RESPONSE TO INITIAL ASSESSMENT REPORT

APPLICATION A576

labelling of alcoholic beverages

with a

pregnancy warning label

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LIST OF ABBREVIATIONS

AAB	Australasian Associated Brewers Inc
ABV	alcohol by volume
ADCA	Alcohol and other Drugs Council of Australia
AERF	Alcohol Education and Rehabilitation Foundation Ltd
AGPN	Australian General Practice Network
ALAC	Alcohol Advisory Council of New Zealand
BMA	British Medical Association
FAS	Foetal Alcohol Syndrome
FASD	Foetal Alcohol Spectrum Disorder
FSANZ	Food Standards Australia and New Zealand
NABIC	National Alcohol Beverage Industry Council
NHMRC	National Health and Medical Research Council
RCOG	Royal College of Obstetricians and Gynaecologists
WHO	World Health Organization

EXECUTIVE SUMMARY

In 1996 ALAC publicly opposed warning labels for pregnancy because of the evidence that it is an ineffective measure. In 2006 ALAC has back flipped its position. By contrast, industry's position has been consistent over time, as has the evidence.

In isolation, everyone agrees that warnings on labels cannot deliver behaviour change yet behaviour change by a population sub-set is the goal, and the current Application can only be considered in isolation as there is no existing complementary communications program. A few hypothetical add-ons are suggested as a strategy which ALAC hopes others may honour in the future. Informed by past experience, no wish list for delivering future measures can be relied upon ('the cheque's in the mail').

Population-level measures such as warning labels are a grossly inefficient means of reaching a population sub-group and can detract from other existing population-level measures on labels such as standard drinks and recycling logos. Targeted interventions are more efficient and appropriate in this instance as there is ample evidence that health advice delivered in a health setting is likely to change behaviour.

Australian brewers have just completed a voluntary program of new labelling at their own expense to accommodate a government request for standard drinks logos. If a new round of labels was ordered now our member companies would lose the benefit of amortising these costs over time.

A Foetal Alcohol Syndrome (FAS) Strategy should not be confused with its subset of a communications strategy designed to change behaviour; means and ends are separate. Experience shows that the motivating trigger for behaviour change has more to do with social awkwardness and group acceptance than warnings of adverse health consequences, unless delivered by a trusted health professional.

There is broad evidence of a safe (low) level of drinking while pregnant, but no scientific consensus on what that level should be. This disagreement is used by some to adopt a more conservative view to move away from a patterns-based approach to consumer advice. The zero tolerance approach of the draft NHMRC guidelines are not primarily intended as consumer advice and they eschew responsibility for tailoring their advice to Australia's drinking culture. The sole Australian survey in the Initial Application shows an existing high-level of awareness of potential risks amongst women of child-bearing age.

Australasian Associated Brewers Inc does not support Application A576.

INTRODUCTION

Australasian Associated Brewers represents some of Australia and New Zealand's largest manufacturing brewers, with members including Foster's Group Limited, DB Breweries, Coopers Brewery and J Boag and Son.

The Associated Brewers is a policy-based organisation that has been representing its members in legislative and regulatory affairs for over 40 years, and maintains a presence in both Canberra and Wellington. The Associated Brewers is a member of the National Alcohol Beverage Industry Council (NABIC) in Australia.

The Associated Brewers has a significant interest in Application A576 ('the application') as its proposals, if implemented, would have a direct cost impact on its member companies.

The Associated Brewers has been careful to adopt an evidence-based approach to this submission. Undoubtedly, some organisations and sections of the community will be quick to invoke emotive and non-scientific arguments in response to the application before Food Standards Australia and New Zealand (FSANZ). The Associated Brewers considers that such arguments are damaging to the credibility of what must be a rigorous, fact-based process.

In maintaining an evidence-based approach, the AAB considers that this submission provides a fair and reasonable representation, supported by sound scientific data, of the issues involved.

This submission is structured in two broad parts: addressing some general overarching comments on the Application and then addressing each of the fifteen specific Initial Assessment Questions posed by FSANZ.

Where appropriate, relevant evidence has been cited to support the claims or points raised in this submission; and a complete list of references cited in this submission has been provided.

Australasian Associated Brewers strongly supports rigorous evidence-based processes, and recognises FSANZ's dedication to these principles. However there are some general aspects of the Initial Assessment Report that deserve comment on behalf of the Associated Brewers.

