FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

11 December 2025
372-25

Rejection – Application A1294

Moringa oleifera as a novel food

FSANZ has assessed an application made by Noosa Organica Pty Ltd to amend the Australia New Zealand Food Standards Code to permit the following novel foods to be sold as food for retail sale or be an ingredient or component in a food for retail sale; *Moringa oleifera* leaves, immature seed pods and oil.

Pursuant to paragraph 30(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act), FSANZ has rejected the application. The reasons for FSANZ's decision are contained in this assessment report.

Information about rights for a review of this decision is provided in this report and in Part 6 of the FSANZ Act.

Table of contents

Supporting document

The following document which informed the assessment of this application is available on the A1294 page on the FSANZ website:

SD Risk and technical assessment

Executive summary

Noosa Organica Pty Ltd applied to Food Standards Australia New Zealand (FSANZ) to amend the Australia New Zealand Food Standards Code (the Code) to permit the following foods derived from the *Moringa oleifera* plant, which are novel foods, to be sold as food for retail sale or be an ingredient or component of a food for retail sale:

- fresh and dried leaf
- immature (green) pods
- oil (from the seed).

FSANZ has completed a risk assessment to evaluate public health and safety concerns that may arise if the proposed sale and use of that food is permitted by the Code. Following consideration of all available data provided in the application and the peer reviewed literature, FSANZ was unable to establish the safety of *Moringa oleifera* (leaves, immature seed pods and oil) for human consumption and has therefore decided to reject the application.

Reasons for decision

After assessing the application and the evidence in accordance with the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act), FSANZ decided to reject the application for the reasons stated in this report. In summary, these are:

- In assessing this application, FSANZ must have regard to the protection of public health and safety and whether the novel food, if permitted, is safe for human consumption.

- FSANZ's risk assessment, using the best available scientific evidence, identified a potential hazard for *Moringa oleifera* leaf but insufficient information was available to characterise the risk. There was also insufficient information to determine whether the same potential hazard is associated with seed pods or oil from *Moringa oleifera*. Therefore, FSANZ was unable to establish that *Moringa oleifera* would not pose a safety concern if permitted for sale. In particular, the best available scientific evidence did not enable key safety considerations such as the following to be adequately characterised:

    - The identity and quantity of undesirable substances potentially present in relevant parts of the *Moringa oleifera* plant.
    - The potential for adverse effects in the short term or long term, such as established by guideline-compliant toxicity studies in animals.
    - The abortifacient effects of *Moringa oleifera* observed in animal studies for the leaf and aqueous or ethanolic extracts of the leaf.
    - Anecdotal reports of use of *Moringa oleifera* as a contraceptive and abortifacient in humans.
    - The potential genotoxicity of *Moringa oleifera* addressing all genotoxicity endpoints, as demonstrated by appropriate studies conducted according to relevant guidelines.

Given the above, FSANZ was unable to conclude that *Moringa oleifera* (leaves, immature seed pods and oil) would not pose a safety concern if permitted as a food for retail sale or as an ingredient or component in food for retail sale. FSANZ's assessment was also that the associated potential cost to consumer health of such a permission would outweigh its direct and indirect benefits.

1 Introduction

1.1 The Applicant

The applicant is Noosa Organica Pty Ltd, a primary producer based in Australia.

1.2 The Application

The purpose of the application is to amend the Australia New Zealand Food Standards Code (the Code) to permit the following foods from the *Moringa oleifera* plant, which are novel foods, to be sold as food for retail sale or be ingredients or components in food for retail sale:

- fresh and dried leaf
- immature (green) pods
- oil (from the seed).

The foods are proposed to be used as a vegetable (leaves and immature pods) and as an oil, as a nutritional food source. The target population is the general population.

According to information provided by the applicant, the following food preparation and consumption of *Moringa oleifera* is intended, based on its use in other markets.

Fresh leaf
Intended to be consumed fresh or cooked as a salad vegetable or cooked vegetable. The application refers to the use of the leaf in soups, risottos, muffins, salad, porridges, frittata, hummus and chutney.

Dried leaf
Intended to be consumed with water to make a beverage, and as an ingredient in juice, bread, yoghurt, biscuits.

Immature (green) pods
Immature (green) pods, comprises both the pod (capsule) and any seeds within the pod. It is intended that the outer pod could be peeled (e.g. with a standard potato peeler) to remove some of the fibrous material and that the pods could be consumed raw or cooked, and consumption could include both the outer pod (capsule) and the seeds within. Some cooking methods would involve removal of the pod (capsule) and consumption of the inner flesh and seeds only.

