

AUSTRALIAN CONSUMERS' ASSOCIATION

RESPONSE TO THE

FOOD REGULATION DISCUSSION PAPER

ON

**Review of FSANZ assessment and approval
processes and treatment of confidential
commercial information**

26 July 2005

ACA

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INDEPENDENT INFORMATION FOR SMART CONSUMERS

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The Australian Consumers' Association (ACA) appreciates the opportunity to provide comments on the discussion paper on the review of the Food Standards Australia New Zealand (FSANZ) assessment and approval processes and treatment of confidential commercial information. ACA is an independent not-for-profit, non-party-political organization established in 1959 to provide consumers with information and advice on goods and services, health and personal finances, and to help maintain and enhance the quality of life for consumers. ACA provides consumer education, conducts surveys into consumer attitudes, lobbies for improved conditions for consumers and distributes unbiased consumer advice.

Independent from government and industry, ACA lobbies and campaigns on behalf of consumers to advance their interests. ACA is primarily funded through subscriptions to its magazines, fee-for-service testing and other related expert services. There is no government funding for normal running expenses of ACA, and no commercial sponsorship or advertising.

ACA's Involvement in Food Policy and Regulation

For many years ACA has been involved in food regulatory processes through involvement in stakeholder committees and working groups, providing input through formal submission processes, and lobbying activities designed to ensure that consumer issues are given sufficient consideration in the area of food policy and standard development. Key areas of involvement in recent years include health and nutrient claims, fortification, primary production and processing standards and country of origin labelling, to name just a few.

In ACA's opinion, one of the key strengths of the current process is openness and transparency. While ACA does not always feel that consumer and public health issues have been given adequate attention, nor do we always support the conclusions and recommendation FSANZ reaches in assessing proposals and applications, we are generally comfortable with the level of information available in the assessment reports, and as one of a small number of consumer groups that has regular input into FSANZ processes we are generally aware of what is expected of us.

Consumer Consultation

ACA is the only organisation in Australia that advocates on behalf of consumers in relation to a wide range of matters relating to food policy and regulation. In some cases, ACA may be the only Australian consumer voice on these issues. However, as a non-government, not-for-profit organisation ACA's resources are limited. We are unable to provide input on all issues where we feel there needs to be adequate attention to consumer issues.

In comments to the Bansemer Review of FSANZ in 2003, and in our submission to the Australian New Zealand Food Regulation Ministerial Council on the review of stakeholder consultation in 2004, ACA expressed concern that consumer consultation in both processes was inadequate and stakeholder consultation processes did not always serve consumers well. The Bansemer Review made recommendations about the need for improved consultation with consumers. While ACA had preliminary discussion with FSANZ staff about a proposed 'consumer panel' some months ago, we are not aware of any progress on this approach, nor are we aware of any significant improvements in relation to consumer consultation. ACA does acknowledge however, the consumer research conducted by FSANZ into interpretation and intended use of health and nutrient claims. We commend FSANZ for its efforts in conducting this research and hope that FSANZ will consider undertaking more consumer research as part of the assessment of future applications and proposals.

In relation to consumer involvement in food policy development, ACA was disappointed to see that the final Food Regulatory Model did not include Consultative Council. The proposed 'Consultative Council' that appeared in earlier drafts was replaced by a 'Consultative Mechanism', with the intention that a consultative mechanism allowed the Ministerial Council more flexibility in determining the approach to consultation for individual policy matters.

The principle of a flexible stakeholder consultation mechanism has its merits. However, ACA is not confident that the flexible consultative process has served consumers well to date. In ACA's opinion the Consultative Mechanism and Consultative Council are not mutually exclusive concepts. Instead, a Consultative Council could guide ministers in their decision on appropriate consultative methods for various policy development processes.

