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

11 December 2025
372-25

Supporting document

Risk and technical assessment – Application A1294

Moringa oleifera as a novel food

Executive summary

Noosa Organica Pty Ltd has applied 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 in a food for retail sale:

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

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

The main risk assessment findings can be summarised as follows:

***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 studies specific to the green pods or seed oil of *Moringa oleifera* were submitted or located in literature searches.

Risk characterisation

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.

Risk assessments aim to estimate the likelihood and severity of an adverse health effect occurring from exposure to a hazard. As the hazard in the *Moringa oleifera* leaf could not be characterized (and there was insufficient information to determine whether the same potential hazard is associated with seed pods or oil), a safe level of exposure for the requested foods could not be established. While there is a history of use of *Moringa oleifera* in some markets, there are no safety assessments for *Moringa oleifera* published by international food regulatory agencies.

Given the above, a risk estimate could not be calculated for the requested foods, as risk is a function of both the hazard and the level of exposure to that hazard.

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.

Table of contents

1 Introduction

FSANZ received an application from Noosa Organica Pty Ltd 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 in a food for retail sale:

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

The objectives of this assessment were to assess the food technology aspects, safety, and nutritional impact of the addition of these foods to the food supply.

2 Food Technology Assessment

2.1 Objectives of the assessment

The objective of the food technology assessment is to describe the identity of the requested foods (*Moringa oleifera* leaves, immature (seed) pods, and seed oil) and any information relevant to preparation and consumption, the commercial production process for the foods intended for sale, compositional data, and proposed specifications for inclusion in Schedule 3 of the Code.

The stated purpose of the application is to seek approval for the following parts of the *Moringa oleifera* plant, and oil produced from the seeds:

- fresh and dried leaf, as an alternative to, and at similar levels to, other fresh or dried vegetable sources such as spinach, kale or broccoli
- immature (green) pods, as an alternative to, and at similar levels to, other dried food sources such as peas
- seed oil, as an alternative to, and at similar levels to, other food oil sources such as olive oil, sunflower oil or peanut oil.

2.2 Identity and method of consumption

The novel foods are proposed to be used as a vegetable (leaves and immature pods) and an oil, as a nutritional food source. The target population is the general population. Refer to Section 3.1 below for further information.

The following food preparation and consumption information was provided:

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 other markets in soups, risottos, muffins, salad, porridges, frittata, hummus and chutney.

Dried leaf
Examples of food applications provided for the dried leaf are as follows: Water beverage – 2 grams/300ml water; blended juice - 5 - 20% in blended juice; and smoothies – 1.5 - 4.5% w/w. Other examples provided in the application are use in bread, yoghurt and biscuits.

Immature (green) pods
The application refers to consuming the immature (green) pods, which comprises both the pod (capsule) and any seeds within the pod. The outer pod *may* be peeled (e.g. with a standard potato peeler) to remove some of the fibrous material. The pods may be consumed raw or cooked, and consumption can include both the outer pod (capsule) and the seeds within. Some cooking methods involve removal of the pod (capsule) and consumption of the inner flesh and seeds only.

The immature pods can be consumed as vegetables, while over matured pods are used for seed purposes (Amee et al. 2020).

The tender pods, chopped or cooked, can be used in different dishes (Núñez-Gastélum et al 2022).

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 can be used as an alternative to olive oil.

The oil is described as having a higher oxidative stability than olive oil due to its fatty acid profile and behenic acid content. It is stated to be suitable for high-heat cooking due to its smoke point of 230–240°C.

2.3 Production process

According to the application the novel foods would be produced in Australia. The following is provided about the intended production process for each of the commercially available requested foods:

Fresh and dried leaf
Fresh: hand-picked, washed.
Dried: Machine or hand-picked, washed, dried in food-grade commercial dryer, packed in air-tight, darkened food-grade container.

There is no heat treatment, unless the leaves are dried.

Immature (green) seed pods
Fresh: hand-picked, washed.
Dried: Machine or hand-picked, washed, dried in food-grade commercial dryer, packed in air-tight, darkened food-grade container.

There is no heat treatment, unless the pods are dried.

Seed oil
When the pod is ripe, it turns brown. The seeds are removed, hulled then crushed.
According to the application, cold pressing is the preferred method for *Moringa* seed oil extraction as it neither uses heat nor chemical treatments (such as solvent extraction).

2.4 Compositional data

This section has not been completed, due to the risk assessment findings (refer to Section 3.10 below).

2.5 Specifications – for inclusion in Schedule 3

This section has not been completed, due to the risk assessment findings (refer to Section 3.10 below).

3 Risk Assessment

Moringa oleifera is a fast-growing, drought-tolerant tree native to the Indian subcontinent (Islam et al. 2021). Common names include horseradish tree, drumstick tree, benzolive tree, kelor, marango, mlonge, moonga, mulangay, nébéday, saijhan, sajna or Ben oil tree.

Moringa oleifera has been used for several non-food purposes including biomass production; animal forage; biogas production; as a fertilizer; and to produce gum, pulp, rope, tannin and cosmetics (Fahey 2005). Various parts of the tree are claimed to have pharmacological effects (see Section 3.8). The current application specifically addresses the food use of three parts of the plant: leaf (fresh and dried), immature (green) pods, and seed oil.

3.1 History of use as food

Moringa oleifera has a long history of human use, having been used by ancient civilizations including the Romans, Greeks and Egyptians. It is an important crop in India, Ethiopia, the Philippines and Sudan, and is also grown in numerous other countries in Africa and Asia, as well as in Latin America, the Caribbean, and some Pacific Islands.

Leaves of the tree may be consumed fresh, cooked, or after storage as dried powder (Fahey 2005). Consumption of pods is reported to be popular in Bangladesh (Islam et al. 2021; Razzak et al. 2022) and they are a common ingredient in Thai cuisine (Promkum et al. 2010).

The seed oil, also known as Ben oil or Behen oil, represents approximately 37% of the seed weight. Traditionally it is extracted by cold press extraction, or by boiling de-husked seeds with water, and collecting the oil from the surface of the water (Leone et al. 2016).

3.2 Toxicological aspects of composition

There are qualitative data indicating that *Moringa oleifera* contains toxic substances including cyanogenic compounds, oxalates and saponins. Cyanogenic compounds may be metabolised to cyanide, oxalates at sufficient concentrations may lead to renal damage. Saponins may be irritant to the gastrointestinal tract. Antinutrients present in *Moringa oleifera* include tannins and saponins.

Grosshagauer et al. (2021) note the potential of *Moringa oleifera* products to be contaminated with cadmium, lead, arsenic or mercury from the soil in which the tree is grown and recommend thorough monitoring for these elements and for polycyclic aromatic hydrocarbons (PAHs), which have been found in *Moringa oleifera* tea.

3.3 Effects of preparation

3.3.1 Leaf

Heating of leaves has been found to reduce concentrations of cyanogenic compounds and oxalates, while drying of leaves reduces concentrations of saponins, oxalates and tannins (Muslimin et al. 2023). Cooking of leaves results in decreased levels of phytic acid and tannins (Grosshagauer et al. 2021). However, quantitative data are not available in either publication.

