



Consultation Paper

P1024 Revision of the Regulation of Nutritive Substances and Novel Foods

Call for submissions due 24th March 2016

Unilever Australasia

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Unilever Australasia is pleased to provide the following comments to the FSANZ consultation paper on Nutritive Substances and Novel Foods Regulatory framework for Australia and New Zealand.

Unilever Australasia is an international manufacturer and marketer of food and beverage products and is a market leader in many grocery categories in Australia and New Zealand. Our well known food brands include: Continental, Flora, Flora pro-activ, Lipton, Streets and a number of other smaller brands. Our food and beverage products are used every day by millions of people around the world. Consumers trust us to provide them and their families with products that are suitable for use.

This submission is written on behalf of the total Foods business, taking into consideration the wide range of products we have on the market and our understanding of the needs of the consumers of these products.

We are strongly supportive of the development of an effective framework with the regulatory management options being based on risk, for the regulation of Nutritive substances and Novel Foods in Australia and New Zealand. As a company, we have been very actively involved in both the development and implementation of the Novel foods standard, and submitted the first Novel Foods application for vegetable oil phytosterols in 2000.

We are a member organization of the Australian Food and Grocery Council and the New Zealand Food and Grocery Council, have provided input into their submissions on industry behalf and are fully supportive of these submissions representing industry views.

Overarching principles

We believe that there are a number of overarching principles that should govern changes proposed by FSANZ for Nutritive substances and Novel foods

- The FSANZ proposal should be simple, easy to understand and to explain, and for companies to comply with.
- The regulatory framework should be based on best practice regulatory principles and the Policy Guideline for Addition to Food of Substances other than Vitamins and Minerals.
- They should reflect best international practice regulation and proven methodologies, providing for minimum effective regulation in Australia and New Zealand.
- They should result in a fairer playing field for Australian industry in the global market and in particular with New Zealand.
- They should provide for a genuine tiered approach to risk assessment for nutritive substances and novel foods based on exposure using Australian and New Zealand dietary modelling (when different to rest of world and/or required).
- They should be consistent within the overall system for food regulation and management in Australia and New Zealand, and eliminate all unnecessary regulatory burden and/or duplication.
- Reform implementation and transition should reflect the least disruptive process for industry.
- It should provide opportunities for cheaper and faster entry of innovative and safer products on the Australian market.
- It should implement the government's policy on accepting trusted international assessments, standards and products.

We support the Policy Guideline 'Addition to Food of Substances other than Vitamins and Minerals' as a key consideration for the basis of the regulatory framework.

'High Order' Policy Principles

The *Food Standards Australia New Zealand Act 1991* (the Act) establishes a number of objectives for FSANZ (the Authority) in developing or reviewing of food standards.

1. The objectives (in descending priority order) of the Authority in developing or reviewing food regulatory measures and variations of food regulatory measures are:
 - a) the protection of public health and safety; and
 - b) the provision of adequate information relating to food to enable consumers to make informed choices; and
 - c) the prevention of misleading or deceptive conduct.
2. In developing or reviewing food regulatory measures and variations of food regulatory measures the Authority must also have regard to the following:
 - a) the need for standards to be based on risk analysis using the best available scientific evidence;
 - b) the promotion of consistency between domestic and international food standards;
 - c) the desirability of an efficient and internationally competitive food industry;
 - d) the promotion of fair trading in food;
 - e) any written policy guidelines formulated by the Council for the purposes of this paragraph and notified to the Authority.

Specific Order Policy Principles – Any Other Purpose

The addition of substances other than vitamins and minerals to food where the purpose of the addition is for other than to achieve a solely technological function should be permitted where:

- a) the purpose for adding the substance can be articulated clearly by the manufacturer (ie the 'stated purpose'); and

- b) the addition of the substance to food is safe for human consumption; and
- c) the substance is added in a quantity and a form which is consistent with delivering the stated purpose; and.
- d) the addition of the substance is not likely to create a significant negative public health impact to the general population or sub population; and
- e) the presence of the substance does not mislead the consumer as to the nutritional quality of the food.

As well as encouraging consideration of the overarching principals to the consultation process. We also make the following comments;

Use of International Standards

We welcomed the government's reform program where it is seeking to align regulatory processes as much as possible to eliminate or minimise regulatory compliance burden and the publishing of the government report 'Industry Innovation and Competitiveness Agenda: An Action Plan for a Stronger Australia. And in particular the proposal announced of its proposal:

To reduce duplicative domestic regulation, the Government will adopt the principle that if a system, service or product has been approved under a trusted international standard or risk assessment, then Australian regulators should not impose any additional requirements, unless there is a good and demonstrable reason to do so. This will reduce costs and delays for businesses, increase the supply of products into the Australian market and allow regulatory authorities to focus on higher priorities.

