EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Proposal P1055 – Definitions for gene technology and new breeding techniques) 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 2 of Part 3 of the FSANZ Act specifies that the Authority may prepare a proposal for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering a proposal for the development or variation of food regulatory measures.

The Authority prepared Proposal P1055 to amend definitions of terms used in the Code relating to genetic technologies and provide new defined terms that are clearer and better reflect existing and emerging genetic technologies including new breeding techniques. The Authority considered the proposal in accordance with Division 2 of Part 3 and approved a draft variation – the *Food Standards (Proposal P1055 – Definitions for gene technology and new breeding techniques) Variation* (the approved draft 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 approved 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 sunsetting 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 sunsetting 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 sunsetting 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 purpose of the approved draft variation is to amend definitions of terms used in the Code relating to genetic technologies and provide new defined terms that are clearer and better reflect existing and emerging genetic technologies including new breeding techniques. The approved draft variation also makes other amendments to the Code required as a consequence of the changes to the definitions.

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 2 of Part 3 of the FSANZ Act, the Authority's consideration of Proposal P1055 included two rounds of public comment following an assessment and the preparation of a draft variation and associated assessment summaries.

The first call for submissions was issued on 7 October 2021 and ended on 3 December 2021. The second call for submissions (including the draft variation) was issued on 30 July 2024 and ended on 10 September 2024.

Targeted consultation with an Expert Advisory Group (EAG) was undertaken from April 2020 to April 2023. The EAG was established to provide ongoing technical and scientific advice to the Authority regarding the proposed amendments to definitions of terms used in the Code relating to genetic technologies.

Targeted consultation with government representatives was undertaken from April 2020 to March 2025.

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.

The Office of Impact Analysis (OIA) has exempted FSANZ from the need to prepare a formal Consultation Regulation Impact Statement in relation to the regulatory change proposed (reference number OBPR22-03666). The OIA was satisfied with the consultation undertaken for this proposal.

A Decision Regulation Impact Statement (DRIS) was prepared by the Authority and has been assessed by the OIA as compliant (OBPR22-03666).

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

References to 'the variation' in this section are references to the approved draft variation.

Clause 1 of the variation provides that the name of the variation is the *Food Standards*

(Proposal P1055 – Definitions for gene technology and new breeding techniques) 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.

8. Schedule to the variation

Standard 1.1.1 – Structure of the Code and general provisions

Items [1] to [3] of the Schedule to the variation amend Standard 1.1.1 of the Code. In particular:

Item [1] amends section 1.1.1—2 by omitting the term 'Food produced using gene technology' (wherever that term occurs in that section), and substituting the omitted term with 'Genetically modified food'.

Item [2] amends section 1.1.1—10 by omitting '*food produced using gene technology' (wherever that term occurs in that section), and substituting the omitted term with '*genetically modified food'.

An asterisk placed immediately before a term in the Code means that subsection 1.1.2—2(3) of the Code defines that term or refers to a provision of the Code that defines that term. See section 1.1.1—16 of the Code.

Item [3] amends Note 1 of section 1.1.1—10 by omitting the term 'food produced using gene technology', and substituting the omitted term with 'genetically modified food'.

Notes in the Code are not legally binding for the Code. Instead, their purpose is simply to identify or explain certain matters to the reader.

The effect of the amendments made by **Items [1]** - **[3]** is:

- the terms used throughout Standard 1.1.1, which relate to genetic technologies, reflect the proposed amendments in **items [4]** – **[8]** below, and
- that 'genetically modified food' (GM food), as defined by the new definition in **item [8]** below, is prohibited from sale, and from being used as an ingredient or a component of a food for sale, unless expressly permitted by the Code.

Standard 1.1.2 – Definitions used throughout the Code

Items [4] – **[8]** of the Schedule to the variation amend Standard 1.1.2 of the Code. In particular:

Items [4] – [7] amend subsection 1.1.2—2(3) as follows:

Item [4] repeals the definition for 'food produced using gene technology' in the subsection.

Item [5] repeals the definition for 'gene technology' in the subsection.

Item [6] inserts the following new entry into the subsection:

'***genetically modified food***—see section 1.1.2—16.' (see **item [8]** below).

