COMMONWEALTH DEPARTMENT OF HEALTH AND AGEING

SUBMISSION TO THE

COMMUNITY AFFAIRS COMMITTEE

ON THE

AUSTRALIA NEW ZEALAND FOOD AUTHORITY AMENDMENT BILL 2007

APRIL 2007

INTRODUCTION

The Australia New Zealand Food Authority Amendment Bill 2007 (the Bill) implements amendments suggested by the Australian New Zealand Food Regulation Ministerial Council.

The Bill proposes amendments to the Food Standards Australia New Zealand Act 1991 (the Act) that sets out the **process for developing and amending** joint food standards for Australia and New Zealand.

The amendments will not change or impact on any existing food standards and do not change the underlying intent or overall legislative framework of the Act. FSANZ will maintain the current rigorous scientific assessment for all applications and proposals, focussing on the protection of pubic health and safety.

Editorial notes

The proposed technical amendment to the definition of a Standard (Item 13 of the Bill) that expressly provides that editorial notes and examples are not part of a Standard was raised by a number of those making submissions to the Committee. The amendment is intended clarify the status quo, that editorial notes and examples that are clearly identified as such are not part of a standard.

Editorial notes have traditionally been used in the Food Standards Code. During consultation on this amendment diverse views were expressed. Many found editorial notes useful and preferred that they remain within the Code so that all relevant information is presented in the same document. Some argued for the removal of all editorial notes from the Food Standards Code.

Removing all notes would be a very time consuming and costly exercise that would not add to public health and safety. Providing the advice currently contained in editorial notes in alternative guidance documents would not alter their standing as potential supporting evidence as to the intent of the Standard within a court of law.

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.

'Stop the clock' for up to 18 months while the Ministerial Council is developing policy

The current Act enables the Ministerial Council to issue policy guidelines. FSANZ is required to have regard to any written policy guidelines formulated by the Ministerial Council. The policy guidelines issued by the Ministerial Council must not be inconsistent with the objectives of FSANZ as set out in section 10(1) of the FSANZ Act.

The guidelines articulate the principles within which standards should be developed. Policy guidelines are essential in areas where there may be a diversity of views as to the appropriate approach to matters connected to the development of particular standards. The Ministerial Council has the right to request that any draft standard be reviewed, and to ultimately amend or reject it, if it is (amongst other criteria) inconsistent with a policy guideline. As such, policy guidelines assist FSANZ by providing a context within which they can develop standards and so avoid costly work by the Authority on standards that the Ministerial Council will not agree to.

An applicant may submit an application on any matter at any time. The FSANZ legislation provides no capacity for FSANZ to defer consideration of applications while awaiting policy guidance. However, current experience in these situations is for the Ministerial Council to request that FSANZ undertake a review of a draft standard.

If the Authority were required to continue to assess an application whilst related policy advice was finalised it is likely that Ministerial Council would delay a decision on a draft standard by requesting a review and, in a worst case scenario, it has the capacity to completely reject the draft standard after a second review. Alternatively a standard may be approved and a reassessment required within a short timeframe if the standard was considered out of step with the policy. Neither of these scenarios is considered an efficient or effective use of resources.

During consultations with industry and consumer groups, some industry stakeholders did not support a 'clock stop' while awaiting Ministerial Council policy guidance. This was, however, supported by consumer groups. In both cases, it was noted that if this approach was adopted, the circumstances in which a 'clock stop' could be exercised should be clear and that there should be limits on the time during which assessment is stopped pending finalisation of Ministerial Council policy guidance. The Ministerial Council endorsed this policy approach and requested that the Australian Government Minister for Health include this amendment in the Bill.

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.

High level health claims

The Bill creates a process for assessing high level health claims only and has no bearing on the content of the Nutrition, Health and Related Claims Standard.

The new process, which only deals with high level health claims[1], cannot commence until the Nutrition, Health and Related Claims Standard is approved by the Authority, considered by the Ministerial Council and put in place. It is expected that the Standard will be finalised within the 18 months timeframe provided in the Bill for introduction of this provision.

[1] A high level health claim is a claim that directly or indirectly refers to a serious disease or a biomarker.

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. Significant consultation on this matter has already been undertaken and will continue to inform FSANZ work.

Under the proposed pre-market assessment process for high level health claims, the validity of each high level health claim will be assessed by the Authority with advice from an expert committee. The assessment will focus on the validity of the claims which will be assessed against the criteria for evidence set out in the Nutrition, Health and Related Claims Standard. As indicated above these criteria will have been consulted on during the development of the standard.

The assessment will not address the risk of the food itself, which must already be acknowledged as safe to be permitted in the market. Only the expert committee and States, Territories and New Zealand will be consulted. This will protect commercially valuable material during the assessment process and allows applicants to capture the commercial benefit of their innovation.

If, and when, the Authority approves the inclusion of a high level health claim in the Standard, the amended Standard will be considered by the Ministerial Council in the usual way. This process ensures proper protection of public health and safety.