We believe there is clear scope within the FSANZ proposal to more fully utilise international assessment materials and we are encouraged by FSANZ efforts to include stakeholder consultation throughout the regulatory reform process.

Australia (and New Zealand) are relatively small countries and markets and for these markets to continue to have access to innovative and safe consumer products as part of the global market, it is essential for FSANZ to consider how it can recognise and align with international standards from comparable economies, whilst maintaining public health and safety. These standards are followed by international manufacturers and importers of finished consumer goods who are active in their association with international review bodies and in a second hand fashion by smaller manufacturers and importers of goods in Australia by virtue of the origin of the raw materials that are used in their products. We believe there are opportunities within this proposed regulatory framework to optimise the use of other international risk assessments and consequently reduce the amount of Australian-specific review and assessment required and we look forward to working with FSANZ to promote this optimisation.

Regulatory Options for Nutritive Substances and Novel Foods in Australia & New Zealand

In particular there does need to be consideration of the different regulatory arrangements in place in Australia and New Zealand as this is an area where Australian-based businesses are at a disadvantage compared to New Zealand companies who have access to an additional regulatory

opportunity, the New Zealand Supplemented Food Standard, to support them in promoting innovation in the functional foods area (this standard permits the use of both nutritive substances and novel foods not currently permitted under the Food Standards Code).

In recent years there has been a noticeable increase in consumer interest with respect to the nutrition and potential health impacts of food products and their use in the diet, fuelled by the growing research and communication in this area. As there is currently a difference in the opportunities for Australian and New Zealand introducers of Nutritive Substances and Novel Foods, it is important to ensure that Australian companies and consumers are not disadvantaged by not being able to access new and innovative products.

Regulation for Novel Food Plant Sterols

Novel Food Example:

The proposed regulation for Sterols, a novel food which has been in the ANZ market for the past 16 years, is an example of a substance with a very high level of regulatory scrutiny over this period of time, including all the below regulatory assessments (and some others not specifically listed):

Date	Regulatory Assessment
July 1999	Flora pro-activ launch
16 Dec 1999	Novel Foods standard gazetted
21 Dec 1999	Request for sterol ester Novel Foods application
15 Mar 2000	Vegetable Oil Sterol Ester –Use in Vegetable Oil spreads application – submitted by Unilever (A410)
9 Mar 2000 15 Mar 2000	Vegetable Oil Sterol Esters – use in a range of foods cereal bars, bread, salad dressing, low fat milk, yoghurt applications submitted by GF/DF (A433/434)
1 Jun 2001 5 Jun 2001	Vegetable Oil sterol esters approved as a Novel Food in spreads only. Tall oil sterol application for broad range of foods, reduced to spreads only - submitted by Novartis A417
16 Jun 2001	Novel Foods standard enters into force – products not covered by A410 withdrawn from shelves
20 Jun 2002	Tall oil sterols approved as a Novel Food
30 Sept 2002	Commencement of review for A433/A434
25 Jun 2003	Tall oil sterol application for low and no fat liquid milks submitted by Parmalat (A508)

26 May 2004	Applications A433/A434/A508 under review by FSANZ
13 Apr 2005	Vegetable Oil sterols – use in fruit juice and fruit juice drinks submitted by Coca-Cola South Pacific (A560)
9 Nov 2006	Approval for use of sterols in wider range of foods – cereals, low fat yoghurt and milk A433/A434/A508
19 Dec 2006	Application Vegetable oil sterol esters –use in low fat yoghurt mini drinks – rejected
19 Feb 2010	Raisio application for use of stanols in all approved formats Approval report for A1024 Equivalence of Plant Stanols, Sterols and their fatty acid esters.

Currently and as part of the proposed regulatory drafting, plant sterols are the only listed approved novel food that has very specific case-by-case food matrix permissions. This is overly onerous and constraining, where both the novel ingredient and the food delivery matrix are closely regulated. We are supportive of working with FSANZ to explore potential regulatory options that move forward the regulatory management for use of plant sterols in an acceptable range of foods that does not rely on a format by format application process. One example for how this could be taken forward is the EU list of foods that are suitable for addition of sterols.

Finally we are willing to work with FSANZ to workshop options for a more effective regulatory framework for nutritive substances and novel foods, considering the learnings that can be gained from other international regulatory agencies and also the limitations of the current system in place in the *Food Standards Code*. We are also strongly supportive of consideration of a fair and equitable framework across both Australia and New Zealand.

Should you require further information relating to this submission, please do not hesitate in contacting me directly.

Yours sincerely


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