20 December 2017
[35-17]

Approval report – Application A1143

Food derived from DHA Canola Line NS-B50027-4

Food Standards Australia New Zealand (FSANZ) has assessed an Application made by Nuseed Pty Ltd to seek approval for food derived from canola line NS-B50027-4 genetically modified to introduce, into the seed, the pathway for producing the long-chain omega-3 fatty acid docosahexaenoic acid (DHA) from oleic acid.

On 14 September 2017 FSANZ sought submissions on a draft variation and published an associated report. FSANZ received three submissions.

FSANZ approved the draft variation on 6 December 2017. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 19 December 2017.

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

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Supporting documents

The following documents[1] which informed the assessment of this Application are available on the FSANZ website:

SD1 Safety Assessment Report (at Approval)
SD2 Nutrition Risk Assessment Report (at Approval)

[1] http://www.foodstandards.gov.au/code/applications/Pages/A1143-DHA-Canola-Line-NS–B500274.aspx

Executive summary

Food Standards Australia New Zealand (FSANZ) received an Application from Nuseed Pty Ltd on 10 February 2017. The Applicant requested a variation to Schedule 26 in the *Australia New Zealand Food Standards Code* (the Code) to include food from a new genetically modified (GM) canola (*Brassica napus*) line, NS-B50027-4 (henceforth referred to as DHA canola). This canola line has been genetically modified to produce omega-3 long chain fatty acids, particularly docosahexaenoic acid, in the seed.

The primary objective of FSANZ in developing or varying a food regulatory measure, as stated in section 18 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), is the protection of public health and safety. Accordingly, the safety assessment is a central part of considering an application.

Schedule 25 of the Code permits several DHA-rich oils from algal sources to be used as novel foods.

The safety assessment of DHA canola is provided in Supporting Document 1 and the Nutrition Risk Assessment is provided in Supporting Document 2. No potential public health and safety concerns have been identified. Based on the data provided in the present Application, and other available information, food derived from DHA canola is considered to be as safe for human consumption as food derived from conventional canola cultivars.

The FSANZ Board has approved the draft variation to Schedule 26 that includes permission for food derived from DHA canola line NS-B50027-4.

1 Introduction

1.1 The Applicant

Nuseed Pty Ltd (Nuseed), a wholly owned subsidiary of Nufarm Limited, is a specialised global seed company.

1.2 The Application

Application A1143 was submitted by Nuseed on 10 February 2017. It seeks a variation to Schedule 26 in the *Australia New Zealand Food Standards Code* (the Code) to include food from a new genetically modified (GM) canola (*Brassica napus*) line NS-B50027-4 (henceforth referred to as DHA canola). This canola line has been genetically modified to introduce, into the seed, the pathway for producing the omega-3 long chain polyunsaturated fatty acid (n-3 LC PUFA) docosahexaenoic acid (DHA) from oleic acid (OA). Other n-3 LC PUFAs in the DHA synthesis pathway, particularly eicosapentaenoic acid, (EPA) would also be present.

Coding sequences from seven genes in the DHA pathway have been introduced as follows:

- Δ12 desaturase *(Lackl-Δ12D)* from the yeast *Lachancea kluyveri*
- Δ15-/ ω3 desaturase *(Picpa- ω3D*) from the yeast *Pichia pastoris*
- Δ6 elongase *(Pyrco-Δ6E)* from the marine microalga *Pyramimonas cordata*
- Δ6 desaturase *(Micpu-Δ6D)* from the marine microalga *Micromonas pusilla*
- Δ5 elongase *(Pyrco-Δ5E)* from the marine microalga *Pyramimonas cordata*
- Δ5 desaturase *(Pavsa-Δ5D)* from the marine microalga *Pavlova salina*
- Δ4 desaturase *(Pavsa-Δ4D)* from the marine microalga *Pavlova salina.*

In addition, DHA canola also contains the phosphinothricin N-acetyltransferase (*pat*) gene from *Streptomyces viridochromogenes* that confers tolerance to the herbicide phosphinothricin – also known as glufosinate ammonium (glufosinate). The glufosinate tolerance was used to select putative transformants during the transformation stage and was not subsequently selected for breeding of the final DHA canola line.

The Applicant has indicated oil from DHA canola may be used as an alternate source of n-3 LC PUFAs in existing food ingredient markets for fish oils or established omega-3 markets. Possible target product examples include:

- dairy products enriched with fish oil: milk (flavoured or plain), cream cheese products, yoghurts, custard desserts and dairy alternatives (soy milk, soy cheese)
- bread and cereals enriched with fish oil or omega-3: muesli, breakfast cereal, cereal bars, white bread, multigrain bread
- spreads, condiments and sauces containing omega-3: margarine (or margarine blends), salad dressings, mayonnaise, dips (e.g. hummus)
- tinned fish in oil: tinned tuna chunks, tinned tuna sandwich filling (plain or flavoured); tinned bean mix.