ACA's concerns in relation to this matter were not addressed in the review of the Ministerial Council stakeholder consultation processes. A copy of ACA's submission is provided as an attachment to this submission. ACA wishes to point out that much of the discussion at the consultation forum in Sydney on 5 July 2005 had implications for consultation at the Ministerial Council level. Given that these issues were raised, but not necessarily addressed, during last year's review of stakeholder consultation, ACA questions whether it is within the scope of the current review to make recommendations in relation to consultation and feedback from the Ministerial Council and Food Secretariat. Despite this, ACA would support the current review making recommendations in this area.

ACA notes that the discussion paper refers to a number of proposals for streamlining, and therefore speeding up the FSANZ assessment processes, including the removal of one or both rounds of public consultation. These ideas were also discussed at the Sydney forum. While the issue of streamlining the process will be addressed later in this submission, we wish to reiterate concerns raised by ACA at the Sydney forum. There appears to have been no significant progress in improving consultation with consumers and we do not support streamlining of current public consultation requirements, until improved consumer consultation mechanisms have been introduced.

As mentioned above, ACA has been involved in a number of committees and working groups including Standard Development Committees (SDC), Standard Development Advisory Committees (SDAC), and Expert Advisory Groups (EAG). It is often difficult to determine where these groups fit in the standard development process and how stakeholder involvement differs from one to the other. In ACA's opinion, the conditions under which FSANZ determines which type of committee or group is required, the role of these committees, and the difference between FSANZ's expectation of committee/group members, requires clarification.

Industry interests v consumer and public health interests

In the discussion paper, and on many occasions during the Sydney forum, terms such as "stifling innovation" and "first market advantage" were used. This signals to ACA that this review is primarily driven by industry interests to have applications and proposals approved in a more timely manner, assuming that the outcome will benefit to manufacturers. There are some cases – biomarker health claims, for example – where processes have taken longer because decisions have not been favourable for industry.

ACA has not found any persuasive arguments that reviewing the timeliness of the current process and provisions for dealing with commercial information is in any way a result of concerns that the current process disadvantages consumers. This is not to say that a lengthy process has not disadvantaged consumers, though this is generally the exception rather than

the rule. ACA's concerns with the outcomes of FSANZ assessments have more to do with what we believe is insufficient attention to some important public health and consumer concerns, not the time taken to reach a decision.

However, one area in which timeliness is a concern for ACA is the use of medicinal herbs in foods. FRSC is developing policy guidelines in this area and has been for over two years. In the meantime, the number of food products, mainly beverages, containing medicinal herbs is increasing. In ACA's opinion, the use of medicinal herbs in food poses genuine food safety risks for some consumers. ACA also has concerns about the advertising and marketing of these products and the inappropriate use of health claims. Until a food standard has been developing, specifying safe and effective levels of medicinal herbs, and appropriate food vehicles, labelling and advertising, ACA believes that the addition of medicinal herbs to foods should be prohibited. In ACA's opinion, under section 24, FSANZ already has the capacity to make this amendment without full consultation, based on the potential health and safety risks.

However, FSANZ has not done this and is unlikely to do so. In reality, a standard on the addition of medicinal herbs to foods is a number of years away and in the meantime the range of products will only increase. This will mean that future standards are likely to be based around the existing market, minimising the impact on industry, when the development of a standard should focus on protecting the health of consumers and preventing them from being misled about the health benefits of products with herbal supplements added.

This review appears to be a response to industry concerns and does not sufficiently address the impact of the current process on consumers and how processes could be improved to protect consumer interests rather than industry interests. A common criticism made by ACA, is that FSANZ places insufficient emphasis on its three primary objectives:

- a) The protection of public health and safety.
- b) The provision of adequate information relating to food to enable consumers to make informed choices.
- c) The prevention of misleading and deceptive conduct.

Instead, FSANZ seems to be far more influenced by the industry issues to which it must have regard (but are not the objectives of FSANZ). These include:

- The promotion of consistency between domestic and international standards.
- The desirability of an efficient and internationally competitive food industry.
- The promotion of fair trading in food.