Similarity with Prior Applications

We believe that this Application raises issues which were a subset of a previous Application (A359) and were adequately addressed by its assessment. The Associated Brewers' submission to A359 (AAB, 1999) dealt directly and fully with a consideration of the evidence on pregnancy labelling as an issue, for example:

> "*Hankin et al* [1993] *specifically sought to study the effectiveness of the USA's warning labels on a group at high risk of delivering a child suffering from Foetal 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.*"

We also note the Applicant's prior views on A306 which called specifically for pregnancy warnings:

> "*ALAC rejects call for health messages on labels*
>
> *Wellington – Health warnings on bottles of alcohol would be ineffective, says the Alcohol Liquor Advisory Council (ALAC).*
>
> *The Australia-New Zealand Food Authority has begun an investigation on whether to include health message on bottle labels and beer cans, after a request from a women's group in Tasmania …*
>
> *Mr MacAvoy said there were more effective ways of getting the message across, such as running mass media advertising campaigns and working through health professionals to inform pregnant women.*
>
> *A private members' bill in Canada on health warnings on bottles and cans had just been rejected, as research found it would not be effective, he said.*[1]"

We note the consistency of our position and the inconsistency of ALAC's, even though the evidence base on the ineffectiveness of warning labels in changing behaviour has been strengthened rather than weakened over time.

Relevance of the Draft Australian Alcohol Guidelines

The Associated Brewers is concerned that care should be taken in the use of the National Health and Medical Research Council's (NHMRC) (2007) draft Australian Alcohol Guidelines for Low-Risk Drinking for informing decisions on how to change consumer behaviour.

The primary objective of A576 is to change consumer behaviour within the drinking culture. But this is *not* the primary objective of the draft NHMRC guidelines. Although it was the primary objective of the current (2001) Australian Guidelines,

[1] Article in the New Zealand Herald, August 5, 1996

which embraced a patterns-based approach, the NHMRC's current proposal has deliberately moved away from this role:

> "*The responsible consumption of alcohol is a health issue, not a cultural issue. People make their own choices – it's not our role to tell them how to behave.*[2]"

When considering the relevance of the draft guidelines, care should be taken to not confuse the ends with the means.

Consideration of the Applicant's Hypothetical Wider Strategy

ALAC openly agrees that changing behaviour is the objective of their application for warning labels and that alcohol warning labels are unlikely to elicit behaviour change when implemented 'in isolation'. The same term is used by the World Health Organization (WHO) Expert Committee on Problems Related to Alcohol Consumption who stress that warning labels "…*show little evidence of reducing alcohol related harm and therefore should not be implemented in isolation as alcohol policies*" (WHO, 2007) (p.70).

The Applicant's argument is founded on the unproven assertion that alcohol warning labels are most likely to be effective when used in conjunction with a wider 'complex intervention', that is, a basket of other measures which they hope may work, but are unproven. The proposition that pregnancy warnings may work in conjunction with a basket of other measures relies solely on repetition for effect and is unburdened by any supporting evidence.

The Application is extremely weak on two other points:

- There is no reliable expectation that the introduction of warning labels would be consistently supported by a basket of other measures over time, which ALAC agrees is necessary because *"Changing people's behaviour can be a long, slow process"* (p.22); and
- ALAC confuses two quite different concepts of a wider generalised strategy associated with the consideration of FAS as an issue and a specific communications strategy which may change behaviour.

This proposal sits resolutely *in isolation*.

ALAC, in its Application (p.13), sketches out a possible future nationwide strategy which (while little more than a wish list) is useful to illustrate both of our points:

> *"ALAC considers the introduction of health advisory labels to be an essential part of a nationwide strategy… when complemented by a number of initiatives aimed at encouraging and enabling abstinence during pregnancy.*
>
> *These initiatives include:*
> - *An overarching strategy document focused on developing intersectoral responses for the prevention of FASD, and, where that fails, the diagnosis and treatment of those with FASD;*
> - *Research to increase knowledge of the prevalence of alcohol consumption in pregnancy in the last five years, the level of awareness among women of child*

[2] Media release, NHMRC Committee Chair Professor Jon Currie, 22/01/08

bearing age on the effects of alcohol in pregnancy, and the most effective source of providing information on the impact of alcohol in pregnancy;

- *Education initiatives and the development and dissemination of resources to complement the labelling and build on the message to the community of abstinence during pregnancy. Some of these will be developed and delivered with alcohol industry partners such as the Beer, Wine and Spirits Council of New Zealand (BWS); and*
- *Further study of the international and national evidence on what constitutes harmful consumption (although it is useful to note here that BWS recommends abstinence during pregnancy).*"

ALAC makes it clear here that there is no existing research on the most effective method of providing information on the impact of alcohol in pregnancy. This does not stop them, in describing their policy partnership with the Alcohol and other Drugs Council of Australia (ADCA) and others, pre-judging the results of the proposed research by asserting that it will recommend warning labels. We note that ALAC's policy partnership with ADCA, cited in an extensive footnote to dot point two, no longer exists. We also note that the Beer, Wine and Spirits Council of New Zealand cited in dot point three no longer exists.