DHA oil could be used in the future with new processing or micro-encapsulation/micro-emulsion technologies. These possibilities could include foods like frozen/chilled meals, juice/smoothies or soups.

1.3 The current standards

Pre-market approval is necessary before a GM food may enter the Australian and New Zealand food supply. Approval of such foods is contingent on completion of a comprehensive pre-market safety assessment. Standard 1.5.2 sets out the permission and conditions for the sale and use of food produced using gene technology (a GM food). Foods that have been assessed and approved are listed in Schedule 26.

Section 1.5.2—4 of Standard 1.5.2 also contains specific labelling provisions for approved GM foods. Subject to certain exceptions listed below, GM foods and ingredients (including food additives and processing aids from GM sources) must be identified on labels with the words 'genetically modified', if novel DNA or novel protein (as defined in Standard 1.5.2) is present in the food. Foods listed in subsections S26—3(2) and (3) of Schedule 26 must also be labelled with the words 'genetically modified', as well as any other additional labelling required by the Schedule, regardless of the presence of novel DNA or novel protein in the foods. These foods are considered to have an altered characteristic, such as an altered composition or nutritional profile, when compared to the existing counterpart food that is not produced using gene technology.

The requirement to label food as 'genetically modified' does not apply to GM food that:

- has been highly refined (other than food that has been altered), where the effect of the refining process is to remove novel DNA or novel protein
- is a substance used as a processing aid or a food additive, where novel DNA or novel protein from the substance does not remain present in the final food
- is a flavouring substance present in the food in a concentration of no more than 1 g/kg (0.1%)
- is intended for immediate consumption and which is prepared and sold from food premises and vending machines, including restaurants, take away outlets, caterers, or self-catering institutions
- is unintentionally present in the food in an amount of no more than 10 g/kg (or 1%) of each ingredient.

If the GM food for sale is not required to bear a label, the labelling information referred to in section 1.5.2—4 must accompany the food or be displayed in connection with the display of the food (in accordance with subsections 1.2.1—9(2) and (3) of Standard 1.2.1).

Standard 1.5.1 – Novel foods and Schedule 25 – Permitted novel foods, contain permissions for the sale of novel foods that have been assessed and approved by FSANZ. Several DHA-rich oils derived from different marine micro-algae species are listed in Schedule 25 and permitted for use in all foods; only one of these is permitted in infant formula products in accordance with Standard 2.9.1 – Infant formula products (see also discussion in section 2.3.1).

Schedule 3 – Identity and purity, includes specifications for the following oils derived from marine micro-algae species rich in DHA:

- oil derived from the algae *Crypthecodinium cohnii* rich in docosahexaenoic acid (DHA)
- oil derived from marine micro-algae (*Schizochytrium* sp.) rich in docosahexaenoic acid (DHA) (2 specifications)
- oil derived from marine micro-algae (*Ulkenia* sp.) rich in docosahexaenoic acid (DHA).

All of these specifications refer to minimum levels of DHA and maximum *trans* fatty acids; a maximum EPA level is also established for the *Schizochytrium* sp oil permitted only for use in infant formula products.

1.4 Reasons for accepting Application

The Application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the FSANZ Act
- it related to a matter that warranted the variation of a food regulatory measure
- it was not so similar to a previous application for the variation of a food regulatory measure that it ought to be rejected.

1.5 Procedure for assessment

The Application was assessed under the General Procedure.

1.6 Decision

The draft variation as proposed following assessment was approved without change. The variation takes effect on the date of gazettal. The approved draft variation is at Attachment A.

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

2 Summary of the findings

2.1 Summary of issues raised in submissions

A total of three submissions were received, all from jurisdictions, none of which were opposed to the proposed draft variation to Schedule 26. There were, however, several issues raised and these are addressed in Table 1.

Table 1: Summary of issues

Issue	Raised by	FSANZ response (including any amendments to drafting)
Policy issues regarding nutritionally modified foods by means of genetic modification were raised, including that: • Policy Guidelines should be reviewed to consider new fortification technologies; this matter has been raised with the Food Regulation Standing Committee (FRSC). • it is an important precedent that approval be considered in relation to biofortification policy. • Codex Alimentarius is currently in the process of drafting a definition for biofortification.	• Victorian Government Departments of Health & Human Services and Economic Development, Jobs, Transport & Resources (Vic Govt) • SA Health	Noted. Policy review and development is the role of FRSC and the Forum on Food Regulation (the Forum), and not FSANZ. As above. The ongoing work by the Codex Committee on Nutrition and Foods for Special Dietary Uses in drafting a biofortification definition is noted. No definition is yet confirmed and cannot be used as clear guidance at this time.

