FULL ASSESSMENT REPORT
AND REGULATION IMPACT ASSESSMENT

SUBJECT: A359 – LABELLING OF ALCOHOLIC BEVERAGES

EXECUTIVE SUMMARY

The Australia New Zealand Food Authority (ANZFA) received an application from the Society Without Alcoholic Trauma (SWAT) on 22 April 1998, requesting to include in the *Food Standards Code* (FSC) a requirement that all alcoholic beverages be labelled with the statement "This product contains alcohol. Alcohol is a dangerous drug".

ANZFA rejects the application for the following reasons:

- Scientific evidence for the effectiveness of warning statements on alcoholic beverages shows that while warning labels may increase awareness, the increased awareness does not necessarily lead to the desired behavioural changes in 'at-risk' groups. In fact, there is considerable scientific evidence that warning statements may result in an increase in the undesirable behaviour in some 'at risk' groups.

- In the case of alcoholic beverages, simple, accurate warning statements, which would effectively inform consumers about alcohol-related harm, would be difficult to devise given the complexity of issues surrounding alcohol use and misuse, and the known benefits of moderate alcohol consumption.

- Costs associated with alcohol related harm are high in both Australia and New Zealand. Estimates vary, but studies undertaken by national governments on a regular basis show a steady downward trend in alcohol consumption and in alcohol-related harm. In Australia alcohol-related mortality rates decreased by 20% between 1990 and 1997; in New Zealand alcohol-related mortality rates decreased by 38% between 1980-82 and 1994-96. These decreases are related to reductions in overall alcohol consumption in both countries: 25% in New Zealand since 1980 and 1997; and 12% in Australia between 1990 and 1997. These cost reductions are due at least in part to the implementation of successful public health initiatives based on harm reduction strategies.

- Comprehensive public health strategies aimed at reducing alcohol-related harm are implemented in both Australia and New Zealand. These strategies concentrate on those interventions already identified as being effective including controlling price, availability and the advertising of alcoholic beverages; identifying and targeting 'at risk' groups with health campaigns aimed at reducing alcohol-related harm; and devoting considerable resources to the discouragement of drink-driving.

- When consumed at low to moderate levels alcohol has significant health benefits. These benefits result in a lower overall mortality for those who drink alcohol in moderation as compared with those who abstain from alcohol or consume it at higher levels. These health benefits are mainly due to the reduction in the risk for coronary heart disease, a major cause of death in Australia and New Zealand in middle and old age. As alcohol consumption increases beyond low to moderate levels, these health benefits are countered by a rise in alcohol-related harm to health.

- Although risks for some cancers and liver cirrhosis are increased, even at levels of alcohol intake regarded as moderate, these excess risks are more than outweighed by reduced rates of coronary heart disease.

- The available scientific and medical evidence suggests that there is no evidence that light drinking by pregnant women harms the fetus. In Australia the incidence of alcohol consumption in pregnant women is low and consumption at hazardous or harmful levels is uncommon. Evidence also indicates that the incidence of Fetal Alcohol Syndrome (FAS) is rare, even among 'heavy drinkers', and is highly concentrated in areas of low socio-economic status, where heavy drinking is associated with smoking, poor nutrition, poor health, increased stress and use of other drugs. Whereas none of the individual factors gives rise to FAS themselves, it is possible, if not likely, that they exacerbate the effects of heavy alcohol intake, resulting in FAS.

- The National Health Advisory Committee (NHAC) of the National Health and Medical Research Council (NHMRC) is currently reviewing its 1992 recommendations regarding responsible drinking behaviour. The review is also paying specific attention to the issues associated with FAS.

- In both Australia and New Zealand, alcoholic beverages are currently required to be labelled with alcohol content information. In Australia, all alcoholic beverages are also required to be labelled with information on the number of standard drinks. ANZFA's recent review of provisions regulating alcoholic beverages in Australia and New Zealand proposed that mandatory standard drinks labelling be extended to products sold in New Zealand. This information, together with existing public health and education initiatives, provide consumers with sufficient information to make informed decisions about the alcohol they consume.

- While alcohol is, in fact, a drug, foods containing alcohol are regarded as foods and are regulated in food standards. Evidence strongly suggests that the general population has a significant level of understanding of the risks and benefits of alcohol consumption. The Full Assessment report concludes that a statement on the label of alcoholic beverages to the effect that alcohol is a dangerous drug is not likely to provide any additional useful information to the consumer.

- Simple, direct comparisons of tobacco warning statements with alcohol warning statements are not valid because of the differences between the two with respect to health risks and benefits. There is no level of tobacco consumption that can be considered to be safe or low risk. Therefore warning messages for tobacco could be easily devised. On the other hand, low to moderate consumption of alcohol confers significant health benefits and brief, accurate health messages that pertain to the majority of consumers relating to alcohol use would be difficult to devise.

- There is no international consensus on the use of warning labels on alcoholic beverages. Nine countries, including the USA, prescribe warning statements for alcoholic beverages. Health warnings were considered and rejected by the New Zealand, United Kingdom and Canadian governments and are not used in any European country. There is a lack of evidence as to the effectiveness of warning labels on alcoholic beverages in protecting public health and safety, reducing health, social and economic costs or providing additional useful information to consumers. This lack of evidence may leave Australia open to challenge through the WTO if the application were to be accepted.

- There is an existing framework for the regulation and self-regulation of advertising and sponsorship of alcoholic beverages and also for the regulation of availability. In addition, interventions to minimise alcohol-related harm are already in place and supported by the alcoholic beverages industry.

- The size and placement of existing alcohol labelling information has been considered as a part of the review of food standards and the development of a joint FSC. ANZFA is recommending that, unless otherwise expressly permitted, all information required to be on a food label must be written or set out legibly and prominently and in the English language.

- The costs to industry of labelling alcoholic beverages with a warning statement are not expected to be high. However, scientific evidence shows that warning statements are not effective in modifying at risk behaviour in relation to consuming excessive amounts of alcohol. Additionally, strategies are already in place in Australia and New Zealand, based on their public health on policy on alcohol, and are seemingly effective, as demonstrated by the trend of decreasing alcohol consumption and decreasing alcohol-related costs and harm in both countries.

- The Regulation Impact Statement concludes that requiring the labelling of alcoholic beverages with a warning statement would offer no clear benefits to government, industry or consumers but would introduce costs to government, industry and consumers.

- Requiring the labelling of alcoholic beverages with a warning statement does not fulfil ANZFA's objectives in relation to section 10 of the *Australia New Zealand Food Authority Act 1991*. Scientific evidence shows that warning statements are not effective in modifying at risk behaviour in relation to consuming excessive amounts of alcohol, and would therefore not provide any additional protection of public health and safety. Information to enable consumers to make an informed decision or prevent fraud and deception is already provided by existing labelling requirements and public health policies and campaigns.

BACKGROUND

The Australia New Zealand Food Authority (ANZFA) received an application from the Society Without Alcoholic Trauma on 22 April 1998, requesting to include in the Food Standards Code a requirement that all alcoholic beverages be labelled with the statement:

> *Alcohol is a dangerous drug*.

After a significant period of consultation with the applicant, during which time the 'clock was stopped', the applicant re-submitted the application to require all alcoholic beverages be labelled with the statement:

This product contains alcohol. Alcohol is a dangerous drug.

The applicant is concerned that the dangers of alcohol, as a result of its being a drug, are not sufficiently well known and seeks to bring this to the attention of consumers with labelling on all containers of alcoholic beverages which states:

This product contains alcohol. Alcohol is a dangerous drug.

The application implies that a greater knowledge by the consumer that alcohol is a drug will result in changes in behaviour, which in turn will lead to a reduction in the social and economic costs to society from excessive alcohol consumption.

PROBLEM

There is currently a problem in Australia and New Zealand due to the significant health, social and economic costs of excessive alcohol consumption. However, there is evidence that light to moderate consumption of alcohol results in health benefits for some population groups. In addition, there are currently comprehensive public health strategies in place in Australia and New Zealand aimed at reducing alcohol-related costs.

OBJECTIVE

The objective of this assessment is to determine whether the overall benefits to the community of mandating the proposed warning label on alcoholic beverages would exceed the overall costs.

RELEVANT PROVISIONS

Both the Australian Food Standards Code and the New Zealand Food Regulations regulate alcoholic beverages. However, there is no requirement in either regulation for the labelling of alcoholic beverages with a warning statement.

Recently Ms Dianne Yates, MP, House of Representatives, New Zealand, presented a supplementary order paper calling for health warning labels on liquor cans and bottles. Warnings were to alert the consumer about the risks of drinking during pregnancy, drinking and driving or operating machinery, and a general health warning. The supplementary order paper was voted down in parliament by one vote.

The New Zealand Ministry of Health (MoH) stated that it has considered the idea of alcohol health warnings since 1989. The MoH further stated that, while they are seen as a good idea in principle, there is limited evidence indicating their efficacy. Furthermore, given the positive health effects of moderate alcohol consumption on certain population groups, the health messages would have to be tempered with a number of provisos or caveats.

Codex does not specifically regulate alcoholic beverages.

The United States of America (USA) implemented health warning legislation in 1989, which requires the following statements to appear on the label of alcoholic beverages:

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 alcohol impairs your ability to drive a car or operate machinery, and may cause health problems

Eight other countries (Brazil, Colombia, Costa Rica, Ecuador, Mexico, South Korea, Venezuela and Zimbabwe) also require warning statements on alcoholic beverages. The label messages vary in each county, for example, Brazil, Colombia, Costa Rica and Mexico have general messages that warn of the risks of excessive alcohol consumption while warning labels in South Korea and Zimbabwe contain more specific information on risks.

Both the United Kingdom (UK) and Canada have also considered the use of warning statements on the label of alcoholic beverages. However, both countries rejected alcohol warning label legislation.

No European country has passed health warning label legislation for alcoholic beverage containers.

PUBLIC CONSULTATION

A Preliminary Assessment document on Labelling of Alcoholic Beverages, Application A359, was circulated for six weeks of public comment in May 1999.

Sixty-two submissions were received in response to s.14 of the *Australia New Zealand Food Authority Act, 1991* (the Act) gazettal notices for Application A359. Submissions were received from a range of Government agencies, public health organisations, alcohol industry organisations, religious and family welfare organisations, and individuals, both from New Zealand and Australia. A summary of submissions in support of and in opposition to the Application is at Attachment 2. In addition to the application the SWAT also made a submission at Full Assessment, this submission is attached in full at Attachment 3.

Generally, Government, industry and some public health organisations were opposed to the Application. The majority of public health organisations, religious and family welfare organisations and submissions from individuals were in favour of the Application.

In addition, approximately 150 campaign letters in support of the application were received. Most of these letters simply stated support of the application, while many also expressed concerns about the human, social and financial costs to Australia and New Zealand caused by excessive alcohol consumption.
Some letters provided statistics on the size of the problem of alcohol abuse and its related costs. Many letters specifically raised the issue of Fetal Alcohol Syndrome.

ANZFA also received a petition, sponsored by the SWAT and containing 4882 signatures, in support of the application.

OPTIONS (INCLUDING ALTERNATIVES TO REGULATION)

The options being considered in relation to this issue are:

Option One

Include a provision in the *Food Standards Code* that all alcoholic beverages must be labelled with the statement:

> *This product contains alcohol. Alcohol is a dangerous drug.*'

Option Two

Do not change the current or the proposed provisions for the labelling of alcoholic beverages and rely on existing regulatory and non-regulatory provisions in place in Australia and New Zealand (i.e. retain the *status quo*).

The nature of this issue is highly complex, with many social, cultural and economic factors to be taken into consideration. Non-regulatory codes of practice, education campaigns and industry self-regulation are already in place, as is additional government regulation in the form of liquor licensing, drink driving regulations, host responsibilities legislation etc. These alternative regulatory and non-regulatory initiatives are discussed in detail in **Section 2, Public Health Policy on Alcohol in Australia and New Zealand**, below.

AFFECTED PARTIES

Groups which are likely to be affected in relation to this application include:

- governments in both Australia and New Zealand;
- alcoholic beverage manufacturers, packers and importers; and
- consumers, including those groups who may derive benefits from alcohol consumption and those groups who may be 'at risk' from excessive alcohol consumption.

ASSESSMENT

ISSUES RAISED BY PUBLIC SUBMISSIONS

1 EFFECTIVENESS OF WARNING LABELS ON ALCOHOLIC BEVERAGES

1.1 Comment Received

1.1.1 Evidence supporting effectiveness of warning labels

The **Alcohol Advisory Council of WA**; **Alcohol Healthwatch, NZ; National Centre for Epidemiology and Population Health (Australian National University)(NCEPH); Fetal Alcohol New Zealand; New Zealand Drug Foundation (NZDF); Ms Yates; Alcohol and Public Health Research Unit NZ;** and the **Group Against Liquor Advertising (GALA)** considered that there was sufficient evidence that warning statements on alcoholic beverages were effective at influencing knowledge, awareness and behaviour, to warrant accepting this application.

The **Alcohol and Public Health Research Unit NZ** considered that warning statements were effective, citing references which they considered supported the effectiveness of warning statements in the USA and from research carried out in New Zealand. **Alcohol Healthwatch NZ** and the **NCEPH** also provided information supported by references on the benefits of warning statements.

Alcohol Healthwatch, NZ; NCEPH; Fetal Alcohol New Zealand; NZDF and **Ms Yates** noted that alcohol warning labels had been effective in raising awareness.

Alcohol and Public Health Research Unit NZ supported the introduction of health warnings on alcohol containers and advertisements with each label bearing a single message from a rotated set of several strongly worded alcohol related health risk messages. This support was based on available research which indicates that alcohol health warnings can be an effective, low cost, and publicly supported consumer protection mechanism to raise awareness about alcohol related harm and influence the social climate in which drinking occurs.

1.1.2 Evidence supporting non-effectiveness of warning labels

The **Australian Drug Foundation (ADF); Anglican Diocese of Melbourne Social Responsibilities Committee; Australian Wine Research Institute (AWRI); Beer Wine & Spirits Council of NZ; Distilled Spirits Association of NZ; Brown-Forman Beverages Australia Pty Ltd; Dietitians Association of Australia (DAA); Distilled Spirits Industry Council of Australia Inc (DSICA); National Alcohol Beverage Industries Council Inc (NABIC); National Council of Women of NZ; NZ Licensing Trusts Association; MoH; Quay Group; Queensland Health Environmental Health Unit; Victorian Food Safety Council; WA Food Advisory Committee** and the **Winemakers' Federation of Australia (WFA)** generally considered that research showed that warning labels were ineffective. Some submissions commented that while there was evidence that warning statements on alcoholic beverages raised the awareness of consumers, there was evidence that they were unlikely to influence behaviour.

The **AWRI** provided an extensive literature review on whether the inclusion of a warning on the labels of products, including of alcoholic beverages in the USA, had been effective and successful in educating the general public about the potential harms of a particular product, and hence whether the behaviour of the public, both general and specific, had been significantly influenced.