3.3.2 Green pods

Grosshagauer et al. (2021) commented that tannins in *Moringa oleifera* pods may limit availability of micronutrients and presented data to show that cooking green pods halved the concentration of tannins. Levels of phytates, which may also act as antinutrients, were unaffected by cooking.

3.3.3 Seed oil

No information on the effects of processing on seed oil was located.

3.4 Potential for allergenicity

Allergic or anaphylactic responses to consumption of raw and cooked *Moringa oleifera* leaves or cooked pods have been reported (Ichrak 2022; Iddagoda et al. 2023), although allergic response is rare (Ichrak 2022).

The proteins responsible for those reactions have not been fully characterised (Iddagoda et al. 2023). Recent work by D'Auria et al. (2023) suggests that allergens in the leaf may include nonspecific lipid transfer proteins (nsLTPs) and morintides m01 and m02, which are chitin-binding peptides found in *Moringa oleifera* (Kini et al. 2017).

3.5 Toxicity studies *in vitro* and in animals

3.5.1 Leaf

3.5.1.1 In vitro data

Asare et al. (2012) found that aqueous extract of *Moringa oleifera* leaf was cytotoxic to human peripheral blood mononuclear cells at a concentration of 20 mg/mL.

3.5.1.2 Acute animal studies

Mice

Acute toxicity study in mice (Awodele et al. 2012). Regulatory status: Not GLP, no test guideline cited.

This study, conducted in male albino mice, has the limitation that the test article was the lyophilized aqueous extract of *Moringa oleifera* rather than whole leaf. Mice, 5/group, were administered 0, 400, 800, 1600, 3200 or 6400 mg/kg bw by oral gavage. The control article/vehicle was distilled water. All mice survived for 24 h, but some that were administered ≥ 3200 mg/kg bw were noted to have reduced locomotion and behavioural 'dullness'. No other adverse effects were reported.

Acute toxicity study in mice (De Barros et al. 2022). Regulatory status: GLP status unstated; conducted in accordance with OECD Guideline 423.

There were two test articles in this study: Dried, powdered *Moringa oleifera* leaf and a filtered aqueous extract of the leaf (leaf infusion). Male and female Swiss mice were gavaged with a single dose of leaf infusion or powder (2000 or 5000 mg/kg for each test article) or vehicle (0.9% NaCl) and maintained with observation for 14 days. On Day 14, mice were killed, and blood, liver, kidneys and spleen were collected.

In the 2 h observation period following dosing, mice treated with 5000 mg/kg bw of infusion or leaf powder were observed to be agitated, with increased ambulation, but there was no corresponding effect at the lower dose of 2000 mg/kg. Neither test article had any effect on feed consumption, water intake or bodyweight gain during the observation period, or on standard haematological and serum chemistry parameters at termination. Treatment had no effect on organ weights or histopathology of liver, kidneys or spleen. The acute oral LD_{50} was greater than 5000 mg/kg bw in mice.

Rats

Acute toxicity study in rats (Moodley 2017). Regulatory status: GLP status unstated, conducted in accordance with OECD Guideline 423.

The acute toxicity of dried powder of *Moringa oleifera* leaf to male and female Sprague Dawley rats was investigated. No adverse reactions were observed in rats of either sex at the starting dose of 2000 mg/kg bw. Female rats were dosed first and observed for 14 days. This was followed by dosing male rats, which were observed for 7 days. There were no abnormal clinical observations and no abnormalities at gross necropsy. It was concluded that the acute oral LD_{50} of *Moringa oleifera* leaf powder is greater than 2000 mg/kg bw in the rat.

3.5.1.3 Short-term toxicity studies

Mice

28-day gavage toxicity study in mice (De Barros et al. 2022). Regulatory status: GLP status unstated; conducted in accordance with OECD Guideline 407.

The test animals in this study were Swiss mice. Two test articles were investigated; dried leaf powder and filtered aqueous extract of the leaf (leaf infusion). Physiological saline was used as the vehicle and control article. Mice, 5/sex/group, were gavaged daily with 0, 250, 500 or 1000 mg/kg bw of test article. At scheduled termination, blood, liver, kidneys and spleen were collected from each mouse.

All mice survived to the end of the study. The leaf infusion did not have any adverse effects on group mean values for bodyweight gain, food consumption, water consumption, haematology findings, clinical chemistry findings, relative organ weights or histopathology findings, compared to those of controls.

Treatment with the leaf powder at ≥ 500 mg/kg bw/day significantly decreased bodyweight gain in both sexes, in association with decreased feed consumption and water consumption. Group mean values for alanine amino transferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP), gamma-glutamyl transferase (GGT) and bilirubin were significantly increased in mice treated with 1000 mg/kg bw/day leaf powder.

Group mean values for relative organ weights were not significantly different to control values, but fat droplets in hepatocytes were increased in female mice dosed with ≥500 mg/kg bw/day leaf powder, and male mice dosed with 1000 mg/kg bw/day leaf powder. Renal changes were observed in both sexes at 1000 mg/kg bw/day leaf powder, and included increased glomerular size with reduced intracapsular space, and marked reduction in the luminal size of proximal convoluted tubules.

Rats

Five-week dietary study in rats (Zvinorova et al. 2014). Regulatory status: Not GLP, no test guideline cited

Male Sprague Dawley rats, 8/group, were fed a diet containing *Moringa oleifera* leaf powder for five weeks, commencing when they were weanlings (Zvinorova et al. 2014). Two control groups were fed either normal rat feed fed at 20% of body mass or normal rat feed at 14% of body mass ('feed-restricted'). The treatment groups were fed the same rat feed into which the *Moringa oleifera* leaf powder had been incorporated at 20% w/w, either at 20% body mass or 14% body mass. At the end of the study, blood, femurs, tibias, and the abdominal gastrointestinal tract were collected from each rat.

Treatment had no effect on overall bodyweight gain. The feed-restricted group consuming *Moringa oleifera* leaf powder had approximately 5% less linear growth of their femurs and tibias, compared to controls, with no change in bone density. The only part of the abdominal gastrointestinal tract affected by *Moringa oleifera* leaf powder was the caecum, which was approximately 20% heavier in the treated group that was not feed-restricted, compared to its control group. The group mean value for liver weight was also significantly higher in these rats than in untreated controls. There were no histological correlates in either organ. There were no significant differences between groups in clinical chemistry parameters or in hepatic concentrations of lipid or glycogen.

The authors speculated that the decreased growth in long bones could be due to oxalates in *Moringa oleifera* restricting calcium availability.

3.5.1.4 Long term animal studies

No long-term toxicity/carcinogenicity studies were submitted or located.

3.5.1.5 Reproductive and developmental animal studies

Mouse – powdered leaf

Reproductive toxicity study in mice (Zeng et al. 2019). Not GLP, no test guideline cited.

Zeng et al. (2019) conducted a study in which NIH Swiss mice were fed a diet containing dried powdered *Moringa oleifera* leaf at concentrations of 0, 4% or 8% (equivalent to 0, 5200 and 10400 mg/kg bw/day, respectively).[1] Breeding pairs were maintained on this diet through six pregnancies. Parameters measured during completed pregnancies and lactations were litter size, litter birth weight, average birth weight, litter survival until weaning age (21 days), litter weaning weight, and average weaning weight. The breeding mice were bled and then killed on Day 14 of the seventh pregnancy. Sperm from the epididymides was assessed, and testis was quick-frozen for later examination.