Issue	Raised by	FSANZ response (including any amendments to drafting)
FSANZ should consider a 'stop clock' on the application until a biofortification policy is developed.	• SA Health	FSANZ must process applications in accordance with the *FSANZ Act 1991.* Section 109 of that Act sets out when FSANZ may stop the clock on an application. It permits FSANZ to suspend consideration of an application if the Forum has notified FSANZ that the Forum is formulating a policy guideline and the application, in FSANZ's opinion, would be affected by that policy guideline, once formulated. In addition, if the application is a paid application, suspension of processing can only occur with the applicant's consent. In this case, no such notification has been received from the Forum. Application A1143 is also a paid application.
Consumers should be informed of the nutritional change through mandatory additional labelling	• SA Health	FSANZ provided rationale in the Call for Submissions against mandating an additional labelling statement that this canola line has been modified to contain DHA as an omega-3 fatty acid. This rationale is repeated in section 2.3.2.2 of this report. FSANZ maintains the view that additional labelling should not be mandated. This aligns with the approach taken for four of the five previously assessed foods that are genetically modified for the purpose of changing the nutritional profile but have no additional labelling requirement: – high oleic acid soybean line DP-305423-1 – herbicide-tolerant high oleic acid soybean line MON87705 – soybean line MON87769 producing stearidonic acid – reduced acrylamide potential and reduced browning potato line E12 (containing reduced levels of asparagine, fructose and glucose).
The drafting excluding the use of oil from DHA canola in infant formula products may be more appropriately placed in Standard 2.9.1 than in Schedule 26	• SA Health	Having the exclusion in Schedule 26, which is linked to Standard 1.5.2, is consistent with the approach taken with similar approvals in the Code e.g. conditions of use of approvals associated with Standard 1.5.1 – Novel Foods, are explicitly stated in Schedule 25 – Permitted novel foods
While it is noted that specific information on the fatty acid profile of DHA canola is currently CCI, it is recommended that high level information be provided in Table 10 of SD1.	• New Zealand Ministry for Primary Industries (NZ MPI)	Table 10 in SD1 has been updated to include the probability outcomes of the statistical analysis and to indicate, in an analyte where there was a significant difference between DHA canola and the AV Jade control, whether the DHA canola mean was higher or lower than the AV Jade mean.
Specific information about *trans* fatty acids in DHA canola should be provided in the SD1 and discussed or cross-referenced in SD2	• NZ MPI	Section 5.3.2 of SD1 has been updated to include the identity of the DHA canola 18:3 *trans* fatty acids (which make up the greatest contribution to the total *trans* fatty acids), and recent information provided by the Applicant on the results of testing for *trans* fatty acids in a laboratory–scale production of refined, bleached and deodorised (RBD) DHA canola oil. Section 1 of SD2 has been updated to include a cross reference to the discussion on the nutritional impact of *trans* fatty acids in DHA canola in section 6.1 of SD1.

Issue	Raised by	FSANZ response (including any amendments to drafting)
If, in the future, oil from DHA canola were permitted to be used in infant formula products, a specification in Schedule 3 would be needed.	• NZ MPI	Noted. Should permission for use in infant formula products be sought and approved in the future, a specification in Schedule 3 – Identity and purity, would be considered.

2.2 Safety and nutrition risk assessment

In conducting an assessment of food derived from DHA canola, a number of criteria have been addressed including: a characterisation of the transferred gene sequences, their origin, function and stability in the canola genome; the changes at the level of DNA and protein in the whole food; compositional analyses; an evaluation of intended and unintended changes; and a nutrition assessment comprising a hazard assessment and a dietary intake assessment.

FSANZ's safety assessment, as reported in Supporting Document 1 (SD1) and which deals with the genetic modification *per se,* did not identify any potential public health and safety concerns. FSANZ concluded from its safety assessment that based on the data provided in the Application and other available information, food derived from DHA canola is considered to be as safe for human consumption as food derived from conventional canola cultivars. SD1 focusses on human food safety and therefore does not address any risks to the environment that may occur as the result of growing GM plants used in food production or any risks to animals that may consume feed derived from GM plants. Some changes in the SD1 released with the call for submissions have been made; these relate to correction of typographical errors and to the updating of information on the fatty acids in DHA canola (as indicated in Table 1 above).

