FOOD STANDARDS AUSTRALIA NEW ZEALAND AMENDMENT BILL 2007

THE INQUIRY

1.1 The Food Standards Australia New Zealand Amendment Bill 2007 was introduced into the Senate on 28 March 2007. On 29 March 2007, the Senate, on the recommendation of the Selection of Bills Committee (Report No. 5 of 2007), referred the Bill to the Community Affairs Committee (the Committee) for report.

1.2 The Committee received 15 submissions relating to the Bill and these are listed at Appendix 1. The Committee considered the Bill at a public hearing in Canberra on 23 April 2007. Details of the public hearing are referred to in Appendix 2. The submissions and Hansard transcript of evidence may be accessed through the Committee's website at http://www.aph.gov.au/senate_ca .

THE BILL

1.3 The purpose of this Bill is to amend the *Food Standards Australia New Zealand Act 1991* to expedite the development of food regulatory measures (commonly referred to as food standards) by Food Standards Australia New Zealand (FSANZ) and improve the framework within which FSANZ operates and food standards are made.[1]

1.4 The Explanatory Memorandum to the Bill states:

In summary, this Bill:

- reforms the assessment and consultation process to:
  - match the process with the nature and scope of the application or proposal under consideration
  - create more meaningful opportunities for consultation with stakeholders
- harmonises as far as possible the processes for the assessment of applications and proposals
- allows for alignment of the policy setting process of the Council and the standard development and approval process of FSANZ
- aligns the processes for setting of Maximum Residue Limits of the Australian Pesticides and Veterinary Medicines Authority and of FSANZ

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1 *Explanatory Memorandum*, Food Standards Australia New Zealand Amendment Bill 2007, p. 3.

- recognises the potential need to develop urgent standards due to unforeseen negative impacts on trade
- removes the ability for the Council to request a second review while maintaining appropriate oversight of standards by the Council – this amendment is subject to changes to the Food Treaty between Australia and New Zealand
- creates a process for expert scientific assessment of future high level health claims – the later commencement of this provision allows time for finalisation of the Nutrition, Health and Related Claims Standard currently under development.

The Bill also makes a number of minor amendments to the legislation to remove unnecessary red-tape and duplication and to improve clarity.[2]

1.5 The Explanatory Memorandum also states the financial impact of the Bill is cost neutral.

> Cost savings achieved through efficiencies will be reinvested through improved planning and making consultation more effective. The current resources within the Authority will be refocused accordingly. To assist with the transition to the new system the Australian Government has provided $2.9 million over two years to the Authority and the Department of Health and Ageing…[3]

BACKGROUND

1.6 In 1991 States and Territories entered into an arrangement with the Commonwealth agreeing to adopt food standards developed by the National Food Authority. In 1996 New Zealand became a partner in the Australian food regulatory system following the ratification of a Treaty between the two countries, resulting in the establishment of the Australia New Zealand Food Authority (ANZFA).[4]

1.7 In November 2000, the Council of Australian Governments agreed to a new food regulatory system in response to the recommendations of the Food Regulation Review (the Blair Report). The package of reforms included a new food regulatory system, an Inter-Governmental Agreement on food regulation, and a Model Food Act for implementation in all Australian jurisdictions. New Zealand again joined the system by way of a Treaty between the two countries. In 2001, amendments were made to the *Food Standards Australia New Zealand Act 1991* (the Act) to reflect the new co-operative bi-national system for food regulation.[5] It established a new independent statutory authority, Food Standards Australia New Zealand (FSANZ) to

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2 *Explanatory Memorandum*, p. 4.

3 *Explanatory Memorandum*, p. 4.

4 Food Regulation Standing Committee, *Review of FSANZ assessment and approval processes and treatment of confidential commercial information*, Discussion paper, July 2005, p. 12.

5 *Explanatory Memorandum*, p. 5.

develop and approve science-based food standards and conferred policy responsibility for the food regulatory framework on a Ministerial Council.