Supplementation of dams with *Moringa oleifera* leaf was associated with greater litter size and greater survival to weaning when compared to controls, although the effect was slight and there was a lack of a clear dose-response relationship. In sires, supplementation was associated with a reduction in sperm abnormality rate although there was not a clear dose-response relationship. In male mice, there were no treatment-related effects on group mean values for serum testosterone or in expression levels of androgen receptor (AR), phosphoglycerate kinase 2 (Pgk2), protamine2 (Prm2), or B cell leukemia/lymphoma2 (Bcl2) in testis. In female mice, there were no treatment-related changes in group mean values for

[1] Using JECFA (2016) conversion

serum estradiol and or in expressions of estrogen receptor beta (ERβ), Bcl2, Bax, and vascular endothelial growth factor receptor (VEGFR) in ovary.

Rat – powdered leaf

Dietary reproductive study in rats (Ekhator and Osifo 2015). Not GLP, no guidelines cited.

The abortifacient potential of powdered *Moringa oleifera* leaf was assessed by Ekhator and Osifo (2015).

Timed-pregnant Sprague Dawley rats, 5/group, were fed dried, powdered *Moringa oleifera* leaf at 0 or 30% w/w (equivalent to 0 or 18,000 mg/kg bw/day) in the feed from gestational day (GD) 5 to 15. Body weights of all female rats were recorded prior to mating, after mating, and on GDs 3, 9 and 14. Group mean bodyweights of the control group steadily increased through the gestational period. Group mean bodyweights of the treated group were lower than the premating value after mating and on GDs 3 and 9, and only slightly above the premating value on GD 14. None of the treated rats produced a litter, whereas the rats in the control group all produced litters.

Rat - aqueous leaf extracts

No evidence of toxicity was observed in male Sprague Dawley rats gavaged with a single dose of an aqueous extract of *Moringa oleifera* leaf at 1000 or 3000 mg/kg bw (Asare et al. 2012).

Adedapo et al. (2009) conducted a 21-day oral gavage study of an aqueous leaf extract in male Wistar rats, 6/group, at doses of 0, 400, 800 and1600 mg/kg bw/day. Findings included haematological changes (decreased PCV) at ≥ 800 mg/kg bw/day, and some evidence of adverse effects on liver function, including decreased serum proteins, elevated ALT and AST at 1600 mg/kg bw/day. Significantly higher ALP was observed at ≥800 mg/kg bw/day. No significant changes were observed on microscopic examination of organs.

Awodele et al. (2012) observed no adverse effects in a study of aqueous extract of *Moringa oleifera* leaf in male rats, 6/group, dosed with 0, 250, 500 or 1500 mg/kg bw/day for 60 days. Treatment had no effect on bodyweight gain, haematological parameters, or serum markers of liver or kidney function.

Nath et al. (1992) prepared an aqueous extract of *Moringa oleifera* leaf from dried, powdered leaf. The dried extract was administered in water by gavage to rats at a dose equivalent to 175 mg/kg of the starting material (dried, powdered leaf). Water was used as the control article. Timed-pregnant rats, 7/group, were gavaged from GD 0 to GD 10 with 0 or 175 mg/kg as starting material. Rats were killed on GD 20. Implantation rates were similar between the control group and the treatment group, but all implantations were resorbed in the treatment group, whereas there were no resorptions in the control group.

In a study conducted by Attah et al. (2020), aqueous extracts of dried powdered *Moringa oleifera* leaf, obtained using either cold or hot water, were administered by gavage to timed-pregnant rats (6/group) either prior to mating, or from GD 1 through to GD 14 inclusive. The cold extract was administered at a dose of 58 mg/kg bw/day whereas the hot extract was administered at 50 mg/kg bw/day. A control group were dosed with water. Every one of the rats dosed with the cold extract before mating failed to produce any pups. Rats dosed with the hot extract prior to mating had a much-reduced birth rate, with only eight pups produced from six rats, compared to a total of 33 pups produced from the six control rats. Rats dosed with the hot extract during pregnancy produced only 18 pups in total, and rats dosed with the cold extract during pregnancy produced only nine pups in total. No teratogenic effects were

observed in surviving pups of treated dams. The authors also reported *in vitro* evidence that the extracts increase uterine contractility.

Laoung-on et al. (2021) investigated the effects on male Wistar rats of an aqueous extract made from dried, pulverised *Moringa oleifera* leaf. Rats, 8/group, were gavaged with doses of 0, 0.55, 1.10 or 2.20 mg/kg bw/day for 30 days. Sexual behaviour towards oestrous female rats was tested on days 28 to 30. Video recording was made for 30 min after an oestrous female was introduced into a dimly lit open-field cage, and courtship, mount latency, intromission latency, mount frequency, intromission frequency, and copulatory efficiency were recorded. Smears were made of vaginal fluid of female rats to confirm the presence of sperm. Male rats were then bled for testosterone measurement and then killed. Testes were collected, weighed and processed for microscopic examination. All the treated groups showed significantly increased group mean values for duration of courtship behaviour compared to the control group, although other parameters assessed from video recordings were not altered. There were no treatment-related effects on group mean values for serum testosterone level or relative testis weight. Group mean values for seminiferous tubule diameter, epithelial height and epithelial area were greater in the treated groups than the controls, but there was not a clear dose-response relationship. Group mean numbers of Type A spermatogonia, total spermatogenic cells and Sertoli cells were significantly greater in treated rats than control rats, but without a clear dose-response relationship.

Rat - alcohol leaf extracts

The acute toxicity of a methanol/water (80:20 v/v) extract of *Moringa oleifera* leaves to female Wistar rats was investigated by Okumu et al. (2003), using the up-and-down procedure described in OECD Guideline 425. The only dose used was 2000 mg/kg bw. All treated rats survived to scheduled termination but treated rats showed a significant increase in serum AST compared to controls dosed with physiological saline, and mild hepatic necrosis was found in treated rats on histopathological examination. The acute oral LD_{50} of the extract was > 2000 mg/kg bw in the rat.

Olayemi et al. (2016) conducted a 28-day toxicity study of a methanolic extract of *Moringa oleifera* leaf in male Wistar rats. Rats, 5/group, were administered 0, 100, 200, 400 or 1000 mg/kg bw/day by gavage. Distilled water was the vehicle and the control article. Blood was collected for haematology and clinical chemistry at the end of the in-life phase. An unspecified list of organs was collected and processed for histopathology. No treatment-related changes in haematological parameters were observed, and serum markers of liver or kidney damage were not increased. The histopathology results were not clearly reported.