So, just 24 months on, ALAC's nationwide strategy can be fairly summarised as:

- write a future strategy
- partners withdrawn
- partner no longer exists
- keep up-to-date with research

Our point here is of the danger of assuming that actions which are proposed as part of a basket of future measures will be realised, especially consistently over any length of time. Additionally, it is important not to confuse policy development endeavours (such as the first and last dot points) with components of an effective communications strategy. They are not.

The Associated Brewers is very proud to have sponsored the production of materials in support of the *Pregnancy Lifescripts* initiative in Australia, which promotes the use of brief interventions directly to the target audience, providing health advice in a health setting which has been shown to be very effective (Floyd et al., 2007). But even with this initiative we are unaware of any guarantees of sufficient long term funding for the effective dissemination and promotion of the *Pregnancy Lifescripts* materials over time.

So it is clear that a) warning labels don't work in isolation; b) there are no existing long-term programs involving measures which are already in place; and, c) implementation of the few vague ideas cited in the Application as possible parts of a future basket of measures cannot be relied upon.

The Associated Brewers considers it inappropriate that any such hypothesised wider initiative, that clearly does not or indeed may never exist, should be considered as supporting evidence for implementation of warning labels. It is unacceptable to suggest, as ALAC has done, that compulsory regulation should be imposed to require

a label, which has only tenuous scientific support, on the proviso that an allegedly complementary initiative may or may not proceed in the future.

The Associated Brewers supports assessment of A576 on its own merits, and not on the merits of a purely theoretical, unscrutinised initiative. The Applicant has not sought FSANZ assessment of its good intentions, nor those of other people concerned about FAS (which includes industry). Rather, the Applicant has initiated an assessment of the effectiveness of a specific measure which, if introduced at this time, will be introduced in isolation.

Consideration of the International Perspective

We agree that there is no international consensus on the use of warning labels on alcoholic beverages. It is worth noting how few countries have introduced it (either voluntarily or compulsorily). Of these, only the United States has had warnings in place long enough to study their consequences, and the accepted view is that they do not change behaviour.

Both Canada and the European Union have considered and discarded proposals for mandatory warnings. We note the following update from Finland circulated in the Centre for Beverage Alcohol's daily news monitoring service:

> ***YLE News, 16 January 2008****: The Health and Social Services Minister Paula Risikko announced that she is proposing scrapping plans to introduce warning labels on bottles and cans containing alcohol. The Minister does not believe that the labels would have much of an impact on excessive drinking in the country or contribute to harm reduction.*
>
> *Legislation passed in the previous Parliamentary term called for warning labels to be placed on containers of alcoholic beverages from the beginning of 2008. The European Commission (EC) ruled that the labels are in violation of European Union (EU) rules. It called for the general warning about alcohol to be removed and added that Finland must accept the national warning labels of other EU countries. (Summary)*

Scope of the Application

Here the Associated Brewers poses a question that seeks clarification on the application and its assessment: Would the use of the current definition of 'package' require warning labels to be affixed to all kegs and all glassware in all licensed premises as these may be considered containers "*…by which food intended for sale is partly encased…*"?

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

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

As a general proposition the brewing industry has a proud history of positive collaboration with others on projects to minimise the harms associated with alcohol misuse, including the creation of ALAC itself (Royal Commission of Inquiry, 1974):

> "*The New Zealand Liquor Industry Council presented evidence by Miss Frances Suzan King-Hall, of London, England, who is a practising consultant in public health. She is well qualified and experienced in this profession….*
>
> *She advocated the establishment of a standing consultative committee to deal with the vexed question of alcohol associated problems …*
>
> *Therefore we support the principle of establishing such a standing committee which we suggest could be named the Alcoholic Liquor Advisory Council.*"

The Associated Brewers – which is the brewers association for Australia and New Zealand – has long supported both population-based (e.g. voluntary implementation of standard drinks logos) and targeted programs which are evidence-based; examples of which are described below.

