13 September 2024
307-24

Call for submissions – Application A1300

A1300 – Vitamin K2 (as Menaquinone-7) as a permitted form of Vitamin K in FSMP

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Novozymes Australia Pty Ltd to amend the Australia New Zealand Food Standards Code to permit the use of Vitamin K_2 (as menaquinone-7) as a permitted form of vitamin K in food for special medical purposes and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

Submissions on this application need to be made through the Consultation Hub (https://consultations.foodstandards.gov.au/).

All submissions on applications and proposals will be published on our website. We will not publish material that we accept as confidential. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1982*. Submissions will be published as soon as possible after the end of the submission period.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at information for submitters.

For information on how FSANZ manages personal information when you make a submission, see FSANZ's Privacy Policy.

FSANZ also accepts submissions in hard copy to our Australia and/or New Zealand offices. There is no need to send an email or hard copy of your submission if you have submitted it through the FSANZ Consultation Hub.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 11 October 2024

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

For information about making a submission, visit the FSANZ website at current calls for public comment and how to make a submission.

Questions about making a submission or application and proposal processes can be sent to standards.management@foodstandards.gov.au.

Submissions in hard copy may be sent to the following addresses:

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PO Box 5423
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Supporting document

The following document which informed the assessment of this Application is available on the FSANZ website:

SD1 Risk and technical assessment – Application A1300

Executive summary

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Novozymes Australia Pty Ltd to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of vitamin K_2 (as menaquinone-7) as a permitted form of vitamin K in food for special medical purposes (FSMP). FSMP partially or totally replace the daily diet and are recommended for use under medical supervision.

Division 3 of Standard 2.9.5 of the Code permits substances that may be added to FSMP, including vitamins and their permitted forms (see paragraph 2.9.5—6(1)(a) which refers to substances that are listed in Column 1 of the table to section S29—20 and that are in a corresponding form listed in Column 2 of that table).

In the Code, vitamin K is currently explicitly permitted for use in FSMP as vitamin K_1 (as phylloquinone) (see section S29—7). FSANZ undertook an assessment to determine the bioavailability and nutritional equivalence of menaquinone-7 (MK-7) in comparison with phylloquinone. The assessment also considered whether there were any safety concerns from the use of MK-7 in FSMP. Based on the available evidence, FSANZ considers that MK-7 is a safe and bioavailable form of vitamin K.

FSANZ's safety and technical risk assessment concluded there is no evidence of a public health and safety concern associated with the use of MK-7 as a permitted form of vitamin K in FSMP under the existing regulatory measures of Standard 2.9.5.

FSANZ has prepared a draft variation to the Code, which if approved would amend the table to section S29—20, by including vitamin K_2 (as menaquinone-7) as a permitted form of vitamin K that may be added to FSMP.

The draft variation does not include any amendments to the existing compositional, labelling or other requirements for FSMP. There is a specification in the Code for MK-7 (see S3—3(b)) with which the applicant's MK-7 would have to comply.

The draft variation, if approved, would permit the use of vitamin K_2 (as menaquinone-7) as a form of vitamin K in FSMP in accordance with the Code.

FSANZ now seeks submissions on the draft variation (Attachment A).

1 Introduction

1.1 The Applicant

Novozymes Australia Pty Ltd (Novozymes), a subsidiary of Novonesis, is a biotechnology-based company covering the consumer, agricultural and industrial sectors.

1.2 The Application

The purpose of this application is to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of vitamin K_2 (as menaquinone-7) as a permitted form of vitamin K in food for special medical purposes (FSMP). The dietary intake of vitamin K is recommended by the Nutrient Reference Values for Australia and New Zealand (NRV) (NHMRC 2006), and the applicant intends to add menaquinone-7 (MK-7) as a form of Vitamin K to FSMP

There are two main biologically active forms of vitamin K: phylloquinone (vitamin K_1), and menaquinone (vitamin K_2). The application states that MK-7 is a specific form of vitamin K_2, with a unique chemical structure and metabolism that affects the bioavailability and potential health outcomes. Vitamin K compounds, including MK-7, are fat-soluble vitamins, are considered an essential cofactor in humans, and are naturally occurring in food.