Oil
The oil extracted from the seed (known as ‘ben oil’ due to the docosanoic acid, also called behenic acid) is high in oleic acid (70%) and could be used as an alternative to olive oil.

1.3 The current standard

Australian and New Zealand food laws require food for sale to comply with relevant requirements in the Code. The requirements in the Code relevant to this application are summarised below.

1.3.1 Novel foods

Section 1.1.2—8 describes which foods are novel foods for the purposes of the Code. It defines a ‘novel food’ as a ‘non-traditional food’ that requires an assessment of public health and safety considerations having regard to:

(a) the potential for adverse effects in humans; or
(b) the composition or structure of the food; or
(c) the process by which the food has been prepared; or
(d) the source from which it is derived; or
(e) patterns and levels of consumption of the food; or
(f) any other relevant matters.

A 'non-traditional' food is defined in the Code as, among other things, a food that does not have a history of human consumption in Australia or New Zealand.

Paragraphs 1.1.1—10(5)(b) and 1.1.1—10(6)(f) provide that, unless expressly permitted by the Code, a food offered for retail sale must not be a novel food or have a novel food as an ingredient or component.

Section 1.5.1—3 provides that the Code permits a food offered for retail sale (other than an infant formula product) to consist or contain a novel food if the novel food is listed in the table to section S25—2 and any associated conditions of use specified in that table are complied with.

The table to section S25—2 (Sale of novel foods) lists permitted novel foods together with their conditions for use including use levels, restrictions on use and labelling requirements.

Novel foods must undergo pre-market assessment and approval by FSANZ before they can be listed in the table to section S25—2.

Moringa oleifera products (leaf, seed pods, oil) are not currently listed in the above table as permitted novel foods.

The Advisory Committee on Novel Foods (ACNF) considered *Moringa oleifera* leaf at four meetings (2009, 2014, 2015, 2020) and *Moringa oleifera* (powdered mix of seed, leaf and fruit (seed pod)) at three meetings (2012, 2014, 2015)[1]. The ACNF provides a view on whether foods are novel or not, for Code purposes. On each of the considerations, the ACNF concluded that *Moringa oleifera* leaf and *Moringa oleifera* (powdered mix of seed, leaf and fruit (seed pod), respectively, was a novel food and therefore required assessment and approval before *Moringa oleifera* leaf or *Moringa oleifera* (powdered mix of seed, leaf and fruit (seed pod)) or a food containing *Moringa oleifera* leaf or *Moringa oleifera* (powdered mix of seed, leaf and fruit (seed pod)) could be offered for retail sale in Australia and New Zealand.

The ACNF noted that safety was not established due to the potential for pharmacological effects based on its use as traditional medicine (*Moringa oleifera* leaf) and the potential for adverse effects in humans (*Moringa oleifera* - powdered mix of seed, leaf and fruit (seed pod)).

1.3.2 Labelling

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

Standard 1.2.1 sets requirements for applying labelling and information to food for sale that is packaged, unpackaged or not required to bear a label. Food for sale includes retail sales, food sold to a caterer and other sales of food.

Section 1.2.3—4 requires certain foods and substances (e.g. allergens) to be declared when present as ingredients in a food for sale.

[1] Refer to the published Advisory Committee on Novel Foods Record of Views

Standard 1.2.4 generally requires food for sale to be labelled with a statement of ingredients listing each ingredient in the food. Section 1.2.4—4 requires ingredients to be listed by a common, descriptive or generic name (if any). Permitted generic names of ingredients are listed in the table to section S10—2.

Standard 1.2.7 sets out the restrictions, requirements and conditions for making voluntary nutrition, health and related claims made about food.

Standard 1.2.8 generally requires food products to be labelled with nutrition information.

Section 1.5.1—3 allows the retail sale of a permitted novel food if the food is listed in the table to section S25—2 and any associated conditions of use (including in some instances the use of a specific name) are met.

1.3.3 Identity and purity requirements

Paragraph 1.1.1—15(1)(d) requires that, when added to food in accordance with the Code, or sold for use in food, a substance that is a novel food must comply with any relevant identity and purity specifications set out in Schedule 3 of the Code.

1.4 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).

There are no international standards for novel foods or for the use of the *Moringa oleifera* leaves or pods. However, there is a Codex Standard that applies to the seed oil - Codex Standard for Edible Fats and Oils Not Covered By Individual Standards (CXS 19-1981)[2].