Rethinking Drinking: Alcohol Information Nights

This is a targeted program aimed at encouraging parents and students to discuss alcohol issues, and builds on our pre-existing *Rethinking Drinking: You're in Control* classroom teaching materials which are used in many Australian schools.

rethinking drinking
www.rethinkingdrinking.org

The *Rethinking Drinking: Alcohol Information Nights* program is a web-based resource that aims to provide practical help to students and parents on how to minimise the harms associated with alcohol misuse through information evenings. These events, held in schools, are attended by a local General Practitioner (GP) who provides a presentation at the session. This provides easy access to the professional advice and recommendations of a medical practitioner, which in turn helps promote the message of harm minimisation and responsible drinking. The website can be

viewed at www.rethinkingdrinking.org. The development of this web-based resource and a recent trial of Alcohol Information Nights were enabled by a grant from the Alcohol Education & Rehabilitation Foundation Ltd (AERF).

Pregnancy Lifescripts

In another targeted program, the Associated Brewers has recently sponsored the production of a *Pregnancy Lifescripts* DVD with our project partner, the Australian General Practice Network (AGPN). The DVD builds on the *Pregnancy Lifescripts* materials developed for the Australian Department of Health & Ageing. The DVDs were distributed to attendees at the AGPN's conference in November 2007, and provide GPs with simple, evidence-based tools to assist in the provision of structured, consistent lifestyle advice on alcohol use to pre-pregnant, pregnant and breastfeeding women.

The DVD features three educational vignettes explaining effective methods to instruct clinically proven lifestyle risk management. The DVD also contains a number of PC-based features which provide printable PDF resources to assist GPs in the consultation process.

This resource is an efficient and, if the program is continued, an effective means of addressing the concerns in the study cited by ALAC as a justification for the application (i.e. Payne et al., 2005) which found that "…*FAS is likely to be under-ascertained in Australia* ***due to a lack of knowledge of FAS by health professionals***" (p.1, emphasis added).

Our members would be pleased to provide further support for the *Pregnancy Lifescripts* project as an alternative to compulsory labelling which we believe is ineffective. We have had similar indications of support from another major company in the sector.

Comments on Application A576

ALAC (2006) notes in its application (p.21) that warning labels are generally unlikely to elicit behaviour change in target populations. ALAC implies the solution to behaviour change lies in a "*complex intervention*" (p.22) which is upheld to involve a number of essential initiatives (p. 13).

The notion that ALAC itself observes that warning labels are unlikely to elicit behaviour change exposes the core weakness of its application. The Applicant's suggestion that labelling become a *compulsory* regulated component of a *non-compulsory*, purely hypothetical strategy is unreasonable.

Comments on FSANZ Initial Assessment Report

In citing existing strategies or programs targeted to address FASD, FSANZ notes (section 3.5.3.2) the Australian Brewers Foundation, a past program of the Australasian Associated Brewers. FSANZ is correct in reporting that this independent, industry-funded program promoted research into the relationship between alcohol and health. While the grants scheme was operating (it was finalised in 2005), grants totalling A$3.5 million were funded by industry across over 20 years of operation.

What published and unpublished information is available that may provide answers to the risk assessment questions regarding FASD to be assessed at Draft Assessment?

The Associated Brewers' response to this question is structured to address each of the three identified risk assessment questions in turn.

Risk Assessment Question One

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

The strength of scientific evidence to suggest low levels of alcohol consumption are harmful to a foetus is low (e.g. Lipson & Webster, 1990; Abel, 2006; Henderson, Gray & Brocklehurst, 2007). With one standard drink representing 10 grams of alcohol (NHMRC, 2001), Henderson et al. (2007) concluded that their identified 'low' level consumption of <84 grams of alcohol per week (i.e. 1.2 standard drinks per day), yielded no consistently significant effects on any of the negative pregnancy outcomes they measured, which included foetal alcohol effects.

Findings remain inconsistent and conflicting as to exactly what level of alcohol intake can damage a foetus (Maier & West, 2001; O'Leary, 2004; Mukherjee et al., 2005; Abel, 2006; RCOG, 2006*a*; BMA, 2007). There can be no doubt that *heavy* maternal drinking during pregnancy bears a strong association with the incidence of FAS, indeed alcohol *abuse* was specifically identified as the aetiology underlying FAS in its initial clinical recognition (Abel, 2006), and thus links to low alcohol consumption have a spurious relationship to clinical history. The general consensus predominates that it is *heavy, binge-drinking* behaviour that poses the most risk (Riley & McGee, 2005; Abel, 2006; BMA, 2007), and it is a small minority of women who drink heavily during pregnancy that give birth to a FAS-diagnosed child (Goodlett, Horn & Zhou, 2005).