The **AWRI** submission concluded, based on a review of the available scientific literature, that a health warning label must be simple, accurate and potentially apply to the majority of consumers. The majority of consumers in Australia consume alcohol at a low risk level, and hence the health warning does not apply to them. In addition, the AWRI argued that while the proposed label is simple, it is also simplistic and inaccurate, in that it does not reflect all the accepted actions and activities or usages of alcohol. The AWRI submitted that information targeting the consumer must be balanced in order for an informed decision to be made.

This view was reflected in many other submissions (**Beer Wine & Spirits Council of NZ; Distilled Spirits Association of NZ; Brown-Forman Beverages Australia Pty Ltd; DSICA; NABIC; NZ Licensing Trusts Association** and the **Quay Group**).

The **MoH** has considered the issue of alcohol warnings since 1989. The **MoH** considered that while a good idea in principle there is limited evidence indicating their efficacy and to date research into health warnings on alcohol products has been inconclusive.

Further, the **MoH** submitted that the Liquor Review Advisory Committee found, on the basis of the information presented, that 'there was nothing in the way of evidence to suggest that such controls (labels) have any beneficial impact'.

The **MoH** considered that there is limited evidence to indicate the effectiveness of health warnings to provide a clear non-confusing reminder of hazards which ultimately may lead to a change in behaviour. From the evidence it appears as though increases in knowledge about the negative effects of high alcohol consumption may increase over time. This is a positive result, but the **MoH** concluded it would not sufficiently justify mandatory health warning labels.

The **Population Health Division of the Commonwealth Department of Health and Aged Care (H&AC)**(incorporating the Tobacco and Alcohol Strategies Section and the Food Policy Section) suggested that to date, there is no empirical evidence from within Australia or overseas to suggest that the labelling of alcoholic products with strong health warnings effectively reduces the abuse of alcohol or substantially changes consumer attitudes towards such products.

The **Quay Group** cited the NZ Government advisor on alcohol, the Alcohol Advisory Council, as being opposed to warning labels on beverages and considers them ineffective at achieving their chief purpose – the reduction of harm from excessive drinking:

> *…Health messages are not the most effective means of achieving a well-informed populace. Labels which utilise a "bumper sticker" approach, which are nebulous, inaccurate or which tell people not to do something they may enjoy, do not assist individuals in making informed choices. Rather, these sorts of initiatives may well be an exercise in making it appear that 'something is being done' rather than for any utilitarian purpose*" (ALAC 1996).

WA Food Advisory Committee stated that warning statements should be considered after undertaking independent research and evaluation of the effectiveness of such statements, thereby providing credible scientific evidence.

1.1.3 What makes an effective warning statement?

The **ADF** contended that research shows that warning labels are most effective when the language used is simple, clear, easily understood and provides new information that is believable. This was supported by the **AWRI** submission which suggested that a health warning label must be simple, accurate and potentially applies to the majority of consumers. Any information targeting the consumer must be balanced in order for an informed decision to be made.

The **MoH** stated that in designing an effective warning label for alcoholic beverages there are three considerations:

1 A warning label message should highlight the severity of the consequences of drinking, taking into perspective both the positive and negative viewpoints.
2 The message needs to emphasise the probability of the consequences.
3 The message should be clear as to the behavioural recommendations in averting the threat for the individual.

Alcohol and Public Health Research Unit NZ quoted research that found that the most effective label design was one making strong references to danger, cancers, injury and road fatalities, and providing explicit measures for moderate drinking by men or women.

1.1.4 At risk groups

Australian Associated Brewers Inc (AAB); Anglican Diocese of Melbourne; Beer Wine & Spirits Council of NZ; Confédération Européenne des Producteurs de Spiritueux, (CEPS); NABIC; Distilled Spirits Association of NZ; Brown-Forman Beverages Australia Pty Ltd; WFA and the **AWRI,** pointed out that the majority of consumers drink alcohol responsibly, thus for the majority of drinkers, warning labels are irrelevant.

Anglican Diocese of Melbourne commented that ABS data indicate that over 90% of Australians consume alcohol as an important component of their social, cultural and religious life. Of these drinkers, less than 10% come to notice with any problems associated with their drinking.

NABIC suggested that the application 'fails the ANZFA test relating to unawareness of risk to health' as almost two thirds (64%) of all persons could identify low risk level of drinking, as defined by the NHMRC. Awareness of sensible drinking levels is already at a high level despite the relative absence of promotion.

The **AAB, Beer Wine & Spirits Council of NZ; Distilled Spirits Association of NZ; Brown-Forman Beverages Australia Pty Ltd; CEPS; NABIC; Victorian Food Safety Council** and **WFA** considered that population-wide control strategies such as health warning labels are ineffective at targeting 'at-risk' groups such as pregnant women, ethnic minorities, young people and drink drivers.

Many submissions (**AAB; AWRI; Beer Wine & Spirits Council of NZ; Distilled Spirits Association of NZ; Brown-Forman Beverages Australia Pty Ltd; CEPS; NABIC; Victorian Food Safety Council** and **WFA**) suggested that those most at risk of misusing alcohol are those least likely to modify their behaviour in response to a warning label.

The **AWRI** stated that the literature demonstrates that 'at risk' groups behave differently to the 'not at risk' population. Specific and targeted campaigns and programs which address the specificities rather than the generalities will only succeed in reducing, for example the incidence of FAS and drink driving in these groups.

The **Victorian Food Safety Council** considered that a label statement is not an appropriate means of educating the community about the importance of responsible alcohol consumption, nor of targeting sub-populations, such as young people, who are most at risk in relation to alcohol abuse.

The **WFA** stated that there is evidence that to be effective, targeting 'at risk' members of the community needs to be done in a much more strategic manner for specific programs which will deliver maximum opportunity for effectiveness are being developed by Government in conjunction with industry (National Youth Alcohol Advertising Campaign, 1999)

1.1.5 Behaviour is a result of many factors

ADF considered that warning statements were unlikely to be effective given the many other factors that must be addressed to achieve behaviour change. Behaviour is the result of a complex interaction between knowledge, personal experience, beliefs and other influencing factors. Similarly, the **Quay Group** considered that warning statements are a crude measure ill suited for the resolution of complex social and personal problems that contribute to alcohol abuse. The **Distilled Spirits Association of NZ and Brown-Forman Beverages Australia Pty Ltd** considered effective health action relies on identifying the different problems and needs of different individuals. Accordingly, targeting the minority abuser problem, fostering a culture of moderation, promoting an environment of 'personal accountability', increasing education, promoting safe and sensible drinking habits and increasing prevention work would be far more effective alternatives than a warning on a label.

1.1.6 Warnings may have the opposite effect

Some submissions (**AAB; Beer Wine & Spirits Council of NZ; NABIC; Queensland Health** and **WFA**) pointed out that there was evidence that warning statements may have the opposite effect to what was intended. This was in regard both to encouraging existing heavy drinkers (at risk groups) to increase their consumption (a 'forbidden fruit' mentality) and discouraging drinking among moderate consumers of alcohol and thus deprive them of protection against the most common cause of death in Australia, cardiovascular disease.

Mission Australia, Sydney did not endorse the use of preventative labelling on the entire range of products containing alcohol. Just as labelling alcohol as a 'drug' may bring more attention to the status of alcohol within younger age groups, labelling some alcohol products may bring unnecessary attention to the product's alcohol content.

1.1.7 Used in conjunction with other initiatives

Alcohol and Public Health Research Unit NZ; Alcohol Healthwatch, NZ; Ms Attwood; National Council of Women of Australia; ADF; Fetal Alcohol New Zealand and **GALA** generally considered that warning labels needed to be supported by other harm reducing strategies. Warning labels would help inform and remind the public of the risk associated with alcohol consumption, or as part of an integrated package of education and environmental strategies, could contribute to a stronger public health goal of influencing attitudes and actual behaviour around alcohol. Warning labels would help reinforce, but not replace other forms of education on alcohol.

NZ Licensing Trusts Association considered that in the absence of a comprehensive health promotion program aimed at reducing alcohol-related problems, warning labels were unlikely to have much effect.

Fetal Alcohol New Zealand considered that reducing heavy and hazardous drinking by women requires a multi-faceted approach of which warning labels can be a part. A stand alone initiative should not be expected to single-handedly achieve the desired behavioural change. Successful public health outcome can only be achieved through a complex set of interacting strategies. A public health strategy is as much about raising awareness as it is about changing behaviour.

1.1.8 Other warning statements or a range of warning statements rotated

While supporting the principle of warning labels on alcoholic beverages, some submissions (**Alcohol and Public Health Research Unit, NZ; ADF; Caroline Chisholm Centre for Health Ethics Inc; Mission Australia, Sydney; NCEPH; NZ Drug Foundation** and the **Royal New Zealand College of General Practitioners**) did not support the proposed warning statement. Many provided examples of alternative statements which could be considered.

GALA; Mission Australia, Sydney; Alcohol and Public Health Research Unit, NZ and the **Alcohol Advisory Council of WA** considered a more effective scheme would involve the rotation of a set of health and safety messages in a similar fashion to the way warnings on tobacco are rotated. **Alcohol Advisory Council of WA** considered that rotating messages containing clear health and safety information would help avoid a number of problems identified in new analysis from the Social Issues Research Centre (SIRC) which indicates that health warnings may have hidden psychological side effects, e.g. 'warning fatigue', 'riskfactorphobics', and 'forbidden fruit effect'.

1.2 Assessment

As pointed out in many submissions, there are several key elements that would characterise an effective health warning label and other health message statements. These elements have been determined by various researchers in order to optimise the effectiveness of health message statements. A summary of these 'best practice' characteristics include:

- that a health message must be simple and accurate;
- that a health message should provide information that is new and that is believable;
- that a health message should apply to a majority of consumers;
- that a health message should highlight the dangers and severity of consequences of the targeted behaviour;
- that the health message should emphasise the probability of the consequences; and
- that a health message should clearly recommend safe behaviours that avert the threat to the consumer.

Warning labels on alcoholic beverages were introduced in the USA in 1988. The legislation requiring warning labels for alcoholic beverages in the USA included provision for regular evaluation of their effectiveness. The National Institute on Alcohol Abuse and Alcoholism provided significant funding for numerous studies designed to evaluate the effectiveness of the warnings. The results of these evaluations suggest that while warning labels may have increased reported awareness of the dangers of heavy drinking, they have not had an effect on the alcohol consumption patterns of heavy drinkers.

Andrews *et al* (1991) found that 'frequent drinkers (i.e. those consuming alcohol more than once a week) perceived warnings as significantly less believable and less favourable than did occasional or non-drinkers of alcohol'.

In later research Andrews (1995) found that 'although frequent and heavier drinkers are aware and have knowledge of consumption risks, they are also likely to discount such information and are quite reticent to change patterns of abusive behaviour'.

Hankin *et al* (1993) specifically sought to study the effectiveness of the USA's warning labels on a group at risk of delivering a child suffering from Fetal Alcohol Syndrome. Hankin found that pregnant heavy drinkers presenting to an inner city prenatal clinic were unlikely to believe the information provided by the label and equally unlikely to modify their at-risk behaviour.

MacKinnon *et al* (1993) measured the effectiveness of warning labels in the USA by testing a group of adolescents immediately before warning labels were introduced and again a year after their introduction.

MacKinnon *et al* found that although the introduction of the label resulted in 'increases in awareness, exposure and recognition memory, there were no substantial changes in alcohol use or beliefs about the risks written on the warning'.

The findings outlined above are consistent with a large body of evidence from numerous studies on the effectiveness of the USA warning labels. Overall the studies found that there were no significant or substantial positive changes in actual or intended behaviour regarding the consumption of alcohol, or in the attitudes, beliefs and perceptions about the risks described on the warning labels (Mayer *et al*, 1991; Marzis *et al*, 1991; Kaskutas & Greenfield, 1992; Greenfield *et al*, 1993; Hilton, 1993; MacKinnon *et al*, 1993; USA Department of Health and Human Services, 1993).

Furthermore, the general public who consumed a chronic heavy amount of alcohol, that is, the groups 'at risk', believed that there was less risk associated with the consumption of alcohol than those who abstained, or consumed a light or moderate amount of alcohol (Andrews *et al*, 1991; Patterson *et al*, 1992; Hankin, 1994). These results were consistent with earlier studies that suggested women 'at risk' were less responsive to media/promotion campaigns (Little *et al*, 1981; Streissguth *et al*, 1982; Weiner *et al*, 1989; Kaskutas & Graves, 1994).

In New Zealand, the MoH has considered the issue of alcohol warnings since 1989. MoH considered that warning labels were a good idea in principle and that an effective warning label would provide a clear, non-confusing reminder of hazards, which ultimately might lead to a change in behaviour. However after evaluating the available evidence MoH concluded that:

- there was limited evidence to indicate the effectiveness of health warning labels; and
- although such warnings may lead to increased awareness over time about the negative effects of high alcohol consumption, this positive result would not sufficiently justify mandatory health warning labels.

The MoH pointed out that the difference between alcohol and tobacco consumption was that there was no safe level of tobacco consumption, nor any health benefits due to tobacco use. Tobacco warnings therefore could be short and punchy, adding to the strength and recollection of the message i.e. 'smoking kills'. On the other hand, moderate alcohol consumption is not harmful and may be beneficial to certain population groups.

Due to the known positive effects of moderate alcohol consumption any health warning label would have to be qualified, which would limit its impact.

The [NZ] Liquor Review Advisory Committee found, on the basis of the information presented, that 'there was nothing in the way of evidence to suggest that such controls (labels) have any beneficial impact'.

Canada and the United Kingdom (UK) have also recently assessed applications for health warning labels for alcoholic beverages. While both the Addiction Research Foundation (ARF) and Canadian Centre for Substance Abuse (CCSA) support the principle of warning labels, they consider that, in practice, their effect on consumer beliefs and behaviour would be minimal (Canada House of Commons Standing Committee on Health 1996). The CCSA stated that they have:

> *seen no direct, incontrovertible evidence that applying warning labels to alcoholic beverage containers has any impact on reducing the problems associated with abusive drinking.*

It was also stated by the ARF that 'judging from the fairly subtle effects that these types of warnings have on beliefs and behavioural intentions, it is unlikely that warning labels, effectively worded and prominently placed, will have a large effect on behaviour in and of themselves' (Canada House of Commons Standing Committee on Health 1996).

The UK House of Lords rejected legislation for health warning labels on alcoholic beverages in 1991. The then Parliamentary Secretary of Health argued that '…the problem of alcohol misuse is complex. It would be rather difficult to devise a clear, non-misleading and concise message which would effectively inform consumers about all aspects of the alcohol-related harm' [Hansard Parliamentary Debates (Lords) 1991].

1.3 Conclusion

There is strong support for the principle of requiring warning statements on alcoholic beverages because of their perceived effectiveness. However, the scientific evidence for the effectiveness of warning statements comprises a demonstration of increased awareness of the problem. Behaviour change is assumed to result from increased awareness. While it is true that warning labels may increase awareness, there is also convincing scientific evidence that increased awareness does not necessarily lead to the desired behavioural changes in 'at-risk' groups. In fact there is considerable scientific evidence that warnings statements may result in an increase in the undesirable behaviour in some 'at risk' groups.

