

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1310 – Food derived from insect-protected soybean line MON94637) Variation

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 A1310 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) – soybean line MON94637. Soybean line MON94637 has been genetically modified for protection against lepidopteran insect pests. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation - the *Food Standards (Application A1310 – Food derived from insect-protected soybean line MON94637) Variation*.

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

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 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.

3. Purpose

The Authority has approved a draft variation amending the table to subsection S26—3(4) in Schedule 26 of the Code to permit the sale and use of food derived from soybean line MON94637, in accordance with the Code. Soybean line MON94637 has been genetically modified for protection against lepidopteran insect pests.

4. Documents incorporated by reference

This 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 A1310 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 7 January 2025 for a six-week consultation period. Further details of the consultation process, the issues raised during consultation and by whom, and the Authority's response to these issues are available in an approval report published on the Authority's website at www.foodstandards.gov.au.

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA).¹ Impact analysis is no longer required to be finalised with the OIA. Prior to those changes, the OIA advised FSANZ that a Regulatory Impact Statement (RIS) was not required for applications relating to GM foods (updated OIA reference: **OIA23-06225**). This is because applications relating to permitting the use of GM foods that have been determined to be safe are considered to be minor and deregulatory in nature, as their use will be voluntary if the draft variation relating to the application is approved. Under the new approach, FSANZ's assessment is that a regulatory impact statement is not required for this application.

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

Clause 1 of the variation provides that the name of the variation is the *Food Standards (Application A1310 – Food derived from insect-protected soybean line MON94637) Variation*.

Clause 2 of the variation provides that the Code is amended by the Schedule to the variation.

Clause 3 of the variation provides that the variation will commence on the date of gazettal of the instrument.

Item [1] of the Schedule to the variation amends Schedule 26 of the Code by inserting, in

¹ <https://oia.pmc.gov.au/resources/guidance-impact-analysis/regulatory-impact-analysis-guide-ministers-meetings-and-national>

alphabetical order, a new paragraph '(t)' into the column headed '*Food derived from:*' for item 7 of the table to subsection S26—3(4) of the Code. Item 7 of this table is headed 'Soybean'.

The new paragraph (t) refers to 'insect-protected soybean line MON94637'.

The effect of the variation is to permit the sale and use of food derived from soybean line MON94637 in accordance with the Code.