

Project Officer Application A1239
Food Standards Australia New Zealand
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Tēnā koe,

Application A1239 Food derived from EPA and DHA producing and herbicide-tolerant canola line LBFLFK

Thank you for the opportunity to comment on the call for submissions for Application A1239 to permit the sale and use of food from canola line LBFLFK. Canola line LBFLFK has been genetically modified to produce omega-3 long chain polyunsaturated fats (LC-PUFAs) in the seed, including eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA); and have tolerance to imidazolinone herbicides.

If approved, it is understood that canola line LBFLFK would primarily be imported into New Zealand as imported food products. This could include canola oil, meal, or protein isolate which could be used in a various food products to provide an alternative source of dietary LC-PUFAs. Viable seeds from canola line LBFLFK would not be permitted without prior assessment and approval by the Environmental Protection Authority. New Zealand Food Safety (NZFS) has the following comments to make:

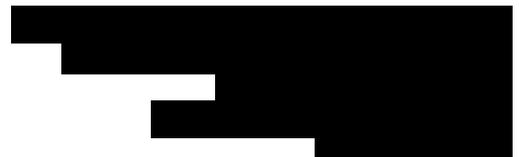
Safety assessment

We note that FSANZ has concluded that no potential public health and safety concerns have been identified in the assessment of canola line LBFLFK, based on the data provided in the application, and other available information, food derived from LBFLFK is considered to be as safe for human consumption as food derived from conventional canola varieties.

The novel proteins that will be present in LBFLFK have either been assessed previously by FSANZ or are likely to be substantially similar to proteins already present in the human diet. In addition, the process for producing edible canola oil will largely remove any protein present. However, while the insertion of genetic material through the transformation process appears to have been straightforward, we note that no analysis was provided of whether the insertion points disrupted any known functional genes within the canola genome.

Nutrition assessment

FSANZ has concluded that consumption of oil from canola line LBFLFK will not pose a nutritional risk to the Australian and New Zealand populations. NZFS conditionally supports FSANZ's conclusion on nutritional safety but seeks confirmation on the nutritional safety for high consumers;



or clarification as to why the usual dietary exposure assessment was not conducted. An upper level of intake (UL) has been established by the NHMRC for the omega-3 LC PUFAs (DHA, EPA, DPA). These are the fatty acids which have been modified in canola line LBFLFK. Usually, in FSANZ dietary exposure assessments the proportion of the population that would exceed the UL would be calculated, or the intakes of high consumers (90th or 95th percentile) would be reported to assess nutritional safety. The approach to report the mean intakes of omega-3 LC PUFAs for consumers of canola oil and compare this to the 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'^{1,2}. As such, further clarification as to why this approach was taken is requested.

No dietary intake data for individual omega-3 LC PUFAs is available for New Zealand, and NZFS agrees with FSANZ that the baseline intake of omega-3 LC PUFAs in Australia can be used to approximate the corresponding intake in New Zealand.

NZFS agrees that *trans* fatty acids (TFA) need not be included in the dietary intake assessment, since the TFA content in the canola line LBFLFK is comparable to conventional canola oil. The Application shows that the TFA content in canola line LBFLFK is marginally, yet statistically significantly, higher than that of the control (Kumily)³. NZFS notes that this represents only a marginal and low amount of the total fatty acids (0.3%) and is minor compared to the amount of TFA produced from processing the canola seed to oil.

NZFS agrees that oil from the canola line LBFLFK could potentially provide an additional source of EPA and DHA in a bioavailable form.

Labelling

Requirement to be labelled as 'genetically modified'

NZFS supports the proposed labelling approach, in which all products derived from the canola line LBFLFK with an altered fatty acid profile must be labelled with a mandatory "genetically modified" statement, regardless of whether the product contains novel protein or novel DNA.

Need for additional labelling requirements

FSANZ did not consider it necessary to specify additional labelling requirements which would alert consumers to the nature of the genetic modification. We agree with the conclusion of FSANZ, that mandatory labelling regarding EPA and DHA content is not warranted for the reasons outlined in Section 2.2.3.2 of the Call for Submissions (CFS) report. As highlighted by FSANZ, consumers may find reference to individual fatty acids like EPA and DHA confusing. A mandatory statement about EPA and DHA could imply that a product containing the canola line LBFLFK contributes a nutritionally significant amount of these fatty acids, which could conflict with nutrition content claim requirements specified in the Food Standards Code.

Voluntary representations made about food

The existing labelling requirements to make a health claim or nutrition content claim in the Food Standards Code will apply to food derived from canola line LBFLFK. If a product containing

¹ <https://www.foodstandards.gov.au/publications/Documents/Principlespractices%20exposure%20assessment%202009.pdf>

² <https://www.foodstandards.gov.au/science/exposure/Pages/protectinghighconsum4441.aspx>

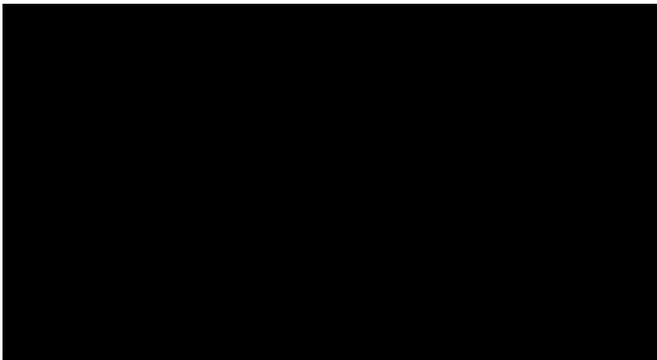
³ Page 239 of the Application: <https://www.foodstandards.gov.au/code/applications/Documents/A1239%20Application.pdf>

LBFLFK meet the conditions for a claim, then food producers can consider making claims on a voluntary basis (as outlined in Section 2.2.3.3 of the CFS document). From the information on EPA and DHA content provided in Table 1 of *Supporting Document 2: Nutrition Risk Assessment – Application A1239*, it is realistic that some products containing canola line LBFLFK as an ingredient could meet the conditions for a pre-approved health claim or nutrition content claim.

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 claim or health claim...”. NZFS suggests that this sentence is amended to specify “*Products containing* oil from the canola line LBFLFK...”. The saturated fatty acid (SFA) and TFA content per 100 g has not been reported for oil from the canola line LBFLFK, but conventional canola oil contains more SFA and TFA⁴ than the maximum level allowed to make a nutrition content claim or health claim about omega-3 or EPA + DHA.

Restrictions on use

NZFS supports FSANZ's decision to prohibit the use of oil from the canola line LBFLFK in infant formula products, for the reasons described in Section 2.2.1 of the CFS report.



⁴ Food Composition Database New Zealand