In the case of alcoholic beverages, simple, accurate warning statements, which would effectively inform consumers about alcohol-related harm, would be difficult to devise given the complexity of issues surrounding alcohol use and misuse. (see **Section 4, Health Benefits of Moderate Alcohol Consumption**, below).

2 PUBLIC HEALTH POLICY ON ALCOHOL IN AUSTRALIA AND NEW ZEALAND

2.1 Comment received

Submissions from **Alcohol & Public Health Research Unit, New Zealand; Alcohol Healthwatch, New Zealand; Ms Elaine J Atwood; Caroline Chisholm Centre for Health Ethics Inc; GALA, New Zealand; Mission Australia; NZDF** and the **Public Health Service New Zealand, Nelson Health Promotion Unit** suggested that health warning labels (not necessarily with the wording suggested in the SWAT application) on alcoholic beverages would complement education campaigns and other harm reduction strategies by contributing to overall health knowledge, and would be another opportunity for reinforcing messages about potential alcohol-related harm.

The **ADF** considered that all strategies that help reduce the incidence and degree of drug related harm should be seriously considered. However **ADF** concluded on balance that rather than warning labels consumers should be provided with improved information on alcoholic beverage labels, including information on how alcohol could be used less harmfully.

Submissions from **AAB; AWRI; Beer, Wine and Spirits Council of New Zealand; Brown-Forman Beverages Australia Pty Ltd; CEPS, Alcohol & Society Standing Committee; Distilled Spirits Association of New Zealand; DSICA; National Alcohol Beverages Industries Council; New Zealand government's Ministry of Health (also submitted on behalf of the Ministry of Agriculture and Forestry, Ministry of Foreign Affairs and Trade, Ministry of Commerce and the Alcohol Advisory Council of NZ); New Zealand Licensing Trusts Association; Quay Group Inc; Queensland Health, Environmental Health Unit; Victorian Food Safety Council, Food Standards Sub-committee** (joint submission with **Drugs Policy Unit, Department of Human Services**); **Western Australia Food Advisory Committee;** and **WFA** pointed out that warning labels were unlikely to provide any added benefit over existing harm reduction strategies implemented by governments in Australia and New Zealand and that research had shown that warning labels on alcoholic beverages were unlikely to be effective at changing 'at-risk' alcohol consumption.

NCEPH was reluctant to support any particular wording in a warning label at this stage but recommended that ANZFA agree in principle to health warning labelling and request the National Expert Advisory Group on Alcohol, which reports to the Australian National Council on Drugs, to commission research to determine the most appropriate wording. *The* **NSW Drug Awareness Council** (formerly the **NSW Temperance Alliance**) submitted that labelling was a government responsibility with a precedent in the USA.

The **Population Health Division, H&AC** considered that there are other more effective State, Territory and Commonwealth initiatives either in place or being developed to address any health and safety implications associated with (excessive) alcohol consumption.

Additionally, the **Population Health Division, H&AC** considered that excessive alcohol consumption is a complex social and health problem and needs a coordinated response delivered through a range of service systems, including health and community services. Community education is also an important element in addressing this issue. Effective community education strategies need to be well targeted and underpinned by market research and tested with the target audience as a positive first step in addressing the health and safety implications of (excessive) alcohol consumption.

2.2 Assessment

Recognition of the complex issues relating to alcohol use, has led to the development of comprehensive national government public health policies on alcohol in both Australia and New Zealand.

2.2.1 New Zealand government public health policy on alcohol warning labels

The New Zealand government's combined submission came from the Ministry of Health and was also submitted on behalf of the Ministry of Agriculture and Forestry, Ministry of Foreign Affairs and Trade, Ministry of Commerce and the Alcohol Advisory Council of NZ)

After considering all the available evidence, MoH concluded that there was limited evidence to indicate the effectiveness of health warnings. Instead the MoH public health policy on alcohol concentrated on those interventions already identified as effective. These measures include:

- measures to control the supply of alcohol;
- initiatives to help reduce hazardous use of alcohol;
- health promotion materials;
- excise tax on alcohol;
- the promotion of host responsibility; and
- the investment of considerable resources and effort into discouraging drink-driving.

The MoH supports the introduction of standard drinks labelling on alcoholic beverages in preference to health warning messages.

2.2.2 Australian Commonwealth and State public health policy on alcohol

The National Drug Strategy is a joint Commonwealth-State health and law enforcement initiative which addresses both licit and illicit drug issues. Expenditure on this strategy is about $22 million a year. A recent independent evaluation of the drugs strategy (Single & Rohl, 1997) found that during the five years of the strategy there were declines in smoking, and an increase in responsible drinking patterns.

Since the mid 1980s, the proportion of adult drinkers who consumed alcohol at hazardous levels has been reduced from about one in three (31.6 per cent) to about one in four people (27.4 per cent). In the two years between 1992-93 and 1994-95, the annual number of hospital separations for conditions associated with alcohol consumption declined by more than twelve per cent. Between 1990 and 1995, the number of deaths due to alcohol use declined by twelve per cent.

The overall objective of the *National Health Policy on Alcohol in Australia* (1990) has been the minimisation of the harm associated with the use of alcohol. Achieving this objective required that comprehensive programs for public education and health promotion be implemented together with enhanced professional training and education and access to early forms of treatment.

From the *Evaluation of the National Drug Strategy 1993-1997*, harm minimisation for alcohol is not aimed at zero consumption, but is to 'avoid problems when you drink' and 'reduce the proportion of the population who drink regularly at levels above those identified by the NHMRC as low risk' (Single & Rohl, 1997). That is, it focuses on decreasing the risk and severity of adverse consequences arising from alcohol consumption without necessarily decreasing the level of consumption.

Complementing harm minimisation strategies there are a number of strategies developed from control policies in four major areas:

- price (including excise and taxation);
- availability (including restriction on sale to licensed premises, prohibitions on sale to minors);
- legal policies (including drink driving limits and penalties); and
- advertising and marketing (including control of the depiction of alcoholic beverages on labels and in advertising).

Strategies that implement control policies regulating advertising and marketing of alcoholic beverages include:

- measures that ensure the depiction of alcoholic beverages in all forms of advertising and marketing as a beverage to be consumed in moderation and responsibility;
- development with the alcohol industry of comprehensive voluntary codes to cover issues related to both the content of advertising and marketing strategies generally;
- the monitoring of the effectiveness of voluntary codes by the Standing Committee of Officials to the Ministerial Council on Drug Strategy of those codes;
- the depiction of the alcohol content of beverages on all containers of alcoholic beverages in a way readily understandable by the public;
- the encouragement of sponsorship of sporting, cultural and other recreational activities by bodies other than alcohol companies; and
- the avoidance of messages which may counter educational programs. In particular, limiting the image of products being based on success, social and sexual prowess, and good health.

As mentioned earlier the *National Drug Strategy 1993–1997* has been effective in reducing premature death, illness and injury associated with alcohol use and reducing the proportion of people who consume alcohol at levels likely to be hazardous or harmful. Building on this result, the cornerstone of the NDS *1999 Alcohol Action Plan* continues to be harm minimisation for ‘at risk’ groups. The strategies of the NDS are targeted to the high risk groups in the general population. These ‘at risk’ groups include: young people, drink drivers, indigenous Australians, alcohol consumers in the workplace, excessive consumers of alcohol, and alcohol consumers in prison.

2.3 Conclusion

Comprehensive public health strategies aimed at reducing alcohol-related harm are implemented in both Australia and New Zealand. These strategies concentrate on those interventions already identified as being effective including controlling price, availability and the advertising of alcoholic beverages; identifying and targeting 'at risk' groups with health campaigns aimed at reducing alcohol-related harm; and devoting considerable resources to the discouragement of drink-driving.

There have been significant decreases in alcohol-related harm in both Australia and New Zealand in recent years (see **Section 3, Costs of alcohol misuse**, below). It is unlikely that mandatory warning labels on alcoholic beverages would provide any further harm reduction than that which would be provided by the continuation of existing public health strategies.

In both Australia and New Zealand, alcoholic beverages are currently required to be labelled with alcohol content information. In Australia, all alcoholic beverages are also required to be labelled with information on the number of standard drinks. ANZFA's recent review of provisions regulating alcoholic beverages in Australia and New Zealand proposed that mandatory standard drinks labelling be extended to products sold in New Zealand. This information, together with existing public health and education initiatives provide consumers with sufficient information to make informed decisions about the alcohol they consume.

3 COSTS OF ALCOHOL MISUSE

3.1 Comment Received

ADF; Building Mature Christians Ministries Inc; Fetal Alcohol New Zealand; GALA; Public Health Service, New Zealand; Saltshakers; Salvation Army, Australia Eastern Territory; Salvation Army, Australia Southern Territorial Headquarters; Syndal Baptist Church; Wayside Chapel; Wesley Mission; Woman's Christian Temperance Union of Victoria, NSW, Tasmania and New Zealand, and the **NSW Drug Awareness Council** all expressed extreme concern over the costs of alcohol abuse to Australian and New Zealand society, on a financial, social, health, economic, welfare and family level. The type of harm could be immediate or long term, effecting both the consumer of the products and the wider community (domestic violence, drink driving and sexual assault), and kills many more people each year than illegal drugs. Financial costs may include lost production, lost working efficiency and excessive unemployment. Many of the submissions quoted figures for the estimated financial costs to Australia and New Zealand of alcohol abuse.

ADF contended that the alcohol industry argue that it is only a minority of the population that experience problems due to alcohol, such as alcohol dependence. However it is the problems associated with intoxication that account for the vast majority of harm experiences by our community.

The **Woman's Christian Temperance Union of NSW** suggested that it is a common belief that the 'huge' taxes paid by the liquor industry cover the huge medical costs sustained because of alcohol – but this is a fallacy. Tax paid by the liquor industry is some $1.5 Billion a year, whilst the cost of their industry's damage is around $7 Billion.

DSICA stated that the serious consequences of alcohol misuse are well documented. However, **DSICA** went on to state that there has been a large decline in alcohol consumption since the 1970s with the effect that in the 1990s the vast majority of Australians who consume alcohol do so moderately and responsibly.

DSICA also contended that the estimation of the social costs of alcohol abuse is a difficult and contentious issue with no single generally accepted procedure. Peer review indicates that some estimates significantly overstate external costs.

The **SWAT**, in its submission to the application, argued that the proposition that it is only heavy drinkers that are at risk, not light to moderate drinkers, is false. In support of this argument the **SWAT** quotes from Dr Pols and Professor Hawk, "Is there a safe level of daily consumption of alcohol for men and women?" (2nd Ed 1991):

> *Firstly, the consumption of alcohol is on a continuum in a given population. This means that the notion that there is one population which is 'alcoholic' and another without problems which is 'not alcoholic' is false. Secondly, per capita consumption does bear an important relationship to the total alcohol related morbidity within a population. Thirdly, there is indeed a Ledermann effect of a reduction of alcohol related problems, when the availability of alcohol is restricted by a variety of means. Finally, and perhaps most importantly, it follows that the majority of alcohol related problems are not caused by the heaviest drinkers, but by the majority of the population, those who are 'normal' or 'social' drinkers, simply because of their number.*

3.2 Assessment

The application from the SWAT, and submissions received in relation to the application, express a widespread concern about the adverse affects of alcohol use. These include the consequences of underage drinking, binge drinking and drink-driving. Each of these causes enormous losses - in health, social and economic terms - to the community, the family and the individuals concerned.

3.2.1 Australia

In 1990 the (then) Commonwealth Department of Human Services and Health commissioned an independent assessment of the health, social and economic costs associated with drug consumption in Australia, including alcohol. The resulting report, titled *Estimating the Economic Cost of Drug Abuse*, estimated the economic costs associated with alcohol at $6.03 billion per annum, compared with $1.44 billion for illicit drugs. In deriving the estimate costs were balanced against revenue and savings (for example from premature deaths).

In 1996 the estimation of the economic cost of alcohol consumption imposed on the Australian community was estimated to be more than $4.495 billion every year (The Social Costs of Drug Abuse in Australia in 1988 and 1992). This costing, based on 1994 mortality and morbidity figures, comprised:

- $3.537 billion of tangible costs, including those associated with loss of workforce productivity, health care costs and resources used in addictive alcohol consumption; and
- $0.958 billion of intangible costs, including mortality (value of loss of life to deceased, consumption foregone by deceased, suffering imposed on rest of community) and morbidity (pain and suffering of the sick, and suffering imposed on the rest of the community).

Higgins *et al* (2000) at the Australian Institute of Health and Welfare, cited estimates by Collins & Lapsley (1996): alcohol abuse is estimated to have cost Australian society $145 million in direct health care costs in 1992, and $767 million in road accident costs.

Estimates of social and economic costs due to alcohol misuse are notoriously difficult to estimate objectively. Depending on the assumptions made during the estimation, the total costs can vary manifold even when the same data is used.

A more objective view can be obtained by estimating the numbers of deaths attributable to alcohol, based on official annual death figures. Most Western countries including Australia have a comprehensive register of the causes of death categorised into internationally standardised groupings and sub-groupings.

Typically, estimates of costs due to the hazardous or harmful use of alcohol do not take into account the beneficial effects of alcohol. These beneficial effects have been shown to be significant (see **Section 4, Health benefits of moderate alcohol consumption**, below). Thus in Australia, Holman & Armstrong (1990) estimated that when the protective effect of alcohol on heart disease was included in annual estimates for 1986, deaths for males were decreased from 3129 deaths to –1323. In the same year, for females, estimates of deaths were decreased from 2231 deaths to –578. In other words, the pattern of use of alcohol in Australia in 1986, resulted in a net saving of 1323 male lives and 578 female lives.

English *et al* (1995) did the most recent Australian study of the costs of alcohol use in Australia for the (then) Department of Health and Human Services. They did this by estimating the degree of causality for all major causes of death that could be attributed to alcohol use, based on the available medical and scientific literature worldwide. They considered 16 major cohort studies on alcohol and all-cause mortality. They also examined the association of alcohol with over fifty specific causes of death, including cancer, cirrhosis, gastrointestinal diseases, stroke and coronary heart disease. Estimates of the contribution of alcohol to deaths due to road injuries, fall injuries, fire injuries, drowning, aspiration, occupational/machine injuries, suicide, assault and child abuse were also included. By definition all deaths attributed to alcoholic beverage poisoning, alcohol dependence, alcohol abuse, alcohol psychosis, alcoholic gastritis, alcoholic liver cirrhosis, alcoholic cardiomyopathy and alcoholic poly neuropathy were considered to be caused by harmful or hazardous alcohol use. In all English *et al* (1995) evaluated 2,700 studies.

From these studies, English *et al* (1995) estimated, for each alcohol-related condition, the fraction of deaths attributable to hazardous or harmful alcohol use. These ‘aetiological fractions’ were then applied to the actual numbers of deaths due to these conditions in Australia in 1992.

