28 September 2022
215-22

Approval report – Application A1239

Food derived from EPA and DHA producing and herbicide-tolerant canola line LBFLFK

Food Standards Australia New Zealand (FSANZ) has assessed an application made by BASF Australia Ltd seeking to amend the Australia New Zealand Food Standards Code (the Code) to permit the sale and use of food derived from a new food produced using gene technology: canola line LBFLFK. This canola line has been genetically modified to produce the omega-3 fatty acids (eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA)) in the seed, and for tolerance to imidazolinone herbicides.

On 27 May 2022, FSANZ sought submissions on a draft variation to Schedule 26 of the Code and published an associated report. FSANZ received three submissions.

FSANZ approved the draft variation on 14 September 2022 The Food Ministers' Meeting[1] was notified of FSANZ's decision on 28 September 2022.

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

[1] Formerly referred to as the Australia and New Zealand Ministerial Forum on Food Regulation

Table of contents

Supporting document

The following documents which informed the assessment of this application are available on the FSANZ website[2]:

SD1 Safety Assessment Report
SD2 Nutrition Risk Assessment Report

[2] https://www.foodstandards.gov.au/code/applications/Pages/A1239---Food-derived-from-EPA-and-DHA-producing-and-herbicide-tolerant-canola-line-LBFLFK-.aspx

Executive summary

Food Standards Australia New Zealand (FSANZ) received an application from BASF Australia Ltd to amend the Australia New Zealand Food Standards Code (the Code) to permit the sale and use of food derived from a new food produced using gene technology (GM food): canola line LBFLFK. Canola line LBFLFK has been genetically modified to produce the omega-3 long-chain polyunsaturated fatty acids (LC-PUFAs) eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) in the seed, and for tolerance to imidazolinone herbicides. The applicant has not requested permission to use oil from canola line LBFLFK in infant formula products (includes infant formula, follow-on formula and infant formula products for special dietary use).

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.

The safety assessment of canola line LBFLFK is in Supporting Document 1 (SD1) and the nutrition risk assessment in Supporting Document 2 (SD2). No potential public health and safety concerns have been identified. Based on the data provided and other information, food derived from canola line LBFLFK is considered to be as safe for human consumption as food derived from conventional non-GM canola cultivars.

Following assessment and the preparation of a draft variation, FSANZ called for submissions regarding the draft variation on 27 May 2022. Three submissions were received. FSANZ has had regard to these submissions and addressed issues raised in those submissions (see Section 2.1).

For reasons summarised in this report and following its assessment, FSANZ has decided to approve the draft variation proposed at the call for submissions with one amendment to correct a typographical error. The approved draft variation will amend Schedule 26 of the Code to include a new item 1(i) in the table to subsection S26—3(4) containing a reference to ‘EPA and DHA producing and herbicide-tolerant canola line LBFLFK’ to permit the sale and use of food derived from that canola line. The permission will be subject to the following conditions:

- oil derived from EPA and DHA producing and herbicide-tolerant canola line LBFLFK must not be used as an ingredient in infant formula products, and
- the labelling for food derived from canola line LBFLFK will have to comply with section 1.5.2—4.

The effect of the approved draft variation will be to permit the use and sale of food derived from this canola line in accordance with the Code.

1 Introduction

1.1 The applicant

BASF Australia Ltd is part of the BASF Group and develops products for a range of industries including the agriculture sector.

1.2 The application

Application A1239 was submitted on 24 September 2021. It seeks amendment to the Australia New Zealand Food Standards Code (the Code) to permit the sale and use of food derived from a new food produced using gene technology (GM food): canola line LBFLFK. Canola line LBFLFK has been genetically modified to produce the omega-3 long-chain polyunsaturated fatty acids (LC-PUFAs) eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) in the seed, and for tolerance to imidazolinone herbicides. The applicant has not requested permission to use oil from canola line LBFLFK in infant formula products (including infant formula, follow-on formula and infant formula products for special dietary use).