Simply, scientific evidence does not conclusively support the notion that low levels of maternal alcohol consumption represent a danger to the foetus (Abel, 2006; RCOG, 2006).

Risk Assessment Question Two

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

Following from the above discussion, the concept of a threshold is replete with methodological and theoretical difficulties. It is clear that research supports the notion that low levels of prenatal alcohol consumption, typically defined as less than two standard drinks per day (in absolute terms i.e. *not* average consumption), does not pose a significant risk to foetal health (see Abel, 2006; Henderson et al., 2007). However, a plethora of biological individual differences make the issue of clearly defining an *upper* threshold limit very difficult; variance in numerous biological factors across population groups can greatly change the affects of alcohol on bodily processes (Goodlett et al., 2005; Abel, 2006).

The issue of research methodology presents challenges to any effective threshold measure. Henderson et al. (2007) note the lack of consistency in methodological measures used in FAS research, an issue repeated throughout extant literature (Mukherjee et al., 2005). This exposes a problem inherent in the reporting of alcohol consumption, that is, a tendency to report averages, which fails to distinguish between those consuming small amounts regularly and those who infrequently binge (Lipson & Webster, 1990; Abel, 2006); such problems severely reduce the validity of available data and may misrepresent the risk of teratogenesis (Abel, 2006). Similarly, a tendency to under-report alcohol consumption in some self-report settings (Stratton, Howe & Battaglia, 1996; Del Boca & Darkes, 2003; Abel, 2006) has the potential to reduce the validity of threshold assumptions based on such measures, with the likely effect of *underestimating* the amount of consumption that causes alcohol-related pathology.

Risk Assessment Question Three

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

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

It is clear from the above discussion that prenatal binge-drinking and alcohol abuse are factors that yield a manifold increase in the risk of FAS(D). Certainly, as Lipson and Webster (1990) note, alcohol has a comparatively weak teratogenic effect, such that "*enormous doses*" (p.479) (i.e. binge-drinking) are required to elicit teratogenesis. Thus, the target population at risk of teratogenic effects during pregnancy are those who are chronic excess consumers of alcohol, and as Lipson and Webster state:

> "*..those women whose unborn children are at greatest risk of developing* [FAS(D)] *are the chronic alcoholic women who will not stop their drinking as a consequence of reading labels or signs…*" (p.480)

This clearly suggests that warning labels would have limited or no effect on the behaviour of the at-risk population who are the least receptive to unfocussed or untargeted strategies (Stockley, 2001) or indeed warning labels specifically (Hankin et al., 1993; Nohre et al., 1999).

In addition to chronic alcohol abuse there remain a number of individual differences, genetic and environmental factors which interplay to raise or lower an individual's risk of teratogenesis (see Maier & West, 2001; Abel, 2006; Goodlett et al., 2005). However the body of extant literature remains clear that abuse of alcohol is the single highest risk factor for FAS(D).

Comments on Application A576

ALAC's claim that "*…FASD is caused by maternal consumption of alcohol…*" (p.1) infers that alcohol consumption *of any degree* is likely to cause FASD, this is misleading and not supported by relevant literature (Maier & West 2001; Abel, 2006). Indeed, recent meta-analytical research suggests that there is no convincing evidence of such effects arising from low-moderate prenatal alcohol consumption (Henderson et al., 2007). There remains a high degree of uncertainty surrounding the level of

alcohol consumption which is likely to trigger FASD – a position that ALAC's application directly supports.

On page 8 of the Initial Assessment, there is a table showing the 'statement of reasons' for rejecting Application A359 and ALAC's response. Some of ALAC's responses in this table sidestep the question entirely and bear no relation to the statement.

On the question of possible harm from light drinking we believe that, on balance, it is fair to summarise by saying that the majority of scientific opinion (e.g. Henderson et al., 2007) falls on the side of there being a safe level of drinking during pregnancy, however, there is simply no consensus on what that level may be. It is the latter which fuels the move to adopt more conservative drinking advice in a few countries, such as in the draft Australian Alcohol Guidelines for Low-Risk Drinking (the shift from advice on real drinking scenarios and away from consumer-oriented advice is explicit in the title).

We believe the patterns-based approach which informs the current Australian guidelines is much more effective if the public policy goal is to change drinking behaviour. For example, the current guidelines recognise that some women may drink during pregnancy regardless of the 'low risk – just say no' advice and encourages these people to drink more moderately than they might by acknowledging the possibility.