In all, there were 66,108 deaths of males and 57,543 deaths of females registered in Australia in 1992. English *et al* (1995) estimated that overall 3,660 deaths were attributable to hazardous or harmful alcohol use in Australia in 1992 – this figure comprises 2,521 male deaths and 1,139 female deaths. This accounts for 2.9% of all deaths in Australia in that year (3.8% of male deaths and 2.0% of female deaths).

English *et al's* (1995) methodology is now well established and has been applied to mortality figures in other years to estimate the number of deaths attributable to alcohol. Higgins *et al* (2000), at the Australian Institute of Health and Welfare, have used these 'aetiological fractions' to estimate the numbers of deaths attributable to alcohol from 1990 to 1997. Over this time the numbers of deaths from alcohol have decreased steadily from a rate 460 deaths per million population to 369 deaths per million population – a drop of 20% in 7 years.

This trend in the lowering of harms associated with alcohol use in Australia was confirmed by the recent independent evaluation of the National Drug Strategy (Single & Rohl, 1997):

- since the mid 1980s, the proportion of adult drinkers who consumed alcohol at hazardous levels has been reduced from about one in three (31.6 %) to about one in four people (27.4 %);
- in the two years between 1992-93 and 1994-95, the annual number of hospital separations for conditions associated with alcohol consumption declined by more than 12 %; and
- between 1990 and 1995, the number of deaths due to alcohol use in Australia declined by 12%.

Higgins *et al* (2000) also included data on the drop in overall alcohol consumption in Australia: between 1990 and 1997 the per capita alcohol consumption of persons aged 18 years and over decreased by 12% from 11.5 litres of pure alcohol* per year to 10.1 litres of pure alcohol* per year.

(*alcohol content varies depending on the type of alcoholic beverage consumed. These figures express the amount of pure alcohol contained in the wine, beer or spirits consumed).

3.2.2 New Zealand

The New Zealand government's Ministry of Health publication *Progress on Health Outcome Targets 1998* includes a conservative estimate of external costs associated with alcohol that was in the range of $432 million to $713 million per annum.

The same publication also lists key alcohol-related data over time:

- total alcohol consumption per person has decreased by 25% since 1980, although there has been a slight increase in the past year;
- the decline in alcohol consumption since 1980 may have reached a plateau in recent years; and
- alcohol-related mortality rates have declined 38% between 1980–82 and 1994–96, probably reflecting the decline in overall per capita alcohol consumption over that period.

3.3 Conclusion

Costs associated with alcohol related harm are high in both Australia and New Zealand. Estimates vary, but studies undertaken by national governments on a regular basis show a steady downward trend in alcohol consumption and in alcohol-related harm. In Australia alcohol-related mortality rates have decreased by 20% between 1990 and 1997; in New Zealand alcohol-related mortality rates decreased by 38% between 1980-82 and 1994-96. These decreases are related to reductions in overall alcohol consumption in both countries: 25% in New Zealand since 1980 and 1997; and 12% in Australia between 1990 and 1997.

These cost reductions are due at least in part to the implementation of successful harm reduction strategies (see **Section 2, Public health policy on alcohol in Australia and New Zealand**, above).

4 HEALTH BENEFITS OF MODERATE ALCOHOL CONSUMPTION

4.1 Comment received

Submissions from the **Alcohol Advisory Council of Western Australia; Anglican Diocese of Melbourne, Social Responsibilities Committee; AAB; ADF; Australian Medical Association; AWRI; Beer, Wine and Spirits Council of New Zealand; Brown-Forman Beverages Australia Pty Ltd; CEPS, Alcohol & Society Standing Committee; DAA; Distilled Spirits Association of New Zealand; DSICA; InforMed Systems Ltd; NABIC; NCEPH, Australian National University; New Zealand government's MoH** (also submitted on behalf of the **Ministry of Agriculture and Forestry, Ministry of Foreign Affairs and Trade, Ministry of Commerce and the Alcohol Advisory Council of NZ); New Zealand Licensing Trusts Association; NZDF; Quay Group Inc; Victorian Food Safety Council, Food Standards Sub-committee** (joint submission with **Drugs Policy Unit, Department of Human Services**); **Western Australia Food Advisory Committee** and **WFA** all pointed out that the moderate consumption of alcohol conferred significant health benefits.

GALA stated that there was some evidence that alcohol might confer a small health advantage. However that evidence did not suggest that the effect was due to alcohol but from other substances, particularly in certain types of wine. Therefore, **GALA** concluded, positive health messages should not be considered at this stage because the evidence was as yet inconclusive.

The **SWAT**, in its submission to the application, contended that if alcohol has the health benefits claimed by industry then it would be more appropriately regulated under the *Therapeutic Goods Act*.

4.2 Assessment

Since 1980, more than twenty large studies have consistently found a lower overall mortality rate in moderate drinkers than in non-drinkers or those with higher intakes. These results have been consistently found in both men and women and in diverse populations around the world:

- in the US (Blackwelder *et al*, 1980; Dyer *et al* 1980; Klatsky *et al*, 1981; Kittner *et al*, 1983; Gordon & Doyle, 1987; Bofetta & Garfinkel, 1990; Camacho *et al*, 1987; Fuchs *et al*, 1995; and Camargo *et al*, 1997);

- in the UK (Shaper *et al*, 1988; Doll *et al*, 1994);
- in Europe (Kozarevic *et al*, 1980; Gronbaek *et al*, 1994; Brenner *et al*, 1997 and Keil *et al*, 1997),
- in Australia (Cullen *et al*, 1982; Cullen *et al*, 1993; Simons *et al*, 1996a; and Simons *et al*, 1996b);
- in Japan (Kono *et al*, 1983; Kono *et al*, 1986); and
- in China (Yuan *et al*, 1997).

The results of these studies vary somewhat but, typically, all-cause mortality is reduced by 30% to 50% in men who drink the equivalent of up to four standard drinks per day and in women who drink up to two standard drinks per day. These results hold for all alcoholic beverages whether taken as wine, beer or spirits (Rimm *et al*, 1996; Gorinstein *et al*, 1997; Pellegrini *et al*, 1996; Brenner *et al*, 1997 and Keil *et al*, 1997). For men, the mortality risk appears to remain lower than that of abstainers until alcohol consumption levels equivalent to 5 to 7 standard drinks per day are reached (Duffy, 1995).

It is well accepted that protection against cardiovascular disease is the principal component of the lowered all-cause mortality associated with moderate alcohol consumption. Cardiovascular disease comprises all diseases involving the heart and blood vessels. In Australia its main forms are coronary heart disease, stroke and peripheral vascular disease that are caused by damaged blood supply to the heart, brain and legs (Australian Institute of Health and Welfare, 1998). The main underlying problem in cardiovascular disease is a process known as atherosclerosis that clogs blood supply vessels. It is most serious when it affects the blood supply to the heart, causing angina or a heart attack, or to the brain, which can lead to a stroke. In Australia, in 1996, cardiovascular diseases accounted for 53,989 deaths, or 41.9% of deaths from all causes among Australians, the major cause of deaths in Australia and many other western countries (Australian Institute of Health and Welfare, 1998).

The evidence for the so-called 'cardiovascular protective effect' has been accumulated and confirmed over many years in numerous studies worldwide. For coronary heart disease these include studies by: Bianchi *et al*, 1993; Boffetta & Garfinkel, 1990; Colditz *et al*, 1985; Dyer *et al*, 1980; Garfinkel *et al*, 1988; Garg *et al*, 1993; Gordon & Doyle, 1987; Gordon & Kannel, 1983; Gordon *et al*, 1981; Jackson *et al*, 1991; Kaufman *et al*, 1985; Kittner *et al*, 1983; Kivela *et al*, 1989; Klatsky *et al*, 1981; Lazarus *et al*, 1991; Rimm *et al*, 1991; Rosenberg *et al*, 1981; Scragg *et al*, 1987; Shaper *et al*, 1987; Siscovick *et al*, 1986; Stampfer *et al*, 1988; Suh *et al*, 1992;Suhonen *et al*, 1987;Wannamathee & Shaper, 1992; and de-Labry *et al*, 1992. Two of these seminal studies were carried out in New Zealand (Scragg *et al*, 1987; Jackson *et al*, 1991).

Leading epidemiologist Sir Richard Doll (1997) summarised wide-ranging research findings recently in the British Medical Journal:

> *The evidence for a beneficial effect [from moderate alcohol consumption] is now massive. It includes not only a reduction in the risk of vascular disease but also, because vascular disease is such an important cause of death in middle and old age, a reduction in total mortality.*

Plausible biological mechanisms exist for a causal effect for these cardiovascular health benefits to be attributed to the consumption of alcohol: alcohol elevates serum high density lipoprotein (HDL) cholesterol levels, which are associated with a reduced risk of coronary heart disease (English *et al* 1995). Alcohol also inhibits blood coagulation through reduced plasma fibrinogen concentrations and reduced platelet activity (English *et al* 1995).

These cardiovascular protective effects are seen across all age groups, including men and women older than 65 years of age (Colditz *et al*, 1985; Scherr *et al*, 1992). They are also evident in very young adults. However since cardiovascular and other fatal diseases occur at very low rates in the young, the protective effect is outweighed by traumatic death due to motor vehicle and other accidents. Hence overall death rates for young adult abstainers are lower than for moderate drinkers of the same age (Andreasson *et al*, 1988)

As mentioned earlier, protection against cardiovascular disease is the principal component of the lowered all-cause mortality associated with moderate alcohol consumption. However there is also evidence that associates moderate alcohol consumption with a range of other health benefits. These benefits include a reduction in the risk of developing many diseases with major public health impacts such as diabetes (Perry *et al*, 1995; Rimm *et al*, 1995), peripheral vascular disease (Camargo *et al*, 1997) and osteoporosis (Holbrook and Barret-Connor, 1993; Felson *et al*, 1995; Nguyen *et al*, 1996). Not only are these diseases associated with a large number of deaths in Western populations, they also incapacitate many older people, lowering their quality of life considerably.

The physiological mechanisms for the risk reduction observed in peripheral vascular disease are likely to be similar to those associated with cardiovascular protection (Camargo *et al*, 1997). However for diabetes and osteoporosis the likely mechanisms for the observed lower risk in those with moderate alcohol consumption are not yet known. There is some suggestion that moderate drinkers have an increased sensitivity to insulin which may be protective against the development of diabetes (Kiechl *at al*, 1996; Facchini *et al*, 1994; Mayer *et al*, 1993 *cited in* Rimm *et al*, 1995). It has been speculated that reduced risk of bone fractures may be mediated by effects on bone mineral density (Nguyen *et al*, 1996).

Alcohol is associated with a modest increase in deaths from some cancers. However, most cancers have little of no association with alcohol intake. Increased risks from cancers of the head and neck, liver cancer and breast cancer do occur even when the level of intake is classified as moderate (Longnecker, 1995).

The available evidence indicates that alcohol intake is not associated with an increased risk of cancer of the lung, bladder, prostate, stomach, ovary, endometrium or of melanoma (Longnecker, 1995).

The role of alcohol as a risk factor for liver cirrhosis, accidental death and certain types of cancer are well documented. Alcohol is also a direct cause of death by poisoning. However for the most part, these are not major causes of death in Australia. Although risks for some cancers and liver cirrhosis are increased, even at levels of alcohol intake regarded as moderate, these excess risks are more than outweighed by reduced rates of coronary heart disease (Holman *et al*, 1996a).

4.3 Conclusion

When consumed at low to moderate levels alcohol has significant health benefits. These benefits result in a lower overall mortality for those who drink alcohol in moderation as compared with those who abstain from alcohol or consume it at higher levels. These health benefits are mainly due to reductions in the risk for coronary heart disease, a major cause of death in Australia and New Zealand in middle and old age.

Although risks for some cancers and liver cirrhosis are increased, even at levels of alcohol intake regarded as moderate, these excess risks are more than outweighed by reduced rates of coronary heart disease.

As alcohol consumption increases beyond low to moderate levels, these health benefits are cancelled out by a rise in alcohol-related harm to health, including an increase in the risk of hypertension and stroke which are reduced only at low to moderate alcohol consumption levels

5 FETAL ALCOHOL SYNDROME

5.1 Comment received

Submissions from **Fetal Alcohol New Zealand; Fetal Alcohol Support Trust; Growth Through Moderation Soc Inc; Royal New Zealand College of General Practitioners; Seventh-day Adventist Church, North New Zealand Conference; Women's Christian Temperance Union of New Zealand** and the **Women's Christian Temperance Union Tauranga** all stated their serious concerns regarding alcohol related harm caused by drinking during, or just prior to, pregnancy. The personal and economic costs of Fetal Alcohol Syndrome (FAS) are enormous. New Zealand research has already shown a low average awareness of drinking during pregnancy being a health risk. Submissions considered that all possible measures to raise awareness and change behaviour and reduce the incidence of harm must be taken, including the proposed warning labels. Some of the submissions further considered that the effects of the alcohol could be more specific – such as 'alcohol may be harmful in pregnancy' and/or 'alcohol may harm the baby'.

5.2 Assessment

Fetal Alcohol Syndrome (FAS) is a well established, though rare, adverse outcome of pregnancy in alcoholic mothers. However to establish the incidence of FAS is difficult. Abel (1995) reviewed available data worldwide and estimated the incidence of FAS to be 0.97 cases per 1,000 live births in the general obstetric population and 4.3% among 'heavy' drinkers. However, the incidence is not smoothly spread in the general population but is highly concentrated in areas of low socio-economic status. Abel concluded that:

> *The major determinant for the occurrence of FAS is poverty. [which] provides the kind of host environment that exacerbates alcohol's toxic actions.…low socio-economic status and heavy alcohol consumption is associated with smoking, poor nutrition, poor health, increased stress and use of other drugs. Whereas none of the individual factors gives rise to FAS themselves, it is possible, if not likely, that they exacerbate the effects of heavy alcohol intake, resulting in FAS.*

English *et al* (1995) in their comprehensive review for the (then) Commonwealth Department of Health and Human Services, reviewed the medical literature worldwide on several aspects of alcohol use during pregnancy including FAS. They found that the lack of available data for the effect of alcohol on birth defects permitted only an analysis at the gross level of all birth defects. At that level, the findings were that the estimates of risk due to alcohol use were inconsistent and did not exclude chance as an explanation for the variations observed. Their conclusions were that, except for FAS (which by definition is caused by alcohol) there was inadequate evidence that alcohol during pregnancy caused birth defects. However they were unable to estimate the incidence of FAS in the Australian population due to the paucity of available data.

The current Australian NHMRC guidelines recommend abstinence from alcohol during pregnancy. This recommendation was made on the basis of the best available evidence at the time the recommendations were drafted. This advice was also similar to that given in other parts of the world including Europe and the USA. However, in Europe, the results of a large multi-centre study, the Euromac study (Euromac, 1992), has led to a change in the thinking regarding alcohol consumption in pregnancy in recent years from *any alcohol is harmful* to *some alcohol probably is not harmful*. The Euromac study, found that:

> *This study despite its size, has not provided a definitive answer to whether low levels of alcohol consumption during pregnancy adversely affect the health of the infant. The results show some evidence that drinking more than two drinks per day may be hazardous to intra-uterine growth whereas below this level epidemiological methods have failed to detect any effects.*

In recent years too, there have been a number of studies and review papers (discussed below) which have found no association between light alcohol consumption and damage to the fetus.