Production of omega-3 (n-3) LC-PUFAs in the seeds of canola line LBFLFK is conferred by the expression of 10 enzymes encoded by genes from microalgae, water moulds and moss. Tolerance to imidazolinone herbicides is achieved through expression of a modified form of the enzyme acetohydroxy acid synthase (AHAS), encoded by a modified *csr1-2* gene from the plant *Arabidopsis thaliana.* The AHAS protein has been previously assessed by FSANZ.

Food derived from canola line LBFLFK may enter the Australian and New Zealand food supply as imported food products. These may include canola oil, meal and protein isolate[3] or cooked whole seeds in bread products. Viable seeds from canola line LBFLFK would not be permitted without prior assessment and approval by the Gene Technology Regulator (GTR)[4] in Australia and the Environmental Protection Authority (EPA)[5] in New Zealand.

1.3 The current Standard

Pre-market approval is necessary before GM foods can enter the Australian and New Zealand food supply. GM foods are only approved after a comprehensive pre-market safety assessment. Standard 1.5.2 of the Code sets out the permission and conditions for the sale of food that consists of, or has as an ingredient, a GM food. Foods that have been assessed and approved are listed in Schedule 26 of the Code.

Subject to the exceptions listed below, section 1.5.2—4 requires food to be labelled as 'genetically modified' where novel DNA and/or novel protein is present in the final food.

Additionally, foods listed in subsections S26—3(2), (2A) 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

[3] Protein isolate from canola meal was recently approved as a new food ingredient in Australia and New Zealand under Application A1175.

[4] The Office of the Gene Technology Regulator (OGTR) provides administrative support to the Gene Technology Regulator in the performance of functions under the *Gene Technology Act 2000.*

[5] The EPA implements and enforces the *Hazardous Substances and New Organisms* (HSNO) *Act 1996.*

produced using gene technology.

The requirement to label as 'genetically modified' applies to foods for sale that consist of, or have as an ingredient (including food additives and processing aids), food that is a *genetically modified food*[6]. The requirements imposed by section 1.5.2—4 apply only to foods for sale prescribed by Divisions 2 to 4 of Standard 1.2.1.

The labelling requirement in section 1.5.2—4 does not apply if the genetically modified food:

- has been highly refined (other than food that is considered to have an altered characteristic as described above), 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%); or
- is unintentionally present in the food in an amount of no more than 10 g/kg (or 1%) of each ingredient.

The above labelling requirement also does not apply if the food for sale is intended for immediate consumption, and is prepared and sold from food premises and vending vehicles including restaurants, take away outlets, caterers or self-catering institutions.

If the food for sale is a food not required to bear a label and is not in a package, the labelling information 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)).

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

1.4 Reasons for accepting the application

The application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the *Food Standards Australia New Zealand 1991* (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 with one amendment to correct a typographical error. The approved draft variation takes effect on the date of

[6] Subsection 1.5.2—4(5) defines ***genetically modified food*** to mean a *food produced using gene technology that

a) contains novel DNA or novel protein; or
b) is listed in Section S26—3 as subject to the condition that its labelling must comply with this section (*that being section 1.5.2—4*).

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

FSANZ called for submissions on a proposed draft variation on 27 May 2022. The consultation period was six weeks.

A total of three submissions were received. These were from:

- Victorian Department of Health and the Victorian Department of Jobs, Precincts and Regions
- New Zealand Food Safety (NZFS)
- New Zealand Food & Grocery Council (NZFGC).

No objections were raised to the proposed draft variation to Schedule 26.

In relation to the nutrition risk assessment, NZFS stated their agreement with FSANZ that the baseline intake of n-3 LC PUFAs in Australia can be used to approximate the corresponding intake in New Zealand. No dietary intake data are available for New Zealand for individual n-3 LC PUFAs.

Responses to issues raised in submissions are provided in Table 1.