1.8 The introduction of the present Bill follows a recent review of food standard development, assessment and approval processes and treatment of confidential commercial information.[6] The issues addressed in the Bill have been the subject of consultation with Commonwealth, State and Territory Governments, the New Zealand Government as well as the food industry, consumer and public health groups, and members of the public.[7]

ISSUES

The assessment of applications

1.9 The recent review of the food standard development process and approval processes identified some areas for improvement. FSANZ processes all applications and proposals in the same way, regardless of whether these are for major or minor amendments to a standard. Even applications for minor technical amendments were subject to two rounds of public consultation, three sets of reports and potential reviews requested by the Ministerial Council. Under the Bill, the Act will be amended to enable FSANZ to assess different applications and proposals according to their nature and scope. Three assessment streams will replace the current 'one size fits all' approach.[8]

1.10 In general to amend the Food Standards Code (FSC) FSANZ would undertake one round of public consultation and the assessment process would be completed in 9 months. If an application or proposal related to a minor amendment to a standard (e.g. correction of a typographical error, minor editorial changes or minor changes designed to improve clarity) FSANZ would not undertake public consultation, and the assessment should be completed within three months through consultation with States and Territories. If the application or proposal relates to the development of a new Standard or a major revision to an existing Standard, the Authority would undertake two rounds of public consultation and the assessment would be completed within a maximum of 12 months (the current practice).[9]

1.11 However some submissions raised concerns in relation to the changes to public consultation in some assessments processes. The Australian Medical Association (AMA) argued that 'any proposal that limits or removes public

6 Food Regulation Standing Committee, *Review of FSANZ assessment and approval processes and treatment of confidential commercial information*, Discussion paper, July 2005.

7 *Explanatory Memorandum*, p. 4.

8 *Senate Hansard* 28.3.07, p.6 (Second Reading Speech).

9 *Explanatory Memorandum*, p. 13.

consultation opportunities… would not be in the public interest… [and] this could possibly undermine public confidence in FSANZ'.[10]

1.12 CHOICE indicated its concern that 'efforts to improve the food regulatory system in this way may compromise public health and consumer protection objectives'. While seeing some merit in new processes to expedite minor amendments to the Food Standards Code, CHOICE indicated concern that there was insufficient detail in the Bill in relation to the types of applications and proposals that would be subject to only one round of consultation.

> Section 42 sets out the conditions under which the full assessment and consultation process would be required. According to Section 42, applications that involve scientific and technical complexity will be subject to the full process. It is not clear what issues are considered sufficiently "complex"…[11]

1.13 The Public Health Association of Australia also raised concerns 'that the procedural changes outlined in the amended Bill will have real impact on the avenues for public consultation and the transparency of the process'.[12]

1.14 However the Australian Food and Grocery Council (AFGC) argued that the amendments in the Bill merely allowed a more efficient assessment process where it was appropriate. It stated:

> The step that is being removed in all cases except for major policy initiatives is, if you will, what was previously and is currently the first round of public consultation…There is no detail. There is no amendment that you can have a look at to judge whether or not you are going to be affected…So if it really serves no functional purpose or does not add any value to the process then even though it is taking away one round of public comment it is nonetheless a good move in terms of the regulatory system in this country.[13]

1.15 The Department noted that the amendments in the Bill will not change or impact any existing food standards and do not change the underlying intent or overall legislative framework of the Act and that FSANZ will maintain the current rigorous scientific assessment for all applications and proposals, focussing on the protection of pubic health and safety.[14] The Department also noted that the most valuable input from public consultation occurred where draft changes were available to be commented on. It added:

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10 *Submission* 5, p. 2 (Australian Medical Association).

11 *Submission* 3, p. 3 (CHOICE).

12 *Submission* 13, p. 1 (Public Health Association of Australia).

13 *Committee Hansard* 23.4.07, p. 13 (Australian Food Grocery Council).

14 *Submission* 14, p. 2 (Department of Health and Ageing).

> For a number of the matters that we would probably consider under the one round of public comment, having two rounds of public comment is really not going to add anything to our consultation process…Two rounds of consultation is probably more appropriate with much more difficult and complex matters where we are not totally sure which direction we are going to take.[15]

1.16 Under the Act, FSANZ is established to achieve a high degree of public confidence in the quality and safety of food, as well as an effective, transparent and accountable regulatory framework within which the food industry can work efficiently. Community and consumer input into assessment processes are an invaluable contribution to the development of safer food regulation. Consultation processes ensure that public confidence is maintained in FSANZ and the Food Standards Code. While the Committee agrees that applications should be assessed according to their nature and scope, this should not diminish the commitment to transparent assessment processes informed by appropriate public consultation.