This application does not propose any variation to the existing compositional, labelling or other existing Code requirements for FSMP.

1.3 The current standard

1.3.1 Australia and New Zealand

Australian and New Zealand food laws require food for sale to comply with the following requirements in the Code.

Standard 2.9.5 – Food for special medical purposes regulates the sale, composition and labelling of FSMP. A FSMP is defined in section 1.1.2—5 to mean a food specially formulated for the dietary management of individuals:

i) by way of exclusive or partial feeding, who have special medically determined nutrient requirements or whose capacity is limited or impaired to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients in ordinary food; and
ii) whose dietary management cannot be completely achieved without the use of the food.

A FSMP is a food that is represented as being a food for special medical purposes; or for the dietary management of a disease, disorder or medical condition. A FSMP is intended to be used under medical supervision.

By definition, a FSMP cannot be an infant formula product or a food specially formulated for the dietary management of overweight and obesity and which is not a very low energy food.

1.3.1.1 Permitted use

'Food for special medical purposes' are foods specially formulated for the dietary management of individuals (including children and adults) with certain diseases, disorders or medical conditions. FSMP are required when the dietary management of individuals cannot be easily or completely achieved with other dietary modification including the use of other

special purpose foods. FSMP includes formulated dietary products that are intended for use as the sole source of nutrition, either consumed orally or through an enteral route, in addition to specialised supplementary formulated products. Food regulated by standard 2.9.5 is intended to be used under medical supervision. Due to the specialised nature and purpose of these foods, this standard also includes a restriction on the premises at which, and the persons by whom, FSMP may be sold to consumers.

Subsection 2.9.5—6(1) of the Code permits the addition of the following substances to FSMP:

> *(a) a substance that is listed in Column 1 of the table to section S29—20 and that is in a corresponding form listed in Column 2 of that table;*
> *(b) a substance that is listed in Column 1 of the table to section S29—7 and that is in a corresponding form listed in Column 2 of that table;*
> *(c) any other substance, regardless of its form, that is permitted under this Code to be added to a food, if that substance is added in accordance with any applicable requirement of this Code.*

Paragraph 2.9.5—6(1)(b) of the Code permits the addition of substances listed in Column 1 of the table to section S29—7 to FSMP, expressly permitting the addition of vitamin K in the permitted form of vitamin K_1 as phylloquinone (phytonadione).

This application seeks to include vitamin K_2, (as menaquinone-7) as a permitted form of vitamin K in the table to section S29—20, which lists the substances which may be added to FSMP.

Section 2.9.5—7 of the Code includes compositional requirements for FSMP that are represented as being suitable for use as a sole source of nutrition, including minimum and maximum amounts of each vitamin that these foods must contain. This application does not seek to amend the minimum level or impose a maximum level for vitamin K set in the table to section S29—21.

1.3.1.2 Identity and purity

Subsection 1.1.1—15(2) of the Code requires that a substance used as a nutritive substance must comply with any relevant specification set out in Schedule 3 (‘Identity and purity’)., Therefore, Vitamin K_2 (as MK-7) would be required to comply with the existing specification outlined in paragraph S3—3(b). No new specification will be required in Schedule 3.

1.3.1.3 Labelling requirements

Subsection 1.1.1—10(8) of the Code requires that food for sale must comply with all relevant labelling requirements in the Code for that food.

Paragraph 2.9.5—3(b) states that unless the contrary intention appears, Part 1.2 – ‘Labelling and Other Information Requirements’ does not apply to FSMP. Instead, Division 4 of standard 2.9.5 sets out labelling requirements specific to FSMP, with section 2.9.5—9 detailing the mandatory information that must be provided on the label of FSMP. Paragraph 2.9.5—9(1)(h) provides that the label that is required for FSMP must state the nutrition information in accordance with section 2.9.5—13. Section 2.9.5—13 requires the minimum amount or average quantity of any vitamin that has been used as a nutritive substance in the food to be provided.

1.3.2 International standards

In developing food regulatory measures, FSANZ must have regard to the promotion of

consistency between domestic and international food standards. In terms of food safety, the relevant international standard setting body is the Codex Alimentarius Commission (Codex).