Several Australian studies that surveyed large numbers of birth outcomes failed to detect any cases of FAS (Bell & Lamely, 1989, Gibson *et al*, 1983; Lamely *et al*, 1985; Walpole *et al*, 1990). Walpole *et al* (1990) failed to show any significant relationship between low to moderate maternal alcohol consumption and newborn clinical status. They concluded that:

> *cautionary advice to pregnant women warning that any alcohol taken during pregnancy is potentially harmful to the foetus is inaccurate and therefore probably counter-productive.*

In Australia the incidence of alcohol consumption in pregnant women is low and consumption at hazardous or harmful levels is uncommon. English *et al* (1995), in their study for the (then) Commonwealth Department of Health and Human Services, estimated that among pregnant women in Australia, in 1993, the prevalence of alcohol consumption was:

- 78.7% drank no alcohol;
- 19.6 % drank less than 3 standard drinks per week;
- 1.5% drank 3-6 standard drinks per week;
- 0.09% drank 2-3 standard drinks per day; and
- 0.04% drank more than 4 standard drinks per day.

From these figures they estimated that in Australia, in 1993, 21.2% of pregnant women drank alcohol at low risk levels and 0.1% drank alcohol at hazardous or harmful levels.

From an extensive review of the literature Knupfer (1991) concluded:

> *that there was no evidence that light drinking by pregnant women harms the foetus. Light drinking is the norm in some contexts e.g. some European countries. Should this pattern of drinking cause fetal damage entire populations could be affected.*

Holman *et al* (1996b) stated that the results of their analyses done for the (then) Commonwealth Department of Health and Human Services (English *et al*, 1995) were consistent with this finding, and suggested that:

> *efforts at intervention should be directed more towards the 1.6% of pregnant Australian women who drink at hazardous and harmful levels, than the 19.6% who drink at levels classified by the NHMRC as 'responsible'.*

The National Health Advisory Committee (NHAC) of the National Health and Medical Research Council (NHMRC) is currently reviewing its 1992 recommendations regarding responsible drinking behaviour. The review is undertaking a comprehensive examination of all aspects of responsible drinking behaviour with a focus on the appropriateness of the current '4 and 2' safe drinking levels (i.e. up to four standard drinks per day for men and up to 2 standard drinks per day for women is considered to be a low risk for alcohol-related harm) The review is also paying specific attention to the issues associated with FAS.

The draft recommendations are due for release in later in 2000. The final outcome of the NHMRC review will be particularly relevant to future development of public health policy regarding recommendations on alcohol use during pregnancy.

5.3 Conclusion

Evidence suggests that there are no ill-effects on the fetus from light drinking by the mother. In Australia the incidence of alcohol consumption in pregnant women is low and consumption at hazardous or harmful levels is uncommon. Evidence also indicates that the incidence of FAS is rare, even among 'heavy drinkers', and is highly concentrated in areas of low socio-economic status, where heavy drinking is associated with smoking, poor nutrition, poor health, increased stress and use of other drugs. Whereas none of the individual factors gives rise to FAS themselves, it is possible, if not likely, that they exacerbate the effects of heavy alcohol intake, resulting in FAS

The National Health Advisory Committee (NHAC) of the National Health and Medical Research Council (NHMRC) is currently reviewing its 1992 recommendations regarding responsible drinking behaviour. The review is also paying specific attention to the issues associated with FAS.

6 CONSUMER INFORMATION

6.1 Comment received

6.1.1 Alcohol is a drug

In its further submission to the application **SWAT** contended that the evidence that alcohol is a drug and a dangerous drug would appear to be overwhelming. To support this argument, **SWAT** asserted that:

> *If the alcohol industry promotes its products as beneficial in so many ways, physically and psychologically, does it claim that alcohol is a therapeutic substance within the meaning of that expression as set out [below]*

The *Therapeutic Goods Act* defines 'therapeutic use' as:

a) preventing, diagnosing or alleviating a disease, ailment, defect or injury in persons or animals; or
b) influencing, inhibiting or modifying a physiological process in persons or animals; or
c) testing the susceptibility of persons or animals to a disease or ailment.

The **SWAT** submission then goes on to contend that:

> *If the industry does so claim, it should plainly say so and raise the question during the course of this public debate for determination and dispel all and every confusion as to the true identity of alcohol and alcohol effects as a drug.*

The **SWAT** claim that the dangers of alcohol due to its being a drug are not sufficiently well known, and that this information is necessary in order for consumers to make an informed choice. They further claim that as alcohol is a drug and a dangerous drug, and the producers and distributors of their alcoholic products have with knowledge of the true nature of the substance and of its dangers, failed to disclose these facts they could be guilty of fraud and deception. To support these claims the SWAT cites the Schafer Commission, appointed by the Congress of the United States of America, 1973, which states that:

> *…the public is conditioned to believe that 'street' drugs act according to entirely different principles than 'medical' drugs. The result is that the risks of the former are exaggerated, and the risks of the latter are overlooked. This confusion must be dispelled. Alcohol* is *a drug.*

Some submissions (**Alcohol Healthwatch, NZ; Fetal Alcohol Support Trust; GALA; NCEPH; NSW Drug Awareness Council; Saltshakers** and **Wesley Mission**) commented on the fact that alcohol is a drug. As such it is different to other manufactured products and should attract the same level of precautionary messages as tobacco and prescription drugs. The fact that alcohol is a drug needs to be told simply and clearly.

While agreeing that alcohol was a drug, **ADF; Informed Systems Ltd; Queen Fine Foods** and the **MoH** contended that alcohol is only dangerous under certain circumstances or when it is abused.

AWRI contended that alcohol could be classified as both a drug and a foodstuff. Consistent with drugs and foodstuffs, there is a therapeutic level of consumption above which is a harmful level. This harmful level for alcohol is light to moderate consumption which equates to approximately 30 grams per day for men and women.

Similarly, the **ADF** suggested that the place alcohol holds in our society is ambiguous. Alcohol is a drug but is also recognised as a food under the ANZ Food Standards law. In addition it is subject to other legal controls (liquor licensing, drink driving). This makes it an atypical food and so special consideration must be given to how it is packaged and made available.

The **Population Health Division, H&AC** contended that all foods, even water, have an inherent toxicity if taken in excess. The issue is one of managing risk through avoiding abuse rather than identifying a hazard.

6.1.2 Consumers' right to know

The **Alcohol and Public Health Research Unit; ADF; Fetal Alcohol New Zealand; Public Health Service, New Zealand; GALA; Growth Through Moderation Soc Inc; Mission Australia, Sydney; NSW Drug Awareness Council** and the **Women's Christian Temperance Union of SA** generally considered that the consumer had a 'right to know' and are entitled to information about alcohol and its possible effects on health and behaviour.

GALA; Mission Australia, Sydney; and the **Seventh-day Adventist Church, North New Zealand Conference** cited the use of warning or advisory statements in the current Australian Food Standards Code (for example, the label of foods containing some polyols must carry the statement "Excess consumption may have a laxative effect") as a reason for now including warning statements on alcoholic beverages.

The **Distilled Spirits Association of NZ; Brown-Forman Beverages Australia Pty Ltd** and **DSICA** contended that consumers are already aware of what constitutes responsible drinking and the harms of alcohol misuse.

6.1.3 Provision of consumer information to enable an informed choice

Some submissions (**Alcohol and Public Health Research Unit; Ms Attwood; Public Health Service, New Zealand; Growth Through Moderation Soc Inc; NSW Drug Awareness Council** and the **Wayside Chapel**) considered that this information should be provided in the label of alcoholic beverages. Labelling with warning statements would offer brief yet accurate information on which to base their choices about the use of alcohol.

The **Women's Christian Temperance Union of SA** and the **NSW Drug Awareness Council** specifically expressed concern about the lack of knowledge about and labelling on certain products marketed towards young people, such as alcopops and alcoholic fruit drinks.

The **AWRI; Distilled Spirits Association of NZ; Brown-Forman Beverages Australia Pty Ltd; DSICA; Anglican Diocese of Melbourne** and the **Seventh-day Adventist Church, North New Zealand Conference** all expressed their concern that the public should be provided with accurate balanced complete and credible information in order to educate alcohol consumers to enable them to make informed decisions based on fact rather than fiction. However, these submitters questioned whether a warning statement on the label of alcoholic beverages would achieve this aim.

The **Population Health Division, H&AC** considered that the proposed label does not constitute an appropriate public health awareness strategy or convey the relevant health information to enable consumers to make an informed choice.

6.1.4 Existing labelling requirements for alcoholic beverages

The **AAB; Australian Medical Association; AWRI; DSICA; MoH; National Council of Women of NZ; Queensland Health** and the **Victorian Food Safety Council** pointed out that alcoholic beverages are already required to indicate the percentage of alcohol by volume, and the number of standard drinks. The submitters considered that standard drinks labelling was a more appropriate message and hence medium with which to educate consumers regarding appropriate (light to moderate) consumption, enabling them to monitor and make informed decisions about their alcohol consumption.

MoH stated they would be more inclined to support the introduction of Standard Drink labelling prior to, or in preference to, health warning messages.

The **Population Health Division, H&AC** considered that the current labelling of alcoholic beverages provides the consumer with the relevant information to enable them to make an informed choice with regard to the alcohol content of a product. The Food Policy Section endorsed the current labelling arrangements whereby information is provided on the total number of standard drinks contained in the product.

Similarly, **Queensland Health** considered existing labelling provisions for alcoholic beverages to provide adequate information for consumers. The complex range of short and long term effects of alcohol consumption are more appropriately addressed through government and community education programs.

NCEPH also considered existing labels provided quite a lot of information (standard drinks and %ABV) to assist consumers to make informed decisions as to their consumption levels. Adding an appropriately worded health warning label will reinforce this and enhance public health and safety.

6.1.5 Labelling may create confusion

Ms Attwood; Alcohol Healthwatch, NZ and **NCEPH** did not agree with statements in the Preliminary Assessment Report for A359 that 'consumers would be confused by labelling on a legal food product advising that it was dangerous'. Many foods already carry warnings of different connotations (e.g. allergic reactions to sulphites, products containing royal jelly). Further, warnings already appear on cigarette packets, pharmacological products, cleaning products, children's toys etc. Consumers are used to warning messages and expect possible harmful effects to be advised.

Alcohol Advisory Council of WA and the **DAA** considered that such a message as proposed in A359 would send conflicting message to consumers who are also faced with information regarding the safe use of alcohol, consistent with NHMRC recommended guidelines for safe drinking.

6.2 Assessment

That alcohol is a drug is a true statement. However foods containing alcohol are regulated as foods, such as alcoholic beverages. This management of alcohol as both a drug and as a food is consistent with the treatment of other foods containing pharmacologically active substances. For example kava is regulated as a food, and the content of caffeine in foods is regulated in food standards.

Many foods or components of foods may have a therapeutic action, without being regarded as a therapeutic good. For example, ANZFA is currently undertaking a trial of labelling packages with health claims in relation to folate and its importance in preventing neural tube defects in the fetus. In many cases, where there is a blurred line between what is a therapeutic good and what is a food, it is the way in which a product is represented which is the ultimate determining factor.

The SWAT contends that the dangers of alcohol as a drug are not sufficiently well known. Research surveys conducted by Hall *et al*, (1992) have shown that the general population could identify the primary pharmacological/physiological and social alcohol related-harms and that consumers correctly identified the level of consumption associated with alcohol-related benefits. There is a significant level of knowledge by the Australian population about alcohol related harms and the NHMRC alcohol consumption guidelines. In Australia, Higgins *et al* (2000), at the Australian Institute of Health and Welfare, recently reported that 64% of Australians correctly identified the levels of alcohol consumption associated with a low risk of alcohol-related harm as recommended by the NHMRC in their alcohol consumption guidelines. During consideration of warning statements on alcoholic beverages by the Canadian Parliament, the former Deputy Minister of Community Occupational Health, Alberta, asserted that the established educational programs have 'created a sufficiently aware public that the kind of simple message that can practically be applied to bottles and packages is no longer of any real value' (Canada House of Commons Standing Committee on Health 1996).

Evidence that Australian consumers already have a high awareness of safe levels of alcohol consumption is supported by statistics showing a continuing steady decline in overall per capita consumption of alcohol and steady downward trend in alcohol-related harm (see **Section 3, Costs of alcohol misuse,** above).

If there is a high level of awareness among consumers of the risks and benefits of alcohol consumption then consumers are unlikely to be misled or deceived when purchasing a product containing alcohol.

Many submissions received in support of the application stated that consumers would benefit by increased consumer information and an increased ability for the consumer to make an informed choice. These submissions also supported the consumers 'right to know'.

State and Territory, Federal and New Zealand Governments also support the consumers right to know about the risks of excessive alcohol consumption and have established policies and public health initiatives in order to ensure that the consumer is provided with balanced and accurate information on which they may base their choices (see **Section 2 – Public health policy on alcohol in Australia and New Zealand**).

This is supported by the Population Health Division, H&AC which, in its submission, considered that:

excessive alcohol consumption is a complex social and health problem and needs a coordinated response delivered through a range of service systems, including health and community services. Community education is also an important element in addressing this issue. Effective community education strategies need to be well targeted and underpinned by market research and tested with the target audience as a positive first step in addressing the health and safety implications of (excessive) alcohol consumption.

ANZFA concludes that the proposed statement does not provide the consumer with any useful additional information, and that the proposed statement may in fact make it more difficult for the consumer to make an informed choice.

The first part of the proposed statement, "this product contains alcohol" is a statement of fact. However, consumers are already supplied with this information on the form of the alcoholic content statement. Additionally, consumers are required to purchase alcoholic beverages from separate, licensed, premises, making it highly unlikely that a consumer could unintentionally or accidentally purchase an alcoholic beverage. Therefore, including the statement "this product contains alcohol" on the label of an alcoholic beverage is entirely superfluous.

The second part of the proposed statement "alcohol is a dangerous drug" does not supply the consumer with any useful information on which to base an informed decision and may be misleading.

It is also a statement of fact that alcohol is a 'drug'. However, as discussed above, consumers are aware of the risks and benefits associated with alcohol consumption. Stating this on the label will not supply any additional useful information upon which the consumer can base an informed decision.

By describing alcohol as a "dangerous" drug implies that any level of consumption of alcohol is dangerous, and does not recognise current scientific research which demonstrates that low to moderate alcohol consumption has a beneficial health impact (see **Section 4 – health benefits of moderate alcohol consumption**). Additionally, the statement does not provide any information to the consumer as to what a safe level of consumption might be, or when consumption of alcohol, or how much, might be unsafe.

The emotive wording of the statement discourages moderate consumption and is premature in the light of the NHMRC review of sensible drinking guidelines. Additionally, it does not recognise possible counter-productive outcomes from warning labels or likely negative consumer response to the warning by those most at risk and by heavy drinkers (see **Section 1– Effectiveness of Warning Labels on Alcoholic Beverages**).

