19 June 2024
294-24

Approval report – Application A1261

Irradiation – Increase in maximum energy level

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Steritech Pty Ltd to increase the maximum energy level for machines generating X-rays used to irradiate food, from 5 megaelectronvolts (MeV) to 7.5 MeV, provided the X-ray target of the machine source is made of tantalum or gold.

On 2 February 2024, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received eight submissions.

After having regard to the submissions received, FSANZ approved the draft variation on 4 June 2024. The Food Ministers' Meeting[1] was notified of FSANZ's decision on 19 June 2024.

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

[1] Formerly referred to as the Australia and New Zealand Ministerial Forum on Food Regulation

Table of contents

Supporting document

The following document, which informed the assessment of this application, is available on the FSANZ website[2]:

SD1 Risk and technical assessment report (at Approval)

[2] Application A1261 - Irradiation – Increase in maximum energy level: | Food Standards Australia New Zealand

Executive summary

Steritech Pty Ltd applied to Food Standards Australia New Zealand (FSANZ) to amend the Australia New Zealand Food Standards Code (the Code) to increase the maximum energy level at which machine sources generating X-rays may irradiate food from 5 megaelectronvolts[3] (MeV) to 7.5 MeV, provided the X-ray target of the machine source is made of tantalum or gold.

FSANZ has concluded that the proposed amendment is technologically justified. Increasing the maximum energy from 5 to 7.5 MeV would increase the efficiency of generating X-rays to irradiate food by approximately 40-50%. Increasing the efficiency of X-ray generation would therefore increase the treatment efficiency of pests and the rate of throughput for irradiating food.

The safety assessment concluded there were no public health and safety concerns associated with increasing the maximum energy level for machine sources generating X-rays permitted to irradiate food from 5 to 7.5 MeV provided the X-ray target used by the machine source is made of tantalum or gold. There would be no change to the irradiation dose applied to food as a result of increasing the maximum energy from 5 to 7.5 MeV and therefore no chemical changes to the food composition or nutritional impacts would be likely to occur.

Following assessment and the preparation of a draft variation to the Code, FSANZ called for submissions regarding the draft variation from 2 February 2024 to 15 March 2024. FSANZ received eight submissions as well as one late submission. Issues raised in these submissions have been addressed in the report.

Based on the information above and on other relevant considerations set out in this report, FSANZ has approved the draft variation to the Code proposed at the call for submissions. The approved draft variation will 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 either: a maximum energy level of 5 MeV; or a maximum energy level of 7.5 MeV, provided the X-ray target used by the machine source is made of tantalum or gold.

[3] One electron volt (eV) equals the amount of kinetic energy gained by a single electron accelerating from rest through an electric potential difference of one volt in a vacuum. I MeV = a million (10^6) eV

1 Introduction

1.1 The applicant

The applicant, Steritech Pty Ltd, is an Australian business that provides sterilisation and decontamination services, including using irradiation to treat food, quarantine goods, health care products, packaging and pet products.

1.2 The application

The purpose of the application was to amend the Australia New Zealand Food Standards Code (the Code) to increase the maximum energy level permitted for machines generating X-rays to irradiate food from 5 to 7.5 megaelectronvolts[4] (MeV), provided the machine's X-ray target is made of tantalum or gold.

In order to use X-rays to irradiate food, X-rays are produced when an electron beam produced in an accelerator strikes a heavy metal target converting electron beam energy into X-rays.

No other changes to the Code were requested as part of the application. That is, the application did not request any changes to the foods that are permitted to be irradiated or the dose range and other conditions for such irradiation of the foods. The applicant did not request any changes to how irradiation of foods can be achieved by gamma rays from cobalt 60 (^{60}Co) or from high energy electrons.

1.3 The current Standard

Australian and New Zealand food laws require that food for sale must comply with relevant requirements in the Code. The requirements relevant to this application are summarised below.

1.3.1 Permitted use

Paragraphs 1.1.1—10(5)(d) and (6)(h) of the Code provide that a food for sale must not consist of, or have as an ingredient or a component, a food that has been irradiated, unless expressly permitted by the Code. Division 2 of Standard 1.5.3 of the Code contains the relevant requirements related to permissions for the irradiation (and re-irradiation) of food. In summary, fresh fruit and fresh vegetables may be irradiated for the purpose of pest disinfestation for a phytosanitary objective (i.e. to stop the spread of pests between quarantine zones in Australia and New Zealand). As part of Application A1193, FSANZ determined that only a small proportion of fresh produce would be subject to irradiation for this purpose. Herbs and spices may be irradiated for the purpose of controlling sprouting and pest disinfestation, including the control of weeds, and for the purpose of bacterial decontamination.