1.3.2.1 Codex Alimentarius (Codex)

Codex has not established compositional standards relating to foods which may be considered FSMP internationally, except for foods used in weight control diets (Codex 2023a) and very low energy diets for weight reduction (Codex 2023b). In Australia and New Zealand, the definition of FSMP in section 1.1.2—5 of the Code excludes a food which is specially formulated for the dietary management of overweight and obese and which is not a very low energy food. Irrespective of the current requirements of the Code in this regard, the Codex standards mentioned above do not specify permitted forms for nutrients, including vitamin K.

Codex has, however, established a list of permitted forms for nutrients for FSMP for infants and young children (Codex 2023c; Codex 2023d). Vitamin K is permitted in the form of vitamin K_1. As mentioned, Codex does not define the compositional requirements for FSMP or define a list of substances used for nutritive purposes in FSMP.

1.3.2.2 United States (US)

Vitamin K_2 (as MK-7) has been determined as 'Generally Recognized as Safe' (GRAS) in the US to be added to nutritional beverages (GRAS notice GRN 887) via the GRAS process system, with a US Food and Drug Administration (FDA) 'no questions' letter (US FDA 2020). The nutritional beverages category that is the subject of this notification covers equivalent products to FSMP.

1.3.2.3 European Union (EU)

Menaquinone (occurring principally as MK-7) is permitted to be used as a source of vitamin K in both Foods for Special Medical Purposes and Total Diet Replacement Products for Weight Control in Regulation (EU) No 609-2013 (EU 2013).

1.4 Reasons for accepting Application

The application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act)
- it related to a matter that warranted the variation of a food regulatory measure.

1.5 Procedure for assessment

The application is being assessed under the General Procedure outlined in the FSANZ Act.

2 Summary of the assessment

2.1 Risk assessment

FSANZ has assessed the public health and safety risks associated with vitamin K_2 (as MK-7) for its proposed inclusion as a permitted form of vitamin K in FSMP. FSANZ conducted the comprehensive risk assessment following the internationally recognised risk analysis framework based on a weight of evidence approach, combining information and scientific evidence provided by the applicant with independent sources. The risk assessment is included in Supporting Document 1 (SD1). This section provides a summary of this

assessment.

The food technology assessment concluded that MK-7 can be added and incorporated in a uniform manner into food products in the same way as other lipid soluble vitamins, including vitamin K_1. It has good stability at both standard and accelerated storage conditions. There is a specification for MK-7 in the Code with which the applicant's MK-7 would have to comply.

In order to determine whether MK-7 is an equivalent source of vitamin K in the diet, FSANZ considered human studies that measured the absorption of MK-7 and the effect of MK-7 supplementation on biomarkers of vitamin K status. Following supplementation, blood MK-7 concentrations increased compared to placebo or baseline in all studies, with greater levels of absorption compared to vitamin K_1 at similar intake. Supplementation with MK-7 also resulted in an improvement in biomarkers for vitamin K status at doses of 90 to 360 µg/day. FSANZ concluded that, based on the available evidence in human studies, MK-7 is a bioavailable form of vitamin K which would be expected to support normal physiological function at doses of 90 to 360 µg/day. Due to a lack of human studies that compare the bioavailability of MK-7 with vitamin K_1 at current recommended levels, FSANZ cannot determine to what extent MK-7 would support essential requirements for vitamin K at current Adequate Intakes (AI), when it is the only form of vitamin K in the diet. However FSMP are used under the supervision of a medical practitioner and can be modified as required.

No evidence was identified to indicate that MK-7 would inhibit the absorption of other nutrients.

There is a history of safe human consumption of MK-7 from the diet, and MK-7 is also produced endogenously by gastrointestinal bacteria. No adverse effects of MK-7 were identified in toxicity studies in laboratory animals and clinical studies in humans. Toxicity studies with the structurally related compound MK-4 (menatetrenone) were also considered as supporting evidence. A comparison of estimated dietary intakes of MK-7 to the no observed adverse effect level (NOAEL) in a chronic toxicity study with MK-4 resulted in a large margin of exposure (< 5400), indicating no safety concerns.