Item [7] repeals the entry for 'novel food' in the subsection, and substitutes it with the following entries arranged in alphabetical order:

'***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.'

The entries for 'novel DNA' and 'novel protein' are new, but the existing entry for 'novel food' remains unchanged.

The amendments in **items [6]** and **[7]** are consequential to the amendment in **item [8]** below.

Item [8] adds two new provisions to Standard 1.1.2 after section 1.1.2—15, each of which sets out a new definition that applies throughout the Code. The new provisions are sections 1.1.2—16 and 1.1.2—17.

Section 1.1.2—16 sets out the new definition for 'genetically modified food'.

Subsection 1.1.2—16(1) provides that a reference in the Code to '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.

Subsection 1.1.2—16(2) defines a 'null segregant' for the purposes of section 1.1.2—16 as meaning 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.

The term 'novel protein' is defined in subsection 1.1.2—2(3) of the Code (see **item [7]** above).

The terms 'used as a food additive' and 'used as a processing aid' are defined in sections 1.1.2—11 and 1.1.2—13 of the Code respectively.

The term 'novel DNA' is defined in new section 1.1.2—17 (see below).

The intent of **paragraph 1.1.2—16(1)(a)** is to ensure that all food that is an organism (plants, animals, and single cell organisms) and cells (cells isolated from a multicellular organism that are then grown in culture) or derived from organisms and cells can be captured for pre-

market assessment and approval as GM food under the Code if those organisms or cells contain novel DNA.

Paragraph 1.1.2—16(1)(b) provides that the followings foods are not a 'genetically modified food' despite paragraph 1.1.2—16(1)(a):

- Food additives and processing aids. These substances are excluded as they are already regulated by other parts of the Code where they are subject to pre-market assessment and approval.
- Substances used to support the growth and viability of cells or process cells in culture as part of the production of cell-cultured food. These substances are excluded as they are not added for the express purpose of being an ingredient of the food.
- Food from grafted plants, where it is derived from the part of a grafted plant that does not contain novel DNA or novel protein. These foods are excluded as they are equivalent to food derived through conventional breeding approaches.
- Food derived from a null segregant. These foods are excluded as they are equivalent to food derived through conventional breeding approaches.

The intent of the definition for 'null segregant' in subsection 1.1.2—16(2) is to make clear that a null segregant organism, cell or cells is not a GM food for the purposes of the Code. It has never been the intent to capture and regulate food from a null segregant organism, cell or cells as GM food under the Code.

The new definition of GM food in effect reframes the Code's regulatory approach to GM food, where food is now considered GM food based on the presence of novel DNA in the genome of the organism or cells from which food is derived. This represents a change from the previous approach where food is considered to be GM food if it is derived using gene technology, irrespective of the outcome of that genetic modification process.

The intent is to only regulate foods as GM foods under the Code when the outcome of the genetic modification process is different to what is likely to be achievable through conventional breeding approaches. This will ensure GM foods are regulated in a way that is commensurate with risk, and also remove ambiguity about what foods are GM foods for the purposes of the Code.

Section 1.1.2—17 sets out the new definition for 'novel DNA'.

The new definition sets out what types of DNA are 'novel DNA' for the purposes of the new definition for GM food (see above). The new definition is also relevant for the purposes of labelling (see **item [20]** below).

Subsection 1.1.2—17(1) provides that a reference in the Code to '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.

Subsection 1.1.2—17(2) defines 'crossable species' for the purposes of section 1.1.2—17 as meaning 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 1.1.2—17(1)(a).

Subsection 1.1.2—17(3) provides that, despite subsections 1.1.2—17(1) and 1.1.2—17(2), flanking left and right border DNA sequences arising from *Agrobacterium*-mediated transformation is not novel DNA for the purposes of the Code.

Paragraph 1.1.2—17(1)(a) provides that 'novel DNA' means DNA that, among other things, 'a person has inserted into the genome of an organism, cell or cells'. The paragraph's purpose is to ensure that foods in which the insertion of 'novel DNA' has occurred through a natural process, without any intervention by a person, are not captured and regulated as GM food by the Code. The paragraph will apply to and capture the insertion of 'novel DNA' through the use of automated process, as such processes would be under the control or direction of a person.

