

# Commonwealth of Australia

# **Gazette**

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# **Food Standards**

# Amendment No. 243

The following instruments are separate instruments in the Federal Register of Legislation and are known collectively in the Food Standards Gazette as Amendment No. 243

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# Food Standards (Proposal P1055 – Definitions for gene technology and new breeding techniques) 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 this variation.

Dated 19 August 2025

Renee Sopdeisshi'

Renee Sobolewski Acting Delegate of the Board of Food Standards Australia New Zealand

#### Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC 183 on 2 September 2025. 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 (Proposal P1055 – Definitions for gene technology and new breeding techniques) Variation.

#### 2 Variation to Standards in the Australia New Zealand Food Standards Code

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

#### 3 Commencement

The variation commences on the date of gazettal.

#### Schedule

#### Standard 1.1.1 - Structure of the Code and general provisions

[1] Section 1.1.1—2

Omit "Food produced using gene technology" (wherever occurring), substitute "Genetically modified food".

[2] Section 1.1.1—10

Omit "\*food produced using gene technology" (wherever occurring), substitute "\*genetically modified food".

[3] Section 1.1.1—10 (Note 1)

Omit "food produced using gene technology", substitute "genetically modified food".

#### Standard 1.1.2 - Definitions used throughout the Code

[4] Subsection 1.1.2—2(3) (definition for food produced using gene technology)

Repeal the definition.

[5] Subsection 1.1.2—2(3) (definition of *gene technology*)

Repeal the definition.

[6] Subsection 1.1.2—2(3)

Insert:

genetically modified food—see section 1.1.2—16.

[7] Subsection 1.1.2—2(3) (entry for novel food)

Repeal the entry, substitute:

novel DNA—see section 1.1.2—17.

**novel food**—see section 1.1.2—8.

novel protein means a protein encoded by novel DNA.

[8] After section 1.1.2—15

Add:

# 1.1.2—16 Definition of genetically modified food

- (1) In this Code, *genetically modified food* means a food that:
  - (a) is any of the following:
    - (i) an organism that contains \*novel DNA;
    - (ii) food derived from an organism that contains novel DNA;
    - (iii) cells that contain novel DNA;
    - (iv) food derived from cells that contain novel DNA; and
  - (b) is not any of the following:
    - (i) a substance \*used as a food additive;
    - (ii) a substance \*used as a processing aid;

- (iii) a substance used to:
  - (A) support the growth and viability of cells during cell culture; or
  - (B) process cells during cell culture;
- (iv) food that is derived from part of a grafted plant, where that part does not contain novel DNA or \*novel protein;
- (v) food derived from a null segregant.
- (2) In this section, a null segregant means an organism, cell or cells that:
  - (a) is descended from an organism, cell or cells that contain \*novel DNA; and
  - (b) does not contain novel DNA.

#### 1.1.2—17 Definition of *novel DNA*

- (1) In this Code, novel DNA means DNA that:
  - (a) a person has inserted into the genome of an organism, cell or cells; and
  - (b) is one of the following:
    - (i) DNA from a species that is not a crossable species;
    - (ii) DNA that:
      - (A) is from a crossable species; and
      - (B) contains a coding region that was rearranged or recombined prior to the insertion referred to in paragraph (1)(a);
    - (iii) DNA that is not from an existing species.
- (2) In this section, *crossable species* means a species of organism, cell or cells that can be crossed or hybridized with the species of organism, cell or cells referred to in paragraph (1)(a).
- (3) Despite subsections (1) and (2), novel DNA does not include flanking left and right border sequences arising from *Agrobacterium*-mediated transformation.

# Standard 1.2.1 – Requirements to have labels or otherwise provide information

#### [9] Paragraph 1.2.1—8(1)(k)

Omit "\*foods produced using gene technology", substitute "\*genetically modified food".

# [10] Paragraph 1.2.1—9(3)(b)

Omit "foods produced using gene technology", substitute "\*genetically modified food".

# [11] Paragraph 1.2.1—9(3)(ba)

Omit "foods produced using gene technology", substitute "genetically modified food".

#### [12] Paragraph 1.2.1—15(f)

Omit "foods produced using gene technology", substitute "\*genetically modified food".