1.4.1 International situation

The applicant provided information on the international situation in section J.2 of the application.

Health Canada lists the following foods from *Moringa oleifera* as non-novel as the ingredient has a history of safe use: 'Moringa leaf powder', 'Moringa root', and 'Winged Ben seed oil' (for use at levels corresponding to a food flavouring). Refer to the List of Determinations of Foods and Food Ingredients that Are Not Novel - Canada.ca.

In the European Union (EU), novel foods are any food that was not used for human consumption to a significant degree before 15 May 1997. The EU Novel Food status Catalogue lists the parts of the *Moringa oleifera* plant having a history of use within the EU, prior to 1997. The listing is as follows:

- Leaves and fruits (pods/capsules containing the seeds) - not a novel food – the product was used for human consumption to a significant degree within the EU, prior to 1997.
- Seeds and oil - not novel in food supplements - the product was used in food supplements prior to 1997.

The government of the Philippines passed a Malunggay Development Act in 2007 to promote the production, processing, marketing and distribution of *Moringa oleifera*, which they call

[2] Standards | CODEXALIMENTARIUS FAO-WHO

Malunggay[3].

1.5 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.

1.6 Procedure for assessment

The application was assessed under the General Procedure in the FSANZ Act.

1.7 Decision

The application was rejected for the reasons stated in this report.

1.8 Procedure for assessment

The application was assessed under the General Procedure in accordance with the FSANZ Act.

After assessing the application, FSANZ prepared a preliminary Rejection Report. The report including the Supporting Document (SD) was provided to the applicant in October 2025. The applicant was given the opportunity to comment on the preliminary conclusions reached and the reasoning used to arrive at these preliminary conclusions. The applicant in its response did not provide any comments on the content of the preliminary report or seek any change to FSANZ's assessment and preliminary conclusions.

FSANZ subsequently rejected the application for the reasons stated in this report.

2 Summary of the findings

2.1 Risk assessment

FSANZ's approach to analysing food related public health and safety risks is outlined in our guide to Risk Analysis in Food Regulation. The risk analysis process used by FSANZ is based on the internationally accepted Codex Risk Analysis Framework[4]. Risk analysis consists of three components: risk assessment, risk management and risk communication.

Risk assessment is the central component of risk analysis and provides a scientific basis for risk management decisions on measures that may be needed to protect public health. Risk assessment comprises the four steps of (i) hazard identification; (ii) hazard characterisation; (iii) exposure assessment; and (iv) risk characterisation. Hazard identification and hazard characterisation are together called hazard assessment.

[3] https://legacy.senate.gov.ph/lis/bill_res.aspx?congress=14&q=SBN-1799
[4] https://openknowledge.fao.org/items/189f588e-0157-486d-9c5b-b906d7986192

Risk assessments aim to estimate the likelihood and severity of an adverse health effect occurring from exposure to a hazard. The term hazard refers to a chemical (including nutrient), microbiological or physical agent in food with the potential to cause an adverse health effect. As described in our Risk Analysis in Food Regulation guide, a chemical hazard includes novel foods and ingredients.

Hazard identification seeks to clearly describe the hazard being assessed and to identify potential adverse health effects that could occur as a result of exposure to the substance, food ingredient or food.

Hazard characterisation seeks to characterise toxicological responses in laboratory animals and/or humans to various levels of exposure (i.e. doses). Hazard characterisation focuses on establishing a 'safe' level of exposure; that is, a level below this threshold level of exposure. This level can be used to establish what is generally referred to as the 'health-based guidance value' (HBGV), which reflects the level of the food that can be ingested over a defined time period (e.g. lifetime or 24 hours) without appreciable health risk.

An *exposure assessment* seeks to provide an estimate of the magnitude, frequency and duration of exposure to the hazard or, the magnitude of nutritional intake found in the diet.

Risk characterisation—the last step in risk assessment—seeks to integrate information from the hazard and exposure assessments to generate a risk estimate. It is a qualitative and/or quantitative estimation, including attendant uncertainties, of the likelihood of occurrence and severity of known or potential adverse health effects in a given population.

In summary, risk is a function of both the hazard and the level of exposure to that hazard. A food risk assessment therefore consists of an assessment of the hazard and an assessment of exposure which together enable characterisation of the risk.