Information as to a safe level of consumption is already provided by standard drink labelling requirements, in conjunction with government and industry education campaigns informing consumers of the recommended daily number of standard drinks for men and women to maintain a healthy life. While the proposed statement may not confuse consumers, who already have a high awareness of the NHMRC alcohol consumption guidelines, the statement is not consistent with those guidelines and Government policies in relation to alcohol.

6.3 Conclusion

While alcohol is, in fact, a drug, foods containing alcohol are regarded as foods and are regulated in food standards. The general population appears to have a significant level of understanding of the risks and benefits of alcohol consumption. A statement on the label of alcoholic beverages to the effect that alcohol is a dangerous drug is not likely to provide any additional useful information to the consumer.

Information on the alcohol content of a beverage is already available to the consumer in the form of percentage alcohol by volume statements and standard drink labelling. This information, in conjunction with community education programs as to a safe level of alcohol consumption, provides consumers with accurate information to enable them to make informed decisions about the amount of alcohol they consume.

7 MERITS OF THE SPECIFIC WARNING STATEMENT PROPOSED

7.1 Comments received

The **Alcohol Advisory Council of WA** suggested the words 'this product contains alcohol' on a container of alcohol was entirely redundant.

The **NCEPH** suggested that while the proposed statement was factually correct, in the absence of research into its impacts they were reluctant to support any particular wording at this stage.

The **NZDF** opposed the specific wording of the statement, believing it was too general to be effective.

Submissions from the **Alcohol Advisory Council of WA; AAB; Anglican Diocese of Melbourne; AWRI; CEPS; Distilled Spirits Association of NZ; Brown-Forman Beverages Australia Pty Ltd; DSICA; NABIC; MoH; NZ Licensing Trusts Association; Victorian Food Safety Council** and the **WFA** all provided comments specifically on the accuracy and usefulness of the proposed statement. Submissions considered that the application was premised on a dated approach to alcohol and the consumer, that alcohol is a harmful and hazardous drug, that there is no safe level of consumption, and that all consumers are equally vulnerable to its effects. Some submissions considered that the linkage and emotive comparisons with illicit drugs was not valid; beer, wine and spirits are legal food products. Moderate and responsible consumption of these beverages has an established social acceptance and a rightful place in the community, whereas illicit drugs have no such place. Labelling using language that strongly condemns (i.e. 'dangerous drug') is not consistent with most people's view of the product in the community.

Submissions considered that the statement inferred that alcohol is the singular cause of problems. There was a failure to acknowledge the crucial role of biological, psychological, personal and complex social factors which are the root of abuse problems.

Submissions contended that while the dangers of excessive alcohol consumption on an individual and social level have been well described it is now well accepted that alcohol in moderation has a number of health benefits. Therefore the unqualified statement that 'alcohol is a dangerous drug' is at best misleading and would require qualifying statements if consumers are not to be misled.

The **Population Health Division, H&AC** considered that the proposed warning label is too general and may appear confrontational for what is a legal food product and largely socially acceptable product. Further, the proposed label does not tell the consumer why alcohol is a 'dangerous drug' or what are the health and safety implications associated with the consumption of the product regardless of the level of intake.

The **Alcohol Advisory Council of WA** and the **DAA** suggested that such a message would send conflicting message to consumers who are also faced with information regarding the safe use of alcohol, consistent with NHMRC recommended guidelines for safe drinking.

The **ADF; AWRI; Ms Attwood; Distilled Spirits Association of NZ; Brown-Forman Beverages Australia Pty Ltd; DAA; DSICA; National Council of Women of NZ** and the **WFA** considered that the proposed statement did not provide any useful information as to a safe level of consumption or about how to use alcohol less harmfully.

The **AWRI** has provided an extensive evaluation of the current literature in relation to the accuracy of the proposed warning, and the associated assumptions on which the warning is based.

7.2 Assessment

As considered in many submissions the specific statement proposed in the application, while being (in part) a statement of fact may be misleading, in that alcohol is not dangerous in all circumstances, and does not provide the consumer with any additional useful information on which to base an informed decision about the amount of alcohol being consumed. These issues are considered in greater detail above in **Section 6, Consumer Information**.

The proposed statement is unsatisfactory in terms of likely effectiveness because:

- it does not recognise significant health benefits arising from moderate alcohol consumption;
- it does not recognise possible counter-productive outcomes from warning labels;
- it does not recognise likely negative consumer response to the warning by those most at risk and by heavy drinkers;
- it is a de facto prohibition notice and as such represents a control theory which has been largely discredited;
- it discourages moderate consumption and is premature in the light of the NHMRC review of sensible drinking guidelines; and
- it does not provide any useful information as to a safe level of consumption.

7.3 Conclusion

Due to the number and complexity of the issues surrounding the use of alcohol, devising a warning statement which could simply and accurately provide useful and meaningful information to consumers is impossible.

8 COMPARISON WITH TOBACCO

8.1 Comments received

The **MoH; Alcohol Advisory Council of WA** and the **WFA** considered that a comparison could not be made between warning statements on tobacco and alcoholic beverages. The difference between alcohol and tobacco consumption is that there is no safe level, or positive benefit to health of tobacco consumption, whereas moderate alcohol consumption is not harmful and may be beneficial to certain population groups. Tobacco warnings can be short and punchy, adding to the strength and recollection of the message, i.e. 'smoking kills'. Due to the known positive effects of moderate alcohol consumption any health warning label would have to be qualified, this would limit its impact.

In its submission to the Application, **SWAT** considered that there are distinctions between alcohol and tobacco that demonstrate there could be no valid comparison between the two.

Ms Attwood suggested that without properly quantified research a comparison with the warning on tobacco products cannot be made.

Alternatively, **GALA** and **Wesley Mission** considered that as the government warns people of an even greater killer – namely tobacco, by the same reasoning alcohol should also be labelled as such.

Queensland Health; Informed Systems Ltd and the **National Council of Women of NZ** suggested that studies on the effectiveness of tobacco warnings show that they have had little impact on consumption. Studies also suggest that the use of warning statements on products such as alcohol and tobacco have the opposite effect on the 18-25 year old age group.

The **Royal New Zealand College of General Practitioners; NCEPH** and the **Seventh-day Adventist Church, North New Zealand Conference** considered that labelling of tobacco products has been found to be an effective part of the attempt to reduce harm from tobacco.

8.2 Assessment

English *et al's* (1995) methodology (described in **Section 3, Costs of alcohol misuse**, above) is now well-established and has been applied to mortality figures in other years to estimate the number of deaths attributable to alcohol. Higgins *et al* (2000), at the Australian Institute of Health and Welfare, have used these 'aetiological fractions' to estimate the numbers of deaths attributable to alcohol from 1990 to 1997. Over this time the numbers of deaths from alcohol have decreased steadily from 460 deaths per million population to 369 deaths per million population – a drop of 20% in 7 years.

Higgins *et al* (2000) at the Australian Institute of health and Welfare also estimated deaths attributable to tobacco 1990 to 1997. There has been a steady decrease from 2,399 deaths per million population to 1,903 deaths per million population – a drop of 20%.

There is no known consumption level of tobacco that confers health benefits. All tobacco consumption is likely to be harmful. Thus health warnings for tobacco may be brief and accurate and would apply to all sectors of the population. In the case of alcohol, there are levels of consumption that result in significant health benefits. These benefits vary with age, gender and other factors that are too complicated for a simple message or messages.

8.3 Conclusion

Simple, direct comparisons of tobacco warning statements with alcohol warning statements are not valid because of the differences between the two with respect to health risks and benefits. There is no level of tobacco consumption that can be considered to be safe or low risk. Therefore warning messages for tobacco could be easily devised. On the other hand, low to moderate consumption of alcohol confers significant health benefits and brief accurate health messages that pertain to the majority of consumers relating to alcohol use would be difficult to devise.

9 USA AND INTERNATIONAL PERSPECTIVE

9.1 Comment received

A number of submissions (**Alcohol Healthwatch, NZ; Growth Through Moderation Soc Inc; GALA; NSW Drug Awareness Council; Seventh-day Adventist Church, North New Zealand Conference; Women's Christian Temperance Union of New Zealand** and **Ms Yates**) point out that warning statements are in fact already required in a number of other countries, including the United States, setting a strong precedent. The current international trend is towards warning labels being required. These submitters also point out that alcoholic products exported to these countries from Australia and New Zealand is already being labelled appropriately.

DSICA cited a recent survey of countries that have mandated health warning labels. This survey established that health warning labels have been legislated in nine countries. These are the United States of America, Brazil, Colombia, Costa Rica, Ecuador, Honduras, Mexico, Zimbabwe and South Korea.

GALA contended that warning statements on alcohol must be displayed in nine countries, including the USA. **GALA** goes on to state that France, Canada, Taiwan, Thailand and South Africa are considering imposing warning statement requirements.

DSICA contended that there is no international standard for alcohol warning labels, with messages varying widely from general messages that warn of the risks of excessive alcohol consumption (Brazil, Colombia, Costa Rica and Mexico) to messages that give specific information on risks (United States, South Korea and Zimbabwe). None of the messages refer to alcohol as a drug. No alcohol beverage warning label statement is mandated by Codex.

Distilled Spirits Association of NZ; Brown-Forman Beverages Australia Pty and the **Quay Group** noted that the majority of Governments in other countries do not require warning labels on alcoholic beverages. Expert agencies and government officials in NZ, Australia, Canada, and Western Europe have rejected proposed warning messages on labels. At the same time, health benefit labels on wine have been officially sanctioned in the USA and NZ. Specifically, the Canadian Government in 1996 rejected proposals for health warning labels after research found they would not be effective. The British and EU governments have reached similar conclusions.

CEPS; DSICA and **NABIC** expressed concern that the introduction of health warning labels would disrupt trade, would not promote consistency between domestic and international food standards and would be in breach of Australia and New Zealand's WTO obligations.

However, **Ms Attwood** believed Australia can justify such labelling in the international arena as we have had standard drink labelling since 1995.

9.2 Assessment

Australia and New Zealand food regulations require mandatory labelling statements that provide information to the consumer about alcohol content of the product. This includes standard drinks labelling. However, Australia has justified the labelling of alcoholic beverages with standard drinks as it provides consumers with useful accurate information. When used in conjunction with community information campaigns on safe and responsible drinking guidelines, standard drinks can be used to base informed decisions on the amount of alcohol a consumer chooses to consume.

While some countries, including the USA, require warning statements on alcoholic beverages, there is no international consensus on their use. Health warnings were considered and rejected by New Zealand, United Kingdom and Canadian governments and are not required in any European country. In addition there is no specific Codex standard in relation to alcoholic beverages or the use of warning statements on their labels.

The current scientific evidence is that health warning statements of the type proposed by the SWAT application are not an effective means of changing behaviour. In addition there are other proven effective strategies already in place. When implementing regulation in Australia that is not consistent with WTO obligations, Australia must be able to prove that the regulation was necessary in order to protect pubic health and safety or provide adequate information to consumers.

9.3 Conclusion

There is no international consensus on the use of warning labels on alcoholic beverages. Nine countries, including the USA, prescribe warning statements for alcoholic beverages. Health warnings were considered and rejected by New Zealand, United Kingdom and Canadian governments and are not used in any European country. There is a lack of evidence as to the effectiveness of warning labels on alcoholic beverages in protecting public health and safety, reducing health, social and economic costs or providing additional useful information to consumers. This lack of evidence may leave Australia open to challenge through the WTO if the application were to be accepted.

10 ALCOHOL ADVERTISING

10.1 Comment received

Alcohol Healthwatch, NZ; Fetal Alcohol New Zealand; Seventh-day Adventist Church, North New Zealand Conference; GALA; Public Health Service, New Zealand; Mission Australia, Sydney; NSW Drug Awareness Council and the **Women's Christian Temperance Union of Tasmania** were very concerned about the amount of advertising of alcoholic beverages and the following comments were made. The glamourisation and normalisation of alcohol due to advertising made it difficult for the general public to make sound judgments around their drinking. Advertisements increase confidence that drinking alcohol is without any risks. Some submitters considered that at risk groups were being targeted by advertising (for example, young women) or that it was not uncommon to find manipulative marketing and advertising techniques being directed towards children and youth (for example, alcoholic icy poles). Submissions stated that alcohol is New Zealand's number one problem drug yet is one of the most heavily advertised products on the market. The public is told alcohol is one of the most damaging drugs but it is encouraged.

Alcohol Healthwatch, NZ; Public Health Service, New Zealand; Seventh-day Adventist Church, North New Zealand Conference and the **NSW Drug Awareness Council** also considered that health and safety messages would provide information to balance the powerfully persuasive images of alcohol advertising.

10.2 Assessment

Alcohol misuse does give rise to harm and injury. This is recognised by public health policy in Australia and New Zealand, which is supported by the alcoholic beverages industry.

As discussed above in **Section 2, Public health policy on alcohol in Australia and New Zealand**, strategies that implement control policies regulating advertising and marketing of alcoholic beverages include:

- measures that ensure the depiction of alcoholic beverages in all forms of advertising and marketing as a beverage to be consumed in moderation and responsibility;
- development with the alcohol industry of comprehensive voluntary codes to cover issues related to both the content of advertising and marketing strategies generally;
- the monitoring of the effectiveness of voluntary codes by the Standing Committee of Officials to the Ministerial Council on Drug Strategy of those codes;
- the depiction of the alcohol content of beverages on all containers of alcoholic beverages in a way readily understandable by the public;
- the encouragement of sponsorship of sporting, cultural and other recreational activities by bodies other than alcohol companies; and
- the avoidance of messages which may counter educational programs. In particular, limiting the image of products being based on success, social and sexual prowess, and good health.

In addition, governments and industry have in place community education campaigns in relation to specific issues including responsible drinking practices and drink driving campaigns.

As discussed above in **Section 1, Effectiveness of warning labels on alcoholic beverages,** warning statements are unlikely to be an effective means of changing consumer beliefs or behaviour and will therefore have no effect in 'balancing' advertising.

The alcoholic beverages industry has funded the development, administration and funding of successful advertising self-regulation mechanisms, including the *Alcohol Advertising Pre-vetting System (AAPS)* and *Alcohol Beverage Advertising Code and Complaint Managing System*.

The Alcohol Advertising Pre-vetting System (AAPS) was established by the Australian Associated Brewers (AAB) and the Distilled Spirits Industry Council of Australia (DSICA) in July 1992.
AAPS was developed with input from the Commonwealth Health Department and the Advertising Federation of Australia and was endorsed by the Media Council of Australia. It underpins the Alcohol Beverages Advertising Code.

Since its inception the AAPS has effectively acted as an industry filter to maintain standards and ensure member companies' compliance to the regulatory codes prior to an advertisement's appearance. Results during the initial years, 1992 to 1994, have been outstanding. Complaints made under the Alcohol Beverages Advertising Code dropped from 35 in 1990 to 0 in 1993 and have since remained at negligible levels.

AAPS has also been breaking ground internationally, with several countries adopting the model or developing systems based upon it.

The Alcohol Beverages Advertising Code and Complaints Management System (ABAC) is the self regulating advertising code of the Australian alcohol beverages industry. ABAC came into operation on 1 July, 1998.

