

## **Submission to:** **Food Standards Australia New Zealand**

---

In response to:

Consultation Paper - PROPOSAL P1024  
Revision of the Regulation of Nutritive Substances & Novel  
Foods

Alison Oliver  
[REDACTED]

Food Environment & Science  
Locked Bag 7,  
Central Coast Mail Centre, NSW 2252  
[REDACTED]  
[REDACTED]  
[REDACTED]

Issue No: 1.0

*"Sharing health and hope  
for a better life"*

**Issue Date: 27/7/2017**

Table of Contents

**Executive Summary..... 4**

**Introduction..... 4**

**General Approach..... 4**

**Proposed Treatment of Foods Captured Under Standard 2.9.5 ..... 5**

**Period of Exclusivity ..... 5**

**Grandfathering of Existing Foods Already on the Market..... 5**

**Conclusions & Recommendations..... 5**

## Executive Summary

Sanitarium is generally supportive of the proposed 2 pathway approach to novel foods and nutritive substances however, the detail of how these pathways will function, particularly the eligible food criteria will determine whether this approach is really feasible and still supportive of food industry innovation. Other issues raised in the Consultation Paper on Proposal P1024 that were of particular concern were: uncertainty over proposed treatment of foods captured by Standard 2.9.5 (Foods for Special Medical Purposes); retention of exclusivity period permissions; and grandfathering of foods on the market prior to a cut-off date.

## Introduction

Sanitarium Health and Wellbeing began in 1898 with the vision to help people 'learn to stay well'. Our mission is to **'inspire and resource our community to experience happy, healthy lives'**. We have been committed to this philosophy for over 100 years and it is the reason we exist today. Sanitarium also believes that good business is based on trust, respect and community involvement. Sanitarium has a strong history of educating the community about healthy eating and healthy lifestyles. All of Sanitarium's activities have twin goals in mind - to provide healthy foods that actively improve our community's health and well-being, and to offer easy-to-understand nutrition information and practical health advice.

Sanitarium Australia and Sanitarium New Zealand are owned and operated by Australian Health & Nutrition Association Limited and New Zealand Health Association respectively. We produce over 150 products and employ approximately 1700 people in our manufacturing and distribution sites throughout Australia and New Zealand.

Sanitarium welcomes the opportunity to comment on the development and evolution of the Australia & New Zealand Food Standards Code. We believe we can provide a unique perspective and give valuable suggestions into the food policy and standards development in Australia and New Zealand.

*Information contained in this submission has been drawn from the experiences of Sanitarium, and contains no commercial-in-confidence material – unless otherwise highlighted.*

## General Approach

Sanitarium is supportive of measures designed to give food manufacturers more confidence that they are compliant with the Food Standards Code. This needs to be balanced with ensuring food industry is not blocked from innovation by onerous and unnecessary regulations. Sanitarium is supportive of the proposed two pathway approach to market of novel foods and nutritive substances as it removes some uncertainty created by the self-substantiation pathway. However, the detail of how these pathways will function, particularly the eligible food criteria will determine whether this approach is really feasible and still supportive of food industry innovation.

## **Proposed Treatment of Foods Captured Under Standard 2.9.5**

Currently Standard 2.9.5-3 states that the following provisions, paragraphs 1.1.1—10(6)(b) (foods used as nutritive substances) and 1.1.1—10(6)(f) (novel foods) do not apply. 2.9.5-6 contains provisions for 'Permitted forms of particular substances'. In light of the above, the proposed removal of the definitions of novel food and nutritive substance and the proposed pathway may restrict or change the current intention of provisions within 2.9.5. It is not clear in the current consultation papers whether this has been considered and/or whether measures will be taken to ensure no unintended changes occur. We recommend this is considered and would like more information on this in the next round of consultation.

## **Period of Exclusivity**

Sanitarium supports the retention of exclusive permissions relating to use of novel foods. Exclusive permissions are an incentive for food industry to strive for innovation. When foods containing novel foods are granted exclusivity periods to allow full consumer and retailer attention on the market, the business case for that product is more attractive making it more likely to achieve launch. The maximum 15 month period currently granted, however, is arguably too brief to enable significant benefit in some cases. Costs to food industry of developing products containing novel foods can be considerable, with time needed to also develop new technology and introduce new processes into manufacturing facilities. It is a high risk scenario for food manufacturers to invest significant time into developing these products without confirmation that any application will be gazetted. Therefore, some of this development will still be occurring within the 15 month exclusivity period, thereby removing some of the exclusivity benefit. An increase of the maximum permitted exclusivity period to 3 years is recommended to help ensure benefit is received by manufacturers who have successfully lodged applications to FSANZ.

## **Grandfathering of Existing Foods Already on the Market**

Sanitarium is cautiously supportive of the approach to exempt foods already on the market prior to the commencement of the new novel foods and nutritive substances provisions (grandfathering). It is a solution that reduces the regulatory burden of introducing new Food Standards Code requirements and therefore desirable, however some points of concern with this approach are: whether this encourages a rush to market of food products possibly containing novel ingredients to avoid being subject to the new provisions; whether novel food applications current in progress would need to be reviewed under the new provisions meaning that applications may need to be revised causing extra costs to the applicant. Sanitarium recommends these issues be considered when developing plans for the introduction of the new provisions.

## **Conclusions & Recommendations**

Sanitarium is generally supportive of the proposed 2 pathway approach and looking forward to reviewing more detail about this in the next round of public consultation.

Sanitarium has the following recommendations in relation to specific issues raised in the current Consultation Paper:

- Clarity over how foods captured by Standard 2.9.5 will be affected by changes to novel foods and nutritive substances provisions in the Code;

- Retention of the exclusivity period permissions and extension to three years for the maximum period;
- Further consideration of how foods already on the market prior to a cutoff date will be subjected to the new provisions in order to adequately protect consumer health and safety;
- Further consideration of how in-progress applications for novel foods will be treated once the new provisions are gazetted.