There is a potential for interaction between MK-7 and vitamin K antagonist (VKA) anticoagulant drugs, but patients on anticoagulant therapy receive medical advice about the risk of an interaction with vitamin K supplements, and individuals consuming FSMP are under medical supervision.

This risk assessment concluded that there are no public health and safety concerns associated with the use of MK-7 as a permitted form of vitamin K in FSMP.

2.2 Risk management

The risk management options available to FSANZ after assessment are to either:

- reject the application, or
- prepare a draft variation to the Code.

For the reasons outlined in this report, FSANZ decided to prepare a draft variation to the Code to include vitamin K_2 (as menaquinone-7) as a permitted form of vitamin K that may be added to FSMP.

On the basis of the findings of the risk assessment (see section 2.1 of this report and SD1), FSANZ considers the use of vitamin K_2 (as MK-7) for the proposed purpose is both safe and technologically justified. The risk management response to matters raised by the risk assessment are detailed below.

2.2.1 Background to overarching risk management strategies in Standard 2.9.5

Standard 2.9.5 – 'Food for special medical purposes' regulates the sale, composition and labelling of foods specially formulated for the dietary management of individuals (including children and adults) with certain diseases, disorders or medical conditions. FSMP are required when the dietary management of individuals cannot be easily or completely achieved with other dietary modification including the use of other special purpose foods. FSMP includes formulated dietary products that are intended for use as the sole source of nutrition, either consumed orally or through an enteral route (for example, naso-gastric tube), in addition to specialised supplementary formulated products. Food regulated by this standard is intended to be used under medical supervision. Due to the specialised nature and purpose of these foods, this standard also includes a restriction on the premises at which, and the persons by whom, FSMP may be sold to consumers.

Nearly all FSMP are imported from the EU or US, with the majority from the EU. In order to limit the impost on manufacturers and therefore ensure continued supply of these products to Australia and New Zealand, the existing compositional (including permitted forms of nutrients) and labelling requirements in Standard 2.9.5 harmonise where possible with overseas regulations.

Standard 2.9.5 allows manufacturers to vary the micronutrient composition of FSMP from the specified limits for a specific medical purpose (including a particular medical condition, disease or disorder). FSANZ's previous assessments in the development of Standard 2.9.5 considered the potential risk of inadequate or excessive nutrient intakes in both children and adults to be minimal as FSMP are used under the supervision of medical practitioners and dietitians and the nutritional status of the patient is closely monitored.

2.2.2 Required permission for substances that may be added to FSMP

The addition in the Code of a new permitted form of nutrient for use in FSMP requires an application to FSANZ to amend the Code. If permission to add a new form is sought, its bioavailability must be assessed and compared with the current permitted forms. Bioavailability in a nutritional context is the proportion of the ingested nutrient that is absorbed and utilised through normal metabolic pathways. Vitamin K does not have standard equivalence factors to determine bioavailability or equivalence. Therefore, assessment was informed by the body of evidence on the effect of MK-7 supplementation on biochemical markers.

FSANZ concluded that based on the best available evidence, MK-7 meets its stated purpose as a bioavailable form of vitamin K in FSMP, which in humans would be expected to support normal physiological function. As demonstrated in the assessment of the human bioequivalence studies (see SD1), MK-7 reacts similarly to vitamin K_1 in the body. As described in section 2.2.1 of this report, the micronutrient composition of FSMP can be varied from the specified limits, noting there is no prescribed maximum level for vitamin K.

The application states that the intended purpose is for MK-7 to be used as a permitted form of vitamin K in FSMP, with no specification of age restrictions. FSANZ has considered the request and completed the assessment within the existing regulatory arrangements. By definition, a FSMP cannot be an infant formula product. However, the FSMP definition does not exclude medical purpose products based on the age for which they are intended. Therefore, according to the definition, a FSMP can include medical purpose products for infants other than infant formula products as defined in Standard 1.1.2 of the Code. For example, Standard 2.9.1 does not include modulatory products such as human milk fortifiers and pre-term supplementary products for infants as these do not meet the definition for an infant formula product. Therefore, these products are captured by Standard 2.9.5 and existing regulatory requirements will apply.

