

**13 December 2016**  
**[31–16]**

## **Supporting document 2**

### Assessment against the Policy Guidelines – Application A1134 Increased Concentration of Plant Sterols in Breakfast Cereals

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Under Section 18 of the FSANZ Act, FSANZ must have regard to any written policy guidelines formulated by the [Australia and New Zealand Ministerial Forum on Food Regulation](#)<sup>1</sup> (the Forum). There are two policies relevant to A1134:

- Policy Guideline on Novel Foods
- Policy Guideline on the Addition to Food of Substances other than Vitamins and Minerals.

FSANZ has had regard to these Policy Guidelines and our assessment is summarised in the tables below.

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<sup>1</sup> <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

# 1 Novel foods

The table below summarises how FSANZ has had regard to the Policy Guideline on Novel Foods.

High Order Policy Principles	Approach	Does the assessment satisfy the Policy Principles
To ensure that priority is given to the protection and improvement of public health and safety in relation to food matters.	Addressed in the section about FSANZ's statutory objectives (section 2.4.2) of the assessment summary.	Yes
To ensure that consumers have access to sufficient information to enable informed and healthy food choices.	Addressed in the section about FSANZ's statutory objectives (section 2.4.2) of the assessment summary and in the section regarding labelling (2.2.4) in the assessment summary.	Yes
Be consistent with and complement Australian and New Zealand national policies and legislation including those relating to nutrition and health promotion.	Plant sterols being added to breakfast cereals is consistent with national nutrition policies in Australia and New Zealand that recommend regular consumption of breakfast cereals, especially those limiting sugar content and higher in fibre. Increased availability of plant sterols through the food supply will assist interested consumers with greater choices for increasing dietary exposures to plant sterols.	Yes
To draw on the best elements of international regulatory systems (i.e. protocols, standards, guidelines, assessment processes) and be responsive to future trends and developments (i.e. CODEX, WHO/FAO).	The Australian and New Zealand approach to regulation of novel foods, which is currently under review, draws on international experience and implementation of best practice.	Yes
To provide a regulatory environment that is timely, cost effective, transparent and consistent with minimum effective regulation, and which encourages fair trade, industry growth, innovation and international trade.	A1134 is a voluntary permission such that manufacturers can choose whether or not to add increased levels of plant sterols to breakfast cereals. FSANZ has broadened the scope of the Application to both portion-controlled and non-portion controlled breakfast cereals that meet the existing nutrient criteria. This allows for industry growth and innovation, and supports fair trade and international trade.	Yes

<b>Specific Order Policy Principles</b>	<b>Approach</b>	<b>Does the assessment satisfy the Policy Principles</b>
To ensure that public and industry confidence in the food system is maintained.	Novel foods or ingredients are required to have a pre-market safety assessment. The hazard assessment, dietary exposure assessment and labelling requirements will provide confidence for the food industry and consumers. Consultation (calling for submissions) allows direct engagement from stakeholders including the public and industry to assist in confidence with the outcomes.	Yes
To provide an assessment process that aims to protect commercially sensitive information and recognise industry's intellectual property to the maximum extent possible.	FSANZ has a specific assessment process in place to ensure access to confidential material provided by the Applicant is limited and protected to the maximum extent possible.	Yes
To ensure consumers are not misled by novel foods or food ingredients, which appear similar to existing foods but may differ in terms of nutrition or function.	Novel foods or ingredients are clearly identified in the Code, and labelling and information requirements are to ensure any declarations and/or claims made on labels are truthful and appropriate for consumers. While FSANZ develops the standards for novel foods, compliance with such requirements is not within FSANZ remit.	Yes

## Substances other than Vitamins and Minerals

The table below summarises how FSANZ has had regard to the Policy Guideline on the Addition to Food of Substances other than Vitamins and Minerals. The 'high order' principles reflect FSANZ's statutory objectives described in section 2.4.2 of the Call for Submissions and are therefore not covered in this table. 'Specific order' policy principles are provided for substances added for a technological function as well as for 'Any Other Purpose'. This Application falls under 'Any Other Purpose' and therefore regard has been given to these policy principles in the assessment of this Application.

### *Specific Order Policy Principles – Any Other Purpose*

<b>Specific Order Policy Principles</b>	<b>Approach</b>	<b>Does the assessment satisfy the Policy Principles</b>
a) the purpose for addition can be articulated clearly by the manufacturer (i.e. the stated purpose)	The purpose for adding increased amounts of plant sterols to foods is clearly articulated by the Applicant (see section 1.2 of the assessment summary).	Yes
b) the addition of the substance to food is safe for human consumption	The safety of plant sterols has been addressed by FSANZ through a number of previous applications and the current risk assessment maintains the safety of plant sterols. Information relevant to this Application is available in SD1 and is summarised in section 2.1 of the Call for Submissions.	Yes

Specific Order Policy Principles	Approach	Does the assessment satisfy the Policy Principles
c) The substance is added in a quantity and a form which is consistent with delivering the stated purpose	<p>The purpose of the Application is to allow increased concentrations of plant sterols in breakfast cereals so that 2 g of plant sterols, the amount needed per day to lower blood cholesterol levels, can be obtained from one serving. This is addressed in section 2.2.2.2 of the assessment summary.</p> <p>In relation to the form of plant sterols that is added to breakfast cereals, the assessment in a previous Application, A1024, concluded that phytosterols, phytostanols and their fatty acid esters are comparable in terms of their efficacy in lowering blood cholesterol, provided plant sterols are adequately incorporated into the food (refer to <b>SD1</b>). SD1 concludes that from a technological perspective, it is possible to add plant sterols at higher levels than currently permitted in breakfast cereals.</p>	Yes
d) The addition of the substance is not likely to create a significant negative public health impact to the general population or sub population	The risk assessment indicates the addition of plant sterols as proposed would not create a significant public health impact. This is discussed in sections 2.1 and 2.4.2.1 of the assessment summary.	Yes
e) The presence of the substance does not mislead the consumer as to the nutritional quality of the food	The Code includes conditions to prevent consumers being misled or deceived. These are discussed in section 2.4.2.3 of the assessment summary.	Yes