Paragraph 1.1.2—17(1)(b) provides that only certain categories or types of DNA will be 'novel DNA' if inserted by a person into the genome of an organism, cell or cells (as required by paragraph 1.1.2—17(1)(a)). That is -

- DNA that is from a species that is unrelated (i.e., not able to be crossed or hybridised) to the species from which food is derived.
- DNA that is from the same or a closely related species (i.e., able to be crossed or hybridised) to the species from which food is derived, but where the coding region (which may encode either a protein or other expressed product such as RNA) has been rearranged or recombined prior to insertion. Such rearrangement or recombination could involve a full coding region, part of a coding region or parts of multiple coding regions;
- DNA that is not from an existing species; for example, where the sequence of the DNA cannot be attributed to an existing species. This would include DNA that has been computationally designed de novo.

The intent of paragraph 1.1.2—17(1)(b) is to limit the scope of what constitutes GM food for Code purposes to foods that are not or would unlikely be produced using conventional breeding methods.

The intent of **subsection 1.1.2—17(3)** is to make it clear that residual left and right border sequences that flank the inserted DNA as a result of using *Agrobacterium*-mediated transformation are not novel DNA for Code purposes, despite being DNA from a non-crossable species. Such DNA is non-coding and does not pose any safety concerns.

The definition of 'novel DNA' provided by section 1.1.2—17 does not refer to or rely on any of the following:

- the genomic location of any inserted DNA;
- codon optimisation of the inserted DNA that does not alter the amino acid sequence of the expressed product.

Standard 1.2.1 – Requirements to have labels or otherwise provide information

Items [9] – **[12]** of the Schedule to the variation amends Standard 1.2.1 of the Code. In particular:

Item [9] amends paragraph 1.2.1—8(1)(k) by omitting the term '*foods produced using gene

technology', and substituting the omitted term with '*genetically modified food'.

Item [10] amends paragraph 1.2.1—9(3)(b) by omitting the term 'foods produced using gene technology', and substituting the omitted term with '*genetically modified food'.

Item [11] amends paragraph 1.2.1—9(3)(ba) by omitting the term 'foods produced using gene technology', and substituting the omitted term with 'genetically modified food'.

Item [12] amends paragraph 1.2.1—15(f) by omitting the term 'foods produced using gene technology', and substituting the omitted term with '*genetically modified food'.

An asterisk placed immediately before a term in the Code means that subsection 1.1.2—2(3) of the Code defines that term or refers to a provision of the Code that defines that term. See section 1.1.1—16 of the Code.

The provisions in Standard 1.2.1 amended by **items [9]** – **[12]** specify how information relating to specific types of food must be provided as follows:

- food for retail sale that is both packaged and required to bear a label because of section 1.2.1—6—on the label of the packaged food;
- food for retail sale that is not required to bear a label because of section 1.2.1—6 (irrespective of whether or not the food is packaged)—on labelling that either accompanies the food, or is displayed in connection with the display of the food;
- food sold to a caterer which is packaged and required to bear a label because of section 1.1.2—12—on the label of the packaged food;
- food sold to a caterer which does not have to bear a label because of section 1.1.2—12—on labelling provided to the caterer with the food.

The effect of the amendments made by **items [9] – [12]** is to apply the labelling and information requirements in Standard 1.2.1 to GM food as defined following the amendment made by **item [8]** above.

Standard 1.2.4 – Information requirements – statement of ingredients

Item [13] of the Schedule to the variation amends Standard 1.2.4 of the Code by repealing paragraph 1.2.4—5(6)(b), and substituting it with:

'(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.'

Subparagraph 1.2.4—5(6)(b) (as amended) includes a reference to section 1.5.2—4 (see **item [20]** below).

Paragraph 1.2.4—5(6)(b) relates to the listing of a compound ingredient in a statement of ingredients when the compound ingredient comprises less than 5% of the food for sale. Existing paragraph 1.2.4—5(6)(b) requires the following to be listed (in brackets) in a statement of ingredients: an ingredient of a compound ingredient if the compound ingredient is required to be listed in accordance with section 1.2.3—4 (i.e. certain foods that are food allergens) only, and any substance used as a food additive in the compound ingredient which performs a technological purpose in the food for sale.