Streamlining the assessment and approval process

No IAR or DAR

ACA believes that this approach might be appropriate for a small number of amendments including typographical errors, changes to formatting or layout, and minor inconsistencies that will not effect the intent or application of the Food Standards Code. However, ACA requests further information about the conditions under which this streamlined approach would be used and the types of amendments (preferably, examples of past applications) that would be potentially assessed in this manner. More information also needs to be provided on the steps FSANZ would take to assess an application that does not require an initial or draft assessment report.

If this option was to be implemented, there must be some mechanism for FSANZ to issue a notification to stakeholders that it intends to amend a standard in a particular way, and an

approximate date when this amendment would take effect. The notification should also encourage stakeholders to contact a particular FSANZ officer by a certain date if they required more information or wished to raise concerns. The notification must provide sufficient detail for the stakeholder to determine if the amendment was sufficiently important to warrant further information from FSANZ or whether they wished to provide comment.

This would provide a compromise between having no opportunity for formal public consultation while still providing some opportunity for stakeholders to seek information or provide input in relation to the amendments. An example of this notification is provided below.

FSANZ intends to make minor amendments to Standard 1.5.2 of the Food Standards Code. The amendments are designed to correct typographical errors and improve the layout of this standard. The exact amendments are outlined below. FSANZ has determined that these amendments would not alter the intent or application of the standard in any way.

These amendments are due to be gazetted on 29 August 2005. Should you require further information, or wish to provide comment on these amendments, please contact John Smith, FSANZ on (02) 6271 2222 or john.smith@foodstandards.gov.au, by close of business on 19 August 2005.

Early Bird Notification/No IAR – Straight to DAR

ACA believes that the suggestion of an Early Bird Notification instead of an Initial Assessment Report may have some merit and is preferable to the previous proposal to remove both rounds of public consultation. However, before we are prepared to support such an approach ACA seeks information about the criteria under which applications or proposals would be eligible for the Early Bird Notification and Draft Assessment Report approach. ACA would appreciate specific examples of previous applications/proposals that would meet these criteria, as well as any applications/proposals currently on the workplan that meet the criteria.

ACA would not support the removal of the initial round of public consultation without some stakeholder notification (eg Early Bird Notification) that FSANZ was reviewing a particular application or proposal with an indication as to when stakeholders could expect a Draft Assessment Report to be released for public consultation. While both round of comments generally have a public consultation period of six weeks. If the initial round is removed extra time should be allowed for stakeholders to prepare their response to the Draft Assessment Report.

ACA is a not for profit organisation with limited funding for consumer advocacy work. Within the area of food policy there are a number of competing priorities and we do not have sufficient capacity to work on all the food issues we would like to address. This means that ACA may decide not to provide a submission on an initial assessment report because there will be a second opportunity to comment when the Draft Assessment Report is released. We expect that this problem is not unique to ACA. Extending the Draft Assessment Report consultation period from six to eight weeks will allow organisations more time to work on a submission but still save approximately four weeks on the total assessment process. The benefits of having a full assessment process, including consultation on both the Initial and Draft Assessment Report, are discussed on more detail below.

Full Assessment Process (IAR, DAR and FAR)

We believe that the vast majority of assessment processes in which ACA has been involved over the last 2 – 3 years, would require a full assessment process. Many of these have been ‘big ticket items’ where a standard has been developed following the development of policy guidelines. We do not believe that the development or existence of a policy negates the need for a full FSANZ assessment process. If anything, the fact that Ministers felt it necessary to develop policy guidelines indicates the significance and the potentially contentious nature of that issue, requiring considerable consultation and debate among stakeholders.

These standards are likely to take many years to develop given the requirement for FSANZ to satisfactorily explore all issues and concerns raised by stakeholders, and identify and assess any relevant research. While it might be the preference of industry to have applications or proposals assessed in a more timely manner, a better standard will be developed if FSANZ is given enough time to consider all aspects of the application/proposal, and seek further information.