DHA is mainly obtained from consuming seafood and marine oils, with a contribution due to endogenous biosynthesis from dietary α-linolenic acid (ALA). DHA plays a role in physiological functions including regulating inflammation and immune function, lipid metabolism, and cardiovascular function.

Supporting Document 2 (SD2) reports on the nutrition risk assessment undertaken by FSANZ and includes a:

- nutrition hazard assessment that considered potential adverse effects associated with DHA intake, and information on the Upper Level of Intake (UL) for omega-3 long chain polyunsaturated fatty acids (n-3 LC-PUFA), defined as the sum of DHA, docosapentaenoic acid (DPA) and EPA

- dietary intake assessment that considered the usual intake of n-3 LC-PUFA from the current food supply (baseline intake) in Australia and New Zealand and two scenarios to account for potential additional intake of DHA due to the introduction of DHA canola oil.

The nutrition hazard assessment concluded that DHA intakes of up to 6 g/day do not raise safety concerns. This value is greater than the UL for n-3 LC-PUFA, namely 3 g/day. The dietary intake estimates for all population groups in both Australia and New Zealand were below the UL of 3 g/day for n-3 LC-PUFA. FSANZ therefore concluded that consumption of DHA canola oil will not pose a nutritional concern to the Australian and New Zealand population.

2.3 Risk management

FSANZ considered a number of risk management issues, specifically public health nutrition issues that may arise should foods derived from DHA canola be sold in Australia and New Zealand, as well as labelling and detection methodology. The safety assessment of the genetic modification (section 2.1 and SD1) concluded that food derived from DHA canola is considered to be as safe for human consumption as food derived from conventional canola cultivars. Specific nutrition issues associated with the GM line of DHA canola are discussed below.

2.3.1 Nutrition issues

The Applicant proposes that oil derived from DHA canola may be used as a substitute ingredient for omega-3 oil or fish oil in existing food ingredient markets. As this is a line that is not yet commercialised, the market uptake of foods containing DHA canola oil is relatively unknown. The dietary intake assessment therefore used two highly conservative scenarios: 1) DHA canola oil replaces all canola oil consumed by Australian and New Zealand populations (scenario 1); and 2) In addition to scenario 1, DHA canola oil also replaces 30% of all non-specified vegetable oil (scenario 2). The assessment estimated intakes of n-3 LC-PUFA and not DHA specifically as nutrient reference values are established only for n-3 LC-PUFA as a group of long chain fatty acids.

FSANZ acknowledges that, in addition to the oil, other foods derived from the DHA canola (e.g. canola meal or seeds) could potentially be used in the food supply. The Applicant notes that DHA canola meal would be used in a manner similar to conventional canola meal, primarily as animal feed, and that canola meal is rarely used in food products. The Applicant also notes that whole canola seed while typically not sold to consumers alone may be added to commercially-produced bread products. FSANZ therefore expects that the consumption of foods, other than the oil, derived from DHA canola in Australia and New Zealand would be minor. Given the highly conservative scenarios used in the dietary intake assessment, the minor consumption of other foods derived from DHA canola would be unlikely to increase population intakes of n-3 LC-PUFA to levels of concern.

DHA canola seeds were found to have a significantly higher level of total *trans* fatty acids than that found in the parental non-GM control and other commercial non-GM canola lines. Although the level was increased, the total *trans* fat level in both the DHA canola seed, and in an experimentally produced RBD oil, was ≤1% of the total fatty acids. As canola oils are diluted when used, the overall level of *trans* fatty acids consumed would also be further reduced. Furthermore, *trans* fatty acids are present in other RBD non-GM vegetable oils, including soybean, sunflower and rice oils, and the *trans* fatty acid content of DHA canola is not expected to vary significantly from these other vegetable oils. Finally, a consideration of the consumption data of *trans* fatty acids in the Australian/New Zealand diets (see section 6.1 of SD1) indicates consumption of food derived from DHA canola does not pose a public health concern. FSANZ therefore concluded that permitting any food derived from DHA canola to be sold in Australia and New Zealand poses no nutritional public health risk as a result of increased n-3 LC-PUFA intake.

Chapter 2 of the Code, Standard 2.9.1 – Infant Formula Products[2] regulates the fatty acid content of infant formula products. In 2017, FSANZ assessed Application A1124 – Alternative DHA-rich Algal Oil for Infant Formula Products which approved the use of DHA rich oil from a new production strain of *Schizochytrium* sp. known as American Type Cell Culture (ATCC) PTA-9695 in infant formula products.