Editorial notes

1.17 The Bill amends the definition of a 'standard' in subsection 3(1) to clarify that boxed text identified as an editorial note or example is not part of a standard. The Australian Beverages Council raised concerns with the use of editorial notes in the Food Standards Code:

> The Council is of the strong opinion that they should not be used at all within the written content of the FSC or any individual Standard as they represent a "lazy" form of regulation. Even though the Act may state that editorial notes are not regulations, no court of law would fail to take note of them. We therefore strongly suggest that such editorial notes be removed from the body of the FSC…Regulations should in themselves be clear and unambiguous and not require "editorials" that are claimed not to be regulations.[16]

1.18 The Australian Beverages Council also raised concerns about the lack of clarity in relation to the process for amending editorial notes. It stated that this risked 'that FSANZ may change these editorial notes with their subsequent potential impact on court rulings without any consultation or any reference to the Minister, Ministerial Council or the Parliament'.[17] The Australian Beverages Council suggested that if editorial notes are retained in the FSC 'then the Bill should contain the detailed procedures, consultation and as a minimum Ministerial approval process, with the option of disallowance by the Senate as per other regulations'.[18]

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15 *Committee Hansard* 23.4.07, p. 36 (Department of Health and Ageing).

16 *Submission* 2, p. 2 (Australian Beverages Council).

17 *Submission* 2, p. 3 (Australian Beverages Council).

18 *Submission* 2, p. 3 (Australian Beverages Council).

1.19 The AFGC also noted that the amendment to subsection 3(1) only deals with the situation where the editorial note or example is 'boxed'. The AFGC suggested the word 'boxed' 'should be omitted, as it does not matter whether or not the text is boxed: if the text is identified as an editorial note or example, that is enough for it not to form part of the Code'.[19]

1.20 The Department indicated that the Bill intended to 'clarify the status quo, that editorial notes and examples that are clearly identified as such are not part of a standard'. The Department also stated that to remove editorial notes would be very time consuming and costly and would not alter their legal standing.[20] FSANZ also noted that it maintained the view editorial notes do not create legally binding requirements. It commented:

> As a matter of law we have seen them as being purely interpretive and as an aid to interpret the actual legal parts of the Food Standards Code, which are the substantive clauses within each standard. Each of those clauses can be easily identified, and that is why for editorial notes we have used a device by boxing them or putting them in boxes to clearly differentiate between the editorial note component or the note component of the standard and the actual legally binding parts of the standard, which are the clauses.[21]

1.21 FSANZ also stated that changes to editorial notes 'are consulted on in terms of the broader package of consulting on a standard; because they are included in the standard they are also consulted on'.[22] In relation to the issue on consultation on editorial notes the Department commented:

> Although the Act provisions would not require the Authority to consult generally on the inclusion of, or amendments to, editorial notes, general legal principles concerning procedural fairness would still apply. This means that where the inclusion of, or amendment to, an editorial note is being proposed that would potentially affect the interests or rights of any party, FSANZ would be obliged to consult on the editorial note change and have regard to any representations made.[23]

Role of the Ministerial Council

1.22 Policy responsibility for the food regulatory framework rests with a Food Regulation Ministerial Council comprising relevant Ministers from all States and Territories Governments as well as the Commonwealth and New Zealand Governments. The Bill amends the Act to reduce from two to one the number of

19 *Submission* 7, p. 7 (Australian Food and Grocery Council).

20 *Submission* 14, p. 2 (Department of Health and Ageing).

21 *Committee Hansard* 23.4.07, p. 28 (FSANZ).

22 *Committee Hansard* 23.4.07, p. 32 (FSANZ).

23 *Submission* 14, p. 2 (Department of Health and Ageing).

occasions on which the Ministerial Council may request FSANZ review a draft standard or a draft variation to a standard.

1.23 CHOICE raised concerns that 'limiting the capacity of Ministers to request a review would limit their ability to protect the interests of consumers'. It commented:

> CHOICE does not support the proposal to amend the FSANZ Act to allow Ministers only one opportunity to request a review. CHOICE suggests that it would be more appropriate to amend the conditions under which Ministers can request a review and the need for FSANZ to consult directly with jurisdictions; and retain the opportunity for a second review should the majority of Ministers feel it is warranted.[24]

