

# Explanatory Statement

## 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.

FSANZ accepted Application A1124 which seeks to permit the addition of DHA-rich algal oil from *Schizochytrium* sp. (American Type Culture Collection (ATCC) PTA-9695) as an additional or alternative source of DHA oil for other currently permitted DHA-rich algal oils added to infant formula products.

The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation setting out amendments to Schedule 3 and Schedule 25.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunseting under the Legislation Act 2003.

## 2. Purpose

The purpose of the draft variation is to permit the voluntary use of oil derived from marine micro-algae *Schizochytrium* sp. (American Type Culture Collection (ATCC) PTA-9695) as a source of DHA in infant formula products.

## 3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

## 4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1124 included one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary.

Submissions were called for on 1 November 2016 for a six-week consultation period.

A Regulation Impact Statement was not required because the variations proposed are voluntary and likely to have a minor impact on business and individuals.

## **5. 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 94 of the FSANZ Act.

## **6. Variation**

**Subitem [1.1]** amends Schedule 3 by inserting a reference into the table to subsection S3—2(2) to oil derived from marine micro-algae *Schizochytrium* sp. (ATCC PTA-9695) and to section S3—36.

**Subitem [1.2]** amends Schedule 3 by inserting new section S3—36 in that Schedule. The new section provides a specification for oil derived from marine micro-algae *Schizochytrium* sp. (ATCC PTA-9695).

**Item [2]** amends Schedule 25 by inserting a reference into the table to section S25—2 to oil derived from marine micro-algae *Schizochytrium* sp. (ATCC PTA-9695). The new reference contains a condition that the oil may only be added to infant formula products in accordance with Standard 2.9.1. The effect of the amendment is to provide a novel food permission for the use of the oil in only infant formula products.