2.1.1 Risk assessment process

FSANZ undertook a risk assessment for this application, based on the toxicological data available to FSANZ at the time of assessment. FSANZ's conclusions from the available evidence from that assessment are set out in the SD and summarised below.

2.1.2 Available evidence

FSANZ has reviewed a large number of publications concerning the safety of *Moringa oleifera* leaves or their extracts. Most of the reported studies were not conducted according to internationally accepted guidelines. Very limited information was available in the application or peer-reviewed literature concerning the safety of the seed pods or oil.

***Moringa oleifera* leaf**

Acute toxicity in animals

The acute oral toxicity of *Moringa oleifera* leaf was low in non-pregnant mice and rats.

Subchronic toxicity in animals

In a 28-day oral toxicity study, daily administration of the leaf powder to mice in the feed was associated with elevated markers of liver damage and microscopic changes in kidneys at 1000 mg/kg bw/day.

In a five-week dietary study, inclusion of 20% w/w *Moringa oleifera* leaf powder in the diet of feed-restricted rats was associated with decreased growth of long bones, which may reflect reduction in calcium availability due to the presence of oxalates in *Moringa oleifera* leaves.

C*hronic toxicity in animals*

No long-term toxicity or carcinogenicity studies of *Moringa oleifera* leaf were available.

Reproductive/developmental toxicity in animals

A dietary study of *Moringa oleifera* leaf in mice, at up to 8% w/w, was associated with slightly increased litter sizes and pup survival. Powdered *Moringa oleifera* leaf at 30% w/w in the diet of pregnant rats resulted in the total loss of all litters. Pre-implantation losses and resorptions of implanted embryos were also reported in a study conducted with aqueous and ethanolic extracts from *Moringa oleifera* leaves at a dose of 175 mg/kg bw.

Genotoxicity assays

A positive result was observed in an *in vivo* micronucleus assay in rats at doses of ≥ 1000 mg/kg bw aqueous extract. Negative results were observed in an in vivo micronucleus assay and a Comet assay at a dose of 2000 mg/kg bw. There is insufficient information to draw conclusions on the genotoxicity of *Moringa oleifera*.

Human data

A range of pharmacological properties have been attributed to *Moringa oleifera*, although the large majority are not based on human evidence. It is unclear which parts of the plant have these effects, how they are prepared, and the doses and dose frequencies at which effects may be observed.

Moringa oleifera has been reported to have a history of use in folk medicine as a contraceptive and abortifacient although the consumption levels associated with these effects are unknown. FSANZ notes that abortifacient effects are consistent with those observed in animal studies.

Allergic or anaphylactic responses to consumption of raw and cooked *Moringa oleifera* leaves or cooked pods have been reported, although they are rare.

Green pods or seed oil

No relevant toxicological data specific to the green pods or seed oil of *Moringa oleifera* were submitted or located in a literature search.

2.1.3 Hazard assessment conclusions

FSANZ's risk assessment, using the best available scientific evidence, identified a potential hazard for *Moringa oleifera* leaf but insufficient information was available to characterise the risk. There was also insufficient information to determine whether the same potential hazard is associated with the seed pods or oil from *Moringa oleifera*. Therefore, FSANZ was unable to establish that *Moringa oleifera* would not pose a safety concern if permitted for sale.

In particular, the best available scientific evidence did not enable key safety considerations such as the following to be adequately characterised:

- The identity and quantity of undesirable substances potentially present in relevant parts of the *Moringa oleifera* plant.

- The potential for adverse effects in the short term or long term, such as established by guideline-compliant toxicity studies in animals.
- The abortifacient effects of *Moringa oleifera* observed in animal studies for the leaf and aqueous or ethanolic extracts of the leaf.
- Anecdotal reports of use of *Moringa oleifera* as a contraceptive and abortifacient in humans.
- The potential genotoxicity of *Moringa oleifera* addressing all genotoxicity endpoints, as demonstrated by appropriate studies conducted according to relevant guidelines.

2.1.4 Dietary exposure assessment

Dietary exposure assessments support the risk characterisation step of the FSANZ scientific risk assessment process as explained in the Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes (FSANZ 2024). As FSANZ could not characterise the hazard (see Section 3.10 Summary of risk assessment findings), a dietary exposure assessment was not conducted for this assessment.

2.1.5 Risk characterisation

A risk estimate could not be calculated, as risk is a function of both the hazard and the level of exposure to that hazard.

