questions:

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

14. What is the likely impact on consumers, industry, and/or government if an advisory statement on the risks of consuming alcohol when planning a pregnancy and during pregnancy is required on alcoholic beverage containers?

15. 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?

8.3 Comparison of options

At this Initial Assessment stage, no comparison of the identified regulatory options can be undertaken. Further information on the risk assessment and risk management aspects of this Application is required for such a comparison to be made at Draft Assessment, using information provided from the Applicant, submissions, research literature and other sources as appropriate.

COMMUNICATION

9. Communication Strategy

FSANZ recognises that FASD is a matter of public concern.

A communications strategy will involve advertising the availability of Assessment Reports for public comment in the national press and making the reports available on the FSANZ website. FSANZ will prepare documentation as necessary to put both on FSANZ's website and as a backgrounder to accompany press releases.

10. Consultation

10.1 Public consultation

The purpose of this Initial Assessment Report is to seek input from stakeholders in relation to the Application and to seek input on the likely regulatory impact at an early stage.

At this stage, FSANZ is seeking public comment to assist in assessing this Application and is particularly interested in receiving further information on the questions asked throughout this report, which are presented as a whole at Attachment 1.

The first public consultation period will remain open for six weeks. Comments made by submitters during this period will be reviewed and reported in the Draft Assessment Report.

All stakeholders who make a submission in relation to the Application will be included on a mailing list to receive further FSANZ documents in relation to the Application. If readers of this Initial Assessment Report are aware of others who might have an interest in this Application, they should bring this to their attention. Other interested parties as they come to the attention of FSANZ will also be added to the mailing list for public consultation.

10.2 Targeted consultation

FSANZ may engage in targeted consultation before the Draft Assessment Report is released, with various stakeholders as appropriate. Those considered for targeted consultation include relevant experts in the fields of alcohol policy development and research, medical associations, public health, consumers and the alcohol industry.

10.3 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are relevant international standards and amending the Code to require a mandatory health advisory label on alcohol beverages may have an effect on international trade as:

- health advisory statements are not currently required on alcoholic beverage containers sold in Australia and New Zealand; and
- there are different approaches internationally with respect to health advisory statements on alcoholic beverages.

This issue will be fully considered at Draft Assessment and, if necessary, notification will be recommended to the agencies responsible in accordance with Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade (TBT) or Sanitary and Phytosanitary Measures (SPS) Agreements. This will enable other WTO member countries to comment on proposed changes to standards where they may have a significant impact on them.

CONCLUSION

11. Conclusion

After considering the requirements for Initial Assessment as prescribed in section 13 of the FSANZ Act, FSANZ has decided to accept the Application for the following reasons:

- The Application seeks approval to require a health advisory label on alcoholic beverage containers advising of the risks of consuming alcohol when planning to become pregnant and during pregnancy. Such an approval, if accepted, would warrant a variation to the Code.

- There is currently no requirement in the Code for a health advisory label on alcoholic beverages advising of the risks of consuming alcohol when planning to become pregnant and during pregnancy.

- The Application is not so similar to any previous application that it ought not be accepted. FSANZ considers that Application A359, which requested the warning statement "This product contains alcohol. Alcohol is a dangerous drug" be placed on the label of alcoholic beverages, differs to the current Application which focuses on maternal alcohol consumption only.

At this stage no other relevant matters are apparent.

ATTACHMENTS

1. Initial Assessment questions for public comment
2. References

Attachment 1

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?

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?

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?

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

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

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?

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?

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?

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?

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?

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?

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

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

14. What is the likely impact on consumers, industry, and/or government if an advisory statement on the risks of consuming alcohol when planning a pregnancy and during pregnancy is required on alcoholic beverage containers?

15. 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?

Attachment 2

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