Sethi et al. (1988) investigated the abortifacient effects of an ethanol:water (90:10) extract from dried powdered *Moringa oleifera* leaf in timed-pregnant rats. The vehicle/control article was 1% gum acacia in water. Rats, 7/group, were gavaged with 0 or 175 mg/kg bw of the test article from GD 5 to GD 10 inclusive. All rats survived to GD20, when they were killed and examined for numbers of corpora lutea, number of implantations, number of resorptions, and for weight and crown-to-rump length of any fetuses. Total numbers of corpora lutea and implantations were the same in the treated group as in the control group, but in the treated group, all the implantations had resorbed. There were no resorptions or abortions evident in the control group.

The effect of an ethanolic extract of *Moringa oleifera* leaf on pregnancy in rats was investigated by Agrawal et al. (2018). The vehicle/ control article was 0.5% gum acacia. Timed-pregnant rats, 6/group, were gavaged with the ethanolic extract from GD 1 to GD 7 at 0,100, 250 or 500 mg/kg bw/day. Rats were examined internally under anaesthesia on GD 10 for counting of corpora lutea and implantations and then allowed to recover and to complete their pregnancies. Pre-implantation loss was statistically significant, compared to

controls, at all doses, while post-implantation loss was significantly increased at ≥ 250 mg/kg bw/day. A dose-response relationship was evident.

3.5.2 Green pods

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

3.5.3 Seed oil

3.5.3.1 In vitro data and acute toxicity studies

No *in vitro* data or acute toxicity studies related to the safety of the seed oil were submitted or located in a literature search.

3.5.3.2 Short term animal studies

Nadeem and Imran (2016) cited a study of the effects of a diet based on *Moringa oleifera* seed oil on albino rats, conducted by Bolanle et al. (2014). FSANZ has been able to only access the abstract of the cited study. Rats of unstated strain and gender were assigned to groups of six. The control group was fed with a diet in which the oil was soya bean, while the treatment group was fed a diet containing *Moringa oleifera* oil, at an unstated concentration. After six weeks on study, blood was collected for haematology and clinical chemistry. No mortalities were observed during the study period. There were no significant differences between the treated and control groups in bodyweight gain, or serum levels of total cholesterol, high-density lipoprotein cholesterol (HDL-C), low-density lipoprotein cholesterol (LDL-C), or triglycerides. No adverse effects on serum urea or serum creatinine were found.

3.5.3.3 Long term animal studies

No long-term toxicity/carcinogenicity studies of the oil were submitted or located in a literature search.

3.5.3.4 Reproductive and developmental animal studies

No studies of the reproductive or developmental safety of the oil in animals were submitted or located in a literature search.

3.6 Genotoxicity studies

Two non-guideline studies investigating the genotoxicity of test articles prepared from *Moringa oleifera* are briefly described below.

De Barros et al. (2022) used blood from mice that had been dosed orally with a single dose of *Moringa oleifera* infusion or powder (5/group), 2000 mg/kg bw, for a comet assay and an *in vivo* micronucleus assay. Negative control groups of mice were treated with physiological saline, whereas positive control groups were treated with methotrexate (20 mg/kg bw). The comet assay was conducted in triplicate. For the micronuclei assay, 2000 polychromatic erythrocytes were examined per mouse. Findings in mice treated with *Moringa oleifera* were comparable to those in negative controls in both assays, while findings in positive control mice confirmed the genotoxicity of methotrexate and the validity of the assays.

Asare et al. (2012) reported the results of an *in vivo* micronucleus assay of an aqueous extract of dried *Moringa oleifera* leaf powder administered by gavage to male Sprague Dawley rats. Rats, 5/group, were gavaged with a single dose of either 1000 or 3000 mg/kg bw of the extract. A negative control group was gavaged with physiological saline, and a positive control group was administered *N*-ethyl-*N*-nitrosourea by intramuscular injection. Rats were killed 48 h after dosing, and bone marrow from femurs was aspirated. The aspirate was stained and examined for polychromatic micronucleated erythrocytes (PCEMN) and normochromatic micronucleated erythrocytes (NCEMN). PCEMN/NCEMN ratios were calculated for each rat.

Group mean values for numbers of PCEMN and NCEMN per 1000 cells examined were 4.8 ± 1.2 and 2.3 ± 0.2, respectively, for the negative control group, and the PCEMN/NCEMN ratio was 2.087. For the 1000 mg/kg bw group, group mean values for numbers of PCEMN and NCEMN per 1000 cells examined were 9.8 ± 2.0 and 5.3 ± 1.8 respectively and the PCEMN/NCEMN ratio was 1.849. For the 3000 mg/kg bw group, group mean values for numbers of PCEMN and NCEMN per 1000 cells examined were 20.2 ± 4.0 and 20.4 ± 0.8 respectively and the PCEMN/NCEMN ratio was 1.442. For the positive control group, group mean values for numbers of PCEMN and NCEMN per 1000 cells examined were 25.4 ± 3.5 and 14.0 ± 1.3 respectively and the PCEMN/NCEMN ratio was 1.245. Differences between the values for the negative control group and the treated groups were statistically significant.

3.7 Human tolerance studies

Adegbite et al. (2016) studied the effects of *Moringa oleifera* leaves on haematological parameters in humans. Baseline blood samples were collected from 20 male and female university students who were then randomly assigned to two groups of 10. The low-dose and high-dose groups consumed powdered *Moringa oleifera* leaf at 38 mg /kg bw/day and 77 mg/kg bw/day for 14 days. At the end of the treatment period, a further blood sample was collected. Both groups showed a slight increase in erythrocyte count, which did not reach statistical significance relative to baseline values, and a slight decrease in leukocyte count which was also not statistically significant. An increase in platelet count, relative to baseline values, was observed in both groups but was only statistically significant at the low dose. The authors attributed the effect on platelets to the intervention, but FSANZ does not agree with this conclusion since there was no dose-response relationship.

Balamurugan et al. (2016) conducted a survey of 120 traditional health practitioners in a district in south India. *Moringa oleifera* was one of the most frequently identified plants for use as a folk medicine. It was reported that powders made from root, bark or leaves of *Moringa oleifera* are used to treat sexually transmitted diseases, as a contraceptive, and as a galactogogue (substance that promotes lactation).

A study of the effects of macerated, lyophilized *Moringa oleifera* leaves on haematological and serological parameters in patients with iron deficiency anaemia was conducted by Suzana et al. (2017). There were 17 anaemic (haemoglobin 8-12 g/dL) women in the treatment group and 18 in the control group. The *Moringa oleifera* leaf preparation was administered in capsules at doses of 1400 mg, daily for three weeks. Supplementation with the extract was associated with significantly higher group mean values for haemoglobin, ferritin, mean corpuscular haemoglobin concentration (MCHC) and red cell distribution width (RDW), and a significantly lower group mean value for platelets, compared to baseline group mean values. Increases in group mean values for several haematological parameters were also observed in the control group, but the treatment group showed significantly greater improvements in haematocrit, mean corpuscular haemoglobin (MCH), and MCHC than the control group, and also showed a significantly lower group mean value for platelet count.