#### Standard 1.2.4 - Information requirements - statement of ingredients

#### [13] Paragraph 1.2.4—5(6)(b)

Repeal the paragraph, substitute:

- (b) if the compound ingredient comprises less than 5% of the food for sale—the following ingredients:
  - (i) any ingredient of the compound ingredient that is required to be listed in accordance with section 1.2.3—4 or section 1.5.2—4; and
  - (ii) any substance \*used as a food additive in the compound ingredient which performs a technological purpose in the food for sale.

#### Standard 1.3.3 - Processing aids

#### [14] Section 1.3.3—6 (Note 2)

Repeal Note 2.

#### Standard 1.5.2 - Food produced using gene technology

#### [15] Standard title

Omit "Food produced using gene technology", substitute "Genetically modified food".

#### [16] Standard title (Note 3)

Repeal the Note, substitute:

**Note 3** Paragraphs 1.1.1—10(5)(c) and (6)(g) provide that a food for sale must not consist of, or have as an ingredient or a component, a genetically modified food, unless expressly permitted by this Code. This Standard contains the relevant permissions. Schedule 26 provides definitions of the terms 'line' and 'transformation event', and lists approved genetically modified foods and any conditions for use of the food.

## [17] Section 1.5.2—1

Omit "Food produced using gene technology", substitute "Genetically modified food".

#### [18] Section 1.5.2—2 (Notes 1 to 3)

Repeal the Notes, substitute:

- **Note 1** Section 1.1.2—16 (Definition of *genetically modified food*) provides as follows:
  - (1) In this Code, *genetically modified food* means a food that:
    - (a) is any of the following:
      - (i) an organism that contains \*novel DNA;
      - (ii) food derived from an organism that contains novel DNA;
      - (iii) cells that contain novel DNA;
      - (iv) food derived from cells that contain novel DNA; and
    - (b) is not any of the following:
      - (i) a substance \*used as a food additive;
      - (ii) a substance \*used as a processing aid;
      - (iii) a substance used to:
        - (A) support the growth and viability of cells during cell culture; or
        - (B) process cells during cell culture;
      - (iv) food that is derived from part of a grafted plant, where that part does not contain novel DNA or \*novel protein;
      - (v) food derived from a null segregant.
  - (2) In this section, a null segregant means an organism, cell or cells that:
    - (a) is descended from an organism, cell or cells that contain \*novel DNA; and
    - (b) does not contain novel DNA.
- Note 2 Section 1.1.2—17 (Definition of novel DNA) provides as follows:
  - (1) In this Code, *novel DNA* means DNA that:
    - (a) a person has inserted into the genome of an organism, cell or cells; and
    - (b) is one of the following:
      - (i) DNA from a species that is not a crossable species;
      - (ii) DNA that:
        - (A) is from a crossable species; and
        - (B) contains a coding region that was rearranged or recombined prior to the insertion referred to in paragraph (1)(a);
      - (iii) DNA that is not from an existing species.
  - (2) In this section, *crossable species* means a species of organism, cell or cells that can be crossed or hybridized with the species of organism, cell or cells referred to in paragraph (1)(a).
  - (3) Despite subsections (1) and (2), novel DNA does not include flanking left and right border sequences arising from *Agrobacterium*-mediated transformation.
- Note 3 In this Code (see section 1.1.2—2)

novel protein means a protein encoded by novel DNA.

Note 4 Definitions for the terms 'line' and 'transformation event' are in Schedule 26.

#### [19] Section 1.5.2—3

Repeal the section, substitute:

# 1.5.2—3 When genetically modified food is permitted for sale

A food for sale may contain, or consist of, a \*genetically modified food if that genetically modified food is:

- (a) listed in Schedule 26; and
- (b) complies with any corresponding conditions listed in that Schedule.

#### [20] Section 1.5.2—4

Repeal the section, substitute:

#### 1.5.2—4 Requirement to label food as 'genetically modified'

- (1) This section applies to a food for sale:
  - (a) that contains, or consists of, a \*genetically modified food that is listed in Schedule 26: and
  - (b) where that genetically modified food:
    - (i) contains novel DNA or novel protein; or
    - (ii) is listed in section S26—3 as subject to the condition that its labelling must comply with this section; and
  - (c) is not a food listed in subsection (2).
- (2) The following are listed foods:
  - (a) a food for sale that contains a \*genetically modified food that is:
    - (i) unintentionally present in the food for sale; and
    - (ii) present in the food for sale in an amount of no more than 10 g in a kilogram of each ingredient;
  - (b) a food for sale that is:
    - (i) intended for immediate consumption; and
    - (ii) prepared and sold from food premises (including restaurants, take away outlets, caterers, self-catering institutions and vending vehicles).
- (3) For the labelling provisions, the information relating to genetically modified food is the statement 'genetically modified' used in conjunction with the name of the genetically modified food.