ABAC was prepared in agreement with all key Australian alcohol beverages manufacturing and marketing industry associations, and key advertising, media, and consumer bodies. ABAC also consulted with relevant Federal government ministers, their advisers and departments, and with the Australian Consumers Association and the Australian Competition and Consumer Commission (ACCC).

ABAC will be operated by a management committee that includes a representative of the Advertising Federation of Australia and a representative from each of the four ABAC Principals:

- Australian Associated Brewers Inc(AAB);
- Distilled Spirits Industry Council of Australia Inc (DSICA);
- Liquor Merchants Association of Australia Ltd (LMA); and
- Winemakers Federation of Australia Inc (WFA).

Members of these four associations are asked to commit to abide by both the code and the decisions of the Complaints Adjudication Panel.

Under ABAC, an independent Complaints Adjudication Panel will assess any complaints about alcohol advertisements to ensure unbiased interpretation of the code and independent adjudication on any complaint about alcohol beverages advertising.

To ensure consistent and effective decision making, three active Panel members will decide any complaints. Two additional Panel members will be available to stand in when needed.

Consistent with the expectations of the broader community, all five Panel members represent broad, mainstream values. They are independent of the alcohol industry and do not represent any particular interest group. The current Panel members are:

- Mr Michael Lavarch, Chief Adjudicator (former Commonwealth Attorney General);
- Ms Ita Buttrose (media personality);
- Dr Anne Roche (Director Qld Alcohol and Drug Research Education Centre);
- Ms Liz Dangar (Chairwoman of Dangar Research); and
- Ms Jean Strachan (Managing Director Inview Market Research).

The Chief Adjudicator of the ABAC Complaints Adjudication Panel will preside over the complaints adjudication process and will advise the Advertising Standards Bureau, the advertiser, and the ABAC Management Committee, in writing, of the outcome of the Panel's decisions. The Bureau will communicate the results to the complainant and to other interested parties.

The Chief Adjudicator will provide the ABAC Management Committee with a report detailing the decisions and recommendations the panel has made during the preceding year. The ABAC Management Committee will circulate the report to relevant State and Federal ministers and appropriate advertising industry bodies, including the Advertising Standards Bureau.

10.3 Conclusion

There is an existing framework for the regulation and self-regulation of advertising of and sponsorship by manufacturers of alcoholic beverages and also for the regulation of availability. In addition, interventions to minimise alcohol-related harm are already in place and supported by the alcoholic beverages industry.

11 SIZE AND PLACEMENT OF ALCOHOL LABELLING INFORMATION

11.1 Comment received

The **Alcohol Advisory Council of WA; Alcohol Healthwatch, NZ; GALA; National Council of Women of NZ** and **Wesley Mission** suggested that current or future labelling requirements for standard drinks and alcohol concentration labelling could be made more effective by being of sufficient size, clarity and contrast making them more noticeable.

11.2 Assessment

This issue has been recently considered by ANZFA in relation to the review of food standards and the development of a Joint *Australia New Zealand Food Standards Code* (joint FSC). Proposal P142 – Review of Print Size and Quality, is recommending that, unless otherwise expressly permitted, all information required to be on a food label must be written or set out legibly and prominently and in the English language.

Generally, ANZFA considered that as legibility is optimised by many equally effective combinations of specific legibility criteria (such as colour contrast, print size, uniform size, style and colour,) it is difficult to determine and justify which criteria are critical to determining the legibility of labels. If regulations prescribe that information must be prominent and legible then it follows that labels must fulfil the requirements of specific legibility criteria, as is best suited in that particular set of circumstances. Prescribing specific legibility criteria will ensure that labels comply to specific conditions but will not ensure that the overall label is indeed prominent and legible.

11.3 Conclusion

This issue has been considered as a part of the review of food standards and the development of a joint FSC. ANZFA recommended that, unless otherwise expressly permitted, all information required to be on a food label must be written or set out legibly and prominently and in the English language.

12 FAILURE TO REQUIRE LABELLING ON ALCOHOLIC PRODUCTS MAY LEAVE INDUSTRY OPEN TO LITIGATION

12.1 Comment received

Alcohol Healthwatch, NZ; Ms Attwood and **GALA** submitted that in the USA many former smokers have sued the tobacco companies for their ill health and often imminent death, as a result of their use of a 'legal' tobacco product. Most of the successful convictions have arisen because originally there was no law to make tobacco companies tell their consumers what harm tobacco causes to their health. It was further submitted that the same position may arise in the future with alcoholic products.

12.2 Assessment

The protection of industry from the potential for legal proceedings, as an objective in itself, does not fall within those specified in section 10 of the Act. There is, of course, the possibility in some cases that, in implementing those section 10 objectives (in particular the protection of public health and safety and the provision of adequate information), the protection of sectors of industry from the prospect of legal proceedings may incidentally be served.

However, there is no authorisation within the Act for ANZFA to consider the protection from legal proceedings as a basis for the development or variation of a food standard.

Even if such a statutory authorisation existed within the Act, the submission is speculative at best, and purports to rely heavily on developments in USA law which are not readily applicable to the contemporary Australian or New Zealand legal scene. For ANZFA to attribute any weight to this type of submission it would need to proceed on the basis of supposition rather than available evidence.

12.3 Conclusion

There is no authorisation within the Act for ANZFA to consider the protection from legal proceedings as a basis for the development or variation of a food standard.

13 COSTS OF LABELLING TO INDUSTRY, GOVERNMENT AND CONSUMERS

13.1 Comments received

Alcohol and Public Health Research Unit; Alcohol Healthwatch, NZ; Ms Attwood; Fetal Alcohol New Zealand; Fetal Alcohol Support Trust; GALA; NCEPH; Seventh-day Adventist Church, North New Zealand Conference and **Ms Yates** considered that costs to industry as a result of labelling alcoholic beverages with a warning statement would be low. There would be reasonable notification of the changed regulations (lead in time) and while there may be initial costs of design, the label becomes part of normal packaging production costs. Additionally, manufacturers change their labelling fairly frequently for marketing purposes.

Many of the submissions pointed out that exported products already have warning labels yet the product remains competitive, suggesting increased costs are minimal. In the USA the labelling requirement has not had much impact on overall sales, which continue a slightly downward trend. Submissions also considered that any increase in costs would eventually be passed on to consumers.

NCEPH pointed out that a number of manufacturers voluntarily label with such statements as 'drink this beverage in moderation' They were not aware that this caused any change in the cost structures.

Several submissions also considered that any increase in costs would eventually be passed on to consumers. **Fetal Alcohol New Zealand** and **Public Health Service, New Zealand** further contended that increasing the cost of alcohol is a positive public health strategy to reduce consumption.

Submissions from the **Beer Wine & Spirits Council of NZ; Distilled Spirits Association of NZ; Brown-Forman Beverages Australia Pty Ltd; CEPS; NZ Licensing Trusts Association; Quay Group** and the **WA Food Advisory Committee** contended that it was most unlikely that presumed social benefits would outweigh the financial costs of a warning label, when there is scant evidence of these benefits. ANZFA's regulatory assessment would need to demonstrate a positive cost/benefit ratio. If imposed, the proposed labelling would impose significant compliance and enforcement costs on Authorities and the drinks industry and would be likely to lead to higher prices for consumers.
Increased costs would penalise the vast majority of Australians and New Zealand consumers who drink moderately, without doing anything to tackle misuse.

The **Beer Wine & Spirits Council of NZ; Distilled Spirits Association of NZ; Brown-Forman Beverages Australia Pty Ltd** and **CEPS** considered that unless sound scientific data can be produced, warning labels on beverages may constitute and artificial and technical barrier to international trade that may have unintended effects in the marketplace, domestic or otherwise.

The **WFA** and the **AWRI** provided extensive data on the contribution the wine industry made to the Australian economy, in terms of direct and indirect employment, value of sales, tax revenue, tourism etc. The submissions contended that labelling wine as a dangerous drug would do enormous damage to a product which contributes positively to both the economic well-being of Australia and to the positive image of Australia overseas created by wine. Such

labelling references would be in direct conflict with how the majority of members of the community view wine as a product.

Beer Wine & Spirits Council of NZ contended that potentially, such labels could infringe the intellectual property embodied within brand and content labels owned by companies producing the beverage. Warning labels could encroach on the commercial meaning and intellectual 'value' of existing commercial labels. Further, warning labels such as the wording proposed by SWAT carry very negative connotations about the safety of alcoholic beverages, which may be interpreted as alarmist and misleading (particularly given the positive health benefits for the majority of moderate consumers). Given these kinds of issues, warning labels on alcoholic beverage containers and/or packaging could raise additional legal and/or policy complications for Governments in both countries.

13.2 Assessment

Total government revenue from the consumption of alcoholic beverages is estimated at $1.8 billion dollars for 1997–98, comprising $1.0 billion dollars from excise duties and $0.7 billion from customs duty, most of which was paid on spirits (Higgins *et al*, 2000).

There is a cost to industry associated with additional or changed labelling requirements. These costs may be significantly greater for small businesses that hold proportionally larger stocks of labels in order to take advantage of economies of scale. These costs can be minimised by allowing an appropriate lead in time, taking advantage of new print runs and the general changes to labels that are made over time. Additionally, given the nature of some alcoholic beverages (particularly wine) and their shelf life, any additional labelling provisions may need to apply only to beverages packaged after a certain date. This phased implementation was used previously during the introduction of standard drink labelling.

As many submissions have contended, labelling costs are not likely to be large, and are likely to be offset to some extent by being passed on to consumers. However, as discussed in **Section 1, Effectiveness of warning labels on alcoholic beverages**, warning labels on alcoholic beverages have been shown to be an ineffective mechanism to reduce harm from excessive alcohol consumption. In addition, there are existing public health policies and initiatives in place (**Section 2, Public Health Policy on Alcohol**), which are being effective at addressing issues relating to excessive alcohol consumption. Additional costs to industry can not be justified where there is no evidence of any anticipated additional benefits to industry, government or consumers.

13.3 Conclusion

The costs to industry of labelling alcoholic beverages with a warning statement are not expected to be high. However, research shows that warning labels on alcoholic beverages are not effective at changing behaviour and reducing harm from excessive alcohol consumption. Additionally, strategies are already in place in Australia and New Zealand, based on their public health on policy on alcohol and supported by industry, and there is already a trend of decreasing alcohol consumption and decreasing alcohol-related costs and harm in both countries.

REGULATION IMPACT ANALYSIS

1 Assessment of Impacts (Costs and Benefits) of Each Option

Option 1 - Include a provision that all alcoholic beverages must be labelled with the statement: *This product contains alcohol. Alcohol is a dangerous drug*.

Benefits of Option 1:

Government
There are no perceived benefits for government. As discussed in the assessment of issues (**Section 1, Effectiveness of Warning Statements**) while the concept of warning labels is a good one in principle, research has shown that in practice they are ineffective at changing behaviour in at risk groups.

Industry
Some submissions suggested that requiring a warning statement on alcoholic beverages may provide manufacturers with some protection from litigation. However, **as discussed in Section 12, Failure to require labelling on alcoholic products may leave industry open to litigation**, the submission is speculative at best and purports to rely heavily on developments in USA law which are not readily applicable to the contemporary Australian or New Zealand legal scene.

Consumers
There are no perceived benefits for consumers. As discussed in the assessment of issues (**Section 1 – Effectiveness of Warning Statements**) while there may be an increase in awareness of warning statements on alcoholic beverages, there is no corresponding change in consumer behaviour. Warning statements on alcoholic beverages have been shown to not be effective in targeting those groups in the community most 'at risk' from excessive alcohol consumption.

Costs of Option 1:

Government
Government would incur the usual costs of enforcement of a regulation.

Information on the alcohol content of alcoholic beverages is already provided in the form of alcohol by volume statements and standard drinks labelling. The proposed statement may represent a duplication of existing regulation, and be inconsistent with Government policies on good regulatory practice.

There will be costs associated with the need for Australia and New Zealand to defend, in the international fora, regulation which may be inconsistent with Australia's and New Zealand's international commitments and WTO obligations.

There may be some costs relating to the undermining of government (and other) health promotion policies and campaigns due to the labelling of alcoholic beverages with a warning statement that is not consistent with current Australian Government policies and guidelines on responsible drinking practices.

Industry
Manufacturers will be faced with increased labelling costs. However, as discussed in Section 13, Costs of labelling to industry, governments and consumers, these costs are not expected to be high and it is likely that these costs will be passed on to consumers.

Consumers
There may be a small increase in cost of alcoholic beverages whether imported or produced domestically, as labelling costs to manufacturers are likely to be passed on to consumers.

In relation to the specific statement proposed, it is possible that consumers may be misled. Alcohol is not 'dangerous' to all consumers in all situations. The statement does not take into account evidence that, when consumed in moderation, alcohol confers significant health benefits to some sections of the community. These issues have been considered in detail in **Section 4, Health benefits of moderate alcohol consumption**, and **Section 6, Consumer Information**.

It is possible that due to the emotive wording of the statement, and the lack of qualifying information, that light to moderate consumers of alcohol may reduce their alcohol intake, thus denying them the positive health benefits it is now recognised are associated with such consumption of alcohol.

Research indicates that there may be a reaction to warning statements by some 'at risk' groups of the community the opposite of what is intended.

Option 2 - Do not change the current or the proposed provisions for the labelling of alcoholic beverages and rely on existing regulatory and non-regulatory provisions in place in Australia and New Zealand (i.e. retain the *status quo*).

Benefits of Option 2:

Government
Australia will be meeting its obligations under the agreement between Australia and New Zealand establishing a system for the development of joint food standards.

Australia and New Zealand will remain consistent with their international commitments and WTO obligations.

Regulatory and non-regulatory interventions (**Section 2, Public health policy on alcohol in Australia and New Zealand**) in relation to alcoholic beverages are already in place and are seemingly effective at reducing the costs to Australia associated with excessive alcohol consumption (**Section 3, Costs of alcohol misuse**).

Industry

Providing for fair trade, domestically and internationally, for all manufacturers of these products.

Consumers
The alcoholic beverages industry, Government and Non Government Organisations all currently provide public education campaigns on the safe drinking, and provide information on safe levels of consumption for at risk target groups (for example, pregnant women), and

for healthy living (for example the NHMRC guidelines).
In addition, existing regulation in the form of liquor licensing regulations, drink-driving regulations etc also provide additional consumer protection.

Consumers of light to moderate amounts of alcohol will not be deterred (due to the emotive wording of the statement, and the lack of qualifying information), from drinking at levels shown to be beneficial to some population groups.

Costs of Option 2:

Government
There are no perceived costs to governments.

Industry
There are no perceived costs to industry.

Consumers
There are no perceived costs for consumers.

2 Conclusions and Recommendations

ANZFA has considered the current government public health policy relating to alcohol in Australia and New Zealand, medically and scientifically evaluated research literature on the costs of alcohol misuse, medically and scientifically evaluated research literature on the health benefits of moderate alcohol consumption, and scientifically evaluated research literature on the effectiveness of health warning labels of alcoholic beverages.

