APPLICATION EXECUTIVE SUMMARY

January 2025

TO:

Food Standards Australia New Zealand

IN RELATION TO:

Application to amend Schedule 25 – Permitted Novel Foods of the Australia New Zealand Food Standards Code - extension of use to permit up to 2.2g per serve of plant sterols in bread & bread products.

This application seeks to request an amendment to the *Australia New Zealand Food Standards Code* (hereafter, the Code) to extend the permitted use of plant sterols[1] to bread and bread products to deliver an average 2g of total plant sterol equivalents per serving. The total maximum requested is 2.2g per serve.

This application is an an extension of a current permission to a new food matrix.

The proposed amendment will provide an additional source of plant sterols in the food supply for consumers seeking to lower their blood cholesterol, a modifiable risk factor for cardiovascular disease.

The proposed change will increase the accessibility to efficacious and recommended amounts of plant sterols for consumers seeking to lower their cholesterol, a modifiable risk factor for cardiovascular disease (CVD) in a daily staple – bread and bread products.

Elevated blood cholesterol is recognised as a modifiable risk factor for CVD (NVDPA, 2012; NHF AU, 2024; NHF NZ, 2024). Based on blood tests taken as part of Australia's most recent national health survey, 32.8% or 5.6 million Australians had abnormal or high total cholesterol levels (ABS, 2013). Approximately one in four New Zealand adults need to manage their cholesterol levels for their heart health.[2]

Bread and bread products are an appropriate vehicle for delivering plant sterols to consumers for the following reasons:

a) Grain (cereal) foods are recommended by the *Australian Dietary Guidelines*[3] and the *Eating and Activity Guidelines for New Zealand Adults*[4]
b) Nutrition profile of bread and bread products proposed to contain sterols will deliver dietary fibre and meet a sodium target of 380mg/100g, and
c) Plant sterol enriched bread and flour products are an effective vehicle for plant sterols.

Overall, bread products are an appropriate format and category to deliver and/or contribute towards the recommended 2g of plant sterols daily to lower cholesterol as part of a healthy diet. A sterol enriched bread with up to 2.2g per serve of plant sterols would provide a feasible and convenient option for consumers to achieve the required 2g each day.

[1] For the purpose of this application document phytosterols, phytostanols and their esters, will be referred to collectively as plant sterols.

[2] https://www.hri.org.nz/health/learn/risk-factors/risk-factors-for-cardiovascular-disease, accessed 10/01/2025
[3] The Australian Dietary Guidelines | Australian Government Department of Health and Aged Care

[4] Eating and activity guidelines – Health New Zealand | Te Whatu Ora

The applicant intends to use a commercially available phytosterol product that has been demonstrated to be soluble and uniformly distributed in bread products. This application does not seek to introduce new types of plant sterols or modify or extend the specifications for the different types of plant sterols that may be used in food in Schedule 25 of the Code.

A FAO JECFA Monograph for phytosterols, phytostanols and their esters was prepared at the 69th JECFA (2002) and published in FAO JECFA Monographs 5 (2008).

An ADI of 0-40 mg/kg bw, expressed as the sum of phytosterols and phytostanols in their free form, was established at the 69th JECFA (2008).

The requirements for Identity and purity for phytosterols, phytostanols and their esters is set out in Schedule 3 of the Code - S3-24 Specification for phytosterols, phytostanols and their esters.

The Applicant's plant sterol will comply with the JECFA Monograph which satisfies the requirements of Schedule 3 of the Code.

In the Approval Report for Application A1249 (November 2022), FSANZ stated:

FSANZ previously concluded there are no toxicological concerns regarding consumption of plant sterol-fortified foods by the general population, and that there is no justification for establishing an acceptable daily intake (ADI) for plant sterols. A review of newly available information does not indicate a need to amend this conclusion.

FSANZ has conducted several assessments of plant sterols in the past, these assessments have evaluated information on the toxicokinetics and metabolism of the plant sterols. The outcome of each previous safety assessment has been that the available data for plant sterols has been considered to provide a high level of confidence in the safety and suitability for use in specific plant sterol enriched products.

FSANZ most recent comprehensive assessment in 2022, as part of A1249 – *Addition of phytosterols, phytostanols or their esters as novel food to plant-based milk alternatives* reported the following regarding the safety of phytosterols (FSANZ 2022):

FSANZ previously concluded there are no toxicological concerns regarding consumption of plant sterol-fortified foods by the general population, and that there is no justification for establishing an acceptable daily intake (ADI) for plant sterols. A review of newly available information did not indicate a need to amend this conclusion.

FSANZ has acknowledged that although it is possible that consumers may use multiple plant sterol-enriched products, which could lead to consumption of plant sterols beyond an adequate level of intake for cholesterol reducing effects, this does not raise public health and safety concerns. The availability of additional and diverse plant sterol-enriched products would benefit consumers by increasing the range of choice available, as well as increasing the likelihood of consumers reaching an adequate intake of plant sterols recommended for cholesterol reduction.

Previous FSANZ evaluations and regulatory outcomes are supportive for plant sterols safety and suitability for amounts of 2g in one serving of plant sterol enriched foods.

The safety of the proposed use of plant sterols can be clearly demonstrated based on previous FSANZ assessments, as well as a subsequent scientific literature review conducted by the applicant. There is no basis to conclude that the proposed use of plant sterols in bread products poses any risk to any segment of the general population.