We also acknowledge that FSANZ might not always predict points of contention for stakeholders, regardless of whether stakeholders have been consulted early in the process. A recent example of this is the Draft Assessment Report for country of origin labelling.

A number of stakeholders participated in an Expert Advisory Group (EAG) convened by FSANZ to assist in the development of the standard. A number of EAG members also provided a submission during the public consultation on the Initial Assessment Report. Many stakeholders also provided earlier input during the development of the policy guidelines on country of origin labelling.

Despite this early consultation, the draft country of origin labelling standard proposed in the Draft Assessment Report astonished some stakeholders. There was considerable public outrage about a specific element of the proposal relating to the requirement, or lack thereof, for country of origin labels on unpackaged foods. In ACA’s opinion, the proposed standard failed to address consumer and industry stakeholders concerns, and we had not expected the proposed standard to differ so significantly from the transitional standard. Recent discussions with some members of the food industry indicate that they shared ACA’s concerns.

What resulted was significant public outcry and media debate. Media interest in the issue of country of origin labelling continues more than two months after the public debate began. ACA believes that despite significant stakeholder involvement early in the process, FSANZ failed to recognise the level of consumer support for having accurate information about the origin of their foods, and industry concerns that consumers would not be able to identify locally produced foods and support local producers and manufacturers. As a result, FSANZ will now have a third round of public consultation on a preliminary Final Assessment Report, extending the process by a number of months.

The benefits of the full assessment process also allows stakeholders to raise specific issues during consultation on the Initial Assessment Report and then see how these issues have been addressed in the Draft Assessment Report. If stakeholders feel that they have not been addressed satisfactorily in the Draft Assessment Report, they have another opportunity to raise them in a second submission.

Also, ACA has limited resources for addressing food issues and preparing submissions, and ACA’s capacity to make a submission will depend on the workload of staff and other competing policy priorities. While ACA may wish to make a submission on the Initial Assessment Report, other priorities may mean that a submission is not made during the first round of public consultation, with the intention of making a submission during the second

round of public consultation. ACA believes that other stakeholders will also be in this position. Therefore, ACA does not support the suggestion put forward by at least one food industry representative at the Sydney forum, that stakeholders should not be able to provide a submission on a Draft Assessment Report, if they have not provided a submission on the Initial Assessment Report.

Expanding the operation of section 36

ACA considers that expanding conditions under which FSANZ can use the section 36 provisions to remove one round of consultation might be appropriate in some cases. However, ACA is unable to support such an option without more information on how these permissions will be expanded, and the sorts of applications to which section 36 would apply.

Expanding the operation of section 24 (matters of urgency)

ACA considers that expanding conditions under which FSANZ can use the section 24 provisions may be appropriate in some cases. Once again, ACA is unable to support such an option without more information on how these permissions might be expanded, and the sorts of applications to which section 24 would apply. Currently, the urgency provisions are limited to public health and safety only. ACA believes that this limitation is appropriate. ACA does not envisage that section 24 would be applicable to many industry applications, as issues relating to trade or product innovation would not be sufficiently 'urgent' to warrant application of urgency provisions.

Stop clocks

ACA supports the suggestion that a stop clock should apply when Ministers are developing policy relating to various applications. ACA believes this should also apply when FSANZ is considering a proposal that has implications for another application. A recent example is the formulated beverage application.

The applicant sought permission to add a range of vitamins and minerals to water based beverages, containing small amounts of fruit juice, flavours, sugar or artificial sweeteners. Two of the substances that the applicant sought to add were folate and iodine. FSANZ is currently assessing two proposals for the mandatory fortification of folate and iodine. Yet FSANZ proposed to permit the addition of iodine and folate. This decision was made without any final decision on mandatory fortification on iodine and folate and ACA finds it difficult to understand how FSANZ could fully assess likely consumption patterns and potential over-consumption without considering the impact of any specific provisions on the mandatory fortification of folate and iodine.