Table 1: Summary of issues / comments

Issue	Raised by	FSANZ response
As the absorption and uptake of n-3 LC-PUFAs is influenced by multiple factors, including total fat content and the presence of inhibitory substances in foods, it is important to evaluate the availability in LBFLFK oil in more depth.	Victorian Department of Health and the Victorian Department of Jobs, Precincts and Regions	The bioavailability of nutrients in general is influenced by multiple factors. As for other vegetable oils, normal dietary consumption of LBFLFK oil will be predominantly from mixed foods of wide-ranging nutrient composition. Therefore, in a total dietary context, the composition of LBFLFK oil itself would be expected to have a minor impact on n-3 LC-PUFA bioavailability from LBFLFK oil.
No analysis was provided of whether the insertion points disrupted any known functional genes within the canola genome	NZFS	Information about the chromosome integration sites for the two T-DNA inserts was provided by the applicant and evaluated by FSANZ as part of the safety assessment. See Section 3.4.3 of the SD1. The genetic modification process typically involves the random insertion of DNA into the genome and may sometimes disrupt an endogenous gene. The integration process is also often accompanied by genome changes (i.e. insertions, deletions, and/or rearrangements) at the site of integration. FSANZ does not require that information be provided

Issue	Raised by	FSANZ response
		about whether any known functional genes have been disrupted by the insertion for the following reasons: • Genome changes are not specific to genetic modification and can also occur spontaneously or as a result of conventional breeding (Schnell et al 2015). • Accumulated evidence and regulatory experience over the last 25 years indicate such changes are unlikely to be of consequence for human health. The compositional analysis (Section 5 of the SD1) determines if, as a result of the genetic modification, any unexpected changes to the composition of the food have occurred. In the case of canola line LBFLFK, FSANZ notes the compositional analysis did not indicate any unintended changes in food composition of significance to human health.
The approach to report the mean intakes of n-3 LC PUFAs for consumers of canola oil and compare this to the upper level (UL) does not appear to be consistent with FSANZ's documented principles for dietary exposure assessment to assess nutrients, or their approach to identify and 'protect high consumers'. Further clarification as to why this approach was taken is requested.	NZFS	The approach taken for the dietary intake assessment assumed two 'worst case' scenarios: I) All the canola oil consumed in the diet is replaced by LFBLFK canola oil and II) All canola oil plus 30% of all unspecified oil are replaced by LFBLFK canola oil. Both of these scenarios are 'overestimating' the consumption of the particular canola mentioned by applicant therefore capturing consumers who would eat a large proportion of their oil consumption as LBFLFK oil. The mean oil consumption amounts and mean n-3 LC PUFA intakes were considered by FSANZ to be representative of longer-term chronic intakes, therefore FSANZ did not report 90th/95th percentile values. In addition, this approach was taken so that the methodology used for this application was consistent with our previous evaluation for A1143 DHA canola NS-B50027-4. In order to assess high consumers of n-3 LC PUFA, FSANZ has reviewed the baseline intakes of n-3 LC PUFA (ABS 2015). The highest 95th percentile usual intake across all age/sex groups (of 558 mg/day) is 18.6% of the UL of 3000 mg/day; and there was 0% of the Australian population exceeding the UL. FSANZ had also determined the n-3 LC PUFA intakes for high consumers of oil (using the 90th percentile two day average consumption of oil and mean baseline n-3 LC PUFA intakes) for both scenarios and these were well within UL value (up to 45% UL across all population groups assessed in scenario 1 and up to 60% UL for scenario 2). FSANZ therefore concludes that there are no public health and safety concerns for high consumers.
Section 2.2.3.3 of the CFS document currently states that "Oil from the canola line LBFLFK may meet the requirements for making a nutrition content	NZFS	FSANZ agrees that some products containing canola line LBFLFK as an ingredient may meet the requirements for making a nutrition content or health claim in relation to their omega-3 FA content or polyunsaturated FA content.

Issue	Raised by	FSANZ response
claim or health claim…". NZFS suggests that this sentence is amended to specify "Products containing oil from the canola line LBFLFK…".		For clarity we have updated text in section 2.3.2.3.
This application appears to be appropriate for collaboration with Health Canada, especially on their respective risk assessments.	NZFGC	Application A1239 did not fit the agreed criteria for safety assessment sharing as Health Canada had already finalised its process some time before FSANZ received the application. To trigger a shared assessment process a product developer must first consult with both FSANZ and Health Canada before submitting to either agency. This is because a slightly different administrative process is required in the case of a shared safety assessment, and cannot be initiated retrospectively. Further information on GM food safety assessment sharing can be found on the FSANZ website[7].

