

# AUSTRALIA AND NEW ZEALAND FOOD REGULATION MINISTERIAL COUNCIL

26 SEPTEMBER 2008

## **FOOD MINISTERS REQUEST A REVIEW OF VARIATION TO STANDARD 2.9.1 – INFANT FORMULA PRODUCTS - THAT HAS RESULTED FROM APPLICATION A594 – ADDITION OF LUTEIN AS A NUTRITIVE SUBSTANCE TO INFANT FORMULA**

The Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) has requested that Food Standards Australia New Zealand (FSANZ) review variation to Standard 2.9.1 – Infant Formula Products that has resulted from Application A594 – Addition of Lutein as a Nutritive Substance to Infant Formula.

Application A594 seeks to amend Standard 2.9.1 – Infant Formula Products to permit the voluntary addition of lutein to infant products.

The Criteria/Ground/s for the review of Standard 2.9.1 – Infant Formula Products are that:

### **It is not consistent with the objectives of the legislation which establishes FSANZ; and It does not protect public health and safety**

There is concern that small studies and unpublished data have been used to justify the proposed draft Standard 2.9.1.

The applicant has not provided sufficient evidence to demonstrate the ‘nutritional purpose’ for which lutein is being added.

It is requested that either more data be provided to support a maximum level of 250µg/L or a lower level be permitted which better reflects that needed to achieve nutritional equivalence with breast fed infants. It is considered that a precautionary approach should be taken in regard to the addition of substances to infant formula due to the vulnerability of this population.

### **It places an unreasonable cost burden on industry or consumers**

The cost-benefit analysis (CBA) provides so little detail that it is impossible to know how this conclusion is derived. The CBA is entirely qualitative with no quantitative values assigned to the costs or benefits to the various stakeholders.

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.