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202-22

Call for submissions – 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 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 increased levels of the omega-3 fatty acids (eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA)) in the seed, and for tolerance to imidazolinone herbicides. A draft regulatory measure has been prepared. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

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

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

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

For information on how FSANZ manages personal information when you make a submission, see FSANZ's [Privacy Policy](#).

Submissions should be made in writing; be marked clearly with the word 'Submission'. You also need to include the correct application or proposal number and name. Electronic submissions can be made through the FSANZ website via the link [how to make a submission](#). You can also email your submission to submissions@foodstandards.gov.au. FSANZ also accepts submissions in hard copy to our Australia and/or New Zealand offices.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 8 July 2022

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

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

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

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Supporting documents

The [following documents](#)¹ which informed the assessment of this application are available on the FSANZ website:

- SD1 Safety Assessment Report
- SD2 Nutrition Risk Assessment Report

¹ <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 request a variation 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 (includes infant formula, follow-on formula and infant formula products for special dietary use).

A safety assessment is a critical part of the assessment approval process for all GM food applications. The completed safety assessment is in Supporting Document 1 (SD1) and the nutrition risk assessment is 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.

If approved, 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 or protein isolate. Viable seeds from canola line LBFLFK would not be permitted without prior assessment and approval by the Gene Technology Regulator (GTR) in Australia and the Environmental Protection Authority (EPA) in New Zealand.

Existing labelling requirements for GM food will apply to food derived from canola line LBFLFK in accordance with the Code.

For reasons set out above and in the assessment summary, FSANZ has decided to prepare a draft variation to 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 proposed permission would 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 would also have to comply with section 1.5.2—4. If approved, the effect of the draft variation would be to permit the sale and use of food derived from this canola line in accordance with the Code.

FSANZ seeks submissions on the draft variation.

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 (includes 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 previously been assessed by Food Standards Australia New Zealand (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 isolate² 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)³ in Australia and the Environmental Protection Authority (EPA)⁴ in New Zealand.

1.3 The current standards

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 produced using gene technology.

² Protein isolate from canola meal was recently approved as a new food ingredient in Australia and New Zealand under Application A1175.

³ 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*.

⁴ The EPA implements and enforces the *Hazardous Substances and New Organisms (HSNO) Act 1996*.

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*⁵. Standard 1.2.1 provides that the requirements imposed by section 1.5.2—4 generally apply only to foods for retail sale and to foods sold to a caterer - see subsection 1.2.1—8(1) and section 1.2.1—15 respectively.

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 is being assessed under the General Procedure.

2 Summary of the assessment

2.1 Safety and nutrition risk assessment

The safety assessment of canola line LBFLFK is provided in Supporting Document 1 (SD1)

⁵ 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*).

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 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)⁶ 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 line LBFLFK.

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

⁶ DPA is the metabolic intermediate between EPA and DHA.

derived from non-GM canola cultivars.

2.2 Risk management

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

2.2.1 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'. FSANZ is proposing to list canola line LBFLFK in the table to subsection S26—3(4). If approved, the proposed amendment would 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 is not seeking 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 Supporting Document 2, 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).

FSANZ is therefore proposing to prohibit the use of oil from canola line LBFLFK in infant formula products, which is consistent with the permission under S26—3 for oil derived from DHA canola line NS-B50027-4.

2.2.3 Labelling

2.2.3.1 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, would 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 and novel protein, and contain 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 would 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. FSANZ is proposing to list food derived from canola line LBFLFK in subsection S26—3(2) of Schedule 26 which will require food derived from canola line LBFLFK with an altered nutritional profile to be labelled with the mandatory ‘genetically modified’ statement irrespective of the presence of novel DNA or novel protein. Similar to whole canola seeds, where the food for sale is not required to bear a label and is not in a package, the mandatory statement ‘genetically modified’ would apply.

Canola meal is a by-product of seed oil extraction. The extraction process means the nutritional profile of meal from canola line LBFLFK is likely to be the same as meal from conventional (non-GM) canola. However, novel DNA and novel protein would be present. Therefore 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. The mandatory ‘genetically modified’ statement would also apply to protein isolate derived from the canola meal.

In summary, Table 1 lists scenarios in which the mandatory labelling statement would or would not apply, if food derived from DHA canola was approved.