Option 1 would introduce some additional labelling costs to alcoholic beverage manufacturers. However, as the evidence indicates that warning statements on alcoholic beverages are not effective at changing behaviour in at risk groups, there are no benefits to be gained by industry, governments or consumers from implementing this regulatory measure. Further, there may be indirect costs to industry, government and consumers as the proposed warning statement may be misleading, may discourage light to moderate drinkers from drinking, in some cases depriving them of significant health benefits, and is not consistent with existing government policies and initiatives in relation to alcohol.

Option 2 introduces no perceived additional costs to consumers, government or industry. Continuing benefits are to be gained by consumers, government and industry from existing government policies and initiatives, supported by non government organisations, and industry. These benefits include the continuing decline in per capita alcohol consumption rates and declining costs due to excessive alcohol consumption.

ANZFA proposes that no changes be made to the current or the proposed provisions for the labelling of alcoholic beverages.

3 Implementation and Review

As the RIS has concluded that the preferred option is to retain the status quo and make no changes to the labelling requirements relating to alcoholic beverages, no issues arise in relation to implementation.

A comprehensive review of food standards (including alcoholic beverages) in Australia and New Zealand has recently been completed. ANZFA expects to make recommendations to the Australia New Zealand Food Standards Council on a Joint *Australia New Zealand Food Standards Code* in November 2000. Another review of food regulation, or review of labelling requirements for alcoholic beverages specifically, would not be expected to take place for a considerable period of time.

The issue of warning statements on alcoholic beverages and the health benefits of a low to moderate consumption of alcohol are the subjects of extensive scientific evaluation. Scientific literature is constantly reviewed by ANZFA in order to maintain an overview of these issues and the need to amend policy or regulation in light of new information.

Any individual or organisation may apply to ANZFA to amend food regulation at any time. Additionally, ANZFA may raise a proposal to amend food regulation should it be considered necessary.

ANZFA SECTION 10 OBJECTIVES (IN DESCENDING ORDER OF PRIORITY)

a. The protection of public health and safety.

Governments in Australia and New Zealand recognise that there is currently a serious public health and safety concern in relation to excessive (short or long term) alcohol consumption or abuse. This has resulted in extensive government, non-government and industry regulatory and non-regulatory interventions designed to establish safe drinking practices and therefore minimise the risk to public health and safety.

Research has shown that warning statements on alcoholic beverages, while increasing consumer awareness, do not result in a corresponding change in consumer behaviour. That is, the use of warning statements does not result in a decrease in alcohol consumption, particularly for those groups that are most 'at risk', and therefore do not result in any protection of pubic health and safety.

Requiring a warning statement on alcoholic beverages is unlikely to result in any additional protection of public health and safety over and above that already being provided by existing public health policies and campaigns.

b. The provision of adequate information relating to food to enable consumers to make and informed choice and to prevent fraud and deception.

Existing provisions in Australia and New Zealand require the concentration of alcohol in an alcoholic beverage must always be declared. In addition, Australia currently requires all alcoholic beverages to be labelled with the number of 'Standard Drinks', and it is being recommended, as a part of the establishment of a joint *Australia New Zealand Food Standards Code*, that this requirement should be made mandatory in New Zealand. These labelling requirements provide consumers with significant information about the amount of alcohol in the product, and, when supported by information provided in public health and education initiatives (for example NHMRC Drinking Guidelines) enable consumers to make informed choices about the amount of alcohol they may choose to consume.

The labelling statement proposed does not provide any additional useful information on which consumers may be able to base an informed decision. Consumers are already aware that 'this product contains alcohol' from the existing alcohol concentration statements. Additionally, alcoholic beverages are restricted to sale only from licensed premises. This means that a consumer must actively seek the appropriate store (or location within a store) from which to purchase alcoholic beverages. This being the case, it is most unlikely a consumer could mistakenly purchase an alcoholic beverage under the impression that it is non-alcoholic.

The statement 'Alcohol is a dangerous drug' also does not provide any additional useful information on which consumers may be able to base an informed decision, and may even be misleading. Alcohol is a 'drug', however, as a result of existing government regulations, polices and education campaigns, supported by non-government organisations and industry, the consumer is already aware of the risks and benefits related to alcohol consumption. Alcohol is 'dangerous' only when used inappropriately, or when used by groups who are 'at risk'. The proposed statement provides no information on a level of consumption that is dangerous or safe, or which consumers may use to make and informed decision. Nor does the statement indicate which consumers (or groups) may be more at risk than others. Indeed, it is unlikely that any statement for alcoholic beverages could be devised which could accurately and usefully present all the information necessary on which a consumer could base an informed decision.

c. The promotion of fair trading in food.

Labelling of alcoholic beverages affects all manufacturers (Australian, New Zealand, and importers) equally. The promotion of fair trading in food is not an issue as the 'level playing field' is maintained.

d. The promotion of trade and commerce in the food industry.

Including the proposed warning statement on the labels of alcoholic beverages may adversely affect trade and commerce in the alcoholic beverages industry. In particular, the wine industry submissions claim that such a statement would do enormous damage to a product that contributes positively to both the economic well-being of Australia and to the positive image of Australia overseas created by wine. Such labelling references would be in direct conflict with how the majority of members of the community view wine as a product.

e. The promotion of consistency between domestic and international food standards.

There are nine countries that require the labelling of alcoholic beverages with a warning statement, including the USA. However, there is no consistency in the wording of the statement between these countries.

Codex does not specifically standardise alcoholic beverages.

New Zealand does not require labelling of alcoholic beverages with a warning statement.

OTHER RELEVANT MATTERS

Onus of Proof

The Applicant's submission of 7 July 1999 queries whether the issue of onus of proof applies in the assessment of an application to develop or vary a food standard. The submission poses the question that if the applicant satisfies ANZFA on an inquisitorial assessment, on the civil standard of proof, is it [the Authority] bound to recommend the labelling as sought or an alternative labelling.

The Applicant's submission at paragraph 9 states:

> *We submit that if SWAT's major premise in our application is established on a balance of probabilities, namely that alcohol is a drug and a dangerous drug, the onus is on the industry to show why our application should not succeed. Further the onus is on the industry to show why ANZFA should not make a recommendation in the terms sought in the application. This in our view would require a clear rebuttal of the premise that alcohol is a drug and a dangerous drug.*

ANZFA does not accept the substance of this aspect of the applicant's submission.

The processes by which ANZFA deals with applications for the development or variation of food standards are prescribed in Part 3 Division 1 of the Act. Subsection 15(3) of the Act relevantly provides that after making a full assessment of the application ANZFA must either prepare in writing a draft standard or draft variation of a standard or reject the application. ANZFA, in arriving at either of these decisions is making an administrative decision. Accordingly, the principles of administrative law, including the rules of natural justice and procedural fairness, apply. That said, the part 3 process cannot be characterised as 'adversarial' in nature. The process, however, may be regarded as 'inquisitorial' because ANZFA has the power to undertake its own inquiries, and is not limited to acting solely on the information presented to it by parties with standing in the matter. The concept of a legal onus of proof on the applicant or an onus on those opposed to the application to 'negative' evidence that alcohol is a dangerous drug is inappropriate in the Part 3 process. The task of ANZFA in processing an application is to inquire into the facts of the matter, not in order to decide whether 'a case' has been proven, but to reach the best decision in the circumstances.

In one practical sense, an applicant for the development or variation a food standard may bear an evidentiary or persuasive burden in circumstances where, for example, the applicant is requested by the ANZFA to provide evidence to support the facts underlying the applicant's claim. This is especially so where the facts are within the applicant's own knowledge. This does not mean, however, that a legal burden of proof arises. Rather, it is simply a matter of ensuring that ANZFA has before it evidence on which it can base the facts asserted by the applicant.

ANZFA, in making an administrative decision, must comply with the requirements of procedural fairness. One aspect of this requirement is that the material facts on which a decision by ANZFA is made must be arrived at on the balance of probabilities (*Minister for Immigration & Ethnic Affairs v Pochi* (1980) 44 FLR 41).

CONCLUSIONS

ANZFA proposes to reject the application for the following reasons:

- Scientific evidence for the effectiveness of warning statements on alcoholic beverages shows that while warning labels may increase awareness, the increased awareness does not necessarily lead to the desired behavioural changes in 'at-risk' groups. In fact, there is considerable scientific evidence that warnings statements may result in an increase in the undesirable behaviour in 'at risk' groups.

- In the case of alcoholic beverages, simple, accurate warning statements, which would effectively inform consumers about alcohol-related harm, would be difficult to devise given the complexity of issues surrounding alcohol use and misuse, and the known benefits of moderate alcohol consumption.

- Costs associated with alcohol related harm are high in both Australia and New Zealand. Estimates vary, but studies undertaken by national governments on a regular basis show a steady downward trend in alcohol consumption and in alcohol-related harm. In Australia alcohol-related mortality rates decreased by 20% between 1990 and 1997; in New Zealand alcohol-related mortality rates decreased by 38% between 1980-82 and 1994-96. These decreases are related to reductions in overall alcohol consumption in both countries: 25% in New Zealand since 1980 and 1997; and 12% in Australia between 1990 and 1997. These cost reductions are due at least in part to the implementation of successful public health initiatives based on harm reduction strategies.

- Comprehensive public health strategies aimed at reducing alcohol-related harm are implemented in both Australia and New Zealand. These strategies concentrate on those interventions already identified as being effective including controlling price, availability and the advertising of alcoholic beverages; identifying and targeting 'at risk' groups with health campaigns aimed at reducing alcohol-related harm; and devoting considerable resources to the discouragement of drink-driving.

- When consumed at low to moderate levels alcohol has significant health benefits. These benefits result in a lower overall mortality for those who drink alcohol in moderation as compared with those who abstain from alcohol or consume it at higher levels. These health benefits are mainly due to reductions in the risk for coronary heart disease, a major cause of death in Australia and New Zealand in middle and old age. As alcohol consumption increases beyond low to moderate levels, these health benefits are countered by a rise in alcohol-related harm to health.

- Although risks for some cancers and liver cirrhosis are increased, even at levels of alcohol intake regarded as moderate, these excess risks are more than outweighed by reduced rates of coronary heart disease.

- The available scientific and medical evidence suggests that there is no evidence that light drinking by pregnant women harms the fetus. In Australia the incidence of alcohol consumption in pregnant women is low and consumption at hazardous or harmful levels is uncommon. Evidence also indicates that the incidence of FAS is rare, even among 'heavy drinkers', and is highly concentrated in areas of low socio-economic status, where heavy drinking is associated with smoking, poor nutrition, poor health, increased stress and use of other drugs. Whereas none of the individual factors gives rise to FAS themselves, it is possible, if not likely, that they exacerbate the effects of heavy alcohol intake, resulting in FAS.

- The National Health Advisory Committee (NHAC) of the National Health and Medical Research Council (NHMRC) is currently reviewing its 1992 recommendations regarding responsible drinking behaviour. The review is also paying specific attention to the issues associated with FAS.

- In both Australia and New Zealand, alcoholic beverages are currently required to be labelled with alcohol content information. In Australia, all alcoholic beverages are also required to be labelled with information on the number of standard drinks. ANZFA's recent review of provisions regulating alcoholic beverages in Australia and New Zealand proposed that mandatory standard drinks labelling be extended to products sold in New Zealand. This information, together with existing public health and education initiatives, provide consumers with sufficient information to make informed decisions about the alcohol they consume.

- While alcohol is, in fact, a drug, foods containing alcohol are regarded as foods and are regulated in food standards. Evidence strongly suggests that the general population has a significant level of understanding of the risks and benefits of alcohol consumption. The Full Assessment report concludes that a statement on the label of alcoholic beverages to the effect that alcohol is a dangerous drug is not likely to provide any additional useful information to the consumer.

- Simple, direct comparisons of tobacco warning statements with alcohol warning statements are not valid because of the differences between the two with respect to health risks and benefits. There is no level of tobacco consumption that can be considered to be safe or low risk. Therefore warning messages for tobacco could be easily devised. On the other hand, low to moderate consumption of alcohol confers significant health benefits and brief, accurate health messages that pertain to the majority of consumers relating to alcohol use would be difficult to devise.

- There is no international consensus on the use of warning labels on alcoholic beverages. Nine countries, including the USA prescribe warning statements for alcoholic beverages. Health warnings were considered and rejected by the New Zealand, United Kingdom and Canadian governments and are not used in any European country. There is a lack of evidence as to the effectiveness of warning labels on alcoholic beverages in protecting public health and safety, reducing health, social and economic costs or providing additional useful information to consumers. This lack of evidence may leave Australia open to challenge through the WTO if the application were to be accepted.

- There is an existing framework for the regulation and self-regulation of advertising and sponsorship of alcoholic beverages and also for the regulation of availability. In addition, interventions to minimise alcohol-related harm are already in place and supported by the alcoholic beverages industry.

- The size and placement of existing alcohol labelling information has been considered as a part of the review of food standards and the development of a joint FSC. ANZFA is recommending that, unless otherwise expressly permitted, all information required to be on a food label must be written or set out legibly and prominently and in the English language.

- The costs to industry of labelling alcoholic beverages with a warning statement are not expected to be high. However, scientific evidence shows that warning statements are not effective in modifying at risk behaviour in relation to consuming excessive amounts of alcohol. Additionally, strategies are already in place in Australia and New Zealand, based on their public health on policy on alcohol, and are seemingly effective, as demonstrated by the trend of decreasing alcohol consumption and decreasing alcohol-related costs and harm in both countries.

- The Regulation Impact Statement concludes that requiring the labelling of alcoholic beverages with a warning statement would offer no clear benefits to government, industry or consumers but would introduce costs to government, industry and consumers.

- Requiring the labelling of alcoholic beverages with a warning statement does not fulfil ANZFA's objectives in relation to section 10 of the *Australia New Zealand Food Authority Act 1991*. Scientific evidence shows that warning statements are not effective in modifying at risk behaviour in relation to consuming excessive amounts of alcohol, and would therefore not provide any additional protection of public health and safety. Information to enable consumers to make an informed decision or prevent fraud and deception is already provided by existing labelling requirements and public health policies and campaigns.

WORLD TRADE ORGANIZATION (WTO) NOTIFICATION

Australia and New Zealand are members of the WTO and are bound as parties to WTO agreements. In Australia, an agreement developed by the Council of Australian Governments (COAG) requires States and Territories to be bound as parties to those WTO agreements to which the Commonwealth is a signatory. Under the agreement between the Governments of Australia and New Zealand on Uniform Food Standards, ANZFA is required to ensure that food standards are consistent with the obligations of both countries as members of the WTO. In certain circumstances Australia and New Zealand have an obligation to notify the WTO of changes to food standards to enable other member countries of the WTO to make comment. Notification is required in the case of any new or changed standards which may have a significant trade effect and which depart from the relevant international standard (or where no international standard exists).

As ANZFA is recommending that no variation to food regulation be made as a result of this application, there is no need to make a notification to the WTO.

ATTACHMENTS

1. Statement of Reasons
2. Summary of Comment Received
3. Society Without Alcoholic Trauma Submission

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