1.24 The AFGC highlighted the processes and procedures for review of regulatory measures set down by the Council of Australian Governments in *Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard-Setting Bodies*. In summary, these guidelines recommend that reviews of a proposed national standard could only be undertaken where two or more jurisdictions of a Ministerial Council request a review and agree to meet its cost or make resources available.[25] The AFGC also commented it 'is the AFGC opinion that much of the delays observed under the current framework could have been reduced if these principles of cost and voting had been in place for the Food Regulation Ministerial Council'.[26]

1.25 The AFGC also raised concerns with the power of the Ministerial Council to amend standards. Under the Act the Ministerial Council has the right to accept, reject or amend draft food regulatory measures submitted to it by FSANZ. The AFGC commented:

> However, it must be remembered that in making such amendment, the Council has undertaken no public consultation, made no scientific or policy assessment and is not subject to external review. The amendment option lacks transparency, accountability and even technical feasibility.
>
> The better solution is for the Council, after such rounds of review as apply, to exercise a power of veto only, not one of amendment.[27]

1.26 The AFGC also argued that removing the power to amend from the Ministerial Council would reduce the potential impact of lobbying on the development of food standards. It commented that 'food regulation and food standards should not

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24 *Submission* 3, p. 5 (CHOICE).

25 Council of Australian Governments, *Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standards-Setting Bodies*, endorsed by COAG April 1995, amended November 1997, June 2004, p. 10 (available from www.coag.gov.au) .

26 *Submission* 7, p. 12 (Australian Food and Grocery Council).

27 *Submission* 7, p. 10 (Australian Food and Grocery Council).

be drafted by ministers on the basis of lobbying, be it from the industry or from any other body'.[28]

'Stop-the-clock' provision

1.27 In the Bill a new 'stop-the-clock' provision has been proposed where the Ministerial Council has notified FSANZ that it is developing a policy guideline and an application relates to the subject matter of the policy guideline being developed. In these cases, consideration of an application can be suspended by FSANZ for up to an additional 18 months.

1.28 The Explanatory Memorandum notes:

> In the food regulation system, the Authority and Council play important and complementary roles. Allowing the Authority the flexibility to 'stop the clock' on an assessment provides the structure needed within the standard-setting process to align it with the Council's policy development role.
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> This also ensures that the standard development process provides regulatory certainty to applicants when policy guidelines are being developed that may affect the outcome of an application. Setting the maximum 'stop the clock' time of 18 months ensures that the Council has enough time to develop a policy guideline, and will avoid the situation in which the Authority must progress an application, even though a new policy guideline may immediately force a review of the resulting standard.[29]

1.29 However a number of industry submissions raised concerns with the new stop-the-clock provision. The Australian Beverages Council argued 'that the proposed "stop-the-clock" delay is unnecessary and will seriously inhibit innovation and the competitiveness of Australian industry'. It noted:

> Most of the Applications that are likely to require a 'policy consideration' by the FRMC are likely to be aimed at the development of new products to service both domestic and overseas export opportunities. They are also invariably 'paid Applications'. We suggest that in these situations where the Applications are paid for, FSANZ should be able to continue its assessment work and Standard development at the same time as the FRMC develops its policy guideline.[30]

1.30 The Australian Beverages Council also argued that if the provision was used FSANZ should immediately return funds paid by applicants for expediting applications until FSANZ is able to recommence the assessment of their applications.[31]

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28 *Committee Hansard* 23.4.07, p. 10 (Australian Food and Grocery Council).

29 *Explanatory Memorandum*, p. 42.

30 *Submission* 2, p. 4 (Australian Beverages Council).

31 *Submission* 2, p. 5 (Australian Beverages Council).

1.31 Bayer CropScience also raised concerns that the delays caused by the proposed new 'stop-the-clock' provision 'could be extremely damaging to a company'. It commented:

> We are extremely concerned that any application can be delayed for up to 18 months, on top of the normal statutory "consideration" period, including any period set aside for referral to Council. This delay is unreasonable and does not provide transparency and predictability of outcome.[32]

1.32 Bayer CropScience suggested that where an application has been submitted before the start of the policy review, the application should be allowed to proceed with the proviso to the applicant that approval may be rescinded or amended, if necessary, following any contrary policy decision.[33]

1.33 While largely supporting the content of the Bill, Monsanto also raised the 'stop-the-clock' provision in their submission. Monsanto recommended that 'communication processes are evolved whereby an applicant is informed in advance that Council is developing policy guidelines that may affect a particular application' to allow applicants to plan accordingly.[34] Similarly Dairy Australia argued that policy development 'needs to be proactive and forward thinking and should occur early upon receipt of an application – not when an application is possibly nearing completion – where this approach could delay an outcome'.[35]