As the Initial Assessment acknowledges, the draft Australian Alcohol Guidelines for Low-risk Drinking are not aimed at the general public. Through its membership of the National Alcohol Beverage Industry Council Inc (NABIC), the Associated Brewers, in a submission to the NHMRC, has indicated its preference for maintenance of the approach taken in the current NHMRC guidelines. That is, an approach where the guidelines are intended as a guide for the general public.

QUESTIONS FOUR AND FIVE – AAB RESPONSE

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

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

The Associated Brewers cannot contribute any data in addition to that cited in the Initial Assessment Report. However, we caution that without a strong baseline or regular data collection the effectiveness of any behavioural change initiative could not be properly evaluated at a later date. The cart is being put before the horse.

The problems with sparse (or no) data on a number of aspects of the issue is marbled throughout the Initial Assessment itself:

- "*…limited data were collected about the consumption of alcohol by women during pregnancy.*" (p.18)
- "*…FAS is not currently under surveillance by the New Zealand Paediatric Surveillance Unit (NZPSU, 2007)*" (p.22)
- "*…figures for the Australian population as a whole are unknown.*" (p22).
- "*…these data may serve as an indirect measure.*" (p.23)

If ALAC's proposal was supported, we would be in a position of never being able to measure the effect. We believe that this is unsatisfactory, and is at odds with an evidence-based approach to public health measures, particularly in relation to a proposal where the Initial Assessment Report states the Applicant "*…does not claim that the presence of the health advisory label will directly lead to behavioural change and a reduction in alcohol consumption.*" (p.24)

QUESTION SIX – AAB RESPONSE

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

The Associated Brewers has not identified any data in addition to that cited in the Initial Assessment Report. However, we do want to comment on the paragraph relating to the Australian survey (Initial Assessment Report, p. 23).

In reporting the survey results where "*…14% indicated a level of disagreement or neither agreement/disagreement.*" FSANZ has identified a methodological flaw in the research. Survey responses disagreeing with a statement and survey responses that are neutral towards a statement (i.e. neither agree nor disagree) are mutually exclusive responses with vastly different implications.

In this case, combination of the two items appears to create stronger support for the 'negative response' category. That is, in combining the 'neutral' and 'disagree' items a false picture is created that infers more people disagree with a statement than may be the case.

This point further highlights the strong need to base assessment on rigorous, peer-reviewed literature. In the absence of this scrutiny, it becomes all too easy for proponents of either side of an argument to create unfair biases and 'pseudo facts'.

Nevertheless, irrespective of the potential methodological flaws, this survey lends support to the view that labelling would be superfluous to raising awareness. A minimum of 86% of Australian women are already very aware of the potential risks. This would be considered an extremely high figure of awareness for any public health issue – even after years of public investment.

QUESTIONS SEVEN AND EIGHT – AAB RESPONSE

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

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

These two questions beg a third question: "What changes drinking behaviour?" A consideration of what works is germane to consideration of ALAC's proposal.

In the Australian experience education about risks and persuasion to change behaviour are two completely different things. In two of the most extensively researched Australian public health campaigns, '*Alcohol. Go Easy*' and '*How will you Feel Tomorrow*', a large volume of market research (both quantitative and qualitative) was commissioned to find a message which might actually change the targeted behaviour. In the case of '*Alcohol. Go Easy*' which sought to introduce the concept of standard drinks and encourage their use, twelve different advertising concepts were subjected to qualitative research during the campaign development phase (DHFS, 1997).

In both examples the chosen pitch of the advertising centred on social acceptance or rejection as the prime motivation for changing behaviour, rather than education about potential health impacts. This would be the same worldwide. The '*Alcohol. Go Easy*' campaign was discontinued after a change of Federal Government in Australia in 1996.

Health information in a health setting can be viewed as a highly effective method of brief intervention (e.g. Floyd, 2007). Conversely, focussing solely on health information in a non-clinical setting may be a barrier to changing behaviour; to put it in the vernacular, it is better to persuade than to preach – unless you are a doctor! This understanding may go some way to explaining why even highly supportive professional health advocates feel constrained to argue that warning labels may, at best, increase awareness, always with the proviso that they be used within a basket of other measures (a 'complex intervention' in ALAC's language) – and over time – but none argue that they change behaviour.

We believe this third question is vital because it suggests a further field for judgement by FSANZ. That is, a careful consideration of marketing theory and practice if the intention is to change behaviour. And if it is not the intention, then why bother?

The Associated Brewers strongly believes that pregnancy advisory statements on alcoholic beverages should *not* be required.

We have already argued that extensive professional marketing research from past public health campaigns suggests that while compliance with a nation's drinking

guidelines may be an acceptable end, such campaigns are not a viable means to achieve that end.

