# EXPLANATORY STATEMENT

*Food Standards Australia New Zealand Act 1991*

## *Food Standards (Application A1300 – Vitamin K2 (as Menaquinone-7) as a permitted form of Vitamin K in FSMP) Variation*

### 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 A1300 which seeks to permit the use of vitamin $K_2$ (as menaquinone-7) as a form of vitamin K in food for special medical purposes (FSMP). The Authority considered the Application in accordance with Division 1 of Part 3 of the FSANZ Act and has prepared a draft variation - the *Food Standards (Application A1300 – Vitamin K2 (as Menaquinone-7) as a permitted form of Vitamin K in FSMP) 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 draft variation.

### 2. Variation is a legislative instrument

The approved draft 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.

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 a draft variation to the Code amending the table to section S29—20 of Schedule 29 to include vitamin $K_2$ (as menaquinone-7) as a permitted form of vitamin K that may be added to food for special medical purposes (FSMP).

## 4. Documents incorporated by reference

The approved draft variation prepared by the Authority does not incorporate any documents by reference.

However, existing provisions of the Code incorporate documents by reference that prescribe specifications for the vitamin form permitted in the approved draft variation. Section 1.1.1—15 of the Code requires certain substances (such as substances used as nutritive substances) to comply with any relevant identity and purity specifications listed in Schedule 3 of the Code.

Schedule 3 incorporates documents by reference to set specifications for various substances in accordance with requirements specified in that Schedule. The documents incorporated include: the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Combined Compendium of Food Additive Specifications (FAO JECFA Monographs 26 (2021)); the United States Pharmacopeial Convention (2022) Food Chemicals Codex (13th edition); and the Commission Regulation (EU) No. 231/2012.

## 5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1300 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 13 September 2024 for a four-week consultation period. Further details of the consultation process, the issues raised during consultation and by whom, and the Authority's response to these issues are available in an approval report published on the Authority's website at www.foodstandards.gov.au.

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA)[1]. Impact analysis is no longer required to be finalised with the OIA. Prior to these changes, the OIA advised FSANZ that a Regulatory Impact Statement (RIS) was not needed for applications relating to nutritive substances. This is because applications relating to permitting the use of nutritive substances that have been determined to be safe are considered to be minor and deregulatory in nature as their use will be voluntary if the draft variation concerned is approved. Under this approach, FSANZ's assessment is that a RIS is not required for this application.

## 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

[1] Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis (pmc.gov.au)

Clause 1 of the draft variation provides that the name of the variation is the *Food Standards (Application A1300 Vitamin K2 (as Menaquinone-7) as a permitted form of Vitamin K in FSMP) Variation.*

Clause 2 of the draft variation provides that the Code is amended by the Schedule to the variation.

Clause 3 of the draft variation provides that the variation will commence on the date of gazettal of the instrument.

**Item [1]** of the Schedule to the draft variation inserts a new entry into the table to subsection S29—20 of the Code. The new entry inserts “Vitamin K” as a substance that may be added to food for special medical purposes. The new entry also inserts the permitted form of Vitamin K as “Vitamin $K_2$ (as menaquinone-7)”.

The effect of this amendment is to permit the addition of vitamin K in the form of Vitamin $K_2$ (as menaquinone-7) to FSMP in accordance with the Code.