1.34 The AFGC focused on how the new 'stop-the-clock' provision in the Bill could be used by FSANZ.

> This has the potential for procedural abuse, even though the suspension in time is limited to a maximum of 18 months, and recognising that the operative word "may" confers a discretion on FSANZ as to whether or not the "clock" should be "stopped".
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> While it is recognised that resources spent on the assessment of applications may be rendered ineffectual by the introduction of subsequent contrary policy, the provision could be used to halt consideration of an application, possibly nearing completion, upon the speculative basis that a policy might be developed that might affect the outcome of the assessment.
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> The better approach in such an instance would be for the "stop the clock" to only occur with the consent of the applicant, or at least to afford the applicant the opportunity for external review through the AAT of any determination by FSANZ to stop the clock for this reason.[36]

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32 *Submission* 10, p. 2 (Bayer CropScience).

33 *Submission* 10, p. 2 (Bayer CropScience).

34 *Submission* 4, p. 2 (Monsanto).

35 *Submission* 11, pp. 3-4 (Dairy Australia).

36 *Submission* 7, pp. 10-11 (Australian Food and Grocery Council).

1.35 CHOICE supported 'the proposal to allow FSANZ to stop the clock on applications when the Ministerial Council is considering policy that will have implications for those applications' in its submission to the review of FSANZ assessment processes. It noted:

> It would be illogical for FSANZ to consider an application when Ministerial Council has not finalised policy guidelines. It could result in a situation where manufacturers intentionally make applications before policy has been finalised because they believe they will achieve a more favourable outcome if no clear policy guidelines exist.[37]

1.36 In relation to the AFGC proposal the Department noted that the issue 'had not been considered in the drafting of the legislation'. It stated that:

> The proposal to put an 18-month time frame on a stop the clock came out of a need to clarify stop-the-clock time. Ministerial Council had been frustrated in the past by applications that were proceeding through when there was concern expressed on the part of Ministerial Council around its view about particular developments within food supply.
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> The intent of this amendment is to put a boundary around that consideration time and ensure that there is a finalisation of policy within an appropriate time line.[38]

1.37 The Department also noted that if FSANZ were required to continue to assess an application while related policy advice was being finalised, it was likely the Ministerial Council would ask for a review of the draft standard or amendment. It argued '[t]his is not considered an efficient or effective use of resources'.

> Setting the maximum 'stop the clock' time of 18 months ensures that the Ministerial Council has enough time to develop a policy guideline, and will avoid the situation in which FSANZ must progress an application, even though a new policy guideline may immediately force a review of the resulting standard. [39]

Certainty for industry

1.38 A number of minor amendments were suggested by industry submissions with the intention of providing provide certainty and predictability for applicants during the assessment process. Bayer CropScience noted that Item 74, s. 31 (2) (c) of the Bill dealing with the call for submissions in relation to a draft food regulatory measure or draft variation of a food regulatory measure does not define the submission period. It

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37 CHOICE, *Submission – Consultation Paper: Proposed Legislative Changes to the Food Standards Australia New Zealand Act 1991*, p. 5.

38 *Committee Hansard* 23.4.07, p. 29 (Department of Health and Ageing).

39 *Submission* 14, p. 3 (Department of Health and Ageing).

suggested this period 'should be defined to provide certainty and predictability to industry'.[40] It commented:

> These could prolong the time taken for approval indefinitely. Based on current experience, the approval process has, in many instances, taken up to 2 years. The amendments in the Bill contain no provisions that could improve this time-line.[41]

1.39 Under the Bill, FSANZ must, within 15 days after an application received, either accept or reject the application. In determining whether to accept or reject an application one of the matters which FSANZ must have regard to is whether the application complies with the guidelines for an application. Dairy Australia indicated it did not support this part of the Bill as '[t]hese guidelines may not be able to be met due to limited scientific data availability, overly prescriptive guidelines etc'.[42]

1.40 The AFGC noted that an applicant may appeal to the Administrative Appeals Tribunal for review of a decision to reject an application, however this appeal right is specifically excluded in the case of a rejection decision based on non-compliance with the application guidelines. It recommended that these decisions should not be excluded from the types of decisions made by FSANZ against which an applicant may apply to the Administrative Appeals Tribunal.[43]