2.2 Safety assessment

The safety assessment of canola line LBFLFK is provided in Supporting Document 1 (SD1) and included the following key elements:

- a characterisation of the transferred gene material, its origin, function and stability in the canola genome;
- characterisation of novel nucleic acids and protein in the whole food;
- detailed compositional analyses;
- evaluation of intended and unintended changes; and
- assessment of the potential for any newly expressed protein to be either allergenic or toxic in humans.

The nutrition risk assessment is provided in Supporting Document 2 (SD2) and is comprised of a hazard assessment and a dietary intake assessment. The nutrition risk assessment focussed on oil as it is the primary product derived from canola intended for human consumption and n-3 LC-PUFAs partition to the oil fraction during the seed refining process.

The hazard assessment considered potential adverse effects associated with n-3 LC-PUFA intake, and information on the Upper Level of Intake (UL) of n-3 LC-PUFA, defined as the sum of EPA, docosapentaenoic acid (DPA)[8] and DHA.

The dietary intake assessment 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 EPA, DPA and DHA due to the introduction of oil from canola

[7] https://www.foodstandards.gov.au/science/international/Pages/GM--food-safety-assessment-sharing.aspx

[8] DPA is the metabolic intermediate between EPA and DHA.

line LBFLFK. This assessment captured consumption of the oil as is and the use of the oil in mixed foods.

In conducting the safety and nutrition risk assessment, FSANZ considered information from a variety of sources including, but not limited to, a data package provided by the applicant (application and study reports), the scientific literature and other applications.

No potential public health and safety concerns were identified by the safety assessment of canola line LBFLFK, which found:

- the introduced DNA is as described and stably inherited across generations;
- the new proteins are expressed at low levels in the canola and are unlikely to be either toxic or allergenic;
- apart from the intended change to the FA profile and a slightly higher content of TFAs in seed and crude oil, canola line LBFLFK is otherwise compositionally equivalent to conventional canola varieties.

The assessment of canola line LBFLFK was restricted to human food safety and nutritional issues. This assessment therefore does not address any risks to the environment that may occur as a result of growing canola line LBFLFK, or any risks to animals that may consume feed derived from canola line LBFLFK. Permission to cultivate canola line LBFLFK or to import viable seeds into Australia or New Zealand would require separate regulatory assessment and approval by the GTR in Australia and by the EPA in New Zealand.

No nutrition issues were identified with the FA composition, and the bioavailability of EPA, DPA and DHA from triglycerides in LBFLFK oil and fish oil is expected to be similar. The hazard assessment concluded that the n-3 LC-PUFA UL of 3 g/day is sufficiently health protective and appropriate for use in risk characterisation. The dietary intake estimates for all population groups assessed in both Australia and New Zealand were below the UL of 3 g/day. It is therefore concluded that consumption of oil from canola line LBFLFK will not pose a nutritional risk to the Australian and New Zealand populations.

Based on the data provided in the present application and other available information, food derived from canola line LBFLFK is considered to be as safe for human consumption as food derived from non-GM canola cultivars.

2.3 Risk management

On the basis of the findings of the risk assessment, FSANZ considered a number of risk management responses to matters relating to foods derived from canola line LBFLFK sold in Australia and New Zealand.

2.3.1 Regulatory approval

Canola line LBFLFK is a GM food for Code purposes as it is developed from ‘an organism that has been modified using gene technology’. The approved draft variation lists canola line LBFLFK in the table to subsection S26—3(4). Following gazettal, this will provide permission for the sale and use of food derived from canola line LBFLFK as a GM food in accordance with the Code.