FSANZ concluded there was no evidence of a public health and safety concern associated with the use of MK-7 as a permitted form of vitamin K in FSMP under the existing regulatory measures of Standard 2.9.5. As described in section 2.1 of this report, there is the potential for an interaction between vitamin K (including MK-7 and any other forms) and vitamin K antagonist anticoagulant drugs. Individuals receiving anticoagulant therapy are provided with advice about the risk of an interaction with vitamin K supplements. This risk is further mitigated by the requirement that FSMP are consumed under medical supervision.

While there are NRV recommendations (adequate intake, AI) for vitamin K for each life stage, there are no upper levels for intake (UL) set for any form of vitamin K (NHMRC 2006). FSANZ's assessment concluded that MK-7 was well tolerated and not associated with significant adverse events in human clinical studies in which it was administered up to 360 µg/day for 12 months, 180 µg/day for 3 years or 1080 µg/day three times per week for 8 weeks (see SD1). As a result, the use of MK-7 is considered safe for adults, adolescents and children.

The AI of vitamin K for women is consistently 60 µg/day, regardless of their pregnancy or lactation status (NHMRC 2006). This is due to vitamin K requirements not differing during pregnancy, and the vitamin K content of human milk being low and not affected by maternal diet (NHMRC 2006). It is therefore expected that the use of MK-7 in FSMP, where prescribed and supervised by a medical practitioner or dietitian, will not represent a safety concern for this subpopulation.

The NRVs are recommendations for dietary intake in healthy populations. However, individual requirements can vary from these population recommendations particularly in unwell or vulnerable groups. These factors are considered on an individual, case by case basis when FSMP are being supplied to patients. Standard 2.9.5 requires manufacturers to provide information regarding the total volume of their product that is required for nutritional adequacy when used as a sole source of nutrition (for example, nutritionally complete in 1.5 litres) in addition to the nutrient composition of a product. These are then used to assess the nutritional adequacy of a product against disease specific requirements where known, or at least against a cautious application of a NRV where indicated for a medical condition. If it is determined that any nutrients are not complete in a given volume over a long period of time, this would be monitored by the medical practitioner or dietitian. Micronutrient supplements or multivitamin preparations can also be used where required to account for any nutrient deficit and ensure nutritional adequacy.

Very Low Energy Diets (VLED) are regulated under Division 5 of Standard 2.9.5, following the approval of Application A1230 – Very Low Energy Diets. Section 2.9.5 – 18 involves the prescription of a set nutrient composition, labelling requirements and optional additional intakes for VLED. The A1230 assessment of VLED on the Australia and New Zealand market concluded that among other nutrients, vitamin K met the relevant NRV requirement, and did not compromise nutritional adequacy or safety (FSANZ 2022). Consequently, vitamin K was not found to be a nutritional requirement of VLED, but may be added at the discretion of the manufacturer. As a specific type of FSMP, the permitted forms of nutrients for VLED are included in section S29—7 and section S29—20. As a result, if approved, the draft variation prepared by FSANZ would permit MK-7 as a source of vitamin K in VLED.

The risk assessment concluded that there is no evidence of a public health and safety concern associated with the use of MK-7 as a permitted form of vitamin K in FSMP within recommended intake levels of vitamin K. This is further supported by the existing requirements in standard 2.9.5 to manage any risks associated with the proposed use of MK-7 as a form of vitamin K, including its intended use under medical supervision and restrictions relating to access and sale. Therefore, FSANZ has prepared a draft variation to permit the use of MK-7 as a form of vitamin K in FSMP.

2.2.3 Labelling requirements

The application does not seek to vary any labelling requirements for FSMP. Division 4 of Standard 2.9.5 sets out labelling requirements specific to FSMP. Section 2.9.5—9 sets out the mandatory labelling information required for FSMP, which relevantly include:

- paragraph 2.9.5—9(1)(e) requires the provision of information relating to ingredients. The use of vitamin K_2 (MK-7) as an ingredient in FSMP would require information to be provided in accordance with section 2.9.5—11.
- paragraph 2.9.5—9(1)(h) requires the provision of nutrition information in accordance with section 2.9.5—13. This includes providing the minimum amount or average quantity of any substance listed in the table to section S29—20 that has been used as a nutritive substance in the food (see subparagraph 2.9.5—13(1)(b)(iii)). This would apply to the use of MK-7 as a permitted form of vitamin K.