1.41 The AFGC also argued that more extensive appeal rights should be considered in relation to internally generated proposals by FSANZ:

> The reason is that where an external applicant actually wants a change, it is the rejection of that change that gives rise to a grievance that external review can address. In the case of internally generated proposals, it is actually the opposite - it is the imposition of a new regulation, for which no external party has applied, that might give rise to a grievance that warrants external review.[44]

1.42 The AFGC also argued that external review should be available for decisions in relation to whether or not information provided by an applicant is 'confidential commercial information' and whether an application confers an 'exclusive capturable commercial benefit' on an applicant for the purposes of fixing a charge.[45]

1.43 The proposed section 29 (2) in the Bill deals with matters which FSANZ must have regard to assessing applications.

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40 *Submission* 10, p. 2 (Bayer CropScience).

41 *Submission* 10, p. 2 (Bayer CropScience).

42 *Submission* 11, p. 4 (Dairy Australia).

43 *Submission* 7, p. 8 (Australian Food and Grocery Council).

44 *Submission* 7, p. 8 (Australian Food and Grocery Council).

45 *Submission* 7, p. 8-9 (Australian Food and Grocery Council).

> In assessing the application, the Authority must have regard to the following matters:
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> (a) whether costs that would arise from a food regulatory measure developed or varied as a result of the application outweigh the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure…

1.44 The AFGC raised in their submission that in this part of the Bill 'express reference is made to "direct and indirect" benefits, but the same language is not used in relation to costs'. They argued that there should be 'equivalence in the terminology: the clause should read either "costs" and "benefits"; or "direct and indirect costs" and "direct and indirect benefits"'.[46]

1.45 Bayer CropScience raised the possibility that in the future genetically modified crops may be developed which have improved health claims.

> Thus an application might be made for a variation to the standard as well as for a high level health claim. It should be made possible to address the two types of applications simultaneously in one consolidated application under the Act and for the assessment process to proceed concurrently.[47]

1.46 Dairy Australia noted the exemption from suit provisions in the Bill which are designed to allow FSANZ to act within the provisions of the Act in good faith, without risking legal action. However it argued that this should be extended to allow FSANZ to provide legally binding advice to stakeholders as part of its role in providing information and advice.

> Dairy Australia puts forward that it should be the role of FSANZ to provide legal advice as FSANZ are the Standards making body and have an intimate and unique knowledge of the Food Standards Code as its writer.[48]

Health claims

1.47 The Bill sets out the new process for the assessment of high level health claims that was developed to encourage industry innovation in the area. The new process is intended to protect commercially valuable material during the assessment process and to allow applicants to capture the commercial benefit of innovation. The Explanatory Memorandum provides that:

> Under the new process, each high level health claim will be assessed by the Authority with advice from an expert committee. The assessment will include a scientific, pre-market assessment against substantiation requirements set out in the Nutrition, Health and Related Claims Standard. States, Territories and New Zealand will also be consulted.

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46 *Submission* 7, p. 9 (Australian Food and Grocery Council).

47 *Submission* 10, p. 3 (Bayer CropScience).

48 *Submission* 11, p. 5 (Dairy Australia).

> During consultation with stakeholders there was some concern expressed that the Bill describes a new process for the assessment of high level health claims, yet the standard under which such claims would be detailed has not yet been finalised. The Bill therefore provides that this Schedule (describing the provisions relating to the assessment of high level health claims) commences on Proclamation or no longer than 18 months after Royal Assent. This should be sufficient time to enable full consideration and finalisation of the Nutrition, Health and Related Claims Standard. [49]

1.48 CHOICE raised concerns about the proposed assessment process for high level health claims. It argued:

> One of the major strengths of the current FSANZ process is its openness and transparency and the consistency of consultation processes for all applications and proposals. The proposed changes to the health claims process remove public consultation altogether. In CHOICE's opinion this threatens the integrity of the FSANZ process and undermines its primary objectives.
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> The establishment of an expert panel to advise FSANZ on applications to amend health claims standard does not go far enough to address CHOICE's concerns. In order to provide adequate protection of consumer and public health interests, applications to amend the health claims standard must be subject to public consultation to enable all public health and consumer stakeholders to comment the implications of and strength of evidence supporting the proposed changes.[50]

1.49 The Dietitians Association of Australia argued that 'applications should only be exempt from public consultation when they contain significant amounts of data which is the intellectual property of the applicant'. It commented that:

> Public Consultation provides confidence in the Food Standards Code and should be included whenever possible in the applications and proposals process. When the supporting information in an application is substantially derived from data in the public domain then the application should still have public consultation as part of the approval process.[51]

1.50 The Dietitians Association of Australia noted that there was no process for the establishment and membership of expert committees outlined in the Bill and sought further information.[52]

1.51 However the AFGC supported that the process in the Bill to deal with the high level health claims which would address the 'significant free-rider effect…where the

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49 *Explanatory Memorandum*, p. 45.