The term ‘used as a food additive’ is defined in section 1.1.2—11 of the Code.

The effect of the amendment in **item [13]** is that a GM ingredient of a compound ingredient is also required to be listed in accordance with section 1.5.2—4, if the compound ingredient comprises less than 5% of the food for sale.

Standard 1.3.3 – Processing aids

Item [14] of the Schedule to the variation amends Standard 1.3.3 of the Code by repealing Note 2 to paragraph 1.3.3—6.

Notes in the Code are not legally binding for the Code. Instead, their purpose is simply to identify or explain certain matters to the reader.

The effect of the amendment in **item [14]** is to remove reference to protein engineered enzymes that are used as food processing aids. The note previously explained requirements for these enzymes in relation to food produced using gene technology, and will no longer be required given the exclusion of substances used as a processing aid from the new definition for GM food in **item [8]** above.

Standard 1.5.2 – Food produced using gene technology

Items [15] – **[20]** of the Schedule to the variation amend Standard 1.5.2 of the Code. In particular:

Item [15] amends the title of Standard 1.5.2 by omitting the term ‘Food produced using gene technology’ from the title and substituting the omitted term with ‘Genetically modified food’.

The effect of this amendment is to rename the Standard as Standard 1.5.2 – Genetically modified food.

Item [16] amends Note 3 to the title of Standard 1.5.2 by repealing Note 3 and substituting the Note with a new Note 3.

Notes in the Code are not legally binding for the Code. Instead, their purpose is simply to identify or explain certain matters to the reader.

New Note 3 identifies the following for the reader:

- 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 GM food, unless expressly permitted by this Code.
- Standard 1.5.2 contains the relevant permissions.
- Schedule 26 provides definitions of the terms ‘line’ and ‘transformation event’; and lists approved GM foods and any conditions for use of the food.

Amendments in **items [15]** and **[16]** are consequential to amendments to definitions in Standard 1.1.2 in **items [4]** – **[8]** above; and Schedule 26 in **items [33]** – **[35]** below.

Item [17] amends section 1.5.2—1 by omitting the term ‘Food produced using gene technology’ and substituting the omitted term with ‘Genetically modified food’.

Section 1.5.2—1 sets out the name of the Standard.

This proposed amendment is consequential to the amendment proposed in **item [15]** above.

Item [18] amends Notes 1 - 3 in section 1.5.2—2 by repealing those Notes and substituting them with new Notes 1 - 4.

Notes in the Code are not legally binding for the Code. Instead, their purpose is simply to identify or explain certain matters to the reader.

New Note 1 sets out a copy of the definitions of GM food and 'null segregant' in new section 1.1.2—16 of the Code (see **item [8]** above).

New Note 2 sets out a copy of the definition of 'novel DNA' in new section 1.1.2—17 of the Code (see **item [8]** above).

New Note 3 sets out a copy of the definition of 'novel protein' proposed in section 1.1.2—2 of the Code (see **item [7]** above).

New Note 4 explains to the reader that definitions of the terms 'line' and 'transformation event' are in Schedule 26.

The amendments in **item [18]** are consequential to amendments to definitions in Standard 1.1.2 in **items [4]** – **[8]** above; and Schedule 26 in **items [33]** – **[35]** below.

Item [19] amends section 1.5.2—3 by repealing the section and substituting it with a new section 1.5.2—3.

Existing section 1.5.2—3 sets out when 'food produced using gene technology' is permitted for sale and provides that:

> 'A food for sale may consist of, or have as an ingredient, a *food produced using gene technology if the food produced using gene technology:
> (a) is listed in Schedule 26 and complies with any corresponding conditions listed in that Schedule; or
> (b) is a substance that is permitted for use as a food additive by Standard 1.3.1 or as a processing aid by Standard 1.3.3.'

New section 1.5.2—3 sets out when GM food is permitted for sale and provides that:

> '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.'

An asterisk placed immediately before a term in the Code means that subsection 1.1.2—2(3) of the Code defines that term or refers to a provision of the Code that defines that term. See section 1.1.2—16 of the Code.