2.2.4 Risk management conclusion

Based on the risk assessment and consideration of the objectives of the FSANZ Act (see section 2.4 of this report) and relevant Ministerial Policy Guidelines (see section 2.4.3 of this report), the risk management conclusion is to prepare a draft variation to permit the addition of vitamin K_2 (as MK-7) as a form of vitamin K in FSMP. If approved, vitamin K_2 (as MK-7) as a permitted form of vitamin K, would be inserted in the table to section S29—20, which sets out substances that may be added to food for special medical purposes and their corresponding permitted forms.

2.3 Risk communication

2.3.1 Consultation

Consultation is a key part of FSANZ's standards development process.

FSANZ developed and applied a standard communication strategy to this application. All calls for submissions are notified via the FSANZ Notification Circular, media release, FSANZ's social media channels and Food Standard News. Subscribers and interested parties are also notified about the availability of reports for public comment.

The process by which FSANZ approaches standards development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on the draft variation.

The draft variation will be considered for approval by the FSANZ Board taking into account all public comments received on this call for submissions.

The applicant and individuals and organisations that make submissions on this application will be notified at each stage of the assessment.

2.3.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are not substantially the same as existing international standards and the proposed measure may have a significant effect on trade.

Amending the Code to permit vitamin K_2 (as MK-7) as a form of vitamin K in FSMP is unlikely to have a significant effect on international trade as this substance is already permitted in similar products in some countries overseas. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or

Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.4 FSANZ Act assessment requirements

When assessing this application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 29 of the FSANZ Act:

2.4.1 Section 29

2.4.1.1 Consideration of costs and benefits

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 Regulation Impact Statement (RIS) was not required for applications relating to the voluntary addition of nutritive substances to foods. 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 the new approach, FSANZ's assessment is that a RIS is not required for this application.

FSANZ, however, has given consideration to the costs and benefits that may arise from the proposed measure for the purposes of complying with FSANZ Act requirements. The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 29(2)(a)).

The purpose of this consideration is to determine if the community, government, and industry as a whole is likely to benefit, on balance, from a move from the status quo (where the status quo is rejecting the application). This analysis considers the costs and benefits of permitting vitamin K_2 (as MK-7) as a permitted form of vitamin K that may be added to FSMP.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, in fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the potential positives and negatives of moving away from the status quo by permitting vitamin K_2 (as MK-7) for voluntary addition to FSMP.

FSANZ's conclusions regarding the costs and benefits of the proposed measure are set out below. However, information received from the call for submissions may result in FSANZ arriving at a different outcome.

Costs and benefits of permitting vitamin K_2 (as MK-7) for voluntary addition to FSMP

Industry may benefit from an additional choice of vitamin K permitted to be used in FSMP. Due to the voluntarily nature of the permission, businesses would only use vitamin K_2 (as MK-7) in FSMP where they believe a commercial net benefit exists for them. Permitting the proposed use of vitamin K_2 (as MK-7) could result in FSMP of greater quality and/or lower cost to consumers.

Approving the proposed draft variation may result in a small but likely insignificant cost to government in terms of an addition to the current range of nutritive substances which are monitored for compliance.

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

Conclusions from cost benefit considerations

FSANZ assessment is that the direct and indirect benefits that would arise from permitting vitamin K_2 (as MK-7) as proposed, are likely to outweigh the associated costs.

2.4.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the application.

2.4.1.3 Any relevant New Zealand standards

The relevant standards apply in both Australia and New Zealand. There are no relevant New Zealand only standards.

2.4.1.4 Any other relevant matters

Other relevant matters are considered below.

2.4.2. Subsection 18(1)

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

2.4.2.1 Protection of public health and safety

FSANZ has undertaken a safety assessment (see section 2.1 of this report and SD1) and concluded there is no evidence of a public health and safety concern associated with the proposed use of vitamin K_2 (as MK-7) as a permitted form of vitamin K in FSMP under the existing regulatory measures of standard 2.9.5.