The effect of the aqueous extract of *Moringa oleifera* leaf on intraocular and blood pressure of thirty normotensive adults was investigated by George et al. (2018). Participants were healthy adults of both sexes in the age range 18 to 35 years. Baseline intraocular pressure (IOP) and blood pressure (BP) was recorded for each participant. Participants were assigned, 10/group, to three treatment groups or a control group, and consumed a single dose of 0, 28.5, 57.0 or 86.7 mg/kg bw aqueous leaf extract, at a constant volume of 250 mL. Participants were blinded to the dose level of extract they were consuming. IOP and BP were measured at intervals of 30 minutes. A dose-related decrease in both parameters was observed at all dose levels of *Moringa oleifera* leaf extract, with the maximum decrease measured at 60 min for BP and 90 min for IOP.

Chaudhary et al. (2022) found that 80% of women in a village called Gora, in Raibarelli district of Uttar Pradesh, used *Moringa oleifera* leaves as an abortifacient in early pregnancy, but no indication of dose was reported.

A study of the effects of *Moringa oleifera*-derived material on markers of oxidative stress in infertile women (Onyeaghala et al, 2024) was reviewed but was not considered useful for assessment because the test material was insufficiently characterised.

3.8 Other studies

A number of review papers attribute a range of pharmacological effects to *Moringa oleifera*, but the great majority are not based on human evidence.

The possibility of pharmacological effects is most often assumed based on chemicals found in *Moringa oleifera*, and less often claimed because of outcomes in studies in animals.

The only effects, listed in Table 1, for which human evidence is cited were related to cosmetic use, and the anti-diabetic effect of reducing blood glucose.

Table 1: Pharmacological properties attributed to *Moringa oleifera*

Property	Reference (review)
Anti-cancer	Fahey (2005), Pandey et al. (2012), Stohs and Hartman (2015), Bhattacharya et al. (2018), Singh and Navneet (2018), Popoola et al. (2020), Azlan et al. (2022), Chaudhary et al. (2022), Kashyap et al. (2022), Liu et al. (2022), Njan et al. (2023), Pareek et al. (2023), Srivistava et al. (2023)
Anti-inflammatory	Fahey (2005), Pandey et al. (2012), Singh and Navneet (2018), Bhattacharya et al. (2018), Popoola et al. (2020), Chaudhary et al. (2022), Liu et al. (2022), Njan et al. (2023), Pareek et al. (2023), Srivistava et al. (2023)
Anti-pyretic	Fahey (2005), Bhattacharya et al. (2018)
Anti-diarrhoeal	Bhattacharya et al. (2018), Chaudhary et al. (2022)
Anthelmintic	Singh and Navneet (2018), Chaudhary et al. (2022), Liu et al. (2022), Njan et al. (2023)
Antibacterial	Fahey (2005), Pandey et al. (2012), Bhattacharya et al. (2018), Singh and Navneet (2018), Popoola et al. (2020), Azlan et al. (2022), Chaudhary et al. (2022), Kashyap et al. (2022), Liu et al. (2022), Njan et al. (2023), Pareek et al. (2023), Srivistava et al. (2023)
Antiplasmodial	Pandey et al. (2012)
Antiparasitic	Fahey (2005), Bhattacharya et al. (2018)
Antifungal	Fahey (2005), Singh and Navneet (2018), Chaudhary et al. (2022), Liu et al. (2022), Njan et al. (2023), Pareek et al. (2023), Srivistava et al. (2023)
Antiviral	Fahey (2005), Singh and Navneet (2018), Azlan et al. (2022), Liu et al. (2022), Srivistava et al. (2023)
Antioxidant	Fahey (2005), Pandey et al. (2012), Stohs and Hartman (2015), Bhattacharya et al. (2018), Singh and Navneet (2018), Popoola et al. (2020), Azlan et al. (2022), Chaudhary et al. (2022), Kashyap

	et al. (2022), Liu et al. (2022), Njan et al. (2023), Pareek et al. (2023), Srivistava et al. (2023)
Immunostimulatory	Fahey (2005), Stohs and Hartman (2015), Bhattacharya et al. (2018), Kashyap et al. (2022), Liu et al. (2022), Njan et al. (2023), Pareek et al. (2023)
Protective against gastric ulcers	Fahey (2005), Pandey et al. (2012), Stohs and Hartman (2015), Bhattacharya et al. (2018), Singh and Navneet (2018), Popoola et al. (2020), Chaudhary et al. (2022), Liu et al. (2022), Njan et al. (2023), Pareek et al. (2023)
Wound healing	Fahey (2005), Pandey et al. (2012), Stohs and Hartman (2015), Bhattacharya et al. (2018), Singh and Navneet (2018), Popoola et al. (2020), Azlan et al. (2022), Chaudhary et al. (2022), Pareek et al. (2023)
Antidiabetic	Popoola et al. (2020), Chaudhary et al. (2022), Azlan et al. (2022), Kashyap et al. (2022), Liu et al. (2022), Pareek et al. (2023), Srivistava et al. (2023)
Cosmetic	Chaudhary et al. (2022)
Reduction in sebum	Bhattacharya et al. (2018)
Anti-asthmatic	Fahey (2005), Pandey et al. (2012), Chaudhary et al. (2022), Bhattacharya et al. (2018), Singh and Navneet (2018), Liu et al. (2022), Srivistava et al. (2023)
Treatment for bronchitis	Fahey (2005)
Prevention of blindness	Chaudhary et al. (2022)
Treatment for eye infections	Singh and Navneet (2018), Chaudhary et al. (2022)
Treatment for earache	Fahey (2005)
Treatment for throat infection	Fahey (2005)
Treatment for anaemia	Fahey (2005), Bhattacharya et al. (2018), Pareek et al. (2023)
Treatment for dysentery	Fahey (2005)
Treatment for systemic lupus erythematosus	Fahey (2005)
Treatment for splenomegaly	Fahey (2005), Pandey et al. (2012)
Treatment for irregular menses	Pandey et al. (2012)
Treatment for stomachache	Pandey et al. (2012)
Treatment for constipation	Pandey et al. (2012)
Treatment for haemorrhoids	Pandey et al. (2012)
Treatment for lumbago	Pandey et al. (2012)
Treatment for anaphylaxis	Pandey et al. (2012), Bhattacharya et al. (2018), Pareek et al. (2023)
Treatment for dental caries	Njan et al. (2023)
Treatment for snakebite	Pareek et al. (2023)
Neuroprotective	Popoola et al. (2020), Azlan et al. (2023), Pareek et al. (2023)
Beneficial to the liver	Fahey (2005), Pandey et al. (2012), Azlan et al. (2022), Stohs and Hartman (2015), Bhattacharya et al. (2018), Liu et al. (2022), Njan et al. (2023), Pareek et al. (2023), Srivistava et al. (2023)
Beneficial to the kidneys	Stohs and Hartman (2015), Bhattacharya et al. (2018), Azlan et al. (2022), Njan et al. (2023)
Beneficial to the myocardium	Pandey et al. (2012), Bhattacharya et al. (2018), Singh and Navneet (2018), Popoola et al. (2020), Azlan et al. (2022), Pareek et al. (2023)
Beneficial to bones	Srivistava et al. (2023)
Beneficial to joints	Fahey (2005), Pandey et al. (2012), Kashyap et al. (2022)
Beneficial to the thyroid	Fahey (2005)
Treatment for hyperthyroidism	Pandey et al. (2012), Njan et al. (2023)
Anti-obesity	Bhattacharya et al. (2018), Kashyap et al. (2022), Pareek et al. (2023)
Beneficial to the prostate	Fahey (2005)
Beneficial to the testes	Stohs and Hartman (2015), Bhattacharya et al. (2018), Pareek et al. (2023)