Section 1.5.3—7 lists the forms of ionising radiation that may be used to irradiate food. These are:

(a) gamma rays from the radionuclide cobalt 60;
(b) X-rays generated by or from machine sources operated at an energy level not exceeding 5 megaelectronvolts;

[4] One electron volt (eV) equals the amount of kinetic energy gained by a single electron accelerating from rest through an electric potential difference of one volt in a vacuum. I MeV = a million (10^6) eV

(c) electrons generated by or from machine sources operated at an energy level not exceeding 10 megaelectronvolts.

1.3.2 Labelling requirements

Subsection 1.1.1—10(8) provides that food for sale must comply with all relevant labelling requirements imposed by the Code for that food.

Sections 1.2.1—8 and 1.2.1—9 contain information requirements for foods that are required to bear a label, and for those not required to bear a label, respectively, including information requirements relating to irradiated food.

Section 1.5.3—9 requires that if the food has been irradiated, or if an ingredient or component of the food has been irradiated, then there must be a statement to the effect that the food, or the ingredient or component of that food, has been treated with ionising radiation.

1.4 International standards

In developing food regulatory measures, FSANZ must have regard to the promotion of consistency between domestic and international food standards. The relevant international standard setting agencies are the Codex Alimentarius Commission (Codex) and the International Plant Protection Convention (IPPC). The IPPC is a United Nations agency within the Food and Agriculture Organization (FAO) for the protection of the world's plant resources. Both agencies endorse the use of food irradiation.

A recent 2023 FAO IPPC International Standard for Phytosanitary Measures (ISPM 18, IPPC 2023) lists the methods used to treat food using irradiation, which includes X-rays (up to 7.5 MeV) generated from machine sources. International Standards for Phytosanitary Measures (ISPMs) are the standards issued by the IPPC.

The relevant Codex standard is the Codex General Standard for Irradiated Foods (CXS 106-1983, Rev.1-2003) (CAC 2003). Under this standard, food may be irradiated to a maximum dose of 10 kGy, provided irradiation fulfils a technological requirement and/or is beneficial in protecting consumer health. This standard also states that irradiation must not be used as a substitute for good hygienic and good manufacturing practices or good agricultural practices. Codex standard CXS 106-1983 recommends three forms of ionising radiation to treat food. It has a similar limit of energy level for X-rays generated from machine sources at or below an energy level of 5 MeV as currently in the Code. It is noted that the Codex standard was initially issued in 1983, and last updated in 2003. It is only more recently that higher energy sources for generating X-rays have become commercially available to irradiate food.

1.4.1 National standards comparable to application

Five countries have amended their irradiation legislation from that originally consistent with the Codex standard CXS 106-1983 to increase the generating energy of X-rays from 5 to 7.5 MeV. The USA (US FDA 2004), Canada (CG 2016) and South Korea (MFDS 2020) have regulated to permit the increased energy of the electron beam of up to 7.5 MeV to generate the X-rays, and the use of tantalum or gold as the X-ray target material to irradiate food. India (GI 2012) and Indonesia (NADFC 2013, in Indonesian) also permit the use of X-rays generated from machines operating up to 7.5 MeV, but they do not appear to specify the X-ray target material.

The relevant USA regulation is section 179.26 – Ionizing radiation for the treatment of food, within the Code of Federal Regulations (CFR), Title 21 (US CFR Title 21 §179.26). The

energy sources include both:

- X-rays generated from machine sources at energies not to exceed 5 million electron volts (MeV) [also equivalent and consistent with 5 megaelectronvolts].
- X-rays generated from machine sources using tantalum or gold as the target material and using energies not to exceed 7.5 (MeV).

Canada (Canadian Food and Drug Regulations) and South Korea are consistent with the USA regulations. That is, the X-ray generation energy source maximum level is 5 MeV, unless the X-ray target material is tantalum or gold in which case the maximum energy level is 7.5 MeV.

1.5 Reasons for accepting application

The application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act); and
- it related to a matter that warranted the variation of a food regulatory measure.

1.6 Procedure for assessment

The application was assessed under the General Procedure in the FSANZ Act.

1.7 Decision

For the reasons outlined in this report, FSANZ decided to approve the draft variation that was set out in the call for submissions. The approved draft variation takes effect on gazettal and is at Attachment A.

The related explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ called for submissions on the draft variation to the Code from 2 February 2024 to 15 March 2024. Eight submissions were received during the consultation process. One late submission was also received.

New Zealand Food Safety and the New Zealand Food & Grocery Council submissions supported the draft variation.

