

## 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)<sup>1</sup>, 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](http://www.legislation.gov.au)).

This instrument is not 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 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.

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<sup>1</sup> 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.

### 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.