Beneficial to the urinary bladder	Fahey (2005)
Anti-catarrhal	Fahey (2005)
Anti-hypertensive	Fahey (2005), Pandey et al. (2012), Stohs and Hartman (2015), Bhattacharya et al. (2018), Singh and Navneet (2018), Chaudhary et al. (2022), Kashyap et al. (2022), Liu et al. (2022), Njan et al. (2023), Pareek et al. (2023), Srivistava et al. (2023)
Analgesic	Fahey (2005), Pandey et al. (2012), Singh and Navneet (2018), Stohs and Hartman (2015), Bhattacharya et al. (2018), Popoola et al. (2020), Chaudhary et al. (2022), Kashyap et al. (2022), Pareek et al. (2023)
Anti-migraine	Bhattacharya et al. (2018)
Memory enhancement	Njan et al. (2023)
Sedative	Pareek et al. (2023)
Contraceptive	Fahey (2005), Pandey et al. (2012)
Abortifacient	Fahey (2005), Pandey et al. (2012), Bhattacharya et al. (2018), Singh and Navneet (2018), Njan et al. (2023), Pareek et al. (2023)
Aphrodisiac	Fahey (2005)
Galactogogue	Fahey (2005), Raguinin et al. (2014), Bhattacharya et al. (2018), Njan et al. (2023)
Antispasmodic	Fahey (2005), Pandey et al. (2012), Singh and Navneet (2018), Liu et al. (2022), Njan et al. (2023)
Anti-epileptic	Fahey (2005), Pandey et al. (2012), Stohs and Hartman (2015), Bhattacharya et al. (2018), Njan et al. (2023), Pareek et al. (2023), Srivistava et al. (2023)
Muscle relaxant	Bhattacharya et al. (2018)
Purgative	Fahey (2005), Singh and Navneet (2018)
Carminative	Fahey (2005)
Rubifacient	Fahey (2005), Pandey et al. (2012), Singh and Navneet (2018), Njan et al. (2023)
Vesicant	Fahey (2005)
Hypocholesterolaemic	Fahey (2005), Pandey et al. (2012), Stohs and Hartman (2015), Bhattacharya et al. (2018), Singh and Navneet (2018), Liu et al. (2022)
Anti-hyperlipidaemic	Njan et al. (2023), Srivistava et al. (2023)
Anti-sclerotic	Njan et al. (2023)
Hypoglycaemic	Fahey (2005), Pandey et al. (2012), Stohs and Hartman (2015), Bhattacharya et al. (2018), Singh and Navneet (2018), Njan et al. (2023)
Diuretic	Fahey (2005), Pandey et al. (2012), Bhattacharya et al. (2018), Liu et al. (2022), Pareek et al. (2023)
Anti-diuretic	Njan et al. (2023)
Antiurolithiac	Pandey et al. (2012), Bhattacharya et al. (2018), Singh and Navneet (2018), Liu et al. (2022), Njan et al. (2023), Pareek et al. (2023)
Antipyretic	Pandey et al. (2012), Singh and Navneet (2018), Pareek et al. (2023)
CNS depressant	Stohs and Hartman (2015), Bhattacharya et al. (2018), Singh and Navneet (2018)
Anxiolytic	Singh and Navneet (2018), Pareek et al. (2023)
Protective against irradiation	Pandey et al. (2012), Stohs and Hartman (2015), Srivistava et al. (2023)
Protective against cerebral hypoxia	Stohs and Hartman (2015)
Protective against Alzheimer's disease	Pandey et al. (2012), Stohs and Hartman (2015) Bhattacharya et al. (2018
Increases platelet counts	Pareek et al. (2023)
Inhibits platelet aggregation	Pandey et al. (2012)
Inhibits peripheral conversion of triiodothyronine to thyroxine	Pandey et al. (2012)

FSANZ notes that some of these effects could be adverse rather than therapeutic in some people. For example, decreasing blood glucose is desirable in people with diabetes, but is potentially harmful in people with normal or subnormal blood glucose levels. It is also noted that some of the claimed effects contradict others. For example, *Moringa oleifera* is claimed to be a purgative but is also claimed to be anti-diarrhoeal and beneficial in dysentery. Different references describe it as either diuretic or anti-diuretic.

3.9 Safety assessment by other international or national agencies

The powdered leaf, whole or minimally processed root, and the seed oil of *Moringa oleifera* were determined by Health Canada to be not novel, based on history of safe use as food[2].

Moringa oleifera was on the market in the European Union (EU) prior to 15 May 1997 and is therefore not subject to Novel Food Regulation (EU) 2015/2283. Only leaves and seed pods are permitted to be sold.

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 Malunggay[3].

The European Food Safety Authority (EFSA) undertook an assessment[4] of a leaf powder from a related species, *Moringa stenopetala*, in 2019. Adverse effects on fertility of laboratory rodents in studies of *Moringa stenopetala* and studies of *Moringa oleifera* were among the reasons that EFSA raised safety objections to the placing of *Moringa stenopetala* leaf powder on the market in the EU.

3.10 Summary of risk assessment findings

The applicant seeks to amend the Code to permit the following foods derived from the *Moringa oleifera* plant, which are novel foods, to be a sold as food at 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).

***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.

[2] https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/requesting-novelty-determination/list-non-novel-determinations.html
[3] https://legacy.senate.gov.ph/lis/bill_res.aspx?congress=14&q=SBN-1799
[4] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2019.EN-1672

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 the 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.

4 Nutrition Risk Assessment

The objectives of the nutrition risk assessment were to:

- compare the composition of *Moringa oleifera* leaves, immature seed pods and oil to comparison foods
- evaluate whether the consumption of these products would cause a nutritional imbalance in the diet
- determine the effect of these products on the absorption of other nutrients.

The applicant suggested comparison foods of spinach, green beans and olive oil for *Moringa oleifera* leaves, immature seed pods and oil respectively. Based on the available literature, potential changes in the absorption of other nutrients due to consumption of Moringa immature seed pods and leaves were studied in terms of the presence of anti-nutritional factors including phytic acid, tannins, oxalates, trypsin inhibitors and cyanogenic glycosides.

The nutrition risk assessment was not completed due to the risk assessment findings (see Section 3.10 above).

5 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 was unable to establish that *Moringa oleifera* would not pose a safety concern if permitted for sale, a dietary exposure assessment was not conducted for this assessment.

6 Risk characterisation

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.

Risk assessments aim to estimate the likelihood and severity of an adverse health effect occurring from exposure to a hazard. As the hazard of *Moringa oleifera* leaf could not be characterized (and there was insufficient information to determine whether the same potential hazards are associated with seed pods or oil), a safe level of exposure for the requested foods could not be established. While there is a history of use of *Moringa oleifera* in some markets, there are no safety assessments for *Moringa oleifera* published by overseas food regulatory agencies that would demonstrate safety.