[2] https://www.legislation.gov.au/Series/F2015L00409

The assessment had regard to the Policy Guideline on *Regulation of Infant Formula Products*[3] and reviewed studies of this particular oil in relation to infant health. However, in relation to the assessment of A1143, no such studies are available on the use of the DHA canola oil and infant health. Therefore the approved draft variation does not permit the use of oil derived from DHA canola in infant formula products. The exclusion of the oil from infant formula products is based on a lack of specific data in Application A1143 regarding use in infant formula products, rather than from any identified safety concern.

2.3.2 Labelling

2.3.2.1 Requirement to be labelled as 'genetically modified'

In accordance with the labelling provisions in Standard 1.5.2 and subject to certain exceptions listed in Part 1.3 above, food derived from DHA canola would generally be required to be labelled as 'genetically modified' if it contains novel DNA or novel protein. In addition, if the product is listed in section S26—3 of Schedule 26 labelling must comply with section 1.5.2–4 of Standard 1.5.2 (such food has altered characteristics).

FSANZ has determined that whole seeds from DHA canola contain novel DNA and novel protein and contain an altered nutritional profile that is outside the compositional variation found in existing counterpart food. As such, whole seeds will require the mandatory statement 'genetically modified' on the label of a package of food. Where food products include whole canola seeds as ingredients but are not required to bear a label (for example, 'fresh' bread containing whole canola seeds that is made and packaged on the premises from which it is sold), the mandatory statement will need to accompany the food or be displayed in connection with the display of the food.

Canola oil is the major product of DHA canola intended for human consumption (see section 2.1 of SD1). DHA canola oil is unlikely to contain novel DNA or novel protein due to the refining process used to extract the oil from the seed. The product will, however, have a nutritional profile that differs from canola oil derived from conventional (non-GM) canola seeds. FSANZ has approved a draft variation to list food derived from DHA canola in subsection S26—3(2) of Schedule 26. The purpose of this listing is to ensure food derived from GM canola with an altered nutritional profile is labelled with the mandatory 'genetically modified' statement irrespective of the presence of novel DNA or novel protein. Similar to whole canola seeds, the labelling information will apply to food containing canola oil as an ingredient where the food is not required to bear a label.

Canola meal is a by-product of seed oil extraction. The extraction process means that the nutritional profile of the DHA canola meal is likely to be the same as for meal from conventional (non-GM) canola seeds. However, novel DNA and novel protein will be present in the DHA canola meal. Mandatory labelling will therefore apply to the meal if it was used as an ingredient in a packaged or an unpackaged food.

In summary, Table 2 lists scenarios in which the mandatory statement will or will not apply to food derived from DHA canola.

[3] http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx

Table 2: Application of labelling requirements for food derived from DHA canola

DHA canola food/ingredient	Mandatory statement
Contains novel DNA or novel protein	✓
Contains altered fatty acid profile	✓
Novel DNA or protein absent but contains altered fatty acid profile	✓
Novel DNA or protein not present and no altered fatty acid profile i.e. the same as its conventional (non-GM) counterpart	×

Existing labelling provisions specify that food intended for immediate consumption that is prepared and sold from food premises and vending vehicles is exempt from GM food labelling requirements (see section 1.3).

However, paragraph 1.2.1—15(f) of Standard 1.2.1 requires information relating to foods produced using gene technology to be on labelling for food sold to a caterer. Subsection 1.1.2—2(3) of Standard 1.1.2 defines 'caterer' to mean a person, establishment or institution (for example, a catering establishment, a restaurant, a canteen, a school, or a hospital) which handles or offers food for immediate consumption. Consequently, in relation to such food, a consumer may seek information about the food from the food business. Any representations made by the food business about a food derived from DHA canola would be subject to other Australian and New Zealand laws designed to prevent misleading or deceptive conduct, including in relation to food.

2.3.2.2 Need for additional labelling requirements

Labelling of GM food is intended to address the objective set out in paragraph 18(1)(b) of the FSANZ Act—the provision of adequate information relating to food to enable consumers to make informed choices. For this reason, FSANZ considered whether additional labelling (i.e. in addition to the mandatory 'genetically modified' statement described above) is required to alert consumers to the nature of the altered characteristic in GM canola when compared to non-GM canola products.