2.4.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

Under Standard 2.9.5, FSMP are intended to be used under medical supervision, ultimately allowing medical practitioners and dietitians to determine whether the FSMP is appropriate and safe for their patient's specific needs.

Existing labelling requirements for FSMP would apply if vitamin K_2 (as MK-7) is added to FSMP (see sections 1.3.1.3 and 2.2.3 of this report), which would provide information to assist medical practitioners and dietitians and enable informed consumer choice.

2.4.2.3 The prevention of misleading or deceptive conduct

There are no issues identified with this application relevant to this objective.

2.4.3 Subsection 18(2) considerations

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

FSANZ has used the best available scientific evidence to assess this application. The applicant submitted a dossier of scientific studies as part of this application. FSANZ also had regard to other relevant information including scientific literature in assessing this application.

- **the promotion of consistency between domestic and international food standards**

FSANZ considered the promotion of consistency between domestic and international food standards and the desirability of an efficient and internationally competitive food industry. The proposed permission in the Code to use vitamin K_2 (as MK-7) as a form of vitamin K in FSMP is consistent with similar permissions for vitamin K_2 (as MK-7) in other countries including United States and Europe. Codex compositional standards relating to foods which may be considered FSMP internationally do not specify permitted forms for nutrients, including vitamin K.

- **the desirability of an efficient and internationally competitive food industry**

The proposed permission in the Code would allow for a competitive food industry in relation to FSMP.

- **the promotion of fair trading in food**

No issues were identified for this application relevant to this objective.

- **any written policy guidelines formulated by the Food Ministers' Meeting**

The *Policy Guideline on the Intent of Part 2.9 of the Food Standards Code – Special Purpose Foods*[2] states the composition of special purpose food should be consistent with the intended purpose. Based on FSANZ's assessment, FSANZ considers that the Policy Guideline has been complied with.

3 Draft variation

The draft variation to the Code is at Attachment A and is intended to take effect on gazettal.

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

4 References

Codex (2023a) Standard for Formula Foods for Use in Weight Control Diets. Codex CXS 181-1991. Codex Alimentarius Commission, Rome. Available online at: https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B181-1991%252FCXS_181e.pdf

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Attachments

A. Draft variation to the Australia New Zealand Food Standards Code
B. Draft Explanatory Statement

Attachment A – Draft variation to the *Australia New Zealand Food Standards Code*

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

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The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by the Delegate]

[Name and position of Delegate]
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Application A1300 Vitamin K2 (as Menaquinone-7) as a permitted form of Vitamin K in FSMP) Variation.*

2 Variation to a Standard in the *Australia New Zealand Food Standards Code.*

The Schedule varies a Standard in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

Schedule

Schedule 29 – Special purpose foods

[1] Section S29—20 (table item dealing with Vitamins)

Insert:

Vitamin K	Vitamin K_2 (as menaquinone-7)

Attachment B – Draft Explanatory Statement

DRAFT 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*.

2. Variation will be a legislative instrument

If approved, the draft variation would be a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and be publicly available on the Federal Register of Legislation (www.legislation.gov.au).

If approved, this instrument would not be 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 Food Ministers Meeting (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 prepared a draft variation to the Code amending the table to section S29—20 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).

The amendment in the draft variation would permit the use of vitamin K_2 (as menaquinone-7) as a form of vitamin K in FSMP in accordance with the Code.

4. Documents incorporated by reference

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

However, existing provisions of the Code incorporate documents by reference that would prescribe specifications for the vitamin form to be permitted in the 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 (2020) United States 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 will include one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. A call for submissions (including the draft variation) will be open for a four-week period.

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA) [3]. 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 was because applications relating to permitting the use of nutritive substances that have been determined to be safe were considered to be minor and deregulatory in nature as their use would 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

If approved, this instrument would be 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

Clause 1 of the draft variation provides that the name of the variation is the *Food Standards*

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

(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.

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

If approved, the effect of this amendment would be to permit the addition of vitamin K in the form of vitamin K_2 (as menaquinone-7) to FSMP in accordance with the Code.