Given the above, a risk estimate could not be calculated for the requested foods, as risk is a function of both the hazard and the level of exposure to that hazard.

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.

7 References

Adedapo AA, Mogbojuri OM, Emikpe BO (2009) Safety evaluations of the aqueous extract of the leaves of Moringa oleifera in rats. Journal of Medicinal Plants Research 3(8): 586-591

Adegbite OA, Omolaso B, Seriki SA, Shatima C (2016) Effects of Moringa Oleifera Leaves on Hematological Indices in Humans. Annals of Hematology and Oncology ; 3(8): 1107

Agrawal SS, Vishal Dm Sumeet G, Shekhar C, Ashish N, Parul D, Ankita S, Prakash A, Prakash T, Kumar P, Varun C (2018). Antifertility Activity of Ethanol Leaf Extract of Moringa oleifera Lam. In female Wistar rats. Indian Journal of Pharmaceutical Sciences 80(3): 565-570

Amee R, Anadani SV, Gajera RR, Prasad RV (2020). Physical characterization and Optimization of Blanching Process of Moringa oleifera (var. PKM-1) Pods. Chemical Science Reviews and Letters 2020, 9 (33), 184-191. DOI:10.37273/chesci.CS20510114.

Asare GA, Gyan B., Bugyei K, Adjei S, Mahama R, Addo P, Otu-Nyarko L, Wiredu EK, Nyarko A (2012). Toxicity potentials of the nutraceutical Moringa oleifera at supra-supplementation levels. Journal of Ethnopharmacology:139(1):265-72

Attah AF, Moody JO, Sonibare MA, Salahdeen HH,Akindele OO, Nnamani PO, Diyaolu OA, Raji Y (2020). Aqueous extract of Moringa oleifera leaf used in Nigerian ethnomedicine alters conception and some pregnancy outcomes in Wistar rat. South African Journal of Botany 129: 255-262

Awodele O, Oreagba IA, Odoma S, Teixeira da Silva JA, Osunkalu VO (2012). Toxicological evaluation of the aqueous leaf extract of Moringa oleifera Lam. (Moringaceae) Journal of Ethnopharmacology. 139(2):330-6.

Azlan UK, Mediani A, Rohani ER, Tong X, Han R, Misnan NM, Jam FA, Bunawan H, Sarian MN, Hamezah HS (2022). A Comprehensive Review with Updated Future Perspectives on the Ethnomedicinal and Pharmacological Aspects of Moringa oleifera. Molecules, 27, 5765. https://doi.org/10.3390/molecules27185765

Balamurugan S, Vijayakumar S, Prabhu S, Morvin Yabesh JE (2018). Traditional plants used for the treatment of gynaecological disorders in Vedaranyam taluk, South India - An ethnomedicinal survey Journal of Traditional and Complementary Medicine 8(2): 308-32.

Bhattacharya A, Tiwari P, Sahu PK, Kumar S (2018). A review of the phytochemical and pharmacological characteristics of Moringa oleifera. Journal of Pharmacy and Bioallied Sciences 10, 181–191

Bolanle AO, Olufunmilayo A, Olorunfemi O, Temitayo O (2014). The effect of Moringa oleifera oil - based diet on growth performance, hematological parameters and plasma lipid profile in albino rats. World Journal of Pharmacy and Pharmaceutical Sciences. 3:121–130.

Chaudhary PH, Tawar MG, Jawkhede VM, Raut PK, Ramteke HR (2022) A Pharmacognosy, Ethanobotany and Phyto-pharmacology of Moringa oleifera Lam. International Journal of PharmTech Research 15(2):73-82 DOI:10.20902/IJPTR.2022.150207

D'Auria G, Nitride C, Nicolai MA, Mamone G, Montesano D, Mills ENC, Ferranti P (2023) Identification of allergen encoding sequences in a novel food ingredient from Moringa oleifera leaves. Food Chemistry 1:401:134185. doi: 10.1016/j.foodchem.2022.134185

De Barros MC, Silva AGB, Souza TGDS, Chagas CA, Machado JCB, Ferreira MRA, Soares LAL, Xavier VL, de Araújo LCC, Borba EFO, da Silva TG, Alves RRV, Coelho LCBB, de Oliveira AM, Napoleão TH, Paiva PMG (2022). Evaluation of acute toxicity, 28-day repeated dose toxicity, and genotoxicity of Moringa oleifera leaves infusion and powder. Journal of Ethnopharmacology 296:115504. doi: 10.1016/j.jep.2022.115504. Epub 2022 Jun 26. PMID: 35760258.

Ekhator CN, UC Osifo (2015). Abortifacient Efficacy of Moringa oleifera Leaves: An Experimental Study on Adult Female Wistar Rats. American Journal of Biology and Life Sciences 2015; 3(6): 269-272

Fahey J (2005). Moringa oleifera: A Review of the Medical Evidence for Its Nutritional, Therapeutic, and Prophylactic Properties. Part 1. Trees Life, 1.0.1201/9781420039078.ch12.

Food Standards Australia New Zealand (2024) Principles and practices of dietary exposure assessment for food regulatory purposes. 2nd edition. Food Standards Australia New Zealand, Canberra

George GO, Ajayi OB, Oyemike AA (2018) Effect of Moringa Oleifera leaf aqueous extract on intraocular and blood pressure of normotensive adults in Edo state, Nigeria. Journal of the Nigerian Optometric Association 20(2): 75 - 81

Grosshagauer S, Pirkwieser P, Kraemer K, Somoza V (2021). The Future of Moringa Foods: A Food Chemistry Perspective. Frontiers in. Nutrition 8:751076. doi: 0.3389/fnut.2021.751076

Ichrak B (2022) Anaphylaxis to Moringa oleifera in North Africa: A case report and review of the literature. Clinical Case Reports 3;10(8): e6193. doi: 10.1002/ccr3.6193

Iddagoda J, Gunasekara P, Handunnetti S, Jeewandara C, Karunatilake C, Malavige GN, de Silva R, Dasanayake D (2023). Identification of allergens in Artocarpus heterophyllus, Moringa oleifera, Trianthema portulacastrum and Syzygium samarangense. Clinical and Molecular Allergy 21(1):6. doi: 10.1186/s12948-023-00187-2.

Islam Z, Islam SMR, Hossen F, Mahtab-Ul-Islam K, Hasan Md R, Karim R (2021). Moringa oleifera is a Prominent Source of Nutrients with Potential Health Benefits. International Journal of Food Science, Aug 10:2021:6627265. doi: 10.1155/2021/6627265.

JECFA (2016) Guidance document for WHO monographers and reviewers evaluating food additives (excluding enzyme preparations and flavouring agents), version 1.0. https://iris.who.int/bitstream/handle/10665/206184/9789241510394_eng.pdf

Kashyap P, Kumar S, Riar CS, Jindal N, Baniwal P, Guiné RPF, Correia PMR, Mehra R, Kumar H (2022). Recent Advances in Drumstick (Moringa oleifera) Leaves Bioactive Compounds: Composition, Health Benefits, Bioaccessibility, and Dietary Applications. Antioxidants, 11, 402. https://doi.org/ 10.3390/antiox11020402

Kini SG, Wong KH, Tan WL, Xiao T, Tam JP (2017) Morintides: cargo-free chitin-binding peptides from Moringa oleifera. BMC Plant Biology 17(1):68. doi: 10.1186/s12870-017-1014-6.