Four individual consumers opposed the draft variation. Two consumer interest groups (Food Intolerance Network and GeneEthics) also opposed the draft variation. The issues raised in these submissions are addressed in Table 1. FSANZ notes that many of the issues raised in submissions are not specific to the proposed variation but apply to food irradiation in general and are therefore out of scope of the application.

Table 1: Summary of issues

Issue/comment	Submitter	FSANZ response
Support for the application		
The submitter agrees with FSANZ's safety and risk assessment that concluded that no potential public health and safety concerns were identified in the assessment of this application. The change is technologically justified. It increases the efficiency of generating X-rays to irradiate food and results in an increase in processing capacity, with no change to the absorbed dose of irradiation in foods. The change is consistent with standards for irradiated foods internationally, including the International Plant Protection Convention (IPPC) 2023 Food and Agriculture Organization (FAO) International Standard for Phytosanitary Measures. The submitter agrees with FSANZ's conclusion that there are no public health and safety concerns associated with the consumption of food irradiated with 7.5 MeV X-rays at the approved dose levels when using tantalum or gold as the X-ray target.	New Zealand Food Safety, and New Zealand Food and Grocery Council	Noted.
Other than the labelling issue [see below], consumers who engaged with the Network understood the advantages of this application and have no substantive issues with the proposed increase in energy used.	Food Intolerance Network	Noted.
Labelling matters		
Expressed a view there is no proper labelling of irradiated foods despite this being a legal requirement. The labelling of irradiated food needs to be accurate, honest and clearly visible.	Individuals Food Intolerance Network	This issue is outside the scope of the application. The existing requirement for mandatory labelling of irradiated foods at section 1.5.3—9 of the Code will continue to apply (see sections 1.3.2 and 2.3.1 of this report). The responsibility for monitoring and enforcing Code requirements, including those that relate to labelling, rests with the relevant

Issue/comment	Submitter	FSANZ response
		enforcement agencies in each Australian state and territory and New Zealand. For imported products, enforcement responsibilities reside with the Department of Agriculture, Fisheries and Forestry (DAFF) in Australia and the Ministry for Primary industries (MPI) in New Zealand.
Noted it is exceptional to see foods labelled as irradiated. Specifically, a survey of 21,000 members of the Food Intolerance Network indicated they had never seen a label indicating any wording suggestive of irradiation.	Food Intolerance Network	This issue is outside the scope of the application. The existing requirement for mandatory labelling of irradiated foods at section 1.5.3—9 of the Code will continue to apply (see section 1.3.2 of this report). Given the limited scope of existing permissions covering fresh fruit and fresh vegetables and herbs and spices (see section 1.3.1 of this report) and, as such, the small proportion of products likely to undergo irradiation, this may in part explain observations regarding the scarcity of irradiation labelling.
FSANZ is urged to delay approving this application until there has been further investigation of what appears to be deliberate dishonesty in labelling.	Food Intolerance Network	The variation will increase the maximum energy level at which machine sources generating X-rays may irradiate food, not change existing labelling requirements. As such, there is no justification for delaying the progress of this application. The responsibility for monitoring and enforcing Code requirements rests with relevant enforcement agencies.
The standard must prescribe that an active framework is put in place to punish food distributors that do not follow the directive to label irradiated food.	Individuals	The responsibility for compliance and enforcement of labelling requirements rests with the relevant enforcement authorities who can apply penalties for non-compliance with the Code.
Refers to comments made in its submission of December 2020 to Application A1193, which they claim were not answered. Specifically, the submitter queries why Australia is the only country which does not require labels to declare that the food is ‘irradiated’ or ‘treated with ionising radiation’ (as in the EU etc.) and instead permits words ‘to the effect’ (Standard 1.5.3—9) that it has been irradiated with the potential to mislead consumers?	Food Intolerance Network	As detailed in section 1.3.2 of this report, the Code does not prescribe the wording of the mandatory statement, rather, requires a statement with words to the effect that the food has been treated with ionising radiation. This is not inconsistent with Codex Standard CXS 1-1985. FSANZ also notes that labelling requirements vary from country to country. For example, as noted by the submitter, the EU requires the words 'irradiated` or 'treated with ionizing radiation` to be included on the label. In contrast, in Canada, labelling regulations require that irradiated food be labelled with the Radura symbol and an explanatory statement such as ‘treated with radiation’, ‘treated by irradiation’, ‘irradiated, or a written statement with the same meaning.