2.2 Risk management

The applicant requested an amendment to the Code to permit the following foods from the *Moringa oleifera* plant, which are novel foods, to be sold as food for retail sale or be ingredients or components in food for retail sale:

- fresh and dried leaf
- immature (green) pods
- oil (from the seed).

FSANZ used an internationally accepted risk analysis framework in our decision making and the best available scientific evidence to assess this application. As explained above, risk analysis consists of three components: risk assessment, risk management and risk communication.

As FSANZ was unable to establish that *Moringa oleifera* leaf, seed pods and oil would not pose a safety concern if permitted for sale (refer to Sections 2.1.2 and 2.1.3 above), granting the permissions sought in and by the application is not supported.

FSANZ considered whether risk management strategies - such as setting compositional requirements - could address the identified safety issue. There is, however, insufficient evidence available to conclude with confidence that there would not be a safety concern even with such measures.

2.3 Risk communication

The process by which FSANZ considers standard development matters is open, accountable, consultative and transparent.

FSANZ communicated with the applicant during the assessment of this application, to provide information on the toxicological concerns identified and discuss options for proceeding.

The decision on this application will be published on the FSANZ website.

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

Background to the consideration of costs and benefits

Section 29 of the FSANZ Act requires FSANZ to have regard to whether costs that would arise from a 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).

Two options have been considered:

- Option 1 – reject the application and maintain the status quo
- Option 2 – permit *Moringa oleifera* leaves, immature seed pods, and oil, which are novel foods, to be sold as food for retail sale or be an ingredient or component in food for retail sale.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures. In fact, most of the effects considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the likely positives and negatives of moving away from the status quo.

FSANZ has decided that a regulation impact statement (RIS) will not be prepared for this application, because option 1 (maintain the status quo) is recommended based on the conclusions of the safety assessment undertaken by FSANZ of *Moringa oleifera* leaves, immature seed pods, and oil.

FSANZ's conclusions regarding the costs and benefits of both options are set out below.

Industry impacts

Option 1 (maintaining the status quo) would not result in any additional costs or benefits for industry.

Under option 2, industry would be permitted to sell *Moringa oleifera* leaves, immature seed pods, and oil, either as an ingredient or as a final food. The permission would be voluntary, and it is expected that businesses would use the permission where a commercial benefit exists for them.

Consumer impacts

Option 1 (maintaining the status quo) would not result in any additional costs or benefits for consumers.

Under option 2, consumers may benefit from greater choice.

However, FSANZ was unable to establish that *Moringa oleifera* would not pose a safety concern if permitted for sale. For more information, refer to Section 2.1 above.

Government impacts

Option 1 (maintaining the status quo) would not result in any additional costs or benefits for governments.

Option 2 may result in a small cost to government in terms of monitoring and compliance. If the risk to consumer health materialises, there will be an increase in healthcare costs for government.

Conclusions from cost benefit considerations

As FSANZ was unable to establish that *Moringa oleifera* would not pose a safety concern if permitted for sale, the evidence suggests the costs of option 2 would outweigh the benefits. Therefore, FSANZ concludes that option 1 (rejecting the application and maintaining the status quo) would be the best option.

2.4.1.2 Other measures

FSANZ must have regard to whether there are other measures (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.

As FSANZ concluded that as the evidence available to FSANZ at the time of its safety assessment did not establish that *Moringa oleifera* leaves, immature pods and oil are safe for human consumption, granting the permissions sought by the application is not supported.

FSANZ considered whether other possible measures could address the identified safety issue. There is, however, currently insufficient evidence available to conclude with confidence that there would not be a safety concern even with such measures.

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

Based on the best available scientific evidence, FSANZ was unable to establish that *Moringa oleifera* leaves, immature pods and oil would not pose a safety concern if permitted for sale. Further information is provided in Section 2.1 above.

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

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

2.4.2.3 The prevention of misleading or deceptive conduct

There were 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 conduct the risk analysis. The risk assessment is provided in the SD. The applicant submitted a dossier of scientific studies as part of the application. This dossier, together with other technical information including scientific literature, was considered by FSANZ in assessing the application.

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

As noted in Section 1.4 above, the relevant international standard setting body is Codex. There is no relevant international standard specifically for the foods from *Moringa oleifera* subject to this application.

FSANZ takes account of all relevant matters when considering applications to vary the Code. This includes safety assessments and opinions from other international food regulatory agencies. It is noted that there are no safety assessments published by international food regulatory agencies.