Table 1: Application of labelling requirements for food derived from canola line LBFLFK

Canola line LBFLFK food/ingredient	Mandatory labelling statement
Contains novel DNA or novel protein	✓
Contains altered FA profile	✓
Novel DNA or protein absent but contains altered FA profile	✓
Novel DNA or protein not present and no altered FA profile i.e. the same as its conventional (non-GM) counterpart	✗

The requirements for labelling as ‘genetically modified’ differ depending on whether or not the GM food is an ingredient of the food for sale. For example, mayonnaise containing oil from canola line LBFLFK that is for retail sale would require the labelling statement. However, FSANZ notes products derived from canola line LBFLFK may be used to manufacture a food that is not itself a food for sale, but is used as an ingredient in foods for retail sale or in a food sold to a caterer (e.g. is present in mayonnaise used as an ingredient in a salad dressing). As such, these ingredients would not be GM foods and would not be subject to labelling requirements set out in section 1.5.2—4.

2.2.3.2 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.

2.2.3.3 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 may meet the requirements for making a nutrition content or health claim in relation to its omega-3 FA content or polyunsaturated FA content. The conditions for making such claims are set out in Schedule 4 and 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 would 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.

2.2.4 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-Committee⁷ 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 PCR⁸-based detection method. This sequence information was supplied by the applicant for A1239.

2.3 Risk communication

2.3.1 Consultation

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

FSANZ developed and applied a standard communication strategy to this application. All calls for submissions are notified via the FSANZ Notification Circular, media release, social media tools and Food Standards News. Subscribers and interested parties are also notified

⁷ Now known as the Implementation Subcommittee for Food Regulation.

⁸ polymerase chain reaction

about the availability of reports for public comment.

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

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

2.3.2 World Trade Organization

As members of the WTO, Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are no relevant international standards and amending the Code to permit food derived from canola line LBFLFK is unlikely to have a significant effect on international trade.

Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.4 FSANZ Act assessment requirements

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

2.4.1 Section 29

2.4.1.1 Consideration of costs and benefits

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 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

If the draft variation is approved, 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. For those food products containing novel DNA or novel protein from canola line LBFLFK, labelling would be required to 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 is 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.

2.4.1.2 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.

2.4.1.3 Any relevant New Zealand standards

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

2.4.1.4 Any other relevant matters

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.

2.4.2 Subsection 18(1)

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

2.4.2.1 Protection of public health and safety

FSANZ'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.

2.4.2.2 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 2.2.3 of this report).

2.4.2.3 The prevention of misleading or deceptive conduct

The provision of DNA sequence information by the applicant (as described in Section 2.2.4 of this report) addresses this objective.

2.4.3 Subsection 18(2)

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 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 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' Meeting⁹**

No specific policy guidelines have been developed.

3 Draft variation

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

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

4 References

Codex (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>

FAOSTAT (2019) Online database of the Food and Agriculture Organization of the United Nations. <http://www.fao.org/faostat/en/#data>, accessed March 2022

Attachments

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

⁹ Formerly known as the Australia and New Zealand Ministerial Forum on Food Regulation

Attachment A – 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

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))
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Attachment B – Draft 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 seeks 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 prepared a draft variation.

2. Variation will be a legislative instrument

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

If approved, this instrument would not be subject to the disallowance or sunset 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 sunset 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 sunset legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the Food Ministers Meeting (FMM). The FMM is established under the Food Regulation Agreement and the international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

The purpose of the 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 would be 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 would also have to comply with section 1.5.2—4.

4. Documents incorporated by reference

This 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 will include 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, will run 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

If approved, this instrument would be exempt from the requirements for a statement of compatibility with human rights as it would be a non-disallowable instrument under section 44 of the *Legislation Act 2003*.

7. Variation

Item [1] of the Schedule to the draft variation would amend 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.

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

Item [2] of the Schedule to the draft variation would amend 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'.

Proposed new paragraph (i) would consist 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 proposed permission for the sale and use of food derived from canola line LBFLFK would be 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 would also have to comply with section 1.5.2—4 (see **item [1]** above).

If approved, the draft variation would permit the sale and use of food derived from canola line LBFLFK in accordance with the Code.