Issue/comment	Submitter	FSANZ response
Safety concerns		
Irradiation of food causes damages to a certain degree of cells in the food. The nature of these damages are completely random. Evidence that has been published indicating that these damages have only minimal adverse effect on the health of the people comes from institutions which were engaged by companies or institutions that have a commercial interest in the advancement of food irradiation. Reliable evidence that irradiation is not harmful for the consumer of the irradiated food does not exist.	Individual	The safety of use of irradiation to treat various foods including fresh produce was fully evaluated within FSANZ assessment reports to earlier irradiation applications including A1193 - Irradiation as a phytosanitary measure for all fresh fruit and vegetables. FSANZ's previous assessments have concluded there are no safety concerns associated with the consumption of fresh fruit and vegetables that have been irradiated with doses of up to 1 kGy. There are a number of compounds, termed radiolytic compounds, which may be generated during the irradiation of food. FSANZ has previously concluded that radiolytic compounds are not produced at levels that are likely to result in harm following irradiation within the approved dose ranges. The levels of these compounds are generally comparable to those naturally present in cooked food. No new evidence was identified during the safety assessment of the present application that would alter FSANZ's previous conclusions. As the maximum doses permitted in the Code will remain unchanged, no new food chemical changes will be associated with an increase to the maximum energy level permitted for X-rays generated by or from machine sources using tantalum or gold.
The genetic structure of food subject to X-rays can also be damaged (like that of bacteria which die when subjected to radiation) and therefore the health of anyone eating that genetically damaged food can be adversely impacted. Irradiation of food intended for consumption should never be allowed.	Individual	See the above response.
Nutritional and quality impacts		
How are the nutritional profiles of modern fresh produce affected by irradiation? There needs to be transparent evidence regarding the	Individual	The proposed increase in maximum energy level for machine sources generating X-rays will not result in an increased absorbed dose in food.

Issue/comment	Submitter	FSANZ response
effects of irradiation on the quality of foods, especially fresh produce which is eaten at high rates.		Therefore, no significant new food chemical changes are expected to be associated with the variation to the Code, as noted within the report. The nutritional impact from the use of irradiation to treat fresh produce was fully evaluated within FSANZ assessment reports to the earlier irradiation application A1193 - Irradiation as a phytosanitary measure for all fresh fruit and vegetables. FSANZ's nutrition risk assessment for A1193 concluded that, based on the available evidence, the effect of irradiation on the micronutrient intake across the Australian and New Zealand populations from fruit and vegetables is minimal.
Better appearance and longer shelf life of the food is only an external property, far less essential than the nutritional quality of the food. Therefore this benefit cannot be offset against the health cost; they differ in importance by an order of magnitude.	Individual	The response provided above applies here.
There is a denial of people's rights to proper disclosure from producers [of irradiated food] as to the products they are likely to consume believing them to be safe and nutritious when the evidence for this is either missing or misleading.	Individual	This is outside the scope of this application. However, as noted above, the nutritional impact from the use of irradiation to treat fresh produce was fully evaluated within FSANZ assessment reports to the earlier irradiation application A1193 A1193 - Irradiation as a phytosanitary measure for all fresh fruit and vegetables | Food Standards Australia New Zealand
Other general questions and issues		
Has the irradiation of fresh produce resulted in actual reductions in the usage of pesticides for phytosanitary measure, which should be the goal of irradiation?	Individual	The scope of FSANZ's assessment does not include direct comparisons with, or impacts on, other potential phytosanitary measures. The uptake of the technology and decision to not use other phytosanitary measures is a matter for individual food businesses. However, FSANZ notes that irradiation permissions in the Code provide the potential to reduce pesticide use. FSANZ is not aware of data on any actual reduction in pesticide usage.
Objects to increasing the irradiation of fresh produce by 50%. Nothing was found in the literature supporting the claim that dosage is the key to the reduction of food	Individual	The permission for irradiation of food within Standard 1.5.3 is linked specifically to the dose of the irradiation, which has not been changed. The variation relates only to the energy used to produce the X-rays, not

Issue/comment	Submitter	FSANZ response
nutrition and that such an increase on top of the existing levels would cause no reduction in food value and nutritional quality.		the doses that X-rays are permitted to treat the different foods.
The industrialisation [taken to include the irradiation of fresh produce] of the food supply is hidden from the public as no reportage in mainstream media will be evident.	Individual	FSANZ notes that all its assessment reports are publicly available on FSANZ's website https://www.foodstandards.gov.au/food-standards-code/applications/Application-A1261-Increase-in-the-maximum-energy-level-for-machines-used-to-generate-X-rays-to-irradiate-food.
The applicant produced around 9000 tonnes of food from its facilities last year and the submitter wishes to know how much was labelled, where did it go (what outlets sold it).	Individual	FSANZ sought advice from the applicant to address this question, with the information received summarised below. Between July 1st 2022 and June 30th 2023, Australian horticultural businesses treated just over 11,000 pallets of fresh produce using phytosanitary irradiation to meet biosecurity requirements. The weight of produce per pallet is variable dependent on the size of pallet and type of produce, but averages less than 1 tonne per pallet. Of the 11,000 pallets treated, approximately 65% (7,000 pallets) was exported, mainly to Vietnam, New Zealand, and the USA with small amounts to Indonesia, Malaysia and Thailand. The balance of approximately 35% (4,000 pallets) was sold to markets within Australia, including Tasmania, South Australia, and Western Australia. The majority of this product was retailed by independent supermarkets and green grocers purchasing through wholesale market agents. Phytosanitary irradiation is one of many biosecurity controls used by the horticulture industry which enables movement of fresh produce across biosecurity borders, enhancing consumer access to Australian grown fresh produce. The destination market determines if there is a pest of concern and what biosecurity controls are required for the product to enter the state or region. Requirements will be specific to a region of production and the crop. The primary use of the phytosanitary irradiation in the domestic market has been to prevent the spread of Queensland fruit fly to regions that do not have it.