**Note** The labelling provisions are set out in Standard 1.2.1. Labelling provisions apply to both packaged and unpackaged genetically modified food.

(4) If the genetically modified food is an ingredient (including an ingredient of a compound ingredient), the information may appear in the label other than in the statement of ingredients.

#### Example

Standards 1.2.1 and 1.2.4 require the labelling of certain foods for sale to include a statement of ingredients. For the purposes of section 1.5.2—4, genetically modified corn meal that is used as an ingredient of a crumbed fish compound ingredient that is in turn used in a mixed ingredient food could be declared in the statement of ingredients for that mixed ingredient food as: Ingredients: Crumb coating (wheat flour, water, canola oil, corn meal (genetically modified), salt, sugar, egg white). Alternatively, the name of the genetically modified ingredient could be declared in the statement of ingredients (eg.: corn meal) in accordance with Standard 1.2.4, with the information required by section 1.5.2—4 appearing elsewhere on the label (eg, contains genetically modified corn meal).

# Standard 2.9.1 - Infant formula products

#### [21] Subparagraph 2.9.1—49(1)(c)(i)

Omit "\*foods produced using gene technology", substitute "\*genetically modified food".

#### Schedule 3 - Identity and purity

#### [22] Subsection S3—35(2)

Omit "protein engineered enzymes" (wherever occurring), substitute "enzymes".

#### [23] Subsection S3—35(2)

Omit "a protein engineered enzyme" (wherever occurring), substitute "an enzyme".

# Schedule 18 - Processing aids

# [24] Subsection S18—4(2) (Note 3)

Repeal the Note.

#### [25] Table to subsection S18—4(5)

Omit ", protein engineered variant" (wherever occurring).

#### [26] Table to subsection S18—9(3)

Omit ", protein engineered variant," (wherever occurring).

#### [27] Table to subsection S18—9(3)

Omit "Protein engineered enzyme" (wherever occurring), substitute "Enzyme".

#### [28] Table to subsection S18—9(3)

Omit "Protein engineered enzymes", substitute "Enzymes".

# [29] Table to subsection S18—9(3) (Note)

Repeal the Note.

#### Schedule 26 - Food produced using gene technology

# [30] Standard title

Omit "Food produced using gene technology", substitute "Genetically modified food".

#### [31] Standard title (Note 1)

Repeal the Note, substitute:

**Note 1** This instrument is a standard under the *Food Standards Australia New Zealand Act 1991* (Cth). The standards together make up the *Australia New Zealand Food Standards Code*. See also section 1.1.1—3.

Genetically modified food is regulated by paragraphs 1.1.1—10(5)(c) and (6)(g) and Standard 1.5.2. This standard lists genetically modified food, and corresponding conditions, for section 1.5.2—3.

#### [32] Section S26—1

Omit "Food produced using gene technology", substitute "Genetically modified food".

#### [33] Subsection S26—2(2) (definition for conventional breeding)

Repeal the definition.

#### [34] Subsection S26—2(2) (definition for *line*)

Repeal the definition, substitute:

#### line means:

- (a) an animal or plant that has genetic material which includes a transformation event or events; or
- (b) an animal or plant that:
  - (i) is descended from an animal or plant described in paragraph (a); and
  - (ii) is the result of conventional breeding of that animal or plant with:
    - (A) any animal or plant that does not contain a transformation event or events; or

- (B) any other animal or plant that contains a transformation event or events, whether expressed as a line or event, that is listed in the table to section S26—3; and
- (iii) is not an animal or plant derived solely as a result of conventional breeding.

# [35] Subsection S26—2(2) (definition for *transformation event*)

Repeal the definition, substitute:

*transformation event* means a unique genetic modification arising from the insertion of novel DNA.

- [36] Section S26—3 (title)
  - Omit "food produced using gene technology", substitute "genetically modified food".
- [37] Subsection S26—3(1)

Omit "food produced using gene technology", substitute "genetically modified food".

- [38] Subsection S26—3(4) (Table heading)
  - Omit "Food produced using gene technology", substitute "Genetically modified food".
- [39] Subsection S26—3(7) (Table heading)

Omit "Food produced using gene technology", substitute "Genetically modified food".