1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

The Authority accepted Application A1249 Addition of phytosterols, phytostanols or their esters as novel food to plant-based milk alternatives which seeks approval for the addition of phytosterols, phytostanols or their esters as novel food to plant-based milk alternatives. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation.

Following consideration by the Food Ministers' Meeting (FMM), section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

2. Variation is a legislative instrument

The approved draft variation, Food Standards (Application A1249 – Addition of phytosterols, phytostanols or their esters as novel food to plant-based milk alternatives) Variation, is a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and is publicly available on the Federal Register of Legislation (www.legislation.gov.au).

This instrument is not subject to the disallowance or sunsetting provisions of the *Legislation Act 2003.* Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunsetting if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunsetting legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the FMM. The FMM is established under the Food Regulation Agreement and the international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

The Authority has approved the draft variation amending Schedule 25 of the Code to permit the addition of phytosterols, phytostanols or their esters as a novel food to plant-based milk alternatives, subject to certain conditions.

4. Documents incorporated by reference

The approved draft variation itself does not incorporate any documents by reference.

However, section 1.1.1—15 of the Code requires certain substances (such as a novel food) to comply with any relevant identity and purity specifications listed in Schedule 3. Schedule 3 incorporates documents by reference to set specifications for various substances in the circumstances specified in that Schedule. The documents incorporated include the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Compendium of Food Additive Specifications (FAO/WHO 2019).

5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1249 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 1 July 2022 for a six-week consultation period.

The Office of Best Practice Regulation (OBPR) granted FSANZ an exemption from the requirement to develop a Regulation Impact Statement (RIS) for this application (OBPR correspondence dated 19 April 2022, OBPR ID:22-02151). This exemption was provided as the OBPR assessed that the proposed change would be deregulatory and the likely impacts to only have a minor effect on consumers, businesses and government.

6. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 44 of the *Legislation Act 2003*.

7. Variation

Item [1] of the Schedule to the approved draft variation amends Schedule 25 by adding three new conditions of use for phytosterols, phytostanols and their esters into the table to section S25-2.

The table to section S25-2 sets out permitted novel foods and their conditions for use.

Specifically, the new conditions of use (numbered 7 to 9) are included, in numerical order, in column 2 for the table item dealing with phytosterols, phytostanols and their esters.

New condition 7 permits the addition of phytosterols, phytostanols and their esters to a beverage derived from legumes, cereals, nuts, seeds, or a combination of those ingredients only if, after the addition, the following compositional limits are met:

- the calcium content of the beverage is no less than 100 mg per 100 mL; and
- the beverage contains no more than 0.75 g saturated fatty acids per 100 mL; and
- the total plant sterol equivalents content of the beverage is no less than 0.8 g and no more than 2.2 g per 250 mL of the beverage.

New condition 8 provides that a beverage to which phytosterols, phytostanols and/or their esters have been added in accordance with new condition 7 may only be sold under the brand SANITARIUM HEALTH FOOD COMPANY during the exclusive use period.

New condition 9 defines 'exclusive use period' for the purposes of new condition 8 as meaning:

> "the period commencing on the date of gazettal of the *(Application A1249 – Addition of phytosterols, phytostanols or their esters as novel food to plant-based milk alternatives) Variation* and ending 15 months after that date."

The effects of the approved draft variation are that:

- phytosterols, phytostanols and their esters may be added, as novel food, to beverages derived from legumes, cereals, nuts, seeds, or a combination of those ingredients, subject to compositional limits;
- the new permission can only be exercised in accordance with the Code, including existing conditions of use in the table to S25—2 for the addition of plant sterols to food;
- beverages to which phytosterols, phytostanols and their esters have been added in accordance with new condition 7 may only be sold under the SANITARIUM HEALTH FOOD COMPANY brand for a 15-month period commencing on the date of gazettal of the approved draft variation.

Existing regulations will apply to all other brands of plant-based milk alternatives until the end of the exclusive use period.

Once the exclusive use period ends, the exclusive use permission will revert to a general permission. This means that the new permission for the addition of phytosterols, phytostanols and their esters as novel food to beverages derived from legumes, cereals, nuts, seeds, or a combination of those ingredients, will then apply to *all* brands of those beverages that meet the specified compositional limits.