Issue/comment	Submitter	FSANZ response
		The applicant also advised that all its products treated by phytosanitary irradiation for consumption in Australia are confirmed to have the correct labelling on the carton at a minimum of two points in the supply chain. The carton labelling is required to assist with biosecurity traceability and contains wording that meets the Code labelling requirements. Without correct labelling product cannot clear biosecurity checks meaning it cannot enter the destination state and be sold. Further additional labelling is often added at the discretion of the retailer using various methods dependent on the retail format and the specific product. Due to the complexity of fresh produce supply chains and retail merchandising, a combination of methods are used including shelf or price tag signage, and large display signs.
The submitter does not support the draft variation as Australia's regulation of fruit and vegetable irradiation should continue to conform with the Codex Alimentarius standards on the maximum energy to produce X-rays [being 5 MeV] and not 7.5 MeV.	GeneEthics	As noted in section 1.4 above, the relevant Codex standard was last updated in 2003, and it is only more recently that higher energy sources for generating X-rays have become commercially available to irradiate food. The other relevant United Nations agency for the irradiation of food is the International Plant Protection Convention (IPPC). The IPPC 2023 International Standard for Phytosanitary Measures lists the methods used to treat food using irradiation, which includes X-rays (up to 7.5 MeV) generated from machine sources. In addition, the USA, Canada, South Korea, India and Indonesia also permit the irradiation of food using X-rays generated by machine sources up to 7.5 MeV.
FSANZ needs to ensure that the irradiation of fresh fruits and vegetables is solely for the fruit fly control approved in A1193, and not for any other purpose.	GeneEthics	Standard 1.5.3 does not prescribe that irradiation of fresh fruits and vegetables must only be undertaken for the control of fruit fly, and not for any other purpose. The purpose for which food may be irradiated in accordance with Standard 1.5.3 is "pest disinfestation for a phytosanitary objective."
Compliance of Code requirements		
What explanation can FSANZ provide as assurance to consumers that the law was followed in relation to labelling and indeed the safety of those products.	Individual	Pursuant to the powers afforded to it under the FSANZ Act, FSANZ is responsible for developing and maintaining the Code, but has no role in the enforcement of its requirements. Consequently, matters relating to compliance and enforcement of labelling or other requirements for

Issue/comment	Submitter	FSANZ response
		irradiated food is outside the scope of the application.
Compliance with the labelling of irradiated fruits and vegetables is strictly enforced and that they not be presented to shoppers as ‘fresh’.	GeneEthics	See the above response.

2.2 Risk assessment

FSANZ conducted a risk assessment relevant to the application which is provided as SD1. The conclusions of the assessment are summarised below.

FSANZ has concluded that the proposed amendment is technologically justified. Increasing the maximum energy level for machine sources generating X-rays from 5 to 7.5 MeV increases the efficiency of generating X-rays to irradiate food by approximately 40-50%.

The induced radioactivity due to irradiation with 7.5 MeV X-rays is much less than the natural radioactivity in non-irradiated food and even less than the natural levels of background radiation consumers are exposed to.

It is the dose of the irradiation absorbed by food that is important for any compositional or nutritional changes to the treated food, not the energy source of the incident radiation. As there is no change to the absorbed irradiation dose due to this application there are no changes to the food composition or nutritional impacts. There are no negative food technology implications in making such a change.

FSANZ's previous evaluations of food irradiation have all concluded that there are no safety concerns associated with the irradiation of the permitted commodities at the approved doses. No new evidence was identified in the updated literature search that would alter these conclusions. As the proposed increase in maximum energy level for machine sources generating X-rays will not result in an increased absorbed dose in food, no new food chemical changes will be associated with the present application. Toxicity and genotoxicity studies with foods irradiated with 7.5 MeV X-rays using doses higher than those approved in the Code also found no evidence of adverse effects.