The applicant did not seek permission for food derived from canola line LBFLFK to be used as an ingredient in infant formula products and the application did not include specific data on its safety in the infant population. Additionally, based on composition information available

under SD2, Table 1 *Levels of EPA, DPA and DHA (as % of total FAs) in LBFLFK oil, conventional canola oils and fish oils*, oil from canola line LBFLFK does not meet the Code requirements relating to the use of LC-PUFA in infant formula products. Specifically, oil derived from canola line LBFLFK does not comply with paragraph 2.9.1—11(1)(d) (as it contains more EPA than DHA) and section S29—8 (as total FA content from the n-3 LC-PUFAs is more than 1% total FAs).

The approved amendment is therefore specific to the population group assessed, and is not approved for use as an ingredient in infant formula products. This is consistent with the permission under S26—3 for oil derived from DHA canola line NS-B50027-4.

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 (see Section 1.3 of this report), food for sale derived from a GM food, such as canola line LBFLFK, will be required to be labelled as 'genetically modified' if (among other things) the GM food:

- contains novel DNA or novel protein; or
- is listed in subsections S26—3(2), 2(A) or (3) of Schedule 26 as being subject to the condition that the labelling must comply with section 1.5.2—4 of Standard 1.5.2 (such food has altered characteristics).

As noted in Section 2.1 of this report, food derived from canola line LBFLFK including canola oil, meal and protein isolate or cooked whole seeds in bread products may enter the Australian and New Zealand food supply as imported food products.

FSANZ has determined that whole seeds from canola line LBFLFK contain novel DNA, novel protein and an altered nutritional profile that is outside the compositional variation found in existing counterpart food. As such, whole canola seeds and food products containing whole canola seeds as an ingredient (e.g. bread products) will require the mandatory statement 'genetically modified' on the label of a package of food. Where products are not required to bear a label and are not packaged (e.g. 'fresh' bread that is made and consumed 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.

Highly refined canola oil is the major product intended for human consumption. 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. Consequently, the approved draft variation lists food derived from canola line LBFLFK in subsection S26—3(2) of Schedule 26 which will require that food to be labelled with the mandatory 'genetically modified' statement irrespective of the presence of novel DNA or novel protein.

Canola meal is a by-product of seed oil extraction. The extraction process means the nutritional profile of meal from canola line LBFLFK would be comparable to meal from conventional (non-GM) canola (Section 5.2.2 of the SD1). However, novel DNA and novel protein will be present. The effect of the approved draft variation will be that meal and food products containing canola meal from canola line LBFLFK as an ingredient that are intended for human consumption will require the mandatory labelling statement in accordance with the Code. The mandatory 'genetically modified' statement will also apply to protein isolate derived from the canola meal.

Section 1.5.2—4 of the Code generally requires a food for sale that consists of a GM food or has a GM food as an ingredient to be labelled as 'genetically modified', unless one of the exemptions listed in that subsection apply. If the GM food is present in the food for sale as an ingredient, the 'genetically modified' statement must be in conjunction with the name of the GM food (subsection 1.5.2—4(2)) and it may be included in the statement of ingredients for the food for sale (subsection 1.5.2—4(3)).

2.3.2.2 Need for additional labelling requirements

FSANZ has also 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 characteristics in foods derived from canola line LBFLFK when compared to non-GM canola products.

Whole seeds and oil and from canola line LBFLFK will contain an altered FA profile. However, similar to previous assessments (e.g. A1143 DHA Canola), FSANZ is not proposing additional mandatory labelling for the following reasons:

- The canola has been genetically modified to contain the n-3 LC-PUFA's EPA and DHA, although other omega 3 FAs are also present. 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 FAs. As such, mandatory labelling that refers to specific FAs, such as EPA, could be confusing to consumers.
- A mandatory statement to the effect that the food has been genetically modified to contain EPA and DHA as omega-3 FAs 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 oil from canola line LBFLFK would simply inform consumers of the presence of omega-3 FAs, irrespective of the amount in the food or ingredient.
- A mandatory statement could also imply that the food contributes a nutritionally significant amount of n-3 LC PUFAs, when the actual amount may be negligible (for example, when oil from canola line LBFLFK is used as a minor ingredient in food). In addition, consumers could assume, inappropriately, that it provides an equivalent amount of n-3 LC PUFAs derived from fish.