50 *Submission* 3, p. 4 (CHOICE).

51 *Submission* 9, p. 2 (Dietitians Association of Australia).

52 *Submission* 9, p. 2 (Dietitians Association of Australia).

process publicises what is going to happen and competitors become aware…12 to 18 months ahead of time' and will allow applicants the 'first to market opportunity'.[53]

1.52 The AFGC also raised concerns with lack of limitations on FSANZ in relation to conduct in considering an application or proposal for new high level health claims. The AFGC argued that:

> While the new provisions do not compel FSANZ to undertake public consultations, they do not prohibit FSANZ from undertaking such consultations if it sees fit…A specific prohibition against public notification and consultation (except at the request or with the consent of the applicant) needs to be added.[54]

1.53 However FSANZ stated that the provisions in relation to high level health claims would prevent FSANZ from undertaking public consultation. It stated:

> The subdivision and the provisions relating to high-level health claims are of specific import. It is statutory interpretation 101 that the ones of specific import would prevail over that generic one. So I think the upshot of that is that FSANZ would not be entitled to consult, irrespective of what the applicant's wishes were.[55]

1.54 The Department noted that the Bill only creates a process for assessing high level health claims and has no bearing on the content of the Nutrition, Health and Related Claims Standard which is being developed. It stated:

> The Nutrition, Health and Related Claims Standard currently under development by FSANZ will outline the rules and criteria for all future nutrition, health and related claims. Issues discussed by the Committee that relate to the types of foods that will be permitted to carry general or high level health claims will be resolved as part of the standard development process.[56]

Public health

1.55 The AMA expressed disappointment that the Bill 'seems to place greater emphasis on improving processes for industry (reducing red tape and streamlining) than it does on the public health implications of food regulation activities undertaken by FSANZ'.[57] The AMA noted that while the Act currently listed the protection of public health as a primary objective, the legislation does not contain a clear definition of public health. It noted the AMA's adoption of policy resolutions and statements

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53 *Committee Hansard* 23.4.07, p. 14 (Australian Food and Grocery Council).

54 *Submission* 7, p. 11 (Australian Food and Grocery Council).

55 *Committee Hansard* 23.4.07, p. 31 (FSANZ).

56 *Submission* 14, p. 4 (Department of Health and Ageing).

57 *Submission* 5, p. 1 (Australian Medical Association).

regarding public health and the use of a precautionary principle in relation to health policy.

> The precautionary principle states that when an activity raises threats of harm to the environment or human health, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically.[58]

1.56 The AMA also supported a more ongoing process of assessment for foods by FSANZ particularly in relation to novel foods as 'sometimes the technology and research methods that bring to light unseen consequences of novel foods' may not be developed until after a novel food is introduced.[59]

1.57 CHOICE also noted the lack of a definition of 'public health' in the Act. It commented:

> This results in varying interpretations of this objective. In some cases it is interpreted as pertaining only to food safety and food-borne illness. Such a limited view of public health and safety only addresses the short-term health impact of food regulation rather than the long-term impact on the health and nutrition of individuals and populations.[60]

1.58 Similarly the Public Health Association of Australia also highlighted the lack of a clear definition of public health and recommended that the Bill be amended to 'incorporate a focus on public health interests and concerns over and above the need for industry marketing initiatives'.[61]

1.59 However FSANZ noted that the Bill 'does not actually disturb section 10…Section 10 sets out FSANZ priorities, and the No. 1 priority of course is public health and safety'.[62] The Department also commented that including a definition of 'public health' in the Act 'may very well put boundaries around it as opposed to allowing us to interpret public health in its broader sense.'[63]

1.60 CHOICE criticised the impact analysis in the Explanatory Memorandum as failing to 'adequately assess the public health impacts of changes to FSANZ process, particularly in relation to the assessment of health claims applications'.