FSANZ concludes there are no public health and safety concerns associated with the consumption of food irradiated with 7.5 MeV X-rays at the approved dose levels when using tantalum or gold as the X-ray target material.

2.3 Risk management

2.3.1 Risk management options

Following assessment, FSANZ prepared a draft variation and called for submissions on that draft variation during a period of six weeks.

The risk management options available to FSANZ following the call for submission are to either:

- approve the draft variation proposed following assessment, or
- approve that draft variation subject to such amendments as FSANZ considers necessary, or
- reject that draft variation.

Having regard to all submissions received, and for reasons set out in this report, FSANZ considers it appropriate to approve the draft variation proposed following assessment without change (see Attachment A).

The approved draft variation amends paragraph 1.5.3—7(b) of the Code to increase the maximum energy level permitted for machine sources generating X-rays to irradiate food, from 5 MeV to 7.5 MeV, provided the X-ray target material used by the machine source is

tantalum or gold.

2.3.2 Public health and safety considerations

The risk assessment concluded there are no public health and safety concerns associated with the consumption of food irradiated with 7.5 MeV X-rays at the approved dose levels within the Code when using tantalum or gold as the X-ray target material.

The IPPC International Standard for Phytosanitary Measures (ISPM 18) lists the methods used to treat food using irradiation, which includes X-rays (up to 7.5 MeV) generated from machine sources. International Standards for Phytosanitary Measures (ISPMs) are the standards issued by the IPPC. The use of a higher energy level for machine sources generating X-rays up to 7.5 MeV provided the X-ray target is made of tantalum or gold is consistent with permissions in the USA, Canada and South Korea.

2.3.3 Labelling of irradiated food

The existing requirement for mandatory labelling of irradiated foods at section 1.5.3—9 of the Code continue to apply.

Section 1.5.3—9 requires that if the food has been irradiated, or if an ingredient or component of the food has been irradiated, then there must be a statement to the effect that the food, or the ingredient or component of that food, has been treated with ionising radiation. When an irradiated ingredient or component is used in a packaged food, the statement may be in the statement of ingredients or elsewhere on the label. The wording of the mandatory statement is not prescribed.

Subsection 1.1.1—8(2) stipulates that the words used in the statement must not contradict or detract from the effect of the statement. Generic legibility requirements apply, which require statements on a label to be legible and prominent so as to contrast distinctly with the background of the label (section 1.2.1—24).

If an irradiated food or a food containing an irradiated ingredient or component is exempt from bearing a label (e.g., unpackaged fruit or vegetables) then section 1.2.1—9 of the Code requires that the statement accompany the food or be displayed in connection with the display of the food.

Food sold to caterers is required to have labelling information relating to irradiated food. This information must be on the label of the food required to bear a label (section 1.2.1—15), or provided to the caterer with the food if the food sold is not required to bear a label (section 1.2.1—13).

The Radura symbol (Figure 1 below) is a standard international symbol indicating that a food product has been irradiated. The Code does not mandate the display of this symbol on the labels of irradiated food. However, there is no restriction in the Code regarding its voluntary use. Even if this symbol is included on the food label, it must still display the mandatory labelling requirements for irradiated foods.

Figure 1 *The Radura symbol*

2.3.4 Risk management conclusion

Having considered all aspects of the assessment against the statutory requirements, FSANZ has decided to approve the draft variation to the Code. That is, to amend paragraph 1.5.3–7(b) as proposed.

The effect of the amendment is to permit food being irradiated in accordance with the Code by using (among other things) X-rays generated by or from machine sources operated at the following energy levels:

- if the machine source uses tantalum or gold as the target material - an energy level not exceeding 7.5 MeV, or
- otherwise - an energy level not exceeding 5 MeV.

2.4 Risk communication

2.4.1 Consultation

Consultation is a key part of FSANZ's standards development process. The process by which FSANZ considers standards matters is open, accountable, consultative and transparent. Public submissions were invited on a draft variation which was released for public comment between 2 February 2024 and 15 March 2024. The call for submissions was notified via the FSANZ Notification Circular, media release, FSANZ's social media channels and Food Standards News. Subscribers and interested parties were also notified.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on applications to amend the Code. All submissions are considered as part of the decision making process by FSANZ. All comments are valued and contribute to the rigour of our assessment.

Documents relating to A1261, including the received submissions, are available on the FSANZ website.

The draft variation was considered for approval by the FSANZ Board having regard to all the submissions made during the call for submissions period.