This amendment:

- removes the reference in section 1.5.2—3 to 'a substance that is permitted for use as a food additive by Standard 1.3.1 or as a processing aid by Standard 1.3.3', as these substances are specifically excluded from the new definition for GM food in **item [8]** above;
- substitutes the term 'food produced using gene technology' with 'genetically modified

food’.

The overall effect of this amendment is to permit a food for sale to contain or consist of a GM food, if both of the following conditions are met:

- the GM food is listed in Schedule 26; and
- the GM food complies with any corresponding conditions in that Schedule.

Item [20] amends section 1.5.2—4 by repealing the section and substituting it with a new section 1.5.2—4. The new section sets out the labelling requirements for GM food as a consequence of the amendments to the definitions in Standard 1.1.2 in **items [4]** – **[8]** above; and Schedule 26 in **items [33]** – **[35]** below.

The new definition of GM food is explained above, see **item [8]** above.

New subsection 1.5.2—4(1) sets out the type of food to which section 1.5.2—4 applies. The subsection provides that the section applies to a food for sale that meets the following conditions:

- the food for sale contains, or consists of, a GM food that is listed in Schedule 26: and
- that GM food either:
  - contains novel DNA or novel protein; or
  - is listed in section S26—3 of the Code as being subject to the condition that its labelling must comply with this section, and
- the food for sale is not a food listed in subsection (2).

A GM food is listed in section S26—3 if and when the Authority determines during pre-market assessment of that food that the food has altered food characteristics as a result of the genetic modification.

New subsection 1.5.2—4(2) sets out the listed foods for the purposes of paragraph 1.5.2—4(1)(c), i.e. food for sale to which requirements in subsection 1.5.2—4 do not apply. The listed foods are as follows:

- a food for sale containing GM food where the GM food is both:
  - unintentionally present in the food for sale; and
  - present in the food for sale in an amount of no more than 10 g in a kilogram of each ingredient; or
- a food for sale that is both:
  - intended for immediate consumption; and
  - prepared and sold from food premises (including restaurants, take away outlets, caterers, self-catering institutions and vending vehicles).

New subsection 1.5.2—4(3) sets out the requirements applying specifically to GM food for the purposes of the labelling provisions in Standard 1.2.1. The new subsection provides that, for those labelling provisions, the information relating to GM food is the statement ‘genetically modified’ used in conjunction with the name of the GM food.

The labelling provisions in Standard 1.2.1 will require this information to appear or be provided as follows:

- food for retail sale that is both packaged and required to bear a label because of

section 1.2.1—6—on the label of the packaged food;

- food for retail sale that is not required to bear a label because of section 1.2.1—6 (irrespective of whether or not the food is packaged)—on labelling that either accompanies the food, or is displayed in connection with the display of the food;
- food sold to a caterer which is packaged and required to bear a label because of section 1.1.2—12—on the label of the packaged food;
- food sold to a caterer which does not have to bear a label because of section 1.1.2—12—on labelling provided to the caterer with the food.

The new Note to subsection 1.5.2—4(3) explains to the reader that:

- the labelling provisions referred to in subsection 1.5.2—4(3) are set out in Standard 1.2.1; and
- the labelling provisions apply to both packaged and unpackaged GM food.

Notes in the Code are not legally binding for the Code. Instead, their purpose is simply to identify or explain certain matters to the reader.

New subsection 1.5.2—4(4) provides that if the GM 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.

An example of how to meet the above requirements is provided. Standards 1.2.1 and 1.2.4 of the Code require the labelling of certain foods for sale to include a statement of ingredients. In this example, GM 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:

> '*Crumb coating (wheat flour, water, canola oil, corn meal (genetically modified), salt, sugar, egg white)*'.

Alternatively, the name of the GM ingredient could be declared in the statement of ingredients (for example: '*corn meal*') in accordance with Standard 1.2.4, with the information required by section 1.5.2—4 appearing elsewhere on the label as, for example: '*contains genetically modified corn meal*'.

