

**AUSTRALIA AND NEW ZEALAND FOOD REGULATION MINISTERIAL COUNCIL**

**26 SEPTEMBER 2008**

**FOOD MINISTERS REQUEST A REVIEW OF VARIATION TO STANDARDS 1.1.1 – PRELIMINARY PROVISIONS, 2.9.1 – INFANT FORMULA PRODUCTS, 2.9.2 – FOOD FOR INFANTS AND 2.9.3 - FORMULATED MEAL REPLACEMENTS AND FORMULATED SUPPLEMENTARY FOODS THAT HAS RESULTED FROM PROPOSAL P306 – ADDITION OF INULIN FRUCTO-OLIGOSACCHARIDE (FOS) AND GALACTO- OLIGOSACCHARIDE (GOS) TO FOOD**

The Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) has requested that Food Standards Australia New Zealand (FSANZ) review variation to Standards 1.1.1 – Preliminary Provisions, 2.9.1 – Infant Formula Products, 2.9.2 – Food for Infants and 2.9.3 – Formulated Meal Replacement and Formulated Supplementary Foods that has resulted from Proposal P306 – Addition of Inulin FOS and GOS to Food.

Proposal P306 seeks to amend Standards:

- 1.1.1 to state that inulin-derived substances are taken not to be nutritive substances;
- 2.9.1 to permit the voluntary addition of inulin-derived substances and GOS, alone or in combination, to infant formula products to a total maximum of 290 mg/100 kJ (0.8g/100mL); and
- 2.9.2 and 2.9.3 to permit the voluntary addition of inulin-derived substances and GOS, alone or in combination, to infant foods and formulated supplementary foods for young children up to a maximum of 0.8 g/100g and 1.6g/serve (0.8 g/100 mL), respectively.

The Criteria/Grounds for this are that:

**It is not consistent with the objectives of the legislation which establishes FSANZ (the Authority)**

The draft variation does not provide regulatory clarity and certainty in relation to the position of substances which are arguably of a nutritive character in infant formula products.

**It does not protect public health and safety**

It is requested that FSANZ address the justification of raising the proposed level of inulin derived substances/GOS from 3g/L to 8g/L in the absence of data to support improved physiological outcomes and assurance of safety at this high level. More data is required to demonstrate the ideal level if inulin-derived substances and GOS, and the ratio (if any) that is optimum.

There is concern that if FSANZ deems inulin derived substances and GOS as non-nutritive in infant formula products, there will not need to be expressed permissions added to these substances. This could set a precedent for other substances that might be added in the future, without adequate safety assessment by FSANZ.

**It does not promote consistency between domestic and international food standards, where these are at variance**

The approach that has been adopted is at variance with the EU standards.

**It is difficult to enforce or comply with in both practical or resource terms**

It is not considered appropriate that changes to standards are proposed without a testing capability being readily available to ensure adequate enforcement by jurisdictions.

Furthermore there is a considerable cost to be incurred by regulators with the development and verification of such methods. This and other costs to regulators is not itemised within the FSANZ benefit cost analysis and no quantitative values are assigned to these costs.

FSANZ has 3 months to review the draft standard and re-affirm, re-affirm with amendments, or withdraw its approval of the draft standard.

## The process for requesting a review

After Food Standards Australia New Zealand (FSANZ) notifies the Australia and New Zealand Food Regulation Ministerial Council (the Council) of a draft standard or variation the Council may request a review if any jurisdiction believes that one or more of the Criteria/Ground/s<sup>1</sup> set out in the Food Regulation Agreement 2000 (as amended in 2008) (the Agreement) or the Agreement between the Government of Australia and the Government of New Zealand concerning a Joint Food Standards System (the Treaty) applies. The Criteria / Ground/s set out in the Agreement and in the Treaty are:

- (i) it is not consistent with existing policy guidelines set by the Ministerial Council;
- (ii) it is not consistent with the objectives of the legislation which establishes FSANZ;
- (iii) it does not protect public health and safety;
- (iv) it does not promote consistency between domestic and international food standards where these are at variance;
- (v) it does not provide adequate information to enable informed choice;
- (vi) it is difficult to enforce or comply with in both practical or resource terms; and / or
- (vii) it places an unreasonable cost burden on industry or consumers.

In exercising this power the Council must comply with the Agreement and the Treaty. Under the Agreement the Council will request a review if any jurisdiction considers that one or more of the Criteria applies. The Council would also, at this point in the process, request a review if New Zealand notifies the Council of concerns that the standard would be inappropriate for New Zealand (Annex C(2) of the Treaty).

If such a review is undertaken and the Council receives notice from FSANZ that the draft standard or variation has been reaffirmed (either entirely or subject to amendments) the Council may request a second<sup>1</sup> review. In exercising this power the Council must comply with the Agreement. Under the Agreement the Ministerial Council will request FSANZ to review the draft standard or variation a second time if it is agreed, by a majority vote, that one or more of the Criteria applies.

<sup>1</sup> This part of the protocol will have to be updated once the 'Agreement between the Government of Australia and the Government of New Zealand Establishing a System for the Development of Joint Food Standards' (the Treaty) has been amended to reduce from two to one the number of occasions on which the Council may request the Authority to review a draft or a variation to a standard. This will harmonize it with the Food Standards Australia New Zealand Amendment Act 2007.