Canola oil and whole seeds from DHA canola will contain an altered fatty acid profile. However, FSANZ has not mandated additional labelling due to the following reasons:

- The canola has been genetically modified to contain the n-3 LC-PUFA, DHA, although other n-3 LC PUFAs (namely EPA and docosapentaenoic acid (DPA)) are also present in small amounts. FSANZ notes that consumers are more likely to have a better understanding of the general terms 'omega-3' and 'polyunsaturated fats' than to have an understanding of the specific fatty acids. As such, mandatory labelling that refers to specific fatty acids, such as DHA, could be confusing to consumers.
- A mandatory statement to the effect that the food has been genetically modified to contain DHA as an omega-3 fatty acid, would be inconsistent with existing omega-3 claim conditions in section S4—3 of Schedule 4 (Nutrition, health and related claims).

  Section S4—3 includes the claim condition that a serving of the food carrying an omega-3 nutrition claim must contain minimum amounts of ALA or EPA and DHA, whereas a mandatory labelling statement for DHA canola seed oil would simply inform consumers of the presence of DHA or omega-3 fatty acids, irrespective of the amount in the food or ingredient.

- A mandatory statement could also imply that the food contributes a nutritionally significant amount of DHA or n-3 LC PUFAs, when the actual amount may be negligible (for example, when oil from DHA canola is used as a minor ingredient in food). In addition, consumers could assume, inappropriately, that DHA provides an equivalent amount of n-3 LC PUFAs derived from fish.

2.3.2.3 Voluntary representations made about food

As a result of the nutrition assessment, FSANZ concluded that oil produced from DHA canola has the potential to be used as a source of omega-3 fatty acids. Canola oil derived from DHA canola may meet the requirements for making a nutrition content claim in relation to its omega-3 fatty acid content or polyunsaturated fatty acid content. The conditions for making such claims are set out in section S4—3 of Schedule 4 and other nutrition content claim requirements are set out in Standard 1.2.7 (Nutrition, health and related claims). The onus is on the supplier to determine whether their food product meets these conditions and requirements before making a nutrition content claim.

Additionally, as mentioned above, representations made about a food derived from DHA canola would also be subject to other Australian and New Zealand laws designed to prevent misleading or deceptive conduct, including in relation to food.

2.3.3 Detection methodology

An Expert Advisory Group (EAG), involving laboratory personnel and representatives of the Australian and New Zealand jurisdictions was formed by the Food Regulation Standing Committee's Implementation Sub-Committee[4] to identify and evaluate appropriate methods of analysis associated with all applications to FSANZ, including those applications for food derived from gene technology (GM applications).

The EAG indicated that for GM applications, the full DNA sequence of the insert and adjacent genomic DNA are sufficient data to be provided for analytical purposes. Using this information, any DNA analytical laboratory would have the capability to develop a PCR-based detection method. This sequence information was supplied by the Applicant for A1143.

2.4 Risk communication

2.4.1 Consultation

Consultation is a key part of FSANZ's standards development process. The process by which FSANZ considers standards matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on issues raised by the Application and the impacts of regulatory options.

Public submissions were invited on a draft variation which was released for public comment between 3 August and 14 September 2017.

The call for submissions was notified via the Notification Circular, media release and through FSANZ's social media tools and the publication, Food Standards News. Subscribers and interested parties were also notified.

[4] Now known as the Implementation Subcommittee for Food Regulation

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Application. Every submission on this Application was considered by the FSANZ Board. All comments are valued and contribute to the rigour of the safety assessment.

Documents relating to Application A1138, including submissions received, are available on the FSANZ website[5].

2.5 FSANZ Act assessment requirements

2.5.1 Section 29

2.5.1.1 Consideration of costs and benefits

The Office of Best Practice Regulation (OBPR), in a letter to FSANZ dated 24 November 2010, granted a standing exemption from the need for FSANZ to prepare a Regulatory Impact Statement in relation to the approval of genetically modified foods (ref 12065).

This standing exemption was provided as such changes are considered as minor, machinery and deregulatory in nature. The exemption relates to the introduction of a food to the food supply that has been determined to be safe.

Notwithstanding the above exemption, FSANZ conducted a cost benefit analysis. That analysis found the direct and indirect benefits that would arise from a food regulatory measure developed or varied as a result of the Application outweigh the costs to the community, government or industry that would arise from the development or variation of that measure.

A consideration of the cost/benefit of the regulatory options is not intended to be an exhaustive, quantitative financial analysis of the options as most of the impacts that are considered cannot be assigned a dollar value. Rather, the analysis seeks to highlight the qualitative impacts of criteria that are relevant to each option. These criteria are deliberately limited to those involving broad areas such as trade, consumer information and compliance.

Option 1 was selected.

Option 1 – Approve the draft variation

Consumers: Food from DHA canola has been assessed as being as safe as food from conventional lines of canola.

Broader availability of imported canola products since, if DHA canola is approved for commercial growing in other countries, there would be no restriction on imported foods containing this line.