In addition to marketing evidence on effective methods of behaviour change, the majority of scientific evidence refutes the hypothesis that warning labels/advisory statements are effective in eliciting actual behaviour change in at-risk populations (Stockley, 2001). Alcohol producers should not be required to commit ongoing expenditure to fund a proposal that is not supported by a conclusive body of scientific evidence.

Within those countries that have mandated alcohol warning labels, including the United States and France, there remains strong debate over what effect these have had on excess alcohol consumption (Stockley, 2001). After almost twenty years of implementation in the United States, there is still a lack of consensus on the actual outcomes of alcohol warning labels.

There has been a large body of cross-disciplinary literature that examines this issue, ranging from an indirect standpoint (e.g. Blume & Resor 2007[3]) to more focussed examinations (e.g. Zuckerman & Chaiken, 1998). Along with limited suggestions that warning labels may be counter-productive in eliciting behaviour change (Snyder & Blood, 1992; ALAC, 2002), the predominant message across relevant scientific literature is that causal links between warning labels and behaviour change are tenuous at best. For example, Greenfield et al. (1999), ardent supporters of warning labels, concede that:

> *"…we cannot conclude with certainty that any of the behavior differences observed between sites, or between those exposed or not exposed to the* [warning] *label, is a direct result of the warning label."* (p.279)

The Applicant's allusion to the notion that warning labels create an increased awareness of FASD as an issue may not be wholly correct. Existing studies already reveal a high degree of knowledge in pregnant women about the problems associated with excess alcohol consumption during pregnancy (Lipson & Webster, 1990), and there is little suggestion that labelling would act to increase this awareness. While research (Greenfield et al., 1999) suggests that alcohol labelling may foster an increased awareness of the existence of labels *per se* (i.e. awareness of the *existence* of the label, but not necessarily awareness of the label's message), evidence of this broad awareness translating into actual behaviour change remains limited across scientific literature, and is not supported by the vast majority of research.

The suggestion that labels are *most* effective when used in conjunction with national information strategies (e.g. Andrews, 1995) does not make sense in light of the above discussion. The literature suggests that warning labels are largely ineffective agents of behaviour change, irrespective of what 'complementary' strategies are in place. In the absence of research isolating the effects of warning labels within wider education initiatives, caution must be taken in the consideration of such conclusions which are open to confound from numerous external variables (see Engs, 1989).

[3] Indirect in that the authors' examination of warning labels is only a corollary to their findings which focus more on broad cultural and education considerations.

Comments on Application A576

As mentioned in response to Questions One and Two, the crux of ALAC's application is that warning labels are unlikely to elicit behaviour change in the absence of a wider education campaign containing numerous initiatives – a "*complex intervention*" (ALAC, 2006; p.22). It is illogical to propose the compulsory introduction of warning labels that the applicant openly expresses are unlikely to be effective, more so when one considers the inconclusive research base on which this proposal is based. The very idea that regulation should be enacted on the grounds that a hypothetical and non-compulsory 'complex intervention' may *possibly* improve its efficacy is ludicrous.

Comments on Initial Assessment Report

As the Initial Assessment report acknowledges, the Applicant does not claim that warning labels are effective agents in eliciting behaviour change. The Associated Brewers believes that this alone is reason to reject the application. Judgment of the proposal, the requirement to implement compulsory warning labels, must be made on its merits alone.

The Associated Brewers considers it inappropriate that the purported effects of warning labels in conjunction with any hypothetical strategy, ostensibly far removed from the auspices of the Food Standards Code, would be considered as support for an application. Regulation should not be made on a contingency basis, especially when the contingency in question, in this case a 'complex intervention' incorporating a basket of other measures, is not compulsory, not defined and not subject to an evidence-based peer review process.

QUESTIONS NINE, TEN, AND ELEVEN – AAB RESPONSE

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

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

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

Irrespective of limited suggestions that warning labels may be counter-productive in eliciting behaviour change (Snyder & Blood, 1992) and majority evidence suggesting they are ineffective behavioural tools (Stockley, 2001), producers and regulators need to be mindful of the psychological implications of their message. Product warning labels, depending on their content, have the potential to cause anxiety among target audiences and complacency in non-target populations (Hastings, Stead & Webb, 2004) – the ethical concerns of implementing a label without a sound basis in scientific evidence are manifold. While research remains inconclusive and limited, the potential for warning labels to create anxiety in pregnant women nonetheless remains. We note that this possibility of adverse consequences from warning labels has been cited in the Initial Assessment Report and by others (e.g. ALAC, 2002; Stark, 2007). With research implicating increased anxiety in negative pregnancy outcomes (e.g. Levin, 1991; Orr et al., 2007), this is a matter worthy of consideration.

