

AUSTRALIA AND NEW ZEALAND FOOD REGULATION MINISTERIAL COUNCIL

19 NOVEMBER 2009

FOOD MINISTERS REQUEST A REVIEW OF STANDARD 1.3.1 – FOOD ADDITIVES THAT HAS RESULTED FROM A1015 – ETHYL LAUROYL ARGINATE AS A FOOD ADDITIVE

The Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) has requested that Food Standards Australia New Zealand (FSANZ) review Standard 1.3.1 – Food Additives that has resulted from consideration of A1015 – Ethyl Lauroyl Arginate as a Food Additive.

The Application seeks to amend Standard 1.3.1 of the Australia New Zealand Food Standards Code (the Code) to include a new food preservative, ethyl lauroyl arginate (ELA). ELA is a synthetically produced cationic surfactant that is intended to be used to protect food against microbial growth and thus spoilage. A cationic surfactant such as this can be used as food preservatives because they can disrupt the integrity of cell membranes in a broad spectrum of bacteria, yeasts and moulds. It is proposed to be used in a wide range of food groups.

The Criteria/Ground/s for the review of Standard 1.3.1 – Food Additives are that:

- **it does not protect public health and safety**

It is considered that the FSANZ risk assessment is not sufficiently robust to clearly support the approval of ELA on safety and efficacy grounds at this time and if approved, ELA will be able to be used as a preservative for a wide range of food categories. Over time it may replace existing approved preservatives which have a history of safe and effective use.

A review is proposed because further work is required to establish clearly the safety and efficacy of ELA, and to clarify whether consumers are likely to exceed the acceptable daily intake for this substance – especially as it is proposed to be used in a wide variety of foods.

- **it is difficult to enforce and comply with in both practical and resource terms**

It is considered that there are issues about the clarity and enforceability of this draft standard that need to be resolved as part of the review process.

- **it places an unreasonable cost burden on industry or consumers**

It is considered that the FSANZ cost-benefit analysis does not provide enough detail to explain how the conclusion was reached that “The regulatory impact assessment concluded that the benefits of the potential use of ethyl lauroyl arginate in the specified food categories outweigh any costs associated with its use”.

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 Ministerial Council) of a draft standard or variation the Ministerial Council may request a review if any jurisdiction believes that one or more of the Criteria/Ground/s¹ set out in the Food Regulation Agreement 2000 (as amended in 2002) (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 Ministerial Council must comply with the Agreement and the Treaty. Under the Agreement the Ministerial Council will request a review if any jurisdiction considers that one or more of the Criteria applies. The Ministerial Council would also, at this point in the process, request a review if New Zealand notifies the Ministerial 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 Ministerial Council receives notice from FSANZ that the draft standard or variation has been reaffirmed (either entirely or subject to amendments) the Ministerial Council may request a second¹ review. In exercising this power the Ministerial 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.

¹ 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.