The aim of this amendment is to:

- simplify and clarify the current labelling provisions under the new definitions for GM food and 'novel DNA';
- remove reference to substances used as a food additive and substances used as a processing aid, as these substances are specifically excluded from the new definition for GM food in **item [8]** above;
- remove current labelling exemptions and requirements that specifically relate to substances used as a food additive (including flavouring substances), and substances used as a processing aid, as such exemptions and requirements are redundant as a consequence of the amendments to definitions in **items [4]** – **[8]** above.

The term 'flavouring substance' is defined in subsection 1.1.2—2(3) of the Code.

The terms 'used as a food additive' and 'used as a processing aid' are defined in sections 1.1.2—11 and 1.1.2—13 of the Code respectively.

Standard 2.9.1 – Infant formula products

Item [21] of the Schedule to the variation amends Standard 2.9.1 of the Code by omitting '*foods produced using gene technology' from subparagraph 2.9.1—49(1)(c)(i), and substituting the omitted term with '*genetically modified food'.

Section 2.9.1—49 sets out the mandatory labelling requirements for special medical purpose products for infants.

The effect of the amendment is that this provision refers to GM food, instead of food produced using gene technology, as a consequence of amendments to definitions of terms used in the Code relating to genetic technologies in **items [4]** – **[8]** above.

The intent of this amendment is to ensure that labelling requirements applying to GM food apply, where relevant, to special medical purpose products for infants.

Schedule 3 – Identity and purity

Items [22] and **[23]** of the Schedule to the variation amend Schedule 3 of the Code. In particular:

Item [22] amends subsection S3—35(2) by omitting 'protein engineered enzymes' (wherever occurring) from the subsection, and substituting the omitted term with 'enzymes'.

Item [23] amends subsection S3—35(2) by omitting 'a protein engineered enzyme' (wherever occurring) from the subsection, and substituting the omitted term with 'an enzyme'

These amendments are a consequence of the amendments to definitions of terms used in the Code relating to genetic technologies in **items [4]** – **[8]** above.

The effect of the amendments set out in **items [22]** and **[23]** is to remove references to 'protein engineered' from Schedule 3 as this term is redundant given the exclusion of substances used as a processing aid from the new definition for GM food in **item [8]** above.

'Protein engineered' is a term used to convey that the enzyme processing aid has an amino acid sequence that is not found in nature and therefore is not subject to the labelling exemption in subsection 1.5.2—4(5). As processing aids are specifically excluded from the GM food definition, labelling requirements for GM food would no longer apply to processing aids. Consequently, the term 'protein engineered' will no longer serve a purpose in the Code.

Schedule 18 – Processing aids

Items [24] – **[29]** of the Schedule to the variation amend Schedule 18 of the Code. In particular:

Item [24] amends Note 3 to subsection S18—4(2) by repealing the Note.

Notes in the Code are not legally binding for the Code. Instead, their purpose is simply to identify or explain certain matters to the reader.

Note 3 to subsection S18—4(2) relates to protein engineered variants of enzymes, which are identified in sections 1.3.3—6 and S18—4 as processing aids permitted to perform any technological purpose if the enzyme concerned is derived from the corresponding source specified in the table.

Item [25] amends the table to subsection S18—4(5) by omitting ‘, protein engineered variant’ (wherever occurring) from the table.

Item [26] amends the table to subsection S18—9(3) by omitting ‘, protein engineered variant,’ (wherever occurring) from the table.

Item [27] amends the table to subsection S18—9(3) by omitting ‘Protein engineered enzyme’ (wherever occurring) from the table, and substituting the omitted term with ‘Enzyme’

Item [28] amends the table to subsection S18—9(3) by omitting ‘Protein engineered enzymes’ from the table, and substituting the omitted term with ‘Enzymes’.

Item [29] amends the Note to the table to subsection S18—9(3) by repealing the Note.

Notes in the Code are not legally binding for the Code. Instead, their purpose is simply to identify or explain certain matters to the reader.

The Note to the table to subsection S18—9(3) relates to protein engineered variants of enzymes, which are listed in the table as processing aids permitted to be used for specific technological purposes.

The effect of the amendments in **items [24]** – **[29]** is to remove terms in Schedule 18 which include references to ‘protein engineered’ because the term ‘protein engineered’ will become redundant given the exclusion of substances used as a processing aid from the new definition of GM food in **item [8]** above.