2.5 FSANZ Act assessment requirements

When assessing this application and the subsequent development of a food regulatory measure, FSANZ had regard to the following matters in section 29 of the FSANZ Act:

2.5.1 Section 29

2.5.1.1 Consideration of costs and benefits

Changes have been made to the impact analysis requirements by the Office of Impact Analysis (OIA)[5]. Impact analysis (including Regulatory Impact Statements, or RISs) is no longer required to be finalised with the OIA.

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

Prior to these changes, the OIA (previously known as the Office of Best Practice Regulation (OBPR)) advised FSANZ 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 once the draft variation concerned has been approved.[6]

Under the new impact analysis requirements, FSANZ must decide whether a RIS should be prepared. FSANZ's assessment was that a RIS was not required in relation to the draft variation because the impacts of the proposed amendment to the Code would be minor (for the same reasons outlined above).

Meeting FSANZ Act requirements

While a RIS has not been prepared, FSANZ is still required by the FSANZ Act to consider the costs and benefits that may arise from the proposed measure.

The Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 29(2)(a)).

The purpose of this consideration was to determine if the community, government and industry is likely to benefit, on balance, from a move from the status quo (where the status quo is rejecting the application).

FSANZ's conclusions regarding the costs and benefits of the proposed measure are set out below. The consideration of the costs and benefits in this section was not intended to be an exhaustive, quantitative economic analysis of the proposed measures. In fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment sought to highlight the likely positives and negatives of moving away from the status quo by approving the draft variation.

Costs and benefits of the proposed increase in maximum energy level for irradiation

The food industry may benefit from the proposed measure. Increasing the maximum energy level of machine sources generating X-rays (as proposed), which are permitted to irradiate food, would reduce costs by enabling a higher energy level for particular sources of irradiation to be used which has greater throughput and shorter turn-around time.[7] It would enable businesses who use irradiation to move away from using cobalt 60 (^{60}Co) which is experiencing supply issues, which may further reduce costs relative to the status quo. A machine source generating X-rays at 7.5 MeV is also 40-50% more efficient compared to machine sources operating at the maximum energy level of 5 MeV.

Irradiation is used on fresh fruit and vegetables to control the spread of insect pests (like fruit-fly), and is required to move fresh fruit and vegetables between quarantine regions within Australia. Therefore, if the cost of irradiation lowers then the cost of inter-Australian trade may also be reduced.

Increasing the permitted energy levels as proposed would lower the cost of exporting irradiated food from Australia and New Zealand to other countries where the proposed maximum energy level also applies, thereby potentially facilitating more international trade.

[6] Refer to the list of carve-outs on the Office of Impact Analysis website.
[7] See SD1, section 2.3.

There would be no cost impact on industry. Use of the higher energy level would be voluntary and therefore individual businesses within the industry would only use it where a commercial net benefit exists for them.

Domestic consumers may benefit from lower cost food if the above savings to industry are passed on. It may also increase supply of fresh fruit and vegetables within Australia, due to lower cost of sending fruit and vegetables outside quarantine zones.

There are not expected to be any significant costs to consumers. As discussed in this report, the requirement to inform consumers still applies, where a particular food is irradiated. Therefore, consumers would have a choice to consume or not consume any impacted products. In addition, FSANZ's risk and safety assessment concluded that food irradiated by X-rays generated by or from machine sources operated at the proposed energy levels are safe to consume.

There are not expected to be any significant costs for government.

Conclusion – benefits of increasing maximum energy level outweigh costs

FSANZ's assessment, at the call for submissions stage was that the direct and indirect benefits that would arise from approving the draft variation most likely outweigh the associated costs. No further information was received during the consultation process that changed that assessment.

2.5.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied because of the application.

2.5.1.3 Any relevant New Zealand standards

The relevant standard applies in both Australia and New Zealand. There are no relevant New Zealand only standards.

2.5.1.4 Any other relevant matters

Other relevant matters are considered below.

2.5.2 Subsection 18(1)

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

2.5.2.1 Protection of public health and safety

FSANZ undertook a safety assessment (see SD1) which is summarised in section 2.2. The safety assessment concluded there were no public health and safety concerns associated with increasing the maximum energy level for machine sources generating X-rays permitted to irradiate food from 5 to 7.5 MeV provided the X-ray target used by the machine source is made of tantalum or gold.

2.5.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

The mandatory labelling requirements for irradiated food as discussed in sections 1.3.2 and

2.3.1 of this report would provide information to enable consumers to make informed choices.

2.5.2.3 The prevention of misleading or deceptive conduct

Submitter concerns related to this objective are addressed in Table 1 above.

2.5.3 Subsection 18(2) considerations

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

FSANZ used the best available scientific evidence to conduct the risk analysis, which is provided in SD1. The applicant submitted a dossier of information and scientific literature as part of its application. This dossier, together with other technical and scientific information, was considered by FSANZ in assessing the application.