Labelling of food derived from DHA canola containing novel DNA, novel protein or an altered fatty acid profile, and is sold packaged (e.g. a bottle of mayonnaise containing DHA canola oil) or unpackaged (e.g. 'fresh' bread containing whole canola seeds that is made and packaged on the premises from which it is sold) would allow consumers wishing to avoid these products to do so.

[5] http://www.foodstandards.gov.au/code/applications/Pages/A1143-DHA-Canola-Line-NS%e2%80%93B500274.aspx

Consumers are able to seek information from food premises (e.g. restaurants, takeaway outlets or caterers) that prepare food intended for immediate consumption using DHA canola products.

If DHA canola is approved for commercial growing in either overseas countries or Australia/New Zealand it could be used in the manufacture of products using co-mingled canola seed. This means that there would be no cost involved in having to exclude the DHA canola seed from co-mingling and hence that there would be no consequential need to increase the prices of foods that are manufactured using co-mingled canola seed.

Government: Approval would avoid any conflict with WTO obligations. As mentioned above, food from DHA canola has been assessed as being as safe as food from conventional lines of canola.

This option would be cost neutral in terms of compliance costs, as monitoring is required irrespective of whether or not a GM food is approved. In the case of approved GM foods, monitoring is required to ensure compliance with the labelling requirements, and in the case of GM foods that have not been approved, monitoring is required to ensure they are not illegally entering the food supply.

Industry: Foods derived from DHA canola would be permitted under the Code, allowing broader market access and increased choice in raw materials.

The segregation of DHA canola seed from conventional canola seed, as for any GM crop, will be driven by industry, based on market preferences. Implicit in this will be a due regard to the cost of segregation.

Retailers may be able to offer a broader range of canola products or imported foods manufactured using canola derivatives.

There may be additional costs to the food industry as food ingredients derived from DHA canola would require the 'genetically modified' labelling statement if they contain novel DNA, novel protein or an altered fatty acid profile.

Option 2 – Reject the draft variation

As food derived from DHA canola has been found to be as safe as food from conventional counterparts, not preparing a draft variation would offer little relative benefit to consumers, government and industry.

The direct and indirect benefits that would arise from a food regulatory measure developed or varied as a result of the application outweigh the costs to the community, Government or industry that would arise from the development or variation of the food regulatory measure.

2.5.1.2 Other measures

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

2.5.1.3 Any relevant New Zealand standards

Standard 1.5.2 and Schedule 26 also apply in New Zealand.

2.5.1.4 Any other relevant matters

The Applicant has submitted applications for regulatory approval of DHA canola to a number of other regulators, as listed in Table 3.

It is the Applicant's intention to commercially cultivate DHA canola in Australia and an application to the OGTR to do this has been submitted. Should cultivation in New Zealand be sought, this would require assessment by the Environmental Protection Authority in New Zealand.

Table 3: List of countries to whom applications for regulatory approval of DHA canola have been submitted

Country	Agency	Type of approval sought	Status
Australia	Office of the Gene Technology Regulator (OGTR)	environment[1]/feed	Under assessment
USA	Food and Drug Administration (FDA)	food/feed	Under assessment
	United States Department of Agriculture Biotechnology Regulatory Services (USDA BRS)	environment[1]	Under assessment
Canada	Health Canada (HC)	food	Under assessment
	Canadian Food Inspection Agency (CFIA)	environment[1]/feed	Under assessment

[1]an authorisation for 'environment' indicates the line can be grown commercially in that country.

2.5.2. Subsection 18(1)

FSANZ has had regard to the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

2.5.2.1 Protection of public health and safety

Food derived from DHA canola has been assessed based on the data requirements provided in the FSANZ *Application Handbook*[6] which, in turn reflect internationally-accepted GM food safety assessment guidelines. No public health and safety concerns were identified in this assessment. Based on the available evidence, including detailed studies provided by the Applicant, food derived from DHA canola is considered as safe and wholesome as food derived from other commercial canola lines.

As a result of the nutrition assessment undertaken by FSANZ, which specifically considered the intake of n-3 LC PUFAs, FSANZ concluded that consumption of food derived from DHA canola will not pose a nutritional risk to the Australian and New Zealand population.

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

Where labelling applies to food derived from DHA canola, this would enable informed consumer choice (see section 2.3.2). Consumers can seek information about food intended for immediate consumption, that is prepared and sold from a restaurant or take away outlet, from the caterer. Information relating to foods produced using gene technology is required on labelling for food sold to a caterer.

[6] http://www.foodstandards.gov.au/code/changes/pages/applicationshandbook.aspx

2.5.2.3 The prevention of misleading or deceptive conduct

The provision of detection methodology by the Applicant (see section 2.3.3) addresses this objective.