2.3.2.3 Voluntary representations made about food

Based on the nutrition assessment (see SD2), FSANZ has concluded that oil from canola line LBFLFK has the potential to be used as a source of omega-3 FAs. Oil from canola line LBFLFK and food products containing oil from the canola line LBFLFK as an ingredient may meet the requirements for making a nutrition content or health claim in relation to their omega-3 FA content or polyunsaturated FA content. The conditions for making such claims are set out in Schedule 4. Other nutrition content and health 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 or health claim.

Representations made about a food derived from canola line LBFLFK will also be subject to other Australian and New Zealand consumer and fair trading laws designed to prevent

misleading or deceptive conduct, including in relation to food.

2.3.3 Detection methodology

An Expert Advisory Group (EAG) comprising laboratory personnel and representatives of Australian and New Zealand jurisdictions was formed by the Food Regulation Standing Committee's Implementation Sub-Committee[9] to identify and evaluate appropriate methods of analysis associated with all applications to FSANZ, including those applications for food produced using 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 for analytical purposes. Using this information, any DNA analytical laboratory would have the capability to develop a PCR[10]-based detection method. This sequence information was supplied by the applicant for A1239.

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 requested 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 27 May 2022 and 8 July 2022. The call for submissions was notified via the FSANZ Notification Circular, media release, FSANZ's social media tools and Food Standards News. Subscribers and interested parties were also notified.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this application. Every submission was considered as part of the decision making process by FSANZ. All comments are valued and contribute to the rigour of our assessment.

Documents relating to Application A1239, including submissions received, are available on the FSANZ website[11].

2.5 FSANZ Act assessment requirements

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

2.5.1 Section 29

2.5.1.1 Consideration of costs and benefits

The Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for applications relating to

[9] Now known as the Implementation Subcommittee for Food Regulation.
[10] polymerase chain reaction
[11] https://www.foodstandards.gov.au/code/applications/Pages/A1239---Food-derived-from-EPA-and-DHA-producing-and-herbicide-tolerant-canola-line-LBFLFK-.aspx

permitting GM foods (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting new GM foods is deregulatory as their use will be voluntary if the application concerned is approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

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

The purpose of FSANZ's consideration was to determine if the community, government, and industry as a whole is likely to benefit, on balance, from a move from the status quo (where the status quo was rejecting the application). This analysis considers permitting the sale and use of food derived from canola line LBFLFK.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures. In fact, most of the effects that were considered could not easily be assigned a dollar value. Rather, the assessment seeks to highlight the likely positives and negatives of moving away from the status quo by permitting the sale and use of food derived from canola line LBFLFK. It is out-of-scope for this consideration to comment on the costs or benefits of using this ingredient for agricultural feed, including feeding to farmed fish.

Costs and benefits of permitting the sale and use of food derived from canola line LBFLFK

The sale and use of foods derived from canola line LBFLFK would be permitted under the Code, allowing broader market access and increased choice in raw materials. Food derived from canola line LBFLFK will have to comply with mandatory labelling requirements in accordance with the Code – this would assist consumers wishing to avoid these products to do so.

Due to the voluntary nature of the permission, manufacturers and retailers would only engage with foods derived from canola line LBFLFK, where they believe a net benefit exists for them. Part of any cost savings to industry may be passed onto consumers.

Consumers may also benefit from a greater choice of sources of omega-3 fatty acids.

There may be small and likely inconsequential costs of monitoring an extra GM food ingredient for regulators to ensure compliance with labelling requirements.

Conclusions from cost benefit considerations

FSANZ's assessment remains that the direct and indirect benefits that would arise from permitting the sale and use of food derived from canola line LBFLFK, most likely outweigh the associated costs.

2.5.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than varying Schedule 26 as a result of application A1239.

2.5.1.3 Any relevant New Zealand standards

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

2.5.1.4 Any other relevant matters

The applicant has submitted applications for regulatory approval of canola line LBFLFK to a number of other countries, listed in Table 2.

Cultivation (environmental release) in Australia or New Zealand would require independent assessment and approval by the GTR and New Zealand EPA, respectively.