However, FSANZ is required to perform an independent safety assessment in accordance with the FSANZ Act. According to that Act, the primary objective for FSANZ when considering variations to the Code is the 'protection of public health and safety', as noted in Section 2.4.2.1 above.

From the risk assessment FSANZ undertook, FSANZ was unable to establish that the requested foods from *Moringa oleifera* would not pose a safety concern if permitted for sale.

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

As outlined in the consideration of costs and benefits (Section 2.4.1.1), FSANZ concludes that the available evidence suggests the costs of option 2 would outweigh the direct and indirect benefits resulting from permitting *Moringa oleifera* leaves, immature pods and oil to be sold for retail sale or be an ingredient or component in a food for retail sale.

- **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 Novel Foods*[5] is relevant to this application.

The High Order Principles in this policy guideline state 'to ensure that priority is given to the protection and improvement of public health and safety in relation to food matters'.

The policy guidance states that the Food Ministers Meeting[6] requests that FSANZ '*Recognise that the standard is there to ensure the safety of new foods coming on to the market and that the standard reflects a risk based approach*.'

As outlined in Section 2.1 above, FSANZ was unable to establish that *Moringa oleifera* would not pose a safety concern if permitted for sale. FSANZ can therefore not conclude that the above policy guidance would be met if permission to sell *Moringa oleifera* leaves, immature seed pods, and oil, is granted.

3 Reasons for decision

FSANZ assessed the application and evidence in accordance with the FSANZ Act.

After making that assessment, FSANZ decided to reject the application.

In making that decision, FSANZ had regard to the following:

- the application
- correspondence from the applicant in relation to the application
- the applicable provisions of the Code
- the FSANZ Act, including each of the matters prescribed in section 29 and 18 of that Act
- the risk assessment and the evidence on which that assessment was based (see the SD)
- other matters as stated in this report
- the applicant's response to the preliminary Rejection Report and supporting document.

After assessing the application and the evidence in accordance with the FSANZ Act, FSANZ decided to reject the application for the reasons stated in this report. In summary, these are:

- FSANZ must have regard to the protection of public health and safety when assessing this application. See paragraphs 29(2)(d), 18(1)(a) and 18(2)(e) of the FSANZ Act.

  Section 18 sets out FSANZ's objectives in developing food standards and variations thereof – this includes when FSANZ assesses an application.

  Paragraph 18(1)(a) states that the primary objective for FSANZ in developing food standards is the protection of public health and safety.

[5] Policy guideline on novel foods | Food Regulation
[6] Formerly the Australia New Zealand Food Regulation Ministerial Council

Paragraph 18(2)(e) states that, when developing food standards, FSANZ must have regard to any relevant written policy guidelines issued by the Forum on Food Regulation. The relevant guideline in this case is the Ministerial Policy Guideline on Novel Foods. That Guideline stipulates, among other things, that novel foods must be safe for human consumption.

Paragraph 29(2)(d) also requires FSANZ to have regard to the above as relevant matters when assessing an application.

- FSANZ's risk assessment, using the best available scientific evidence, identified a potential hazard for *Moringa oleifera* leaf but insufficient information was available to characterise the risk. There was also insufficient information to determine whether the same potential hazard is associated with seed pods or oil from *Moringa oleifera*. Therefore, FSANZ was unable to establish that *Moringa oleifera* would not pose a safety concern if permitted for sale

- In particular, the best available scientific evidence did not enable key safety considerations such as the following to be adequately characterised:

  - The identity and quantity of undesirable substances potentially present in relevant parts of the *Moringa oleifera* plant.
  - The potential for adverse effects in the short term or long term, such as established by guideline-compliant toxicity studies in animals.
  - The abortifacient effects of *Moringa oleifera* observed in animal studies for the leaf and aqueous or ethanolic extracts of the leaf.
  - Anecdotal reports of use of *Moringa oleifera* as a contraceptive and abortifacient in humans.
  - The potential genotoxicity of *Moringa oleifera* addressing all genotoxicity endpoints, as demonstrated by appropriate studies conducted according to relevant guidelines.

Given the above, FSANZ was unable to conclude that *Moringa oleifera* (leaves, immature seed pods and oil) would not pose a safety concern if permitted as a food for retail sale or as an ingredient or component in food for retail sale. FSANZ's assessment was also that the associated potential cost to consumer health of such a permission would outweigh its direct and indirect benefits.

4 Rights of review

Section 143 of the FSANZ Act provides the applicant with a right to apply to the Administrative Review Tribunal for review of the decision to reject the application.