2.5.3 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's approach to the safety assessment of all GM foods applies concepts and principles outlined in the Codex Principles for the Risk Analysis of Foods derived from Biotechnology (Codex 2004). Based on these principles, the risk analysis undertaken for DHA canola used the best scientific evidence available. The Applicant submitted to FSANZ a comprehensive dossier of quality-assured raw experimental data. In addition to the information supplied by the Applicant, other available resource material including published scientific literature and general technical information was used in the safety assessment.

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

This was not a consideration as there are currently no relevant international standards. As noted in Table 1, the Codex Committee on Nutrition and Foods for Special Dietary Uses is undertaking work to develop a definition for biofortification. However, a definition is yet to be confirmed, and therefore the draft definition cannot be considered at this time.

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

The inclusion of GM foods in the food supply, providing there are no safety concerns, allows for innovation by developers, and a widening of the technological base for producing foods. DHA canola is a new food crop designed to provide an alternative source of n-3 LC PUFAs for human consumption and increased demand from aquaculture.

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

Issues related to consumer information and safety are considered in sections 2.2 and 2.3 above.

- **any written policy guidelines formulated by the Forum on Food Regulation**

FSANZ notes the Policy Guideline on the Regulation of Infant Formula Products guides FSANZ to undertake a premarket assessment of any substance proposed to be used in infant formula products. Since no evidence was available for assessment of DHA canola oil in relation to infants, the approved draft variation does not permit food derived from DHA canola in infant formula products.

3 References

Codex (2004) Principles for the risk analysis of foods derived from modern biotechnology. CAC/GL 44-2003. Codex Alimentarius Commission, Rome. http://www.fao.org/fao-who-codexalimentarius/standards/list-of-standards/en/

Attachments

A. Approved draft variation to the *Australia New Zealand Food Standards Code*
B. Explanatory Statement

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

Food Standards (Application A1143 – Food derived from DHA Canola Line NS-B50027-4) Variation

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

Dated [To be completed by Standards Management Officer]

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

Note:

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

1 Name

This instrument is the *Food Standards (Application A1143 – Food derived from DHA Canola line NS-B50027-4) Variation*.

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

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

3 Commencement

The variation commences on the date of gazettal.

Schedule

[1] **Schedule 26** is varied by

[1.1] inserting in subsection S26—3(2) immediately before '2(m)'

1(g),

[1.2] inserting in the table to subsection S26—3(4) in alphabetical order under Item 1

(g) DHA canola line NS-B50027-4, subject to the condition that oil derived from DHA canola line NS-B50027-4 must not be used as an ingredient in infant formula products

Attachment B – Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

The Authority accepted Application A1143 which seeks permission for the sale and use of food derived from a genetically modified canola line, NS-B50027-4, which produces long-chain omega-3 fatty acids, particularly docosahexaenoic acid (DHA) in the seed. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation.

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

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

2. Purpose

The purpose of this instrument is to vary Schedule 26 of the Code to permit the sale, or use in food, of food derived from DHA canola line NS-B50027-4 and to ensure that labelling requirements set out in section 1.5.2–4, in relation to such food, are met.

3. Documents incorporated by reference

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

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1143 included one round of public consultation following an assessment and the preparation of a draft variation. Submissions were called for on 14 September 2017 for a six-week consultation period.

The Office of Best Practice Regulation (OBPR), in a letter to FSANZ dated 24 November 2010, granted a standing exemption from the need for the OBPR to assess if a Regulatory Impact Statement is required for the approval of genetically modified foods (ref 12065). Therefore, a Regulation Impact Statement was not required in this case because the proposed variation to Schedule 26 is likely to have a minor impact on business and individuals.

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variation

Subitem [1.1] inserts into subsection S26—3(2) of Schedule 26 of the Code a reference to item 1(g) of the table to subsection S26—3(4). The effect of this change will be to require a food for sale that consists of DHA canola line NS-B50027-4 or that has the latter as an ingredient to comply with the labelling requirement imposed by section 1.5.2—4 of the Code.

Subitem [1.2] inserts paragraph (g) into item 1 of the table to subsection S26—3(4) in Schedule 26. The new paragraph refers to DHA canola line NS-B50027-4. It also states that oil derived from DHA canola line NS-B50027-4 must not be used as an ingredient in infant formula products. The effect of the change is to permit the sale and use of food derived from that canola line in accordance with Standard 1.5.2, subject to the limitation that oil derived from DHA canola line NS-B50027-4 not be used as an ingredient in infant formula products.