Additionally, a key foundation of the Applicant's proposal, women's 'right to know' the risks of FASD, cannot realistically be provided by a warning label. With a very limited size, it is highly unrealistic to suggest that a label, pictorial or written, can provide a balanced and informed summary of the issues surrounding excessive alcohol consumption and FASD (a fact that ALAC's own alcohol labelling policy directly acknowledges; ALAC, 2002). This is especially so given the lack of consensus surrounding even its basic scientific underpinnings.

QUESTION TWELVE – AAB RESPONSE

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

It remains the Associated Brewers' position that warning labels are ineffective and their introduction is not supported.

All alcohol products are open to abuse, and it is female consumers who abuse alcohol that represent the at-risk population for FASD (Lipson & Webster, 1990). Some consideration should be given to other products which contain alcohol; one need only look at the effects of recent alcohol bans in Alice Springs, where mouthwash was consumed as an alternative to liquor products[4], to see an example of other products which may be abused.

However, we accept that, for administrative efficiency the 0.5% ABV benchmark may be considered useful.

QUESTIONS THIRTEEN AND FOURTEEN – AAB RESPONSE

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

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

Continuance of the *status quo* would permit industry to continue to invest in targeted, effective public health measures, such as the Associated Brewers' involvement in the *Pregnancy Lifescripts* project. We have a long and proven commitment to supporting effective measures and opposing ineffective ones.

The Applicant's assessment of the financial impact on industry is simplistic and unrealistic. Resources are limited, and plate changes for labels are expensive when some companies have a considerable number of stock keeping units, even within a single brand. Implementing warning labels will represent significant ongoing costs.

The Australian industry has just borne these costs to introduce another labelling measure – standard drink logos – over the past two years and it is unreasonable to ask that 'all change' once again without being able to amortise those costs over time.

[4] Transcript of ABC radio report available from http://www.abc.net.au/am/content/2007/s1912040.htm

QUESTION FIFTEEN – AAB RESPONSE

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

Firstly, this question implies that all prenatal alcohol consumption is likely to cause damage to a foetus; as aforementioned, this is misleading and not supported by relevant literature (Maier & West 2001; Abel, 2006).

ALAC's proposal suggests that alcohol labelling would become a platform for the development of public health strategies targeted towards pregnant women (we think it is putting the 'cart before the horse'). The application cites a Western Australian study by Payne et al. (2005) of medical professionals and their lack of knowledge about FASD issues as evidence that labelling is necessary. However, labelling, as an ineffective method of behaviour change, does not offer a solution to a lack of public and professional knowledge of FASD. Payne et al. (2005) proffer educational materials for doctors and their clients as a solution to the lack of FASD knowledge – the paper makes *no* mention of alcohol labelling.

Consistent with Payne et al. (2005) and Floyd et al. (2007), it is suggested that provision of materials and information for health professionals and their clients is the approach most likely to improve diagnosis and prevention of FASD. Evidence from programs undertaken by the Brewers Association of Canada[5] suggests that targeted education campaigns are very effective tools for increasing knowledge of FASD as a public health issue.

To this end, the Associated Brewers sponsored the production of a *Pregnancy Lifescripts* DVD for the Australian General Practice Network as project partners. This provides GPs with a useful resource to assist in the provision of structured, consistent lifestyle advice on alcohol use to pre-pregnant, pregnant and breastfeeding women (see AAB response to Questions One and Two for more detail).

While the initial production costs of such a resource may be high, such an approach is a significantly more efficient method of promoting change by concentrating resources directly to at-risk consumers.

In broad terms, the choice for policy makers in seeking to change drinking behaviour is usually between a population-level measure or a targeted intervention (which more easily lend themselves to multi-stakeholder partnerships; Stimson, 2006). The ALAC proposal seeks to use a population-level measure to target a specific population sub-group. This is grossly inefficient.

Compared to warning labels – which necessitate major initial and ongoing expenditure and are considered ineffective by the majority of scientific research – targeted public-health measures such as the *Pregnancy Lifescripts* DVD are undoubtedly far superior and certainly more efficient as a candidate for changing behaviour over time.

The Associated Brewers, and through it the Australian and New Zealand brewing industry, is committed to delivering on its social responsibility message through the support of targeted, high-quality initiatives through multi-stakeholder partnerships such as the *Pregnancy Lifescripts* initiative.

[5] Overview of programs available at http://www.brewers.ca/default_e.asp?id=11

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