

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1261 – Irradiation – Increase in maximum energy level) 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 purpose of the application was to increase the maximum energy level for machine sources generating X-rays permitted to irradiate food, from 5 to 7.5 megaelectronvolts provided the X-ray target used by the machine source is made from tantalum or gold. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation - the *Food Standards (Application A1261 – Irradiation – Increase in maximum energy level) 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 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 paragraph 1.5.3—7(b) to increase the maximum energy level for machine sources generating X-rays, which are permitted to irradiate food in accordance with the Code, from 5 to 7.5 megaelectronvolts provided the X-ray target used by the machine source is made of tantalum or gold.

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 A1261 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 2 February 2024 for a 6-week consultation period.

Changes have been made to the impact analysis requirements by the Office of Impact Analysis (OIA)¹. Impact analysis (including Regulatory Impact Statements, or RISs) is no longer required to be finalised with the OIA. Prior to these changes, the OIA (previously known as the Office of Best Practice Regulation (OBPR)) advised the Authority that a RIS was not required for applications relating to the irradiation of fruits and vegetables (see OBPR reference number 13845 dated 15 May 2012). The OIA's view was that applications relating to irradiation are part of implementing a regulatory framework, and the impacts are minor in nature where the use of irradiation as a treatment is voluntary if the draft variation concerned has been approved.² Under the new impact analysis requirements, the Authority must decide whether a RIS should be prepared. Under the new approach, the Authority's assessment was that a RIS was not required for this application because the impacts of the proposed amendment to the Code (if approved) would be minor and voluntary.

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

A reference to 'the variation' in this section is a reference to the approved draft variation.

Clause 1 of the variation provides that the name of the instrument is the *Food Standards (Application A1261 – Irradiation – Increase in maximum energy level) 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

¹ [Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis \(pmc.gov.au\)](#)

² Refer to the list of carve-outs on the [Office of Impact Analysis website](#).

the variation.

Schedule to the variation

Item [1] of the Schedule to the variation repeals the existing paragraph 1.5.3—7(b) and substitutes it with a new paragraph 1.5.3—7(b).

Section 1.5.3—7 sets out the three forms of ionising radiation which may be used when irradiating food in accordance with Division 2 of Standard 1.5.3.

Existing paragraph 1.5.3—7(b) referred to X-rays generated by or from machine sources only operated at an energy level not exceeding 5 megaelectronvolts.

New paragraph 1.5.3—7(b) refers to X-rays generated by or from machine sources operated at:

- an energy level not exceeding 5 megaelectronvolts; or
- if the machine source uses tantalum or gold as the X-ray target material - an energy level not exceeding 7.5 megaelectronvolts.

The effect of this amendment is to permit food being irradiated in accordance with Division 2 of Standard 1.5.3 by using (among other specified forms of ionising radiation) X-rays generated by or from machine sources operated at those energy levels. In particular, if a machine source uses tantalum or gold as the X-ray target material, the maximum energy level that the machine source would be able to operate at is 7.5 megaelectronvolts.