Table 2: List of countries to whom applications for regulatory approval of canola line LBFLFK have been submitted

Country	Agency	Type of approval sought	Status
Canada	Canadian Food Inspection Agency (CFIA)	Environmental release, food & feed	Approved
	Health Canada	Food	Approved
China	Ministry of Agriculture and Rural Affairs (MARA)	Food & feed	Submitted
EU	European Food Safety Authority (EFSA)	Food & feed	Submitted
Indonesia	National Agency of Drug and Food Control (NADFC)	Food	Submitted
Japan	Ministry of Health, Labour and Welfare (MHLW)	Food	Submitted
	Ministry of Agriculture, Forestry and Fisheries (MAFF)	Feed	Submitted
Mexico	Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS)	Food & feed	Submitted
Republic of Korea	Ministry of Food and Drug Safety (MFDS)	Food	Submitted
	Rural Development Administration (RDA)	Feed	Submitted
United States	United States Department of Agriculture (USDA)	Environment	Approved
	Food and Drug Administration (FDA)	Food & feed	Approved

Other relevant matters are considered below.

2.5.2. Subsection 18(1)

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

2.5.2.1 Protection of public health and safety

FSANZ's assessment did not identify any public health and safety concerns with food derived from canola line LBFLFK. Based on the best available scientific evidence, including detailed studies provided by the applicant, FSANZ's assessment is that food derived from canola line LBFLFK is considered to be as safe for human consumption as food derived from conventional non-GM canola cultivars. FSANZ's nutritional risk assessment concluded that

consumption of oil from canola line LBFLFK will not pose a nutritional risk to the Australian and New Zealand populations.

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

Existing labelling requirements for GM food will apply to food derived from canola line LBFLFK in accordance with the Code to enable informed consumer choice (see Section 2.3.2 of this report).

2.5.2.3 The prevention of misleading or deceptive conduct

The provision of DNA sequence information by the applicant (as described in Section 2.3.3 of this report) 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, 2009). Based on these principles, the risk analysis undertaken by FSANZ for canola line LBFLFK used the best scientific evidence available. The applicant submitted 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 by FSANZ in the safety assessment.

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

This is not a consideration as there are no relevant international standards.

- **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. Canola line LBFLFK is a new food crop designed to provide consumers with more options for dietary n-3 LC-PUFAs.

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

Issues related to consumer information and safety are considered in Sections 2.2 and 2.3 of this report above.

- **any written policy guidelines formulated by the Food Ministers' Meeting[12]**

No specific policy guidelines have been developed.

[12] Formerly known as the Australia and New Zealand Ministerial Forum on Food Regulation

3 Draft variation

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

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

4 References

Australian Bureau of Statistics (2015) Australian Health Survey: Usual Nutrient intakes, 2011-12 – Australia. Table 8.1 Usual daily intake of long-chain omega 3 fatty acids from foods. Australian Health Survey: Usual Nutrient Intakes, 2011-12 financial year | Australian Bureau of Statistics (abs.gov.au)

Codex (2009) Principles for the risk analysis of foods derived from modern biotechnology. CAC/GL 44-2003. Codex Alimentarius Commission, Rome. http://www.fao.org/3/a1554e/a1554e00.htm

Schnell J, Steele M, Bean J, Neuspiel M, Girard C, Dormann N, Pearson C, Savoie A, Bourbonnière L, Macdonald P (2015) A comparative analysis of insertional effects in genetically engineered plants: considerations for pre-market assessments. Transgenic Res. 24(1):1-17

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 A1239 – Food derived from EPA and DHA producing and herbicide-tolerant canola line LBFLFK) 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 the delegate]

Christel Leemhuis
Delegate of the Board of Food Standards Australia New Zealand

Note:

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

1 Name

This instrument is the *Food Standards (Application A1239 – Food derived from EPA and DHA producing and herbicide-tolerant canola line LBFLFK) Variation*.

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

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

3 Commencement

The variation commences on the date of gazettal.