‘Protein engineered’ is a term used to convey that the enzyme processing aid has an amino acid sequence that is not found in nature and therefore is not subject to the labelling exemption in subsection 1.5.2—4(5). As processing aids are specifically excluded from the GM food definition, labelling requirements for GM food will no longer apply to processing aids. Consequently, the term ‘protein engineered’ will no longer serve a purpose in the Code.

Schedule 26 – Food produced using gene technology

Items [30] – **[39]** of the Schedule to the variation amend Schedule 26 of the Code. In particular:

Item [30] amends the title to Schedule 26 by omitting ‘Food produced using gene technology’ from the title of the Schedule, and substituting the omitted term with ‘Genetically modified food’.

Item [31] amends Note 1 to the title of Schedule 26 by repealing the Note, and substituting it with a new Note 1.

Notes in the Code are not legally binding for the Code. Instead, their purpose is simply to identify or explain certain matters to the reader.

New Note 1 explains to the reader that (among other things):

- paragraphs 1.1.1—10(5)(c) and (6)(g), and Standard 1.5.2, of the Code regulate GM food; and
- Schedule 26 lists GM food, and their corresponding conditions for the purposes of section 1.5.2—3 of the Code (for an explanation of new section 1.5.2—3, see **item [19]** above).

Item [32] amends section S26—1 by omitting ‘Food produced using gene technology’ from the section, and substituting the omitted term with ‘Genetically modified food’.

Section S26—1 states the name of Schedule 26.

The amendments in **items [30]** – **[32]** above are consequential to the amendments to definitions of terms used in the Code relating to genetic technologies in **items [4]** – **[8]** above.

The intent of the amendments in **items [30]** – [**32]** above is to ensure that the relevant provisions refer to the term ‘genetically modified food’ instead of ‘food produced using gene technology’, as the latter term will become redundant as a consequence of amendments to definitions in **items [4]** – **[8]** above.

Item [33] amends subsection S26—2(2) by repealing the definition for ‘conventional breeding’ in the subsection.

The reason for the amendment is that the definition for ‘conventional breeding’, which refers to ‘gene technology’, will become redundant as a consequence of amendments to definitions in **items [4]** – **[8]** above.

Item [34] amends subsection S26—2(2) by repealing the definition for ‘line’ in the subsection, and substituting it with a new definition for ‘line’.

The new definition provides that a reference in Schedule 26 to ‘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.’

The effect of the new definition for ‘line’ is to broaden its scope to both plants and animals. The existing definition for ‘line’ refers only to plants.

Item [35] amends subsection S26—2(2) by repealing the definition for ‘transformation event’ in the subsection, and substituting it with a new definition for ‘transformation event’.

The existing definition for ‘transformation event’ refers to ‘a unique genetic modification arising from the use of gene technology’.

The new definition refers instead to ‘a unique genetic modification arising from the insertion of novel DNA’.

The reason for this amendment is remove reference to ‘gene technology’, and refer instead to ‘novel DNA’, to be consistent with the new definition for GM food in **item [8]** above. The

term ‘gene technology’ will become redundant as a consequence of amendments to definitions in **items [4]** – **[8]** above.

Item [36] amends the title of section S26—3 by omitting ‘food produced using gene technology’ from the title, and substituting the omitted term with ‘genetically modified food’.

Item [37] amends subsection S26—3(1) by omitting ‘food produced using gene technology’ from the subsection, and substituting the omitted term with ‘genetically modified food’.

Item [38] amends the heading of the table to subsection S26—3(4) by omitting ‘Food produced using gene technology’ from the heading, and substituting the omitted term with ‘Genetically modified food’.

Item [39] amends the heading of the table to subsection S26—3(7) by omitting ‘Food produced using gene technology’ from the heading, and substituting the omitted term with ‘Genetically modified food’.

The effect of the amendments set out in **items [36]** – [**39]** will be that these provisions refer to GM food instead of ‘food produced using gene technology’, as the latter term will become redundant as a consequence of amendments to definitions in **items [4]** – **[8]** above.