> The Impact Analysis suggests that the proposed changes to the health claims process will have no impact on health and safety. It also suggests that a greater range of products carrying health claims could be have public health benefits. CHOICE believes that an increase in processed foods

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58 *Submission* 5, p. 4 (Australian Medical Association).

59 *Committee Hansard* 23.4.07 (Australian Medical Association).

60 *Submission* 3, p. 6 (CHOICE).

61 *Submission* 13, pp. 1-2 (Public Health Association of Australia).

62 *Committee Hansard* 23.4.07, p. 30 (FSANZ).

63 *Committee Hansard* 23.4.07, p. 30 (Department of Health and Ageing).

> carrying health claims could actually have adverse public health impacts as consumers will be encouraged to eat more highly-processed foods. [64]

1.61 The Cancer Council of Australia also raised its concerns that weaker measures in relation to food regulation could potentially lead to negative health outcomes for the public. It stated:

> Our major, over-riding concern relates to the broad policy direction relating to FSANZ, which appears to be moving to weaken rather than strengthen regulatory structures and processes relating to the Australian food supply and the way in which it is controlled, promoted and marketed…The Cancer Council Australia believes this is a potentially dangerous direction in terms of future disease burden.[65]

1.62 However the Department argued the amendments in the Bill were focused on 'providing a streamlined process which is more useful for industry innovation'. The Department also stressed that the amendments in the Bill were not intended to change the balance in FSANZ's scientific assessment of food standards.[66]

1.63 The Conservation Council of Western Australia raised its concerns that FSANZ relies on data and research completed by companies submitting their applications. It argued:

> Independent and more vigorous testing…should be carried out in the approval process. We agree that proposals should be assessed according to the nature and scope of the applications but caution against the review process being shortened so that backlog of applications could be cleared.[67]

1.64 However the Department commented:

> …FSANZ does very much seek independent, expert, peer-reviewed advice. It does have a scientific and robust assessment of what is presented to it. It does not merely accept what it is given by proponents of any particular view.[68]

CONCLUSION

1.65 The Committee notes comments in a number of submissions in relation to focus that FSANZ should place on public health and safety in its assessment of application and proposals. These submissions raise issues that go beyond the amendments proposed in the current Bill, however the Committee agrees these issues warrant further consideration.

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64 *Submission* 3, p. 5 (CHOICE).

65 *Submission* 12, p. 1 (The Cancer Council Australia).

66 *Committee Hansard* 23.4.07, p. 37 (Department of Health and Ageing).

67 *Submission* 8, p. 2 (Conservation Council of Western Australia).

68 *Committee Hansard* 23.4.07 p.28 (Department of Health and Ageing).

Recommendation 1

1.66 That the Commonwealth consider clarifying the definition of 'public health' in relation to the objectives of the *Food Standards Australia New Zealand Act 1991* and the assessment of food standards.

1.67 The Committee notes the concerns raised by the Australian Beverages Council that editorial notes included in the Food Standards Code could potentially be misused. However the Committee accepts the assurances of FSANZ that editorial notes are not legally binding and welcomes its commitment to address specific examples raised by the Australian Beverages Council where editorial notes appear to go beyond merely providing an interpretative aid to clauses. The Committee agrees that the minor amendment proposed of the Australia Food and Grocery Council is appropriate.

Recommendation 2

1.68 That the definition of 'standard' contained in proposed subsection 3(1) of the Act be amended to also exclude editorial notes and examples which are not 'boxed'.

1.69 That Food Standards Australia New Zealand clarify the process of amending editorial notes and examples in the Food Standards Code to ensure appropriate policy oversight and public consultation.

1.70 The Committee agrees that where an application comes under the new 'stop-the-clock' provision, the applicant should be able to decide to continue the assessment with the proviso that approval may be rescinded or amended, if necessary, following any contrary policy decision by the Ministerial Council.

Recommendation 3

1.71 That the 'stop the clock' provisions contained in proposed section 109 be amended to provide applicants with an option to proceed with the assessment process, with the understanding that approval may be rescinded or amended, if necessary, following any contrary policy decision by the Ministerial Council.

Recommendation 4

1.72 That subject to the above recommendations, the Committee recommends that the Senate pass the Bill.

Senator Gary Humphries
Chairman

May 2007