Laoung-On J, Saenphet K, Jaikang C, Sudwan P (2021). Effect of Moringa oleifera Lam. Leaf Tea on Sexual Behavior and Reproductive Function in Male Rats. Plants (Basel). 10(10): 2019

Leone A, Spada, A, Battezzati A, Schiraldi A, Aristil J, Bertoli S (2016). Moringa oleifera Seeds and Oil: Characteristics and Uses for Human Health. International Journal of Molecular Sciences, 17(12) 2141. doi: 10.3390/ijms17122141

Liu R, Liu J, Huang Q, Liu S, Jiang Y (2022) Moringa oleifera: a systematic review of its botany, traditional uses, phytochemistry, pharmacology and toxicity, Journal of Pharmacy and Pharmacology 74(3): 296–320, https://doi.org/10.1093/jpp/rgab131

Moodley I (2017) Acute toxicity of Moringa oleifera leaf powder in rats. Journal of Medicinal Plants Studies 5(5): 180-185

Muslimin L, Panigoro R, Nugraha GI, Susanah S, Utama GL, Mas Rizki A, Asyamsumarno T. (2023). The Effect of Anti-nutrition and Bioavailability of Iron of Moringa Oleifera on Rat Hematology Model Iron Deficiency Anemia. Journal of Food and Nutrition Research, 11(1): 25-36. doi: 10.12691/jfnr-11-1-3

Nadeem M., Imran M. (2016). Promising features of Moringa oleifera oil: recent updates and perspectives. Lipids in Health and Disease15(1):212. doi: 10.1186/s12944-016-0379-0.

Nath D., Sethi N., Singh RK., Jain AK. (1992). Commonly used Indian abortifacient plants with special reference to their teratologic effects in rats J. Ethnopharmacology 36(2):147-154

Njan AA, Amali MO, Olatunji LO, Olorundare OE (2023) An Overview of the Ethno-Pharmacological Potentials of Moringa Oleifera Lam, “The Miracle Tree”. Archives of Basic and Applied Medicine 2:135-145

Núñez-Gastélum JA, Arguijo-Sustaita AA, López-Díaz JA, Diaz-Sanchez AG, Hernandez-Pena CC, Cota-Ruiz K (2022). Seed germination and sprouts production of Moringa oleifera: A potential functional food? Journal of the Saudi Society of Agricultural Sciences, https://doi.org/10.1016/j.jssas.2022.12.002.

Okumu MO, Mbaria JM, Kanja LW, Gakuya DW, Kiama SG, Ochola FO, Okumu PO (2003) Acute toxicity of the aqueous -methanolic Moringa oleifera (Lam) leaf extract on female Wistar albino rats. International Journal of Basic and Clinical Pharmacology 5(5) DOI: http://dx.doi.org/10.18203/2319-2003.ijbcp20163153

Olayemi AT, Olanrewaju MJ, Oloruntoba AC (2016). Toxicological evaluation of Moringa oleifera Lam seeds and leaves in Wistar rats Pharmacognosy Communications 6(2) 100-111

Onyeaghala A, Agwu MC, Ogungbemile BD (2024) Effect of Supplementation with Moringa Oleifera on Antioxidant and Oxidative Stress Biomarkers of Infertile Women: A Pilot Open-Label Case-Control Randomized Clinical Study. Qeios. doi:10.32388/KMR4OD.

Pandey A, Pandey RD, Tripathi P, Gupta PP, Haider J, Bhatt S, Singh AV (2012). Moringa Oleifera Lam. (Sahijan) - A Plant with a Plethora of Diverse Therapeutic Benefits: An Updated Retrospection. Medicinal Aromatic Plants 1:1 http://dx.doi.org/10.4172/map.100010

Pareek A, Pant M, Gupta MM, Kashania P, Ratan Y, Jain V, Pareek A, Chuturgoon AA (2023). Moringa oleifera: An Updated Comprehensive Review of Its Pharmacological Activities, Ethnomedicinal, Phytopharmaceutical Formulation, Clinical, Phytochemical, and Toxicological Aspects. International Journal of Molecular Sciences 24: 2098. https://doi.org/10.3390/ijms24032098

Popoola JO, Aworunse OS, Oyesola LO, Akinnola OO, Obembe OO (2020). A systematic review of pharmacological activities and safety of Moringa oleifera. J Herbmed Pharmacology 9(3):174-190. doi: 10.34172/jhp.2020.24

Promkum C, i Kupradinun P, Tuntipopipat S, Butryee C (2010) Nutritive Evaluation and Effect of Moringa oleifera pod on Clastogenic Potential in the Mouse. Asian Pacific Journal of Cancer Prevention 11: 627-632

Raguinin PFN, Dans LF, King JF (2014). Moringa oleifera as a Galactagogue. Breastfeeding Medicine 9(6):323-4. doi: 10.1089/bfm.2014.0002

Razzak A, Roy KR, Sadia U, ZZaman W (2022) Effect of Thermal Processing on Physicochemical and Antioxidant Properties of Raw and Cooked Moringa oleifera Lam. Pods. International Journal of Food Science https://doi.org/10.1155/2022/1502857

Sethi N, Nath D, Shukla S, Dyal R (1988). Abortifacient activity of a medicinal plant Moringa oleifera. Ancient science of life. 7(3&4) 172-174

Singh A, Navneet (2018) Ethnomedicinal, Pharmacological and Antimicrobial Aspects of Moringa oleifera Lam.: A review. The Journal of Phytopharmacology 7(1): 45-50

Srivastava S, Pandey VK, Dash KK, Dayal D, Wal P, Debnath B, Singh R, Dar AH (2023). Dynamic bioactive properties of nutritional superfood Moringa oleifera: A comprehensive review. Journal of Agriculture and Food Research 14:100860. https://www.sciencedirect.com/science/article/pii/S2666154323003678

Stohs SJ, Hartman MJ (2015). Review of the Safety and Efficacy of Moringa oleifera. Phytotherapy Research 29(6):796-804. doi: 10.1002/ptr.5325

Suzana D, Suyatna FD, Azizahwati, Andrajati R, Sari SP, Mun'im A (2017). Effect of moringa oleifera leaves extract against hematology and blood biochemical value of patients with iron deficiency anemia. Journal of Young Pharmacists, 9(1), S79-S84. https://doi.org/10.5530/jyp.2017.1s.20

Zeng B, Luo J, Wang P, Yang L, Chen T, Sun J, Xie M, Li M, Zhang H, He J, Zhang Y, Xi Q (2019). The beneficial effects of Moringa oleifera leaf on reproductive performance in mice. Food Science and Nutrition 7:738–746

Zvinorova PI, Lekhanya L, Erlwanger K, Chivandi E (2014). Dietary effects of Moringa oleifera leaf powder on growth, gastrointestinal morphometry and blood and liver metabolites in Sprague Dawley rats. Journal of Animal Physiology and Animal Nutrition 99(1):21-28. doi: 10.1111/jpn.12182