Schedule

Schedule 26—Food produced using gene technology

[1] Subsection S26—3(2)

Repeal the subsection (not including the note), substitute

(2) Items 1(g), 1(i), 2(m), 7(e), (g) and (h), and 9(a) of the table to subsection (4) are subject to the condition that their labelling must comply with section 1.5.2—4.

[2] Subsection S26—3(4) (table item 1, column headed "*Food derived from:*")

Add:

(i) EPA and DHA producing and herbicide-tolerant canola line LBFLFK, subject to the condition that oil derived from EPA and DHA producing and herbicide-tolerant canola line LBFLFK must not be used as an ingredient in infant formula products (see subsection (2))

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 A1239 which sought to amend the Code to permit the sale and use of food derived from a new food produced using gene technology (GM food) – canola line LBFLFK. Canola line LBFLFK has been genetically modified to produce the omega-3 long-chain polyunsaturated fatty acids - eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) - and for tolerance to imidazolinone herbicides. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation.

Following consideration by the Food Ministers' Meeting (FMM)[13], section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

2. Variation is a legislative instrument

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

This instrument is not subject to the disallowance or sunsetting provisions of the *Legislation Act 2003.* Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunsetting if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunsetting legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the FMM. The FMM is established under the Food Regulation Agreement and the

[13] This was formerly the Australia and New Zealand Ministerial Forum on Food Regulation. The Forum name change took effect on 21 February 2021 following a decision by Ministers.

international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

The purpose of the approved draft variation is to amend Schedule 26 of the Code to permit the sale and use of food derived from a new GM food - canola line LBFLFK, in accordance with the Code. Canola line LBFLFK has been genetically modified to produce the omega-3 long-chain polyunsaturated fatty acids - EPA and DHA; and for tolerance to imidazolinone herbicides.

This permission is subject to the following conditions:

- oil derived from canola line LBFLFK must not be used as an ingredient in infant formula products; and
- the labelling for food derived from canola line LBFLFK must comply with section 1.5.2—4.

4. Documents incorporated by reference

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

5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1239 included one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. The consultation period, including a call for submissions on the assessment and the draft variation, was for six-weeks.

The Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for applications relating to permitting GM foods (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting a new GM food is deregulatory as using the food will be voluntary if the application concerned is approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

6. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 44 of the *Legislation Act 2003*.

7. Variation

Item [1] of the Schedule to the draft variation amends Schedule 26 by repealing subsection S26—3(2) (not including the Note to the subsection), and substituting with a new subsection S26—3(2).

Subsection S26—3(2) currently lists certain items and their corresponding paragraphs from the table to subsection S26—3(4). The table to subsection S26—3(4) lists permitted GM food of plant origin in relation to particular commodities. The items and their corresponding paragraphs listed in subsection S26—3(2) relate to those permitted GM food of plant origin whose labelling must comply with section 1.5.2—4.

The new subsection S26—3(2) includes a reference to new item 1(i) in that list (see **item [2]** below regarding new paragraph (i) of item 1 in the table to subsection S26—3(4)).

Item [2] of the Schedule to the draft variation amends Schedule 26 by adding new paragraph (i) into the column headed '*Food derived from:*' for item 1 of the table to subsection S26—3(4).

As stated above, the table to subsection S26—3(4) lists permitted GM food of plant origin and item 1 of the table relates to the commodity 'Canola'.

The new paragraph (i) consists of the following:

> '(i) EPA and DHA producing and herbicide-tolerant canola line LBFLFK, subject to the condition that oil derived from EPA and DHA producing and herbicide-tolerant canola line LBFLFK must not be used as an ingredient in infant formula products (see subsection (2))'.

Canola line LBFLFK has been genetically modified to produce the omega-3 long-chain polyunsaturated fatty acids - EPA and DHA; and for tolerance to imidazolinone herbicides.

The permission for the sale and use of food derived from canola line LBFLFK is subject to the following conditions:

- oil derived from this canola line must not be used as an ingredient in infant formula products; and
- the labelling for food derived from canola line LBFLFK must comply with section 1.5.2—4 (see **item [1]** above).

The effect of the variation is to permit the sale and use of food derived from canola line LBFLFK in accordance with the Code.