Ministerial Council involvement

Comments made at the Sydney forum, suggested that there was concern among industry stakeholders that FSANZ could go through the entire assessment process and receive endorsement from the Board only to have a proposed standard or amendment rejected by the Ministerial Council. It was also stated that Ministers objections may be based on personal ideologies and one comment even implied that concerns were raised by Ministers from jurisdictions without large food industries, were somehow less important. In response to this, ACA would like to point out that these objections are possibly based on concern that

FSANZ's recommendations may not necessarily be in the best interests of the consumers in their state to approve a particular application.

It is no secret that ACA feels that some FSANZ decisions are made in the best interest of industry stakeholders rather than consumer and public health interests. For this reason, the role of Ministers in giving final approval is vital. When ACA believes that recommendations are not in the best interests of consumers and public health, it is through raising Ministers' awareness of the implications for consumer that, consumer interests may be given greater attention. 'Lobbying' of Ministerial Council members is not practiced by ACA alone. Food industry representatives participate in this sort of campaigning too, perhaps even more so than consumer and public health advocates.

While ACA would support the need for two or more Ministers to call for a review of a FSANZ recommendation, we believe it is hypocritical of industry representatives to suggest that Ministers susceptibility to lobbying is a weakness of the current system. It is inevitable that such practices would continue regardless of changes to the FSANZ assessment and approval process.

Improving the process for making an application

ACA appreciates FSANZ's need for guidance and some level of evidence on an application to determine whether it should be rejected or placed on the workplan. However, consumers are disadvantaged by onerous requirement that places the burden of proof on the applicant. An individual consumer or group of consumers will not have the capacity to provide FSANZ with extensive scientific data and in some cases there may be very little data to support potential consumer concerns, however, this does mean that it is not a valid concern and that it doesn't warrant further investigation by FSANZ.

Recently, a small parent lobby group concerned about the use of food additives in food approached FSANZ regarding the addition of a particular additive to food, suggesting that it should be listed on the label so that consumers who reacted to it were able to avoid products containing this additive. It is ACA's understanding that the potential applicant was advised that there was insufficient data to suggest that this was a significant health concern and that an application was likely to be rejected on the grounds that there was insufficient evidence.

Such a response does not give consumers the impression that FSANZ is a regulator that takes the concerns of consumers seriously. It is unacceptable that consumers should be expected to provide reams of scientific data to support a complaint or potential application; after all it is FSANZ who is the scientific expert, not the consumer. Any amendments to the application requirements must not disadvantage potential consumer applicants, any further than they already do.

Confidential Commercial Information

Generally, ACA does not support protection of commercial information to ensure first market advantage, for the use of health claims on food labels where a range of products from a variety of manufacturers already on the market, would be eligible to make the same claim. ACA has historically opposed the use of health claims on food labels because we believe that they are likely to be used by manufacturers to gain a marketing advantage over competitors, rather than as a means of providing consumers with independent information to assist them to make healthier choices. We also argue that there is insufficient evidence to suggest that the use of health claims on foods have resulted in improved diets in countries that have permitted health claims for a number of years.

The suggestion that there should be some protection around applications and commercial information relating to health claims only confirms ACA's concerns. If the use of health claims on food labels is a genuine effort to assist consumers to make healthier food choices, then any products that is eligible to make a health claim (according to the future health claims standard and provided it meets established qualifying and disqualifying criteria) should be able to use that health claims, regardless of which manufacturer has produced it. To prevent a manufacturer's competitors from using a particular health claim would contradict one of the FSANZ objectives - the provision of adequate information relating to food to enable consumers to make informed choices. Consumers would not have adequate information to make informed choices if one manufacturer had exclusive permission to use a particular health claim as they would not be able to identify other products might have a similar health benefit.

ACA has similar concerns about the use of fortification as a marketing advantage, and would not support exclusive permissions for fortification in order to protect first market advantage and encourage product innovation. If there is concern that the population's intake of a particular nutrient is sub-optimal then giving exclusive permission for one manufacturer to fortify its products appear to be contradictory if the intent of fortification is to improve consumers' intake of particular nutrients.

ACA appreciates that data protection may be of concern to the food industry, because it prevents any market advantage that may be gained from product innovation. However, the current processes are designed to protect public health and safety, and consumer interests, and to do this, there must be openness and transparency. ACA is also concerned that if information is kept confidential then it will not have been subject to peer-review – an important part of the process for establishing the strength of any scientific information.

One suggestion is that special expert committees should be formed to assist FSANZ to evaluate scientific data without the requirement to make the data publicly available. While this may have some merit, the membership of expert panels must be carefully considered to ensure that there are no conflicts of interest, that the appropriate scientific and public health experts or academics are consulted, and that the interests of consumers are adequately represented.

ACA could only support the use of expert committees for the assessment of scientific data, some of which may be confidential commercial information. ACA does not see such committees replacing entire public consultation processes; in fact ACA would find it unacceptable if an entire assessment and approval process could take place without public consultation, simply in order to protect first market advantage.

Another suitable option would be for names of applications to be withheld until they are released for public consultation. This would prevent sending a signal to competitors the exact nature of the application, though the time gained by the initial applicant may not be sufficient to protect their first market advantage. It would however, be a compromise but it may not afford the applicant much advantage over competitors.

At this stage the only area where ACA sees an opportunity for allowing a manufacturer to have exclusive use of a particular health claim is where a food or an ingredient is novel, as defined in the standard on novel foods. A novel food is one that does not have a history of safe consumption in the Australian/New Zealand population. If the first applicant was to patent or trademark the food/ingredient, then this may be able to give them exclusive use of that ingredient. If the manufacturer could substantiate a health claim for that food then they could be given exclusive use based on the novel ingredient.

The way other ACA could support exclusive use of broadly applicable health claims would be if applications were considered on a product-by-product basis, rather than permission being granted as general provisions. However, ACA notes that this is unlikely to happen as rather than speeding up the assessment of applications, it will add to the FSANZ workplan and lead to duplication of work as FSANZ assesses numerous applications for the same health claim. As identified in the discussion paper, such an approach appears to contradict the foundation on which the food regulatory system is based.

ACA does not see convincing arguments as to why openness and transparency should be sacrificed in favour of product innovation, when it comes to fortification and health claims. ACA might support data protection provisions as described in Option C1, provided they were not applicable to health claims and fortification. ACA suggest the food industry should consider whole of industry applications, where industry organisations such as the Australian Food and Grocery Council are funded, through industry, make the application on behalf of the wider food industry.

Closing remarks

There is already the perception among some non-industry stakeholders that FSANZ tends to make recommendations that are more favourable to industry. However, FSANZ, according to the objectives stated in section 10 of the *Food Standards Australian New Zealand Act 1991*, must place the interests of public health and safety and consumers above the interests of industry. While, ACA appreciates that in doing so, the food industry may be disadvantaged to some extent, this does not justify sacrificing the openness and transparency of the current system. ACA does acknowledge that there maybe some appropriate measures for streamlining the assessment and approval process, though further detail on the types of applications that would be eligible for abbreviated assessments is needed before ACA is prepared to support specific approaches.

ACA suggests that before final recommendations are made, the Working Group should undertake a modelling exercise to identify which of the applications and proposals received over the past three to five years, might have been appropriate for a streamlined assessment and approval process. This would give stakeholders a better idea of how a streamlined process would apply and help to estimate the likely impact on the time taken to finalise applications or proposals.

Once again, ACA appreciates the opportunity to provide these comments and trusts that the issues raised in this submission will be given due consideration during the next stage of the review of the FSANZ assessment and approval process and the treatment of confidential commercial information. ACA looks forward to having further opportunities to provide feedback on the review. We would welcome the opportunity to meet with the consultant for a second time to discuss further any matters raised in this submission, should that be considered necessary.