- **the promotion of consistency between domestic and international food standards**

Internationally, food irradiation is approved in more than 60 countries. As noted in section 1.4 of this report, there is a Codex standard for irradiation of food. It is noted that the Codex standard was initially issued in 1983. It is only more recently that higher energy sources for generating X-rays have become commercially available to irradiate food. There is also a recent 2023 FAO IPPC International Standard for Phytosanitary Measures (ISPM 18, IPPC 2023). This lists the methods used to treat food using irradiation, which includes X-rays (up to 7.5 MeV) generated from machine sources. International Standards for Phytosanitary Measures (ISPMs) are the standards issued by the IPPC. Section 1.4.1 of this report notes there are irradiation of food permissions in three countries that are fully consistent with the draft variation and two others that permit using X-rays up to 7.5 MeV but without a qualification on the X-ray target material. Approving the draft variation will promote further consistency between the irradiation of food in Australia and New Zealand with international standards.

- **the desirability of an efficient and internationally competitive food industry**

One of the conclusions of FSANZ's assessment is that increasing the maximum energy level for machine sources generating X-rays from 5 to 7.5 MeV, increases the efficiency of generating X-rays to irradiate food by approximately 40-50%. Such increases in efficiency of X-ray generation have a corresponding increase in irradiation treatment efficiency and rate of throughput of irradiating various food. This would make these food industries more internationally competitive, by allowing irradiation by local food businesses to be consistent and competitive with several international countries.

- **the promotion of fair trading in food**

No issues were identified for this application relevant to this objective.

- **any written policy guidelines formulated by the Food Ministers' Meeting**

There is no policy guideline for irradiated foods.

3 References

Canadian Food and Drug Regulations (Consolidated Regulations of Canada, c. 870), Division 26 – Food Irradiation, B.26.003, available at this link https://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._870/page-53.html?txthl=b.26.003#s-B.26.003, accessed on 4 December 2023

CG (2016) Canada Gazette. Regulations Amending the Food and Drug Regulations (Food Irradiation). Publications. Part 1. Vol 150, No 25, June 18th, 2065-2078.

GI (2012) The Gazette of India. Atomic Energy (Radiation Processing of Food and Allied Products) Rules 2012. Department of Atomic Energy. New Delhi, 24-30 June 2012.

IPPC (2023) IPPC Secretariat. 2023. Requirements for the use of irradiation as a phytosanitary measure. International Standard for Phytosanitary Measures No. 18. Rome. FAO on behalf of the Secretariat of the International Plant Protection Convention.

MFDS (2020). Ministry of Food and Drug Safety. South Korea, Food Code (2020). English Version. Chapter 2. Food Irradiation Standard, p51-52.

NADFC (2013). National Agency of Drug and Food Control of Indonesia. Notification to World Trade Organization (in Indonesian). https://members.wto.org/crnattachments/2017/SPS/IDN/17_5323_00_x.pdf, accessed on 4 December 2023

US FDA (2004). US Food and Drug Administration. Irradiation in the Production, Processing and Handling of Food, Food and Drug Administration. Final rule. FR 69 No 246, 76844-76846.

US CFR Title 21 §179.26, Code of Federal Regulations, Title 21, Chapter I, subchapter B, part 179, section 179.26 – Ionizing radiation for the treatment of food, 21CFR179.26 https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-179/subpart-B/section-179.26, accessed on 4 December 2023.

Attachments

A. Approved draft variation to the Australia New Zealand Food Standards Code
B. Explanatory Statement

Attachment A – Approved draft variation to the Australia New Zealand Food Standards Code

Food Standards (Application A1261 – Irradiation – Increase in maximum energy level) Variation

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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 [To be completed by the Delegate]

[Insert name and position of the Delegate]
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. 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 (Application A1261 – Irradiation – Increase in maximum energy level) Variation*.

2 Variation to a Standard in the *Australia New Zealand Food Standards Code*

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

3 Commencement

The variation commences on the date of gazettal.

Schedule

[1] Standard 1.5.3—Irradiation of food

Paragraph 1.5.3—7(b)

Repeal the paragraph, substitute:

(b) X-rays generated by or from machine sources operated at:

(i) an energy level not exceeding 5 megaelectronvolts; or

(ii) if the machine source uses tantalum or gold as the target material—an energy level not exceeding 7.5 megaelectronvolts;

Attachment B – Explanatory Statement

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 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 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)[8]. 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.[9] 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.

[8] Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis (pmc.gov.au)
[9] Refer to the